WEST VIRGINIA
SECRETARY OF STATE
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ADMINISTRATIVE LAW DIVISION

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OFFICE WEST VIRGINIA
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NOTICE OF RULE MODIFICATION OF A PROPOSED RULE

AGENCY: Insurance Commission TITLE NUMBER: 114

CITE AUTHORITY W.Va. Code §33-2-10 & 33-15A-6

AMENDMENT TO AN EXISTING RULE: YES X NO _____

IF YES, SERIES NUMBER OF RULE BEING AMENDED: 32

TITLE OF RULE BEING AMENDED: Long-Term Care Insurance

IF NO, SERIES NUMBER OF RULE BEING PROPOSED: _____

TITLE OF RULE BEING PROPOSED: _____

THE ABOVE PROPOSED LEGISLATIVE RULE, FOLLOWING REVIEW BY THE LEGISLATIVE RULE MAKING REVIEW COMMITTEE IS HEREBY MODIFIED AS A RESULT OF REVIEW AND COMMENT BY THE LEGISLATIVE RULE-MAKING REVIEW COMMITTEE. THE ATTACHED MODIFICATIONS ARE FILED WITH THE SECRETARY OF STATE.

Virgil T. Helton
Cabinet Secretary
West Virginia Department of Revenue

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TITLE 114
LEGISLATIVE RULES
OFFICES OF THE INSURANCE COMMISSIONER

SERIES 32
LONG-TERM CARE INSURANCE

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TITLE 114
LEGISLATIVE RULES
OFFICES OF THE INSURANCE COMMISSIONER

SERIES 32
LONG-TERM CARE INSURANCE

§114-32-1. General.

1.1. Scope. -- The purpose of this rule is to implement W. Va. Code §33-15A-1 *et seq.*, to promote the public interest, to promote the availability of long-term care insurance coverage, to protect applicants for long-term care insurance, as defined, from unfair or deceptive sales or enrollment practices, to facilitate public understanding and comparison of long-term care insurance coverages, and to facilitate flexibility and innovation in the development of long-term care insurance. This rule is based on the National Association of Insurance Commissioners ("NAIC") "Long-Term Care Insurance Model Regulation" (Model 641, as amended in 2006).

Except as otherwise specifically provided, this rule applies to all long-term care insurance policies including qualified long-term care contracts and life insurance policies that accelerate benefits for long-term care delivered or issued for delivery in this State on or after the effective date hereof, by insurers; fraternal benefit societies; nonprofit health, hospital and medical service corporations; prepaid health plans; health maintenance organizations and all similar organizations. Certain provisions of this rule apply only to qualified long-term care insurance contracts as noted.

Additionally, this rule is intended to apply to policies having indemnity benefits that are triggered by activities of daily living and sold as disability income insurance, if:

a. The benefits of the disability income policy are dependent upon or vary in amount based on the receipt of long-term care services;

b. The disability income policy is advertised, marketed or offered as insurance for long-term care services; or

c. Benefits under the policy may commence after the policyholder has reached Social Security's normal retirement age unless benefits are designed to replace lost income or pay for specific expenses other than long-term care services.

1.2. Authority. -- W. Va. Code §§33-2-10 and 33-15A-6.

1.3. Filing Date. -- ~~June 18, 1993~~

1.4. Effective Date. -- ~~July 19, 1993~~

§114-32-2. Definitions.

For the purpose of this rule the terms "long-term care insurance," qualified long-term care insurance," "group long-term care insurance," "Commissioner," "applicant," "policy" and "certificate" shall have the meanings set forth in W. Va. Code §33-15A-4. In addition, the following definitions apply.

2.1."Exceptional increase" means only those increases filed by an insurer as exceptional for which the Commissioner determines the need for the premium rate increase is justified:

a. Due to changes in laws or regulations applicable to long-term care coverage in this state; or

b. Due to increased and unexpected utilization that affects the majority of insurers of similar products.

2.2. "Incidental," as used in subsection 18.10 of this rule, means that the value of the long-term care benefits provided is less than ten percent (10%) of the total value of the benefits provided over the life of the policy. These values shall be measured as of the date of issue.

2.3. "Qualified actuary" means a member in good standing of the American Academy of Actuaries.

2.4. "Similar policy forms" means all of the long-term care insurance policies and certificates issued by an insurer in the same long-term care benefit classification as the policy form being considered. Certificates of groups that meet the definition in W. Va. Code §33-15A-4(e)(1) are not considered similar to certificates or policies otherwise issued as long-term care insurance, but are similar to other comparable certificates with the same long-term care benefit classifications. For purposes of determining similar policy forms, long-term care benefit classifications are defined as follows: institutional long-term care benefits only, non-institutional long-term care benefits only, or comprehensive long-term care benefits.

§114-32-3. Policy Definitions.

~~3.1.~~ No long-term care insurance policy delivered or issued for delivery in this State shall use the terms set forth below, unless the terms are defined in the policy and the definitions satisfy the following requirements:

3.1. "Activities of daily living" means at least bathing, continence, dressing, eating, toileting and transferring.

~~3.1.2.~~ 3.2. "Acute condition" means that the individual is medically unstable. Such an individual requires frequent monitoring by medical professionals, such as physicians and registered nurses, in order to maintain his or her health status.

~~3.1.1.~~ 3.3. "Adult day care" means a program for six (6) or more individuals, of social and health-related services provided during the day in a community group setting for the purpose

of supporting frail, impaired elderly or other disabled adults who can benefit from care in a group setting outside the home.

3.4. "Bathing" means washing oneself by sponge bath; or in either a tub or shower, including the task of getting into or out of the tub or shower.

3.5. "Cognitive impairment" means a deficiency in a person's short or long-term memory, orientation as to person, place and time, deductive or abstract reasoning, or judgment as it relates to safety awareness.

3.6. "Continence" means the ability to maintain control of bowel and bladder function; or, when unable to maintain control of bowel or bladder function, the ability to perform associated personal hygiene (including caring for catheter or colostomy bag).

3.7. "Dressing" means putting on and taking off all items of clothing and any necessary braces, fasteners or artificial limbs.

3.8. "Eating" means feeding oneself by getting food into the body from a receptacle (such as a plate, cup or table) or by a feeding tube or intravenously.

3.9. "Hands-on assistance" means physical assistance (minimal, moderate or maximal) without which the individual would not be able to perform the activity of daily living.

~~3.1.3.~~ 3.10. "Home health care services" means medical and nonmedical services, provided to ill, disabled or infirm persons in their residences. Such services may include homemaker services, assistance with activities of daily living and respite care services.

~~3.1.4.~~ 3.11. "Medicare" ~~shall be defined as~~ means "The Health Insurance for the Aged Act, Title XVIII of the Social Security Amendments of 1965 as Then Constituted or Later Amended," or "Title I, Part I of Public Law 89-97, as Enacted by the Eighty-Ninth Congress of the United States of America and popularly known as the Health Insurance for the Aged Act, as then constituted and any later amendments or substitutes thereof," or words of similar import.

~~3.1.5.~~ 3.12. "Mental or nervous disorder" shall not be defined to include more than neurosis, psychoneurosis, psychopathy, psychosis, or mental or emotional disease or disorder.

~~3.1.6.~~ 3.13. "Personal care" means the provision of hands-on services to assist an individual with activities of daily living ~~(such as bathing, eating, dressing, transferring and toileting)~~.

~~3.1.7. Subject to the exception set forth in W. Va. Code §33-15A-6(c) for a policy or certificate issued to a group, "preexisting condition" shall not be defined more restrictively than "a condition for which medical advice or treatment was recommended by, or received from, a provider of health care services within six (6) months preceding the effective date of coverage of the insured person."~~

~~3.1.8.~~ 3.14. "Skilled nursing care," "intermediate care," "personal care," "home care," "specialized care," "assisted living care" and other services shall be defined in relation to the level of skill required, the nature of the care and the setting in which care must be delivered.

3.15. "Toileting" means getting to and from the toilet, getting on and off the toilet, and performing associated personal hygiene.

3.16. "Transferring" means moving into or out of a bed, chair or wheelchair.

~~3.1.9.~~ 3.17. All providers of services, including but not limited to "skilled nursing facility," "extended care facility," "intermediate care facility," "convalescent nursing home," "personal care facility," "specialized care providers," "assisted living facility," and "home care agency" shall be defined in relation to the services and facilities required to be available and the licensure certification, registration or degree status of those providing or supervising the services. ~~The definition may require that the provider be appropriately licensed or certified.~~ When the definition requires that the provider be appropriately licensed, certified or registered, it shall also state what requirements a provider must meet in lieu of licensure, certification or registration when the state in which the service is to be furnished does not require a provider of these services to be licensed, certified or registered, or when the state licenses, certifies or registers the provider of services under another name.

§114-32-4. Policy Practices and Provisions.

4.1. Renewability -- The terms "guaranteed renewable" and "noncancellable" shall not be used in any individual long-term care insurance policy without further explanatory language in accordance with the disclosure requirements of section ~~5~~ 6 of this ~~regulation~~ rule.

~~4.1.1.~~ a. ~~No such~~ A policy issued to an individual shall not contain renewal provisions other than "guaranteed renewable" or "noncancellable."

~~4.1.2.~~ b. The term "guaranteed renewable" may be used only when the insured has the right to continue the long-term care insurance in force by the timely payment of premiums and when the insurer has no unilateral right to make any change in any provision of the policy or rider while the insurance is in force, and cannot decline to renew, except that rates may be revised by the insurer on a class basis.

~~4.1.3.~~ c. The term "noncancellable" may be used only when the insured has the right to continue the long-term care insurance in force by the timely payment of premiums during which period the insurer has no right to unilaterally make any change in any provision of the insurance or in the premium rate.

d. The term "level premium" may only be used when the insurer does not have the right to change the premium.

e. In addition to the other requirements of this subsection, a qualified long-term care insurance contract shall be guaranteed renewable, within the meaning of Section 7702B(b)(1)(C) of the Internal Revenue Code of 1986, as amended.

4.2. Limitations and Exclusions. -- ~~No~~ A policy may not be delivered or issued for delivery in this State as long-term care insurance if ~~such~~ the policy limits or excludes coverage by type of illness, treatment, medical condition or accident, except as follows:

~~4.2.1.~~ a. Preexisting conditions or diseases;

~~4.2.2.~~ b. Mental or nervous disorders; however, this shall not permit exclusion or limitation of benefits on the basis of Alzheimer's disease;

~~4.2.3.~~ c. Alcoholism and drug addiction;

~~4.2.4.~~ d. Illness, treatment or medical condition arising out of:

~~a.~~ 1. War or act of war (whether declared or undeclared);

~~b.~~ 2. Participation in a felony, riot or insurrection;

~~c.~~ 3. Service in the armed forces or units auxiliary thereto;

~~d.~~ 4. Suicide (sane or insane), attempted suicide or intentionally self-inflicted injury; or

~~e.~~ 5. Aviation (this exclusion applies only to non-fare-paying passengers).

~~4.2.5.~~ e. Treatment provided in a government facility (unless otherwise required by law), services for which benefits are available under Medicare or other governmental program (except Medicaid), any state or federal workers' compensation, employer's liability or occupational disease law, or any motor vehicle no-fault law, services provided by a member of the covered person's immediate family and services for which no charge is normally made in the absence of insurance;

f. Expenses for services or items available or paid under another long-term care insurance or health insurance policy;

g. In the case of a qualified long-term care insurance contract, expenses for services or items to the extent that the expenses are reimbursable under Title XVIII of the Social Security Act (Medicare) or would be reimbursable but for the application of a deductible or coinsurance amount.

h. 1. This subsection is not intended to prohibit exclusions and limitations by type of provider. However, no long-term care issuer may deny a claim because services are provided in a state other than the state of policy issued under the following conditions:

A. When the state other than the state of policy issue does not have the provider licensing, certification or registration required in the policy, but where the

provider satisfies the policy requirements outlined for providers in lieu of licensure, certification or registration; or

B. When the state other than the state of policy issue licenses, certifies or registers the provider under another name.

2. For purposes of this subdivision, "state of policy issue" means the state in which the individual policy or certificate was originally issued.

~~4.2.6.~~ i. ~~Section 4.2~~ This subsection is not intended to prohibit ~~exclusions and limitations by type of provider or~~ territorial limitations.

4.3. Extension of Benefits. -- Termination of long-term care insurance shall be without prejudice to any benefits payable for institutionalization if ~~such~~ the institutionalization began while the long-term care insurance was in force and continues without interruption after termination. ~~Such~~ The extension of benefits beyond the period the long-term care insurance was in force may be limited to the duration of the benefit period, if any, or to payment of the maximum benefits and may be subject to any policy waiting period, and all other applicable provisions of the policy.

4.4. Continuation or Conversion.

~~4.4.1.~~ a. Group long-term care insurance issued in this State on or after the effective date of this section shall provide covered individuals with a basis for continuation or conversion of coverage.

~~4.4.2.~~ b. For the purposes of this section, "a basis for continuation of coverage" means a policy provision ~~which~~ that maintains coverage under the existing group policy when ~~such~~ the coverage would otherwise terminate and which is subject only to the continued timely payment of premium when due. Group policies ~~which~~ that restrict provision of benefits and services to, or contain incentives to use certain providers ~~and/~~or facilities may provide continuation benefits ~~which~~ that are substantially equivalent to the benefits of the existing group policy. The Commissioner shall make a determination as to the substantial equivalency of benefits, and in doing so, shall take into consideration the differences between managed care and non-managed care plans, including, but not limited to, provider system arrangements, service availability, benefit levels and administrative complexity.

~~4.4.3.~~ c. For the purposes of this section, "a basis for conversion of coverage" means a policy provision that an individual whose coverage under the group policy would otherwise terminate or has been terminated for any reason, including discontinuance of the group policy in its entirety or with respect to an insured class, and who has been continuously insured under the group policy (and any group policy which it replaced), for at least six (6) months immediately prior to termination, shall be entitled to the issuance of a converted policy by the insurer under whose group policy he or she is covered, without evidence of insurability.

~~4.4.4.~~ d. For the purposes of this section, "converted policy" means an individual policy of long-term care insurance providing benefits identical to or benefits determined by the

Commissioner to be substantially equivalent to or in excess of those provided under the group policy from which conversion is made. Where the group policy from which conversion is made restricts provision of benefits and services to, or contains incentives to use certain providers or facilities, the Commissioner, in making a determination as to the substantial equivalency of benefits, shall take into consideration the differences between managed care and non-managed care plans, including, but not limited to, provider system arrangements, service availability, benefit levels and administrative complexity.

~~4.4.5.~~ e. Written application for the converted policy shall be made and the first premium due, if any, shall be paid as directed by the insurer not later than thirty-one (31) days after termination of coverage under the group policy. The converted policy shall be issued effective on the day following the termination of coverage under the group policy, and shall be renewable annually.

~~4.4.6.~~ f. Unless the group policy from which conversion is made replaced previous group coverage, the premium for the converted policy shall be calculated on the basis of the insured's age at inception of coverage under the group policy from which conversion is made. Where the group policy from which conversion is made replaced previous group coverage, the premium for the converted policy shall be calculated on the basis of the insured's age at inception of coverage under the group policy replaced.

~~4.4.7.~~ g. Continuation of coverage or issuance of a converted policy shall be mandatory, except where:

~~a.~~ 1. Termination of group coverage resulted from an individual's failure to make any required payment of premium or contribution when due; or

~~b.~~ 2. The terminating coverage is replaced not later than thirty-one (31) days after termination, by group coverage effective on the day following the termination of coverage:

A. Providing benefits identical to or benefits determined by the Commissioner to be substantially equivalent to or in excess of those provided by the terminating coverage; and

B. The premium for which is calculated in a manner consistent with the requirements of ~~Paragraph 4.4.6~~ subdivision f of this ~~section~~ subsection.

~~4.4.8.~~ h. Notwithstanding any other provision of this section, a converted policy issued to an individual who at the time of conversion is covered by another long-term care insurance policy ~~which~~ that provides benefits on the basis of incurred expenses, may contain a provision ~~which~~ that results in a reduction of benefits payable if the benefits provided under the additional coverage, together with the full benefits provided by the converted policy, would result in payment of more than 100 percent (100%) of incurred expenses. ~~Such~~ The provision shall only be included in the converted policy if the converted policy also provides for a premium decrease or refund which reflects the reduction in benefits payable.

~~4.4.9.~~ i. The converted policy may provide that the benefits payable under the converted policy, together with the benefits payable under the group policy from which conversion is made, shall not exceed those that would have been payable had the individual's coverage under the group policy remained in force and effect.

~~4.4.10.~~ j. Notwithstanding any other provision of this section, ~~any~~ an insured individual whose eligibility for group long-term care coverage is based upon his or her relationship to another person, shall be entitled to continuation of coverage under the group policy upon termination of the qualifying relationship by death or dissolution of marriage.

~~4.4.11.~~ k. For the purposes of this section, a "Managed-Care Plan" is a health care or assisted living arrangement designed to coordinate patient care or control costs through utilization review, case management or use of specific provider networks.

4.5. Discontinuance and Replacement. -- If a group long-term care policy is replaced by another group long-term care policy issued to the same policyholder, the succeeding insurer shall offer coverage to all persons covered under the previous group policy on its date of termination. Coverage provided or offered to individuals by the insurer and premiums charged to persons under the new group policy:

~~4.5.1.~~ a. Shall not result in ~~any~~ an exclusion for preexisting conditions that would have been covered under the group policy being replaced; and

~~4.5.2.~~ b. Shall not vary or otherwise depend on the individual's health or disability status, claim experience or use of long-term care services.

4.6. a. The ~~premiums~~ premium charged to an insured ~~for long-term care insurance~~ shall not increase due to either:

~~4.6.1.~~ 1. The increasing age of the insured at ages beyond sixty-five (65); or

~~4.6.2.~~ 2. The duration the insured has been covered under the policy.

b. The purchase of additional coverage shall not be considered a premium rate increase, but for purposes of the calculation required under section 24 of this rule, the portion of the premium attributable to the additional coverage shall be added to and considered part of the initial annual premium.

c. A reduction in benefits shall not be considered a premium change, but for purpose of the calculation required under section 24 of this rule, the initial annual premium shall be based on the reduced benefits.

§114-32-5. Unintentional Lapse.

Each insurer offering long-term care insurance shall, as a protection against unintentional lapse, comply with the following:

5.1. a. Notice before lapse or termination. No individual long-term care policy or certificate shall be issued until the insurer has received from the applicant either a written designation of at least one person, in addition to the applicant, who is to receive notice of lapse or termination of the policy or certificate for nonpayment of premium, or a written waiver dated and signed by the applicant electing not to designate additional persons to receive notice. The applicant has the right to designate at least one person who is to receive the notice of termination, in addition to the insured. Designation shall not constitute acceptance of any liability on the third party for services provided to the insured. The form used for the written designation must provide space clearly designated for listing at least one person. The designation shall include each person's *full name* and *home address*. In the case of an applicant who elects not to designate an additional person, the waiver shall state: "Protection against unintended lapse. I understand that I have the right to designate at least one person other than myself to receive notice of lapse or termination of this long-term care insurance policy for nonpayment of premium. I understand that notice will not be given until thirty (30) days after a premium is due and unpaid. I elect NOT to designate a person to receive this notice." The insurer shall notify the insured of the right to change this written designation, no less often than once every two (2) years.

b. When the policyholder or certificateholder pays premium for a long-term care insurance policy or certificate through a payroll or pension deduction plan, the requirements contained in subdivision a of this subsection need not be met until sixty (60) days after the policyholder or certificateholder is no longer on such a payment plan. The application or enrollment form for such policies or certificates shall clearly indicate the payment plan selected by the applicant.

c. Lapse or termination for nonpayment of premium. No individual long-term care policy or certificate shall lapse or be terminated for nonpayment of premium unless the insurer, at least thirty (30) days before the effective date of the lapse or termination, has given notice to the insured and to those persons designated pursuant to subdivision a of this subsection, at the address provided by the insured for purposes of receiving notice of lapse or termination. Notice shall be given by first class United States mail, postage prepaid; and notice may not be given until thirty (30) days after a premium is due and unpaid. Notice shall be deemed to have been given as of five (5) days after the date of mailing

5.2. Reinstatement. In addition to the requirement in subsection 5.1 of this section, a long-term care insurance policy or certificate shall include a provision that provides for reinstatement of coverage, in the event of lapse if the insurer is provided proof that the policyholder or certificateholder was cognitively impaired or had a loss of functional capacity before the grace period contained in the policy expired. This option shall be available to the insured if requested within five (5) months after termination and shall allow for the collection of past due premium, where appropriate. The standard of proof of cognitive impairment or loss of functional capacity shall not be more stringent than the benefit eligibility criteria on cognitive impairment or the loss of functional capacity contained in the policy and certificate.

§114-32-56. Required Disclosure Provisions.

~~5.2.~~ 6.1. Renewability. -- Individual long-term care insurance policies shall contain a renewability provision.

a. ~~Such~~ The provision shall be appropriately captioned, shall appear on the first page of the policy, and shall clearly state that the ~~duration, where limited, of renewability and the duration of the term of coverage for which the policy is issued and for which it may be renewed~~ coverage is guaranteed renewable or noncancellable. This provision shall not apply to policies ~~which~~ that do not contain a renewability provision, and under which the right to nonrenew is reserved solely to the policyholder.

b. A long-term care insurance policy or certificate, other than one where the insurer does not have the right to change the premium, shall include a statement that premium rates may change.

~~5.1. Right to Return. -- A long-term care insurance policy or certificate shall have a notice prominently printed on the first page of the policy or certificate or attached thereto, stating in substance that the policyholder shall have the right to return the policy or certificate within the time periods specified in Subsections 5.1.1 and 5.1.2, and to have the premium refunded if, after examination of the policy or certificate, the insured person is not satisfied for any reason.~~

~~5.1.1. For an individual or group long-term care insurance policy or certificate sold by direct solicitation or sold as a replacement policy or certificate, this notice shall state that the policyholder or certificateholder shall have the right to return the policy or certificate within thirty (30) days of its receipt.~~

~~5.1.2. For any other individual or group long-term care insurance policy or certificate not described in Subsection 5.1.1, this notice shall state that the policyholder or certificateholder shall have the right to return the policy or certificate within ten (10) days of its receipt.~~

~~5.3.~~ 6.2. Riders and Endorsements. -- Except for riders or endorsements by which the insurer effectuates a request made in writing by the insured under an individual long-term care insurance policy, all riders or endorsements added to an individual long-term care insurance policy after date of issue or at reinstatement or renewal ~~which~~ that reduce or eliminate benefits or coverage in the policy shall require signed acceptance by the individual insured. After the date of policy issue, any rider or endorsement which increases benefits or coverage with a concomitant increase in premium during the policy term must be agreed to in writing signed by the insured, except if the increased benefits or coverage are required by law. Where a separate additional premium is charged for benefits provided in connection with riders or endorsements, such premium charge shall be set forth in the policy, rider or endorsement.

~~5.4.~~ 6.3. Payment of Benefits. -- A long-term care insurance policy ~~which~~ that provides for the payment of benefits based on standards described as "usual and customary," "reasonable and customary" or words of similar import shall include a definition of ~~such~~ these terms and an explanation of ~~such~~ the terms in its accompanying outline of coverage.

~~5.5.~~ 6.4. Limitations. -- If a long-term care insurance policy or certificate contains any limitations with respect to preexisting conditions, ~~such~~ the limitations shall appear as a separate paragraph of the policy or certificate and shall be labeled as "Preexisting Condition Limitations."

~~5.6.~~ 6.5. Other Limitations or Conditions on Eligibility for Benefits. -- A long-term care insurance policy or certificate containing any limitations or conditions for eligibility other than those prohibited in W. Va. Code §33-15A-6(d) shall set forth a description of ~~such~~ the limitations or conditions, including any required number of days of confinement, in a separate paragraph of the policy or certificate and shall label such paragraph "Limitations or Conditions on Eligibility for Benefits."

~~5.7.~~ 6.6. Disclosure of Tax Consequences. -- With regard to life insurance policies ~~which~~ that provide an accelerated benefit for long-term care, a disclosure statement is required at the time of application for the policy or rider and at the time the accelerated benefit payment request is submitted that receipt of these accelerated benefits may be taxable, and that assistance should be sought from a personal tax advisor. The disclosure statement shall be prominently displayed on the first page of the policy or rider and any other related documents. This subsection shall not apply to qualified long-term care insurance contracts.

6.7. Benefit Triggers. Activities of daily living and cognitive impairment shall be used to measure an insured's need for long term care and shall be described in the policy or certificate in a separate paragraph and shall be labeled "Eligibility for the Payment of Benefits." Any additional benefit triggers shall also be explained in this section. If these triggers differ for different benefits, explanation of the trigger shall accompany each benefit description. If an attending physician or other specified person must certify a certain level of functional dependency in order to be eligible for benefits, this too shall be specified.

6.8. A qualified long-term care insurance contract shall include a disclosure statement in the policy and in the outline of coverage as contained in subsection 29.5 (item 3 "Federal Tax Consequences") that the policy is intended to be a qualified long-term care insurance contract under Section 7702B(b) of the Internal Revenue Code of 1986, as amended.

6.9. A nonqualified long-term care insurance contract shall include a disclosure statement in the policy and in the outline of coverage as contained in subsection 29.5 (item 3 "Federal Tax Consequences") that the policy is not intended to be a qualified long-term care insurance contract.

§114-32-7. Required Disclosure of Rating Practices to Consumers.

7.1. This section shall apply as follows:

a. Except as provided in subdivision b of this subsection, this section applies to any long-term care policy or certificate issued in this state on or after September 1, 2009.

b. For certificates issued on or after the effective date of this rule amended in 2009 by the seventy-ninth West Virginia Legislature under a group long-term care insurance policy as defined in W. Va Code §33-15A-4, which policy was in force at the time this amended

rule became effective, the provisions of this section shall apply on the policy anniversary following April 1, 2010.

7.2. Other than policies for which no applicable premium rate or rate schedule increases can be made, insurers shall provide all of the information listed in this subsection to the applicant at the time of application or enrollment, unless the method of application does not allow for delivery at that time. In such a case, an insurer shall provide all of the information listed in this section to the applicant no later than at the time of delivery of the policy or certificate.

a. A statement that the policy may be subject to rate increases in the future;

b. An explanation of potential future premium rate revisions, and the policyholder's or certificateholder's option in the event of a premium rate revision;

c. The premium rate or rate schedules applicable to the applicant that will be in effect until a request is made for an increase;

d. A general explanation for applying premium rate or rate schedule adjustments that shall include:

1. A description of when premium rate or rate schedule adjustments will be effective (e.g., next anniversary date, next billing date, etc.); and

2. The right to a revised premium rate or rate schedule as provided in subdivision c of this subsection if the premium rate or rate schedule is changed;

e. 1. Information regarding each premium rate increase on this policy form or similar policy forms over the past ten (10) years for this state or any other state that, at a minimum, identifies:

A. The policy forms for which premium rates have been increased;

B. The calendar years when the form was available for purchase; and

C. The amount or percent of each increase. The percentage may be expressed as a percentage of the premium rate prior to the increase, and may also be expressed as minimum and maximum percentages if the rate increase is variable by rating characteristics.

2. The insurer may, in a fair manner, provide additional explanatory information related to the rate increases.

3. An insurer shall have the right to exclude from the disclosure premium rate increases that only apply to blocks of business acquired from other nonaffiliated insurers or

the long-term care policies acquired from other nonaffiliated insurers when those increases occurred prior to the acquisition.

4. If an acquiring insurer files for a rate increase on a long-term care policy form acquired from nonaffiliated insurers or a block of policy forms acquired from nonaffiliated insurers on or before the later of the effective date of this section or the end of a twenty-four-month period following the acquisition of the block or policies, the acquiring insurer may exclude that rate increase from the disclosure. However, the nonaffiliated selling company shall include the disclosure of that rate increase in accordance with paragraph 1 of this subdivision.

5. If the acquiring insurer in paragraph 4 of this subdivision files for a subsequent rate increase, even within the twenty-four-month period, on the same policy form acquired from nonaffiliated insurers or block of policy forms acquired from nonaffiliated insurers referenced in paragraph 4 of this subdivision, the acquiring insurer shall make all disclosures required by subdivision e of this subsection, including disclosure of the earlier rate increase referenced in paragraph 4 of this subdivision.

7.3. An applicant shall sign an acknowledgement at the time of application, unless the method of application does not allow for signature at that time, that the insurer made the disclosure required under subdivision a and e, subsection 7.2 of this section. If due to the method of application the applicant cannot sign an acknowledgement at the time of application, the applicant shall sign no later than at the time of delivery of the policy or certificate.

7.4. An insurer shall use the forms in Appendices B and F to comply with the requirements of subsections 7.2 and 7.3 of this section.

7.5. An insurer shall provide notice of an upcoming premium rate schedule increase to all policyholders or certificateholders, if applicable, at least [forty-five (45) days] prior to the implementation of the premium rate schedule increase by the insurer. The notice shall include the information required by subsection 7.2 of this section when the rate increase is implemented.

§114-32-8. Initial Filing Requirements.

8.1. This section applies to any long-term care policy issued in this state on or after six (6) months after the effective date of this rule, amended in 2009.

8.2. An insurer shall provide the information listed in this subsection to the Commissioner sixty (60) days prior to making a long-term care insurance form available for sale.

a. A copy of the disclosure documents required in section 7 of this rule; and

b. An actuarial certification consisting of at least the following:

1. A statement that the initial premium rate schedule is sufficient to cover anticipated costs under moderately adverse experience and that the premium rate schedule is

reasonably expected to be sustainable over the life of the form with no future premium increases anticipated;

2. A statement that the policy design and coverage provided have been reviewed and taken into consideration;

3. A statement that the underwriting and claims adjudication processes have been reviewed and taken into consideration;

4. A complete description of the basis for contract reserves that are anticipated to be held under the form, to include:

A. Sufficient detail or sample calculations provided so as to have a complete depiction of the reserve amounts to be held;

B. A statement that the assumptions used for reserves contain reasonable margins for adverse experience;

C. A statement that the net valuation premium for renewal years does not increase (except for attained-age rating where permitted); and

D. A statement that the difference between the gross premium and the net valuation premium for renewal years is sufficient to cover expected renewal expenses; or if such a statement cannot be made, a complete description of the situations where this does not occur;

1. An aggregate distribution of anticipated issues may be used as long as the underlying gross premiums maintain a reasonably consistent relationship;

2. If the gross premiums for certain age groups appear to be inconsistent with this requirement, the Commissioner may request a demonstration under subsection 8.3 of this section based on a standard age distribution; and

5. A. A statement that the premium rate schedule is not less than the premium rate schedule for existing similar policy forms also available from the insurer except for reasonable differences attributable to benefits; or

B. A comparison of the premium schedules for similar policy forms that are currently available from the insurer with an explanation of the differences.

8.3. a. The Commissioner may request an actuarial demonstration that benefits are reasonable in relation to premiums. The actuarial demonstration shall include either premium and claim experience on similar policy forms, adjusted for any premium or benefit differences, relevant and credible data from other studies, or both.

b. In the event the Commissioner asks for additional information under this provision, the period in subsection 8.2 of this section does not include the period during which the insurer is preparing the requested information.

§114-32-6 9. Prohibition Against Post-Claims Underwriting.

~~6.1.~~ 9.1. All applications for long-term care insurance policies or certificates except those ~~which~~ that are guaranteed issue shall contain clear and unambiguous questions designed to ascertain the health condition of the applicant.

~~6.1.1.~~ 9.2. a. If an application for long-term care insurance contains a question ~~which~~ that asks whether the applicant has had medication prescribed by a physician, it must also ask the applicant to list the medication that has been prescribed.

~~6.1.2.~~ b. If the medications listed in ~~such~~ the application were known by the insurer, or should have been known at the time of application, to be directly related to a medical condition for which coverage would otherwise be denied, then the policy or certificate shall not be rescinded for that condition.

~~6.2.~~ 9.3. Except for policies or certificates which are guaranteed issue:

~~6.2.1.~~ a. The following language shall be set out conspicuously and in close conjunction with the applicant's signature block on an application for a long-term care insurance policy or certificate:

Caution: If your answers on this application are incorrect or untrue, [company] has the right to deny benefits or rescind your policy.

~~6.2.2.~~ b. The following language, or language substantially similar to the following, shall be set out conspicuously on the long-term care insurance policy or certificate at the time of delivery:

Caution: The issuance of this long-term care insurance [policy] [certificate] is based upon your responses to the questions on your application. A copy of your [application] [enrollment form] [is enclosed] [was retained by you when you applied]. If your answers are incorrect or untrue, the company has the right to deny benefits or rescind your policy. The best time to clear up any questions is now, before a claim arises! If, for any reason, any of your answers are incorrect, contact the company at this address: [insert address].

~~6.2.3.~~ c. Prior to issuance of a long-term care policy or certificate to an applicant age eighty (80) or older, the insurer shall obtain one of the following:

~~a.~~ 1. A report of a physical examination;

~~b.~~ 2. An assessment of functional capacity;

~~c.~~ 3. An attending physician's statement; or

~~d.~~ 4. Copies of medical records.

~~6.3.~~ 9.4. A copy of the completed application or enrollment form (whichever is applicable) shall be delivered to the insured no later than at the time of delivery of the policy or certificate unless it was retained by the applicant at the time of application.

~~6.4.~~ 9.5. Every insurer or other entity selling or issuing long-term care insurance benefits shall maintain a record of all policy or certificate rescissions, both state and countrywide, except those ~~which~~ that the insured voluntarily effectuated and shall annually furnish this information to the Insurance Commissioner in the format prescribed by the National Association of Insurance Commissioners in Appendix A.

§114-32-~~7~~ 10. Minimum Standards for Home Health and Community Care Benefits in Long-Term Care Insurance Policies.

~~7.1.~~ 10.1. A long-term care insurance policy or certificate shall not, if it provides benefits for home health care or community care services, limit or exclude benefits:

~~7.1.1.~~ a. By requiring that the insured~~/~~ or claimant would need care in a skilled nursing facility if home health care services were not provided;

~~7.1.2.~~ b. By requiring that the insured~~/~~ or claimant first or simultaneously receive nursing ~~and~~/or therapeutic services, or both, in a home, community or institutional setting before home health care services are covered;

~~7.1.3.~~ c. By limiting eligible services to services provided by registered nurses or licensed practical nurses;

~~7.1.4.~~ d. By requiring that a nurse or therapist provide services covered by the policy that can be provided by a home health aide, or other licensed or certified home care worker acting within the scope of his or her licensure or certification;

~~7.1.5.~~ e. By excluding coverage for personal care services provided by a home health aide;

~~7.1.6.~~ f. By requiring that the provision of home health care services be at a level of certification or licensure greater than that required by the eligible service;

~~7.1.7.~~ g. By requiring that the insured/claimant have an acute condition before home health care services are covered;

~~7.1.8.~~ h. By limiting benefits to services provided by Medicare-certified agencies or providers; or

~~7.1.9.~~ i. By excluding coverage for adult day care services.

~~7.2.~~ 10.2. A long-term care insurance policy or certificate, if it provides for home health or community care services, shall provide total home health or community care coverage that is a dollar amount equivalent to at least one-half of one year's coverage available for nursing home benefits under the policy or certificate, at the time covered home health or community care services are being received. This requirement shall not apply to policies or certificates issued to residents of continuing care retirement communities.

~~7.3.~~ 10.3. Home health care coverage may be applied to the nonhome health care benefits provided in the policy or certificate when determining maximum coverage under the terms of the policy or certificate.

§114-32-~~8~~ 11. Requirement to Offer Inflation Protection.

~~8.1.~~ 11.1. No insurer may offer a long-term care insurance policy unless the insurer also offers to the policyholder in addition to any other inflation protection the option to purchase a policy that provides for benefit levels to increase with benefit maximums or reasonable durations which are meaningful to account for reasonably anticipated increases in the costs of long-term care services covered by the policy. Insurers must offer to each policyholder, at the time of purchase, the option to purchase a policy with an inflation protection feature no less favorable than one of the following:

~~8.1.1.~~ a. Increases benefit levels annually in a manner so that the increases are compounded annually at a rate not less than five percent (5%);

~~8.1.2.~~ b. Guarantees the insured individual the right to periodically increase benefit levels without providing evidence of insurability or health status so long as the option for the previous period has not been declined. The amount of the additional benefit shall be no less than the difference between the existing policy benefit and that benefit compounded annually at a rate of at least five percent (5%) for the period beginning with the purchase of the existing benefit and extending until the year in which the offer is made; or

~~8.1.3.~~ c. Covers a specified percentage of actual or reasonable charges and does not include a maximum specified indemnity amount or limit.

~~8.2.~~ 11.2. Where the policy is issued to a group, the required offer in ~~Subsection 8.1 above~~ subsection 11.1 of this section shall be made to the group policyholder; except, if the policy is issued to a group defined in W. Va. Code §33-15A-4(e)(4) other than to a continuing care retirement community, the offering shall be made to each proposed certificateholder.

~~8.3.~~ 11.3. The offer in ~~Subsection 8.1 above~~ subsection 11.1 of this section shall not be required of life insurance policies or riders containing accelerated long-term care benefits.

~~8.4.~~ 11.4. a. Insurers shall include the following information in or with the outline of coverage:

~~8.4.1.~~ 1. A graphic comparison of the benefit levels of a policy that increases benefits over the policy period with a policy that does not increase benefits. The graphic comparison shall show benefit levels over at least a twenty (20) year period.

~~8.4.2.~~ 2. Any expected premium increases or additional premiums to pay for automatic or optional benefit increases.

b. An insurer may use a reasonable hypothetical, or a graphic demonstration, for the purposes of this disclosure.

~~8.5.~~ 11.5. Inflation protection benefit increases under a policy which contains ~~such~~ these benefits shall continue without regard to an insured's age, claim status or claim history, or the length of time the person has been insured under the policy.

~~8.6.~~ 11.6. An offer of inflation protection ~~which~~ that provides for automatic benefit increases shall include an offer of a premium which the insurer expects to remain constant. ~~Such~~ The offer shall disclose in a conspicuous manner that the premium may change in the future unless the premium is guaranteed to remain constant.

~~8.7.~~ 11.7. Inflation protection as provided in ~~Subsection 8.1.1 of this section~~ subdivision a, subsection 11.1 of this section shall be included in a long-term care insurance policy unless an insurer obtains a rejection of inflation protection signed by the policyholder as required in this subsection.

~~8.8.~~ 11.8. The rejection shall be considered a part of the application and shall state:

I have reviewed the outline of coverage and the graphs that compare the benefits and premiums of this policy with and without inflation protection. Specifically, I have reviewed Plans _____, and I reject inflation protection.

§114-32-9 12. Requirements for Application Forms and Replacement Coverage.

~~9.1.~~ 12.1. Application forms shall include the following questions designed to elicit information as to whether, as of the date of the application, the applicant has another long-term care insurance policy or certificate in force or whether a long-term care policy or certificate is intended to replace any other accident and sickness or long-term care policy or certificate presently in force. A supplementary application or other form to be signed by the applicant and producer, except where the coverage is sold without a producer, containing ~~such~~ the questions may be used. With regard to a replacement policy issued to a group defined by W. Va. Code §33-15A-4(e)(1), the following questions may be modified only to the extent necessary to elicit information about health or long-term care insurance policies other than the group policy being replaced; provided, however, that the certificateholder has been notified of the replacement.

~~9.1.1.~~ a. Do you have another long-term care insurance policy or certificate in force (including health care service contract, health maintenance organization contract)?

~~9.1.2.~~ b. Did you have another long-term care insurance policy or certificate in force during the last twelve (12) months?

~~a.~~ 1. If so, with which company?

~~b.~~ 2. If that policy lapsed, when did it lapse?

~~9.1.3.~~ c. Are you covered by Medicaid?

~~9.1.4.~~ d. Do you intend to replace any of your medical or health insurance coverage with this policy [certificate]?

~~9.2.~~ 12.2. Producers shall list any other health insurance policies they have sold to the applicant.

~~9.2.1.~~ a. List policies sold ~~which~~ that are still in force.

~~9.2.2.~~ b. List policies sold in the past five (5) years ~~which~~ that are no longer in force.

~~9.3.~~ 12.3. Solicitations Other than Direct Response. -- Upon determining that a sale will involve replacement, an insurer; other than an insurer using direct response solicitation methods, or its producer; shall furnish the applicant, prior to issuance or delivery of the individual long-term care insurance policy, a notice regarding replacement of accident and sickness or long-term care coverage. One (1) copy of ~~such~~ the notice shall be retained by the applicant and an additional copy signed by the applicant shall be retained by the insurer. The required notice shall be provided in the following manner: ~~(See Appendix B)~~

NOTICE TO APPLICANT REGARDING REPLACEMENT OF INDIVIDUAL ACCIDENT AND SICKNESS OR LONG-TERM CARE INSURANCE

[Insurance company's name and address]

SAVE THIS NOTICE! IT MAY BE IMPORTANT TO YOU IN THE FUTURE.

According to [your application] [information you have furnished], you intend to lapse or otherwise terminate existing accident and sickness or long-term care insurance and replace it with an individual long-term care insurance policy to be issued by [company name] Insurance Company. Your new policy provides thirty (30) days within which you may decide, without cost, whether you desire to keep the policy. For your own information and protection, you should be aware of and seriously consider certain factors which may affect the insurance protection available to you under the new policy.

You should review this new coverage carefully, comparing it with all accident and sickness or long-term care insurance coverage you now have, and terminate your present policy only if, after due consideration, you find that purchase of this long-term care coverage is a wise decision.

STATEMENT TO APPLICANT BY PRODUCER [BROKER OR OTHER REPRESENTATIVE]:
(Use additional sheets, as necessary.)

I have reviewed your current medical or health insurance coverage. I believe the replacement of insurance involved in this transaction materially improves your position. My conclusion has taken into account the following considerations, which I call to your attention:

1. Health conditions that you may presently have (preexisting conditions), may not be immediately or fully covered under the new policy. This could result in denial or delay in payment of benefits under the new policy, whereas a similar claim might have been payable under your present policy.

2. State law provides that your replacement policy or certificate may not contain new preexisting conditions or probationary periods. The insurer will waive any time periods applicable to preexisting conditions or probationary periods in the new policy (or coverage) for similar benefits to the extent such time was spent (depleted) under the original policy.

3. If you are replacing existing long-term care insurance coverage, you may wish to secure the advice of your present insurer or its producer regarding the proposed replacement of your present policy. This is not only your right, but it is also in your best interest to make sure you understand all the relevant factors involved in replacing your present coverage.

4. If, after due consideration, you still wish to terminate your present policy and replace it with new coverage, be certain to truthfully and completely answer all questions on the application concerning your medical health history. Failure to include all material medical information on an application may provide a basis for the company to deny any future claims and to refund your premium as though your policy had never been in force. After the application has been completed and before your sign it, reread it carefully to be certain that all information has been properly recorded.

(Signature of Producer, Broker or Other Representative)

[Typed Name and Address of Producer or Broker]

The above "Notice to Applicant" was delivered to me on:

_____ _____

(Applicant's Signature) (Date)

~~9.4.~~ 12.4. Direct Response Solicitations. -- Insurers using direct response solicitation methods shall deliver a notice regarding replacement of accident and sickness or long-term care coverage to the applicant upon issuance of the policy. The required notice shall be provided in the following manner: ~~(See Appendix C)~~

NOTICE TO APPLICANT REGARDING REPLACEMENT OF ACCIDENT AND SICKNESS OR LONG-TERM CARE INSURANCE

[Insurance company's name and address]

SAVE THIS NOTICE! IT MAY BE IMPORTANT TO YOU IN THE FUTURE.

According to [your application] [information you have furnished], you intend to lapse or otherwise terminate existing accident and sickness or long-term care insurance and replace it with the long-term care insurance policy delivered herewith issued by [company name] Insurance Company. Your new policy provides thirty (30) days within which you may decide, without cost, whether you desire to keep the policy. For your own information and protection, you should be aware of and seriously consider certain factors which may affect the insurance protection available to you under the new policy.

You should review this new coverage carefully, comparing it with all accident and sickness or long-term care insurance coverage you now have, and terminate your present policy only if, after due consideration, you find that purchase of this long-term care coverage is a wise decision.

1. Health conditions which you may presently have (preexisting conditions), may not be immediately or fully covered under the new policy. This could result in denial or delay in payment of benefits under the new policy, whereas a similar claim might have been payable under your present policy.

2. State law provides that your replacement policy or certificate may not contain new preexisting conditions or probationary periods. Your insurer will waive any time periods applicable to preexisting conditions or probationary periods in the new policy (or coverage) for similar benefits to the extent such time was spent (depleted) under the original policy.

3. If you are replacing existing long-term care insurance coverage, you may wish to secure the advice of your present insurer or its producer regarding the proposed replacement of your present policy. This is not only your right, but it is also in your best interest to make sure you understand all the relevant factors involved in replacing your present coverage.

4. [To be included only if the application is attached to the policy.] If, after due consideration, you still wish to terminate your present policy and replace it with new coverage, read the copy of the application attached to your new policy and be sure that all questions are answered fully and correctly. Omissions or misstatements in the application could cause an otherwise valid claim to be denied. Carefully check the application and write to [company name and address] within thirty (30) days if any information is not correct and complete, or if any past medical history has been left out of the application.

~~9.5.~~ 12.5. Where replacement is intended, the replacing insurer shall notify, in writing, the existing insurer of the proposed replacement. The existing policy shall be identified by the insurer, name of the insured and policy number or address including zip code. Such notice shall be made within five (5) working days from the date the application is received by the insurer or the date the policy is issued, whichever is sooner.

12.6. Life Insurance policies that accelerate benefits for long-term care shall comply with this section if the policy being replaced is a long-term care insurance policy. If the policy being replaced is a life insurance policy, the insurer shall comply with the replacement requirements of Series 8 of Title 114, West Virginia Code of State Rules. If a life insurance policy that accelerates benefits for long-term care is replaced by another such policy, the replacing insurer shall comply with both the long-term care and the life insurance replacement requirements.

§114-32-~~10~~ 13. Reporting Requirements.

~~10.1.~~ 13.1. ~~Each~~ Every insurer shall ~~report to the Insurance Commissioner annually by June 30 for each agent that agent's total number of replacement sales, total number of policies sold and the total number of lapses of long-term care insurance policies sold annually by the agent~~ maintain records for each producer of that producer's amount of replacement sales as a percent of the producer's total annual sales and the amount of lapses of long-term care insurance policies sold by the producer as a percent of the producer's total annual sales.

13.2. Every insurer shall report annually by June 30 the ten percent (10%) of its producers with the greatest percentages of lapses and replacements as measured by subsection 13.1 of this section. (Appendix G)

~~10.2.~~ 13.3. Reported replacement and lapse rates do not alone constitute a violation of insurance laws or necessarily imply wrongdoing. The reports are for the purpose of reviewing more closely producer activities regarding the sale of long-term care insurance.

~~10.3.~~ 13.4. Every insurer shall report annually by June 30 the number of lapsed policies as a percent of its total annual sales and as a percent of its total number of policies in force as of the end of the preceding calendar year. (Appendix G)

~~10.4.~~ 13.5. Every insurer shall report annually by June 30 the number of replacement policies sold as a percent of its total annual sales and as a percent of its total number of policies in force as of the preceding calendar year. (Appendix G)

13.6. Every insurer shall report annually by June 30, for qualified long-term care insurance contracts, the number of claims denied for each class of business, expressed as a percentage of claims denied. (Appendix E)

~~10.5.~~ 13.7. For purposes of this section:

a. ~~"policy" shall mean~~ "Policy" means only long-term care insurance; ~~and "report" means on a statewide basis.~~

b. Subject to subdivision c of this subsection, "claim" means a request for payment of benefits under an in force policy regardless of whether the benefit claimed is covered under the policy or any terms or conditions of the policy have been met;

c. "Denied" means the insurer refuses to pay a claim for any reason other than for claims not paid for failure to meet the waiting period or because of an applicable preexisting condition; and

d. "Report" means on a statewide basis.

13.8. Reports required under this section shall be filed with the Commissioner.

§114-32-~~11~~ 14. Licensing.

~~No agent is authorized to market, sell, solicit or otherwise contact any person for the purpose of marketing long-term care insurance unless the agent is licensed and appointed by the insurer to sell accident and sickness insurance in this state, prior to soliciting such insurance business.~~

A producer is not authorized to sell, solicit or negotiate with respect to long-term care insurance except as authorized by W. Va. Code §33-12-1 *et seq*.

§114-32-~~12~~ 15. Discretionary Powers of Commissioner.

~~12.1.~~ 15.1. The ~~commissioner~~ Commissioner may upon written request and after an administrative hearing, issue an order to modify or suspend a specific provision or provisions of this ~~regulation~~ rule with respect to a specific long-term care insurance policy or certificate upon a written finding that:

~~12.1.1.~~ a. The modification or suspension would be in the best interest of the insureds; and

~~12.1.2.~~ b. The purposes to be achieved could not be effectively or efficiently achieved without the modification or suspension; and

~~a.~~ c. 1. The modification or suspension is necessary to the development of an innovative and reasonable approach for insuring long-term care; or

~~b.~~ 2. The policy or certificate is to be issued to residents of a life care or continuing care retirement community or some other residential community for the elderly and the modification or suspension is reasonably related to the special needs or nature of such a community; or

~~c.~~ 3. The modification or suspension is necessary to permit long-term care insurance to be sold as part of, or in conjunction with, another insurance product.

§114-32-~~13~~ 16. Reserve Standards.

~~13.1.~~ 16.1. When long-term care benefits are provided through the acceleration of benefits under group or individual life policies or riders to such policies, policy reserves for ~~such~~ the benefits shall be determined in accordance with W. Va. Code §33-7-9(3)(a)(A)(vii). Claim reserves ~~must~~ shall also be established in the case when ~~such~~ the policy or rider is in claim status.

Reserves for policies and riders subject to this subsection should be based on the multiple decrement model utilizing all relevant decrements except for voluntary termination rates. Single decrement approximations are acceptable if the calculation produces essentially similar reserves, if the reserve is clearly more conservative, or if the reserve is immaterial. The calculations may take into account the reduction in life insurance benefits due to the payment of long-term care benefits. However, in no event shall the reserves for the long-term care benefit and the life insurance benefit be less than the reserves for the life insurance benefit assuming no long-term care benefit.

In the development and calculation of reserves for policies and riders subject to this subsection, due regard shall be given to the applicable policy provisions, marketing methods, administrative procedures and all other considerations which have an impact on projected claim costs, including, but not limited to, the following:

~~13.1.1.~~ a. Definition of insured events;

~~13.1.2.~~ b. Covered long-term care facilities;

~~13.1.3.~~ c. Existence of home convalescence care coverage;

~~13.1.4.~~ d. Definition of facilities;

~~13.1.5.~~ e. Existence or absence of barriers to eligibility;

~~13.1.6.~~ f. Premium waiver provision;

~~13.1.7.~~ g. Renewability;

~~13.1.8.~~ h. Ability to raise premiums;

~~13.1.9.~~ i. Marketing method;

~~13.1.10.~~ j. Underwriting procedures;

~~13.1.11.~~ k. Claims adjustment procedures;

~~13.1.12.~~ *l.* Waiting period;

~~13.1.13.~~ m. Maximum benefit;

~~13.1.14.~~ n. Availability of eligible facilities;

~~13.1.15.~~ o. Margins in claim costs;

~~13.1.16.~~ p. Optional nature of benefit;

~~13.1.17.~~ q. Delay in eligibility for benefit;

~~13.1.18.~~ r. Inflation protection provisions; and

~~13.1.19.~~ s. Guaranteed insurability option.

Any applicable valuation morbidity table shall be certified as appropriate as a statutory valuation table by a member of the American Academy of Actuaries.

~~13.2.~~ 16.2. When long-term care benefits are provided other than as in subsection ~~13.1 above~~ 16.1 of this section, reserves shall be determined in accordance with the provisions of Chapter 33, Article 7 of the West Virginia Code relating to accident and sickness insurance policies.

§114-32-~~14~~ 17. Loss Ratio.

17.1. This section shall apply to all long-term care insurance policies or certificates except those covered under sections 8 and 18 of this rule.

~~14.1.~~ 17.2. Benefits under long-term care insurance policies shall be deemed reasonable in relation to premiums provided the expected loss ratio is at least sixty percent (60%), calculated in a manner which provides for adequate reserving of the long-term care insurance risk. In evaluating the expected loss ratio, due consideration shall be given to all relevant factors, including:

~~14.1.1.~~ a. Statistical credibility of incurred claims experience and earned premiums;

~~14.1.2.~~ b. The period for which rates are computed to provide coverage;

~~14.1.3.~~ c. Experienced and projected trends;

~~14.1.4.~~ d. Concentration of experience within early policy duration;

~~14.1.5.~~ e. Expected claim fluctuation;

~~14.1.6.~~ f. Experience refunds, adjustments or dividends;

~~14.1.7.~~ g. Renewability features;

~~14.1.8.~~ h. All appropriate expense factors;

~~14.1.9.~~ i. Interest;

~~14.1.10.~~ j. Experimental nature of the coverage;

~~14.1.11.~~ k. Policy reserves;

~~14.1.12.~~ *l.* Mix of business by risk classification; and

~~14.1.13.~~ m. Product features such as long elimination periods, high deductibles and high maximum limits.

17.3. Subsection 17.2 of this section shall not apply to life insurance policies that accelerate benefits for long-term care. A life insurance policy that funds long-term care benefits entirely by accelerating the death benefit is considered to provide reasonable benefits in relation to premiums paid, if the policy complies with all of the following provisions:

a. The interest credited internally to determine cash value accumulations, including long-term care, if any, are guaranteed not to be less than the minimum guaranteed interest rate for cash value accumulations without long-term care set forth in the policy;

b. The portion of the policy that provides life insurance benefits meets the nonforfeiture requirements of W. Va. Code §33-13-30;

c. The policy meets the disclosure requirements of W. Va. Code §§ 33-15A-6(i), 6(j), and 6(k) of the NAIC Long-Term Care Insurance Model Act;

d. Any policy illustration that meets the applicable requirements of Series 11C of Title 114, West Virginia Code of State Rules; and

e. An actuarial memorandum is filed with the Commissioner that includes:

1. A description of the basis on which the long-term care rates were determined;

2. A description of the basis for the reserves;

3. A summary of the type of policy, benefits, renewability, general marketing method, and limits on ages of issuance;

4. A description and a table of each actuarial assumption used. For expenses, an insurer must include percent of premium dollars per policy and dollars per unit of benefits, if any;

5. A description and a table of the anticipated policy reserves and additional reserves to be held in each future year for active lives;

6. The estimated average annual premium per policy and the average issue age;

7. A statement as to whether underwriting is performed at the time of application. The statement shall indicate whether underwriting is used and, if used, the statement shall include a description of the type or types of underwriting used, such as medical underwriting or functional assessment underwriting. Concerning a group policy, the statement shall indicate whether the enrollee or any dependent will be underwritten and when underwriting occurs; and

8. A description of the effect of the long-term care policy provision on the required premiums, nonforfeiture values and reserves on the underlying life insurance policy, both for active lives and those in long-term care claim status.

§114-32-18. Premium Rate Schedule Increases.

18.1. This section shall apply as follows:

a. Except as provided in subdivision b of this subsection, this section applies to any long-term care policy or certificate issued in this state on or after October 1, 2009.

b. For certificates issued on or after the effective date of this rule, amended in 2009, under a group long-term care insurance policy as defined in W. Va. Code §33-15A-4(e)(1), which policy was in force at the time this amended rule became effective, the provisions of this section shall apply on the policy anniversary following twelve (12) months after the effective date of this amended rule.

c. Except as provided in this section, exceptional increases are subject to the same requirements as other premium rate schedule increases.

d. The Commissioner may request a review by an independent actuary or a professional actuarial body of the basis for a request that an increase be considered an exceptional increase.

e. The Commissioner, in determining that the necessary basis for an exceptional increase exists, shall also determine any potential offsets to higher claims costs.

18.2. An insurer shall provide notice of a pending premium rate schedule increase, including an exceptional increase, to the Commissioner at least sixty (60) days prior to the notice to the policyholders and shall include:

a. Information required by section 7 of this rule;

b. Certification by a qualified actuary that:

1. If the requested premium rate schedule increase is implemented and the underlying assumptions, which reflect moderately adverse conditions, are realized, no further premium rate schedule increases are anticipated;

2. The premium rate filing is in compliance with the provisions of this section;

c. An actuarial memorandum justifying the rate schedule change request that includes:

1. Lifetime projections of earned premiums and incurred claims based on the filed premium rate schedule increase; and the method and assumptions used in determining the projected values, including reflection of any assumptions that deviate from those used for pricing other forms currently available for sale;

A. Annual values for the five (5) years preceding and the three (3) years following the valuation date shall be provided separately;

B. The projections shall include the development of the lifetime loss ratio, unless the rate increase is an exceptional increase;

C. The projections shall demonstrate compliance with subsection 18.3 of this section; and

D. For exceptional increases,

1. The projected experience should be limited to the increases in claims expenses attributable to the approved reasons for the exceptional increase; and

2. In the event the Commissioner determines as provided in subdivision d, subsection 2.1 of this rule that offsets may exist, the insurer shall use appropriate net projected experience;

2. Disclosure of how reserves have been incorporated in this rate increase whenever the rate increase will trigger contingent benefit upon lapse;

3. Disclosure of the analysis performed to determine why a rate adjustment is necessary, which pricing assumptions were not realized and why, and what other actions taken by the company have been relied on by the actuary;

4. A statement that policy design, underwriting and claims adjudication practices have been taken into consideration; and

5. In the event that it is necessary to maintain consistent premium rates for new certificates and certificates receiving a rate increase, the insurer will need to file composite rates reflecting projections of new certificates;

d. A statement that renewal premium rate schedules are not greater than new business premium rate schedules except for differences attributable to benefits, unless sufficient justification is provided to the Commissioner; and

e. Sufficient information for review and approval of the premium rate schedule increase by the Commissioner.

18.3. All premium rate schedule increases shall be determined in accordance with the following requirements:

a. Exceptional increases shall provide that seventy percent (70%) of the present value of projected additional premiums from the exceptional increase will be returned to policyholders in benefits;

b. Premium rate schedule increases shall be calculated such that the sum of the accumulated value of incurred claims, without the inclusion of active life reserves, and the present value of future projected incurred claims, without the inclusion of active life reserves, will not be less than the sum of the following:

1. The accumulated value of the initial earned premium times fifty-eight percent (58%);

2. Eighty-five percent (85%) of the accumulated value of prior premium rate schedule increases on an earned basis;

3. The present value of future projected initial earned premiums times fifty-eight percent (58%); and

4. Eighty-five percent (85%) of the present value of future projected premiums not in paragraph 3 of this subdivision on an earned basis;

c. In the event that a policy form has both exceptional and other increases, the values in paragraph 2 and 4, subdivision b of this subsection will also include seventy percent (70%) for exceptional rate increase amounts; and

d. All present and accumulated values used to determine rate increases shall use the maximum valuation interest rate for contract reserves as specified in the 114CSR44, Appendix A, Section IIA. The actuary shall disclose as part of the actuarial memorandum the use of any appropriate averages.

18.4. For each rate increase that is implemented, the insurer shall file for approval by the Commissioner updated projections, as defined in paragraph 1, subdivision c, subsection 18.2 of this section, annually for the next three (3) years and include a comparison of actual results to projected values. The Commissioner may extend the period to greater than three (3) years if actual results are not consistent with projected values from prior projections. For group insurance policies that meet the conditions in subsection 18.11 of this section, the projections required by this subsection shall be provided to the policyholder in lieu of filing with the Commissioner.

18.5. If any premium rate in the revised premium rate schedule is greater than 200 percent of the comparable rate in the initial premium schedule, lifetime projections, as defined in

paragraph 1, subdivision c, subsection 18.2 of this section, shall be filed for approval by the Commissioner every five (5) years following the end of the required period in subsection 18.4 of this section. For group insurance policies that meet the conditions in subsection 18.11 of this section, the projections required by this subsection shall be provided to the policyholder in lieu of filing with the Commissioner.

18.6. a. If the Commissioner has determined that the actual experience following a rate increase does not adequately match the projected experience and that the current projections under moderately adverse conditions demonstrate that incurred claims will not exceed proportions of premiums specified in subsection 18.3 of this section, the Commissioner may require the insurer to implement any of the following:

1. Premium rate schedule adjustments; or

2. Other measures to reduce the difference between the projected and actual experience.

b. In determining whether the actual experience adequately matches the projected experience, consideration should be given to paragraph 5, subdivision c, subsection 18.2 of this section, if applicable.

18.7. If the majority of the policies or certificates to which the increase is applicable are eligible for the contingent benefit upon lapse, the insurer shall file:

a. A plan, subject to Commissioner approval, for improved administration or claims processing designed to eliminate the potential for further deterioration of the policy form requiring further premium rate schedule increases, or both, or to demonstrate that appropriate administration and claims processing have been implemented or are in effect; otherwise the Commissioner may impose the condition in subsection 18.8 of this section; and

b. The original anticipated lifetime loss ratio, and the premium rate schedule increase that would have been calculated according to subsection 18.3 of this section had the greater of the original anticipated lifetime loss ratio or fifty-eight percent (58%) been used in the calculations described in paragraph 1 and 3, subdivision b, subsection 18.3 of this section.

18.8. a. For a rate increase filing that meets the following criteria, the Commissioner shall review, for all policies included in the filing, the projected lapse rates and past lapse rates during the twelve (12) months following each increase to determine if significant adverse lapsation has occurred or is anticipated:

1. The rate increase is not the first rate increase requested for the specific policy form or forms;

2. The rate increase is not an exceptional increase; and

3. The majority of the policies or certificates to which the increase is applicable are eligible for the contingent benefit upon lapse

b. In the event significant adverse lapsation has occurred, is anticipated in the filing or is evidenced in the actual results as presented in the updated projections provided by the insurer following the requested rate increase, the Commissioner may determine that a rate spiral exists. Following the determination that a rate spiral exists, the Commissioner may require the insurer to offer, without underwriting, to all in force insureds subject to the rate increase the option to replace existing coverage with one or more reasonably comparable products being offered by the insurer or its affiliates.

1. The offer shall:

A. Be subject to the approval of the Commissioner;

B. Be based on actuarially sound principles, but not be based on attained age; and

C. Provide that maximum benefits under any new policy accepted by an insured shall be reduced by comparable benefits already paid under the existing policy.

2. The insurer shall maintain the experience of all the replacement insureds separate from the experience of insureds originally issued the policy forms. In the event of a request for a rate increase on the policy form, the rate increase shall be limited to the lesser of:

A. The maximum rate increase determined based on the combined experience; and

B. The maximum rate increase determined based only on the experience of the insureds originally issued the form plus ten percent (10%).

18.9. If the Commissioner determines that the insurer has exhibited a persistent practice of filing inadequate initial premium rates for long-term care insurance, the Commissioner may, in addition to the provisions of subsection 18.8 of this section, prohibit the insurer from either of the following:

a. Filing and marketing comparable coverage for a period of up to five (5) years; or

b. Offering all other similar coverages and limiting marketing of new applications to the products subject to recent premium rate schedule increases.

18.10. Subsections 18.1 through 18.9 of this section do not apply to policies for which the long-term care benefits provided by the policy are incidental, as defined in subsection 2.2 of this rule, if the policy complies with all of the following provisions:

a. The interest credited internally to determine cash value accumulations, including long-term care, if any, are guaranteed not to be less than the minimum guaranteed interest rate for cash value accumulations without long-term care set forth in the policy;

b. The portion of the policy that provides insurance benefits other than long-term care coverage meets the nonforfeiture requirements as applicable in any of the following:

1. W. Va. Code §33-13-30;

2. W. Va. Code §33-13-30a, and

3. W. Va. Code §33-13A-1 *et seq.*;

c. The policy meets the disclosure requirements of W. Va. Code §§33-15A-6(i), 6(j), and 6(k);

d. The portion of the policy that provides insurance benefits other than long-term care coverage meets the requirements as applicable in the following:

1. Policy illustrations as required by Series 11C of Title 114, West Virginia Code of State Rules;

2. Disclosure requirements in W. Va. Code §33-13-1 *et seq.*; and

3. Disclosure requirements in W. Va. Code §33-13A-1 *et seq.*

e. An actuarial memorandum is filed with the Commissioner that includes:

1. A description of the basis on which the long-term care rates were determined;

2. A description of the basis for the reserves;

3. A summary of the type of policy, benefits, renewability, general marketing method, and limits on ages of issuance;

4. A description and a table of each actuarial assumption used. For expenses, an insurer must include percent of premium dollars per policy and dollars per unit of benefits, if any;

5. A description and a table of the anticipated policy reserves and additional reserves to be held in each future year for active lives;

6. The estimated average annual premium per policy and the average issue age;

7. A statement as to whether underwriting is performed at the time of application. The statement shall indicate whether underwriting is used and, if used, the statement shall include a description of the type or types of underwriting used, such as medical underwriting or functional assessment underwriting. Concerning a group policy, the statement

shall indicate whether the enrollee or any dependent will be underwritten and when underwriting occurs; and

8. A description of the effect of the long-term care policy provision on the required premiums, nonforfeiture values and reserves on the underlying insurance policy, both for active lives and those in long-term care claim status.

18.11. Subsections 18.6 and 18.8 of this section shall not apply to group insurance policies as defined in W. Va. Code §33-15A-4(e)(1) where:

a. The policies insure 250 or more persons and the policyholder has 5,000 or more eligible employees of a single employer; or

b. The policyholder, and not the certificateholders, pays a material portion of the premium, which shall not be less than twenty percent (20%) of the total premium for the group in the calendar year prior to the year a rate increase is filed.

§114-32-~~15~~ 19. Filing Requirement.

Prior to an insurer or similar organization offering group long-term care insurance to a resident of this State pursuant to W. Va. Code §33-15A-5, it shall file with the Commissioner evidence that the group policy or certificate thereunder has been approved by a state having statutory or regulatory long-term care insurance requirements substantially similar to those adopted in this State.

§114-32-~~16~~ 20. Filing Requirements for Advertising.

~~16.1.~~ 20.1. Every insurer, health care service plan or other entity providing long-term care insurance or benefits in this State shall provide a copy of any long-term care insurance advertisement intended for use in this State whether through written, radio or television medium to the Commissioner for review or approval by the Commissioner to the extent it may be required under state law. In addition, all advertisements shall be retained by the insurer, health care service plan or other entity for at least three (3) years from the date the advertisement was first used.

~~16.2.~~ 20.2. The Commissioner may exempt from these requirements any advertising form or material when in the Commissioner's opinion, this requirement may not be reasonably applied.

§114-32-~~17~~ 21. Standards for Marketing.

~~17.1.~~ 21.1. Every insurer, health care service plan or other entity marketing long-term care insurance coverage in this State, directly or through its producers, shall:

~~17.1.1.~~ a. Establish marketing procedures and producer training requirements to assure that:

1. Any marketing activities, including any comparison of policies by its producers or other producers will be fair and accurate; and

~~17.1.2.~~ 2. ~~Establish marketing procedures to assure~~ Excessive insurance is not sold or issued.

~~17.1.3.~~ b. Display prominently by type, stamp or other appropriate means, on the first page of the outline of coverage and policy the following:

"Notice to buyer: This policy may not cover all of the costs associated with long-term care incurred by the buyer during the period of coverage. The buyer is advised to review carefully all policy limitations."

c. Provide copies of the disclosure forms required in subsection 7.3 of this rule (Appendices B and F) to the applicant.

~~17.1.4.~~ d. Inquire and otherwise make every reasonable effort to identify whether a prospective applicant or enrollee for long-term care insurance already has accident and sickness or long-term care insurance and the types and amounts of any such insurance, except that in the case of qualified long-term care insurance contracts, an inquiry into whether a prospective applicant or enrollee for long-term care insurance has accident and sickness insurance is not required.

~~17.1.5.~~ e. Every insurer or entity marketing long-term care insurance shall establish auditable procedures for verifying compliance with this Subsection ~~17.1.~~

~~17.1.6.~~ f. If the state in which the policy or certificate is to be delivered or issued for delivery has a senior insurance counseling program approved by the Commissioner, the insurer shall, at solicitation, provide written notice to the prospective policyholder and certificateholder that ~~such a~~ the program is available and the name, address and telephone number of the program.

g. For long-term care health insurance policies and certificates, use the terms "noncancellable" or "level premium" only when the policy or certificate conforms to subdivision c, subsection 4.1 of this rule.

h. Provide an explanation of contingent benefit upon lapse provided for in subdivision c, subsection 26.4 of this rule and, if applicable, the additional contingent benefit upon lapse provided to policies with fixed or limited premium paying periods in subdivision d, subsection 26.4 of this rule.

~~17.2.~~ 21.2. In addition to the practices prohibited in this State's Unfair Trade Practices Act [W. Va. Code §33-11-1 *et seq.*], the following acts and practices are prohibited:

~~17.2.1. Twisting.~~ – a. Knowingly making any misleading representation or incomplete or fraudulent comparison of any insurance policies or insurers for the purpose of inducing, or tending to induce, any person to lapse, forfeit, surrender, terminate, retain, pledge,

assign, borrow on or convert any insurance policy or to take out a policy of insurance with another insurer.

~~17.2.2.~~ b. High pressure tactics. -- Employing any method of marketing having the effect of or tending to induce the purchase of insurance through force, fright, threat, whether explicit or implied, or undue pressure to purchase or recommend the purchase of insurance.

~~17.2.3.~~ c. Cold lead advertising. -- Making use directly or indirectly of any method of marketing which fails to disclose in a conspicuous manner that a purpose of the method of marketing is solicitation of insurance and that contact will be made by an insurance producer or insurance company.

d. Misrepresentation. Misrepresenting a material fact in selling or offering to sell a long-term care insurance policy.

21.3. a. With respect to the obligations set forth in this subsection, the primary responsibility of an association, as defined in W. Va. Code §33-15A-4(e)(2), when endorsing or selling long-term care insurance shall be to educate its members concerning long-term care issues in general so that its members can make informed decisions. Associations shall provide objective information regarding long-term care insurance policies or certificates endorsed or sold by such associations to ensure that members of such associations receive a balanced and complete explanation of the features in the policies or certificates that are being endorsed or sold.

b. The insurer shall file with the Commissioner the following material:

1. The policy and certificate,

2. A corresponding outline of coverage, and

3. All advertisements requested by the Commissioner.

c. The association shall disclose in any long-term care insurance solicitation:

1. The specific nature and amount of the compensation arrangements (including all fees, commissions, administrative fees and other forms of financial support) that the association receives from endorsement or sale of the policy or certificate to its members; and

2. A brief description of the process under which the policies and the insurer issuing the policies were selected.

d. If the association and the insurer have interlocking directorates or trustee arrangements, the association shall disclose that fact to its members.

e. The board of directors of associations selling or endorsing long-term care insurance policies or certificates shall review and approve the insurance policies as well as the compensation arrangements made with the insurer.

f. The association shall also:

1. At the time of the association's decision to endorse, engage the services of a person with expertise in long-term care insurance not affiliated with the insurer to conduct an examination of the policies, including its benefits, features, and rates and update the examination thereafter in the event of material change;

2. Actively monitor the marketing efforts of the insurer and its producers; and

3. Review and approve all marketing materials or other insurance communications used to promote sales or sent to members regarding the policies or certificates.

4. Paragraphs 1 through 3 of this subdivision shall not apply to qualified long-term care insurance contracts.

g. No group long-term care insurance policy or certificate may be issued to an association unless the insurer files the information required in this subsection with the Commissioner.

h. The insurer shall not issue a long-term care policy or certificate to an association or continue to market such a policy or certificate unless the insurer certifies annually that the association has complied with the requirements set forth in this subsection.

i. Failure to comply with the filing and certification requirements of this section constitutes an unfair trade practice in violation of this State's Unfair Trade Practices Act [W. Va. Code §33-11-1 *et seq.*].

§114-32-~~18~~ 22. Appropriateness of Recommended Purchase.

~~In recommending the purchase or replacement of any long-term care insurance policy or certificate, an agent shall make reasonable efforts to determine the appropriateness of a recommended purchase or replacement.~~

22.1. This section shall not apply to life insurance policies that accelerate benefits for long-term care.

22.2. Every insurer, health care service plan or other entity marketing long-term care insurance (the "issuer") shall:

a. Develop and use suitability standards to determine whether the purchase or replacement of long-term care insurance is appropriate for the needs of the applicant;

b. Train its producers in the use of its suitability standards; and

c. Maintain a copy of its suitability standards and make them available for inspection upon request by the Commissioner.

22.3. a. To determine whether the applicant meets the standards developed by the issuer, the producer and issuer shall develop procedures that take the following into consideration:

1. The ability to pay for the proposed coverage and other pertinent financial information related to the purchase of the coverage;

2. The applicant's goals or needs with respect to long-term care and the advantages and disadvantages of insurance to meet these goals or needs; and

3. The values, benefits and costs of the applicant's existing insurance, if any, when compared to the values, benefits and costs of the recommended purchase or replacement.

b. The issuer, and where a producer is involved, the producer shall make reasonable efforts to obtain the information set out in subdivision a of this subsection. The efforts shall include presentation to the applicant, at or prior to application, the "Long-Term Care Insurance Personal Worksheet." The personal worksheet used by the issuer shall contain, at a minimum, the information in the format contained in Appendix B, in not less than twelve (12) point type. The issuer may request the applicant to provide additional information to comply with its suitability standards. A copy of the issuer's personal worksheet shall be filed with the Commissioner.

c. A completed personal worksheet shall be returned to the issuer prior to the issuer's consideration of the applicant for coverage, except the personal worksheet need not be returned for sales of employer group long-term care insurance to employees and their spouses.

d. The sale or dissemination outside the company or agency by the issuer or producer of information obtained through the personal worksheet in Appendix B is prohibited.

22.4. The issuer shall use the suitability standards it has developed pursuant to this section in determining whether issuing long-term care insurance coverage to an applicant is appropriate.

22.5. Producers shall use the suitability standards developed by the issuer in marketing long-term care insurance.

22.6. At the same time as the personal worksheet is provided to the applicant, the disclosure form entitled "Things You Should Know Before You Buy Long-Term Care Insurance" shall be provided. The form shall be in the format contained in Appendix C, in not less than twelve (12) point type.

22.7. If the issuer determines that the applicant does not meet its financial suitability standards, or if the applicant has declined to provide the information, the issuer may reject the application. In the alternative, the issuer shall send the applicant a letter similar to Appendix D. However, if the applicant has declined to provide financial information, the issuer may use some

other method to verify the applicant's intent. Either the applicant's returned letter or a record of the alternative method of verification shall be made part of the applicant's file.

22.8. The issuer shall report annually to the Commissioner the total number of applications received from residents of this state, the number of those who declined to provide information on the personal worksheet, the number of applicants who did not meet the suitability standards, and the number of those who chose to confirm after receiving a suitability letter.

§114-32-~~19~~ 23. Prohibition Against Preexisting Conditions and Probationary Periods in Replacement Policies or Certificates.

If a long-term care insurance policy or certificate replaces another long-term care policy or certificate, the replacing insurer shall waive any time periods applicable to preexisting conditions and probationary periods in the new long-term care policy for similar benefits to the extent that similar exclusions have been satisfied under the original policy.

§114-32-24. Availability of New Services or Providers.

24.1. An insurer shall notify policyholders of the availability of a new long-term policy series that provides coverage for new long-term care services or providers material in nature and not previously available through the insurer to the general public. The notice shall be provided within twelve (12) months of the date of the new policy series is made available for sale in this state.

24.2. Notwithstanding subsection 24.1 of this section, notification is not required for any policy issued prior to the effective date of this section or to any policyholder or certificateholder who is currently eligible for benefits, within an elimination period or on a claim, or who previously had been in claim status, or who would not be eligible to apply for coverage due to issue age limitations under the new policy. The insurer may require that policyholders meet all eligibility requirements, including underwriting and payment of the required premium to add new services or providers.

24.3. The insurer shall make the new coverage available in one of the following ways:

a. By adding a rider to the existing policy and charging a separate premium for the new rider based on the insured's attained age;

b. By exchanging the existing policy or certificate for one with an issue age based on the present age of the insured and recognizing past insured status by granting premium credits toward the premiums for the new policy or certificate. The premium credits shall be based on premiums paid or reserves held for the prior policy or certificate;

c. By exchanging the existing policy or certificate for a new policy or certificate in which consideration for past insured status shall be recognized by setting the premium for the new policy or certificate at the issue age of the policy or certificate being exchanged. The cost for the new policy or certificate may recognize the difference in reserves between the new policy or certificate and the original policy or certificate; or

d. By an alternative program developed by the insurer that meets the intent of this section if the program is filed with and approved by the Commissioner.

24.4. An insurer is not required to notify policyholders of a new proprietary policy series created and filed for use in a limited distribution channel. For purposes of this subsection, "limited distribution channel" means through a discrete entity, such as a financial institution or brokerage, for which specialized products are available that are not available for sale to the general public. Policyholders that purchased such a new proprietary policy shall be notified when a new long-term care policy series that provides coverage for new long-term care services or providers material in nature is made available to that limited distribution channel.

24.5. Policies issued pursuant to this section shall be considered exchanges and not replacements. These exchanges shall not be subject to sections 12 and 22 of this rule, and the reporting requirements of subsections 13.1 to 13.5 of this rule.

24.6. Where the policy is offered through an employer, labor organization, professional, trade or occupational association, the required notification in subsection 24.1 of this section shall be made to the offering entity. However, if the policy is issued to a group defined in W. Va. Code §33-15A-4(e)(4) the notification shall be made to each certificateholder.

24.7. Nothing in this section shall prohibit an insurer from offering any policy, rider, certificate or coverage change to any policyholder or certificateholder. However, upon request any policyholder may apply for currently available coverage that includes the new services or providers. The insurer may require that policyholders meet all eligibility requirements, including underwriting and payment of the required premium to add such new services or providers.

24.8. This section does not apply to life insurance policies or riders containing accelerated long-term care benefits.

24.9. This section shall become effective on the effective date of this rule, amended in 2009.

§114-32-25. Right to Reduce Coverage and Lower Premiums.

25.1. a. Every long-term care insurance policy and certificate shall include a provision that allows the policyholder or certificateholder to reduce coverage and lower the policy or certificate premium in at least one of the following ways:

1. Reducing the maximum benefit; or

2. Reducing the daily, weekly or monthly benefit amount.

b. The insurer may also offer other reduction options that are consistent with the policy or certificate design or the carrier's administrative processes.

25.2. The provision shall include a description of the ways in which coverage may be reduced and the process for requesting and implementing a reduction in coverage.

25.3. The age to determine the premium for the reduced coverage shall be based on the age used to determine the premiums for the coverage currently in force.

25.4. The insurer may limit any reduction in coverage to plans or options available for that policy form and to those for which benefits will be available after consideration of claims paid or payable.

25.5. If a policy or certificate is about to lapse, the insurer shall provide a written reminder to the policyholder or certificateholder of his or her right to reduce coverage and premiums in the notice required by subdivision c, subsection 5.1 of this rule.

25.6. This section does not apply to life insurance policies or riders containing accelerated long-term care benefits.

25.7. The requirements of this section shall apply to any long-term care policy issued in this state on or after twelve months after the effective date of this rule, amended in 2009.

§114-32-26. Nonforfeiture Benefit Requirement.

26.1. This section does not apply to life insurance policies or riders containing accelerated long-term care benefits.

26.2. To comply with the requirement to offer a nonforfeiture benefit pursuant to the provisions of W. Va. Code §33-15A-9:

a. A policy or certificate offered with nonforfeiture benefits shall have coverage elements, eligibility, benefit triggers and benefit length that are the same as coverage to be issued without nonforfeiture benefits. The nonforfeiture benefit included in the offer shall be the benefit described in subsection 26.5 of this section; and

b. The offer shall be in writing if the nonforfeiture benefit is not otherwise described in the Outline of Coverage or other materials given to the prospective policyholder.

26.3. If the offer required to be made under W. Va. Code §33-15A-9 is rejected, the insurer shall provide the contingent benefit upon lapse described in this section. Even if this offer is accepted for a policy with a fixed or limited premium paying period, the contingent benefit on lapse in subdivision d, subsection 26.4 of this section shall still apply.

26.4. a. After rejection of the offer required under W. Va. Code §33-15A-9, for individual and group policies without nonforfeiture benefits issued after the effective date of this section, the insurer shall provide a contingent benefit upon lapse.

b. In the event a group policyholder elects to make the nonforfeiture benefit an option to the certificateholder, a certificate shall provide either the nonforfeiture benefit or the contingent benefit upon lapse.

c. A contingent benefit on lapse shall be triggered every time an insurer increases the premium rates to a level which results in a cumulative increase of the annual premium equal to or exceeding the percentage of the insured's initial annual premium set forth below based on the insured's issue age, and the policy or certificate lapses within 120 days of the due date of the premium so increased. Unless otherwise required, policyholders shall be notified at least thirty (30) days prior to the due date of the premium reflecting the rate increase.

Triggers for a Substantial Premium Increase

Issue Age	Percent Increase Over Initial Premium
29 and under	200%
30-34	190%
35-39	170%
40-44	150%
45-49	130%
50-54	110%
55-59	90%
60	70%
61	66%
62	62%
63	58%
64	54%
65	50%
66	48%
67	46%
68	44%
69	42%
70	40%
71	38%
72	36%
73	34%
74	32%
75	30%
76	28%
77	26%
78	24%
79	22%
80	20%
81	19%
82	18%
83	17%

84	16%
85	15%
86	14%
87	13%
88	12%
89	11%
90 and over	10%

d. A contingent benefit on lapse shall also be triggered for policies with a fixed or limited premium paying period every time an insurer increases the premium rates to a level that results in a cumulative increase of the annual premium equal to or exceeding the percentage of the insured's initial annual premium set forth below based on the insured's issue age, the policy or certificate lapses within 120 days of the due date of the premium so increased, and the ratio in paragraph 2 of subdivision f is forty percent (40%) or more. Unless otherwise required, policyholders shall be notified at least thirty (30) days prior to the due date of the premium reflecting the rate increase.

Triggers for a Substantial Premium Increase

Issue Age	Percent Increase Over Initial Premium
Under 65	50%
65-80	30%
Over 80	10%

This provision shall be in addition to the contingent benefit provided by subdivision c of this subsection and where both are triggered, the benefit provided shall be at the option of the insured.

e. On or before the effective date of a substantial premium increase as defined in subdivision c of this subsection, the insurer shall:

1. Offer to reduce policy benefits provided by the current coverage without the requirement of additional underwriting so that required premium payments are not increased;

2. Offer to convert the coverage to a paid-up status with a shortened benefit period in accordance with the terms of subsection 26.5 of this section. This option may be elected at any time during the 120-day period referenced in subdivision c of this subsection; and

3. Notify the policyholder or certificateholder that a default or lapse at any time during the 120-day period referenced in subdivision c of this subsection shall be deemed to be the election of the offer to convert in paragraph 2 of this subdivision unless the automatic option in paragraph 3 of subdivision f applies.

f. On or before the effective date of a substantial premium increase as defined in

subdivision d of this subsection, the insurer shall:

1. Offer to reduce policy benefits provided by the current coverage without the requirement of additional underwriting so that required premium payments are not increased;

2. Offer to convert the coverage to a paid-up status where the amount payable for each benefit is ninety percent (90%) of the amount payable in effect immediately prior to lapse times the ratio of the number of completed months of paid premiums divided by the number of months in the premium paying period. This option may be elected at any time during the 120-day period referenced in subdivision d of this subsection; and

3. Notify the policyholder or certificate holder that a default or lapse at any time during the 120-day period referenced in subdivision d of this subsection shall be deemed to be the election of the offer to convert in paragraph 2 of this subdivision if the ratio is forth percent (40%) or more.

26.5. Benefits continued as nonforfeiture benefits, including contingent benefits upon lapse in accordance with subdivision c, subsection 26.4 of this section but not subdivision d, subsection 26.4 of this section, are described in this subsection:

a. For purposes of this subsection, attained age rating is defined as a schedule of premiums starting from the issue date which increases age at least one percent per year prior to age fifty (50), and at least three percent (3%) per year beyond age fifty (50).

b. For purposes of this subsection, the nonforfeiture benefit shall be of a shortened benefit period providing paid-up long-term care insurance coverage after lapse. The same benefits (amounts and frequency in effect at the time of lapse but not increased thereafter) will be payable for a qualifying claim, but the lifetime maximum dollars or days of benefits shall be determined as specified in subdivision c of this subsection.

c. The standard nonforfeiture credit will be equal to 100% of the sum of all premiums paid, including the premiums paid prior to any changes in benefits. The insurer may offer additional shortened benefit period options, as long as the benefits for each duration equal or exceed the standard nonforfeiture credit for that duration. However, the minimum nonforfeiture credit shall not be less than thirty (30) times the daily nursing home benefit at the time of lapse. In either event, the calculation of the nonforfeiture credit is subject to the limitation of subsection 26.6 of this section.

d. 1. The nonforfeiture benefit shall begin not later than the end of the third year following the policy or certificate issue date. The contingent benefit upon lapse shall be effective during the first three (3) years as well as thereafter.

2. Notwithstanding paragraph 1 of this subdivision, for a policy or certificate with attained age rating, the nonforfeiture benefit shall begin on the earlier of:

A. The end of the tenth year following the policy or certificate

issue date; or

B. The end of the second year following the date the policy or certificate is no longer subject to attained age rating.

e. Nonforfeiture credits may be used for all care and services qualifying for benefits under the terms of the policy or certificate, up to the limits specified in the policy or certificate.

26.6. All benefits paid by the insurer while the policy or certificate is in premium paying status and in the paid up status will not exceed the maximum benefits which would be payable if the policy or certificate had remained in premium paying status.

26.7. There shall be no difference in the minimum nonforfeiture benefits as required under this section for group and individual policies.

26.8. The requirements set forth in this section shall become effective twelve (12) months after the effective date of this rule, amended in 2009, and shall apply as follows:

a. Except as provided in subdivisions b and c of this subsection, this section applies to any long-term care policy issued in this state on or after the effective date of this rule, amended in 2009.

b. For certificates issued on or after the effective date of this section, under a group long-term care insurance policy as defined in W. Va. Code §33-15A-4(e)(1), which policy was in force at the time of the effective date of this rule, amended in 2009, this section shall not apply.

c. The last sentence in subsection 26.3 of this section and subdivisions d and f, subsection 26.4 of this section shall apply to any long-term care insurance policy or certificate issued in this state after six (6) months after their adoption, except new certificates on a group policy as defined in W. Va. Code §33-15A-4(e)(1) one year after adoption.

26.9. Premiums charged for a policy or certificate containing nonforfeiture benefits or a contingent benefit on lapse shall be subject to the loss ratio requirements of section 17 or section 18 of this rule, whichever is applicable, treating the policy as a whole.

26.10. To determine whether contingent nonforfeiture upon lapse provisions are triggered under subdivision c or d, subsection 26.4 of this section, a replacing insurer that purchased or otherwise assumed a block or blocks of long-term care insurance policies from another insurer shall calculate the percentage increase based on the initial annual premium paid by the insured when the policy was first purchased from the original insurer.

26.11. A nonforfeiture benefit for qualified long-term care insurance contracts that are level premium contracts shall be offered that meets the following requirements:

a. The nonforfeiture provision shall be appropriately captioned;

b. The nonforfeiture provision shall provide a benefit available in the event of a default in the payment of any premiums and shall state that the amount of the benefit may be adjusted subsequent to being initially granted only as necessary to reflect changes in claims, persistency and interest as reflected in changes in rates for premium paying contracts approved by the Commissioner for the same contract form; and

c. The nonforfeiture provision shall provide at least one of the following:

1. Reduced paid-up insurance;

2. Extended term insurance;

3. Shortened benefit period; or

4. Other similar offerings approved by the Commissioner

§114-32-27. Standards for Benefit Triggers.

27.1. A long-term care insurance policy shall condition the payment of benefits on a determination of the insured's ability to perform activities of daily living and on cognitive impairment. Eligibility for the payment of benefits shall not be more restrictive than requiring either a deficiency in the ability to perform not more than three (3) of the activities of daily living or the presence of cognitive impairment.

27.2. a. Activities of daily living shall include at least the following as defined in section 3 and in the policy:

1. Bathing;

2. Continence;

3. Dressing;

4. Eating;

5. Toileting; and

6. Transferring;

b. Insurers may use activities of daily living to trigger covered benefits in addition to those contained in subdivision a of this subsection as long as they are defined in the policy.

27.3. An insurer may use additional provisions for the determination of when benefits are payable under a policy or certificate; however the provisions shall not restrict, and are not in lieu of, the requirements contained in subsections 27.1 and 27.2 of this section.

27.4. For purposes of this section the determination of a deficiency shall not be more restrictive than:

a. Requiring the hands-on assistance of another person to perform the prescribed activities of daily living; or

b. If the deficiency is due to the presence of a cognitive impairment, supervision or verbal cueing by another person is needed in order to protect the insured or others.

27.5. Assessments of activities of daily living and cognitive impairment shall be performed by licensed or certified professionals, such as physicians, nurses or social workers.

27.6. Long term care insurance policies shall include a clear description of the process for appealing and resolving benefit determinations.

27.7. The requirements set forth in this section shall be effective twelve (12) months after the effective date of this provision and shall apply as follows:

a. Except as provided in subdivision b of this subsection, the provisions of this section apply to a long-term care policy issued in this state on or after the effective date of the rule, amended in 2009.

b. For certificates issued on or after the effective date of this section, under a group long-term care insurance policy as defined in W. Va. Code §33-15A-4(e)(1) that was in force at the time this rule, amended in 2009, became effective, the provisions of this section shall not apply.

§114-32-28. Additional Standards for Benefit Triggers for Qualified Long-Term Care Insurance Contracts.

28.1. For purposes of this section the following definitions apply:

a. "Qualified long-term care services" means services that meet the requirements of Section 7702(c)(1) of the Internal Revenue Code of 1986, as amended, as follows: necessary diagnostic, preventive, therapeutic, curative, treatment, mitigation and rehabilitative services, and maintenance or personal care services which are required by a chronically ill individual, and are provided pursuant to a plan of care prescribed by a licensed health care practitioner.

b. 1. "Chronically ill individual" has the meaning prescribed for this term by section 7702B(c)(2) of the Internal Revenue Code of 1986, as amended. Under this provision, a chronically ill individual means any individual who has been certified by a licensed health care practitioner as:

A. Being unable to perform (without substantial assistance from another individual) at least two (2) activities of daily living for a period of at least ninety (90) days due to a loss of functional capacity; or

B. Requiring substantial supervision to protect the individual from threats to health and safety due to severe cognitive impairment.

2. The term "chronically ill individual" shall not include an individual otherwise meeting these requirements unless within the preceding twelve-month period a licensed health care practitioner has certified that the individual meets these requirements.

c. "Licensed health care practitioner" means a physician, as defined in Section 1861(r)(1) of the Social Security Act, a registered professional nurse, licensed social worker or other individual who meets requirements prescribed by the Secretary of the Treasury.

d. "Maintenance or personal care services" means any care the primary purpose of which is the provision of needed assistance with any of the disabilities as a result of which the individual is a chronically ill individual (including the protection from threats to health and safety due to severe cognitive impairment).

28.2. A qualified long term care insurance contract shall pay only for qualified long term care services received by a chronically ill individual provided pursuant to a plan of care prescribed by a licensed health care practitioner.

28.3. A qualified long-term care insurance contract shall condition the payment of benefits on a determination of the insured's inability to perform activities of daily living for an expected period of at least ninety (90) days due to a loss of functional capacity or to severe cognitive impairment.

28.4. Certifications regarding activities of daily living and cognitive impairment required pursuant to subsection 28.3 of this section shall be performed by the following licensed or certified professionals: physicians, registered professional nurses, licensed social workers, or other individuals who meet requirements prescribed by the Secretary of the Treasury.

28.5. Certifications required pursuant to subsection 28.3 of this section may be performed by a licensed health care professional at the direction of the carrier as is reasonably necessary with respect to a specific claim, except that when a licensed health care practitioner has certified that an insured is unable to perform activities of daily living for an expected period of at least ninety (90) days due to a loss of functional capacity and the insured is in claim status, the certification may not be rescinded and additional certifications may not be performed until after the expiration of the ninety-day period.

28.6. Qualified long-term care insurance contracts shall include a clear description of the process for appealing and resolving disputes with respect to benefit determinations.

114-32-~~20~~ 29. Standard Format Outline of Coverage.

~~20.1.~~ This section of the ~~regulation~~ rule implements, interprets and makes specific, the provisions of W. Va. Code §33-15A-6(g)(1)(A) in prescribing a standard format and the content of an outline of coverage.

~~20.1.1.~~ 29.1. The outline of coverage shall be a free-standing document, using no smaller than ten point type.

~~20.1.2.~~ 29.2. The outline of coverage shall contain no material of an advertising nature.

~~20.1.3.~~ 29.3. Text ~~which~~ that is capitalized or underscored in the standard format outline of coverage may be emphasized by other means ~~which~~ that provide prominence equivalent to ~~such~~ the capitalization or underscoring.

~~20.1.4.~~ 29.4. Use of the text and sequence of text of the standard format outline of coverage is mandatory, unless otherwise specifically indicated.

~~20.1.5.~~ 29.5. Format for outline of coverage: ~~(See Appendix D)~~

[COMPANY NAME]

[ADDRESS - CITY & STATE]

[TELEPHONE NUMBER]

LONG-TERM CARE INSURANCE
OUTLINE OF COVERAGE

[Policy Number or Group Master Policy and Certificate Number]

[Except for policies or certificates which are guaranteed issue, the following caution statement, or language substantially similar, must appear as follows in the outline of coverage.]

Caution: The issuance of this long-term care insurance [policy] [certificate] is based upon your responses to the questions on your application. A copy of your [application] [enrollment form] [is enclosed] [was retained by you when you applied]. If your answers are incorrect or untrue, the company has the right to deny benefits or rescind your policy. The best time to clear up any questions is now, before a claim arises! If, for any reason, any of your answers are incorrect, contact the company at this address: [insert address]

1. This policy is [an individual policy of insurance]([a group policy] which was issued in the [indicate jurisdiction in which group policy was issued]).

2. PURPOSE OF OUTLINE OF COVERAGE. This outline of coverage provides a very brief description of the important features of the policy. You should compare this outline of coverage to outlines of coverage for other policies available to you. This is not an insurance contract, but only a summary of coverage. Only the individual or group policy contains governing contractual provisions. This means that the policy or group policy sets forth in detail the rights and obligations of both you and the insurance company. Therefore, if you purchase this coverage, or any other coverage, it is important that you READ YOUR POLICY (OR CERTIFICATE) CAREFULLY!

3. FEDERAL TAX CONSEQUENCES.

   This [POLICY] [CERTIFICATE] is intended to be a federally tax-qualified long-term care insurance contract under Section 7702B(b) of the Internal Revenue Code of 1986, as amended.

   OR

   Federal Tax Implications of this [POLICY] [CERTIFICATE]. This [POLICY] [CERTIFICATE] is not intended to be a federally tax-qualified long-term care insurance contract under Section 7702B(b)
   of the Internal Revenue Code of 1986 as amended. Benefits received under the [POLICY] [CERTIFICATE] may be taxable as income.

4. TERMS UNDER WHICH THE POLICY OR CERTIFICATE MAY BE CONTINUED IN FORCE OR DISCONTINUED.

   (a) [For long-term care health insurance policies or certificates describe one of the following permissible policy renewability provisions:

      (1) Policies and certificates that are guaranteed renewable shall contain the following statement:] RENEWABILITY: THIS POLICY [CERTIFICATE] IS GUARANTEED RENEWABLE. This means you have the right, subject to the terms of your policy, [certificate] to continue this policy as long as you pay your premiums on time. [Company Name] cannot change any of the terms of your policy on its own, except that, in the future, IT MAY INCREASE THE

PREMIUM YOU PAY.

(2) [Policies and certificates that are noncancellable shall contain the following statement:] RENEWABILITY: THIS POLICY [CERTIFICATE] IS NONCANCELLABLE. This means that you have the right, subject to the terms of your policy, to continue this policy as long as you pay your premiums on time. [Company Name] cannot change any of the terms of your policy on its own and cannot change the premium you currently pay. However, if your policy contains an inflation protection feature where you choose to increase your benefits, [Company Name] may increase your premium at that time for those additional benefits.

(b) [For group coverage, specifically describe continuation/conversion provisions applicable to the certificate and group policy;]

(c) [Describe waiver of premium provisions or state that there are not such provisions.]

5. TERMS UNDER WHICH THE COMPANY MAY CHANGE PREMIUMS.

[In bold type larger than the maximum type required to be used for the other provisions of the outline of coverage, state whether or not the company has a right to change the premium, and if a right exists, describe clearly and concisely each circumstance under which the premium may change.]

6. TERMS UNDER WHICH THE POLICY OR CERTIFICATE MAY BE RETURNED AND PREMIUM REFUNDED.

(a) [Provide a brief description of the right to return–"free look" provision of the policy.]

(b) [Include a statement that the policy either does or does not contain provisions providing for a refund or partial refund of premium upon the death of an insured or surrender of the policy or certificate. If the policy contains such provisions, include a description of them.]

7. THIS IS NOT MEDICARE SUPPLEMENT COVERAGE. If you are eligible for Medicare, review the Medicare Supplement Buyer's Guide available from the insurance company.

(a) [For producers] Neither [insert company name] nor its producers represent Medicare, the federal government or any state government.

(b) [For direct response] [insert company name] is not representing Medicare, the federal government or any state government.

8. LONG-TERM CARE COVERAGE. Policies of this category are designed to provide coverage for one or more necessary or medically necessary diagnostic, preventive, therapeutic, rehabilitative, maintenance, or personal care services, provided in a setting other than an acute care unit of a hospital, such as in a nursing home, in the community or in the home.

This policy provides coverage in the form of a fixed dollar indemnity benefit for covered long-term care expenses, subject to policy [limitations] [waiting periods] and [coinsurance] requirements. [Modify this paragraph if the policy is not an indemnity policy.]

9. BENEFITS PROVIDED BY THIS POLICY.

(a) [Covered services, related deductibles, waiting periods, elimination periods and benefit maximums.]

(b) [Institutional benefits, by skill level.]

(c) [Non-institutional benefits, by skill level.]

(d) Eligibility for Payment of Benefits
[Activities of daily living and cognitive impairment shall be used to measure an insured's need for long-term care and must be defined and described as part of the outline of coverage.]

[Any additional benefit triggers must also be explained. If these triggers differ for different benefits, explanation of the triggers should accompany each benefit description. If an attending physician or other specified person must certify a certain level of functional dependency in order to be eligible for benefits, this too must be specified.]

10. LIMITATIONS AND EXCLUSIONS.

[Describe:

(a) Preexisting conditions;

(b) Non-eligible facilities and provider;

(c) Non-eligible levels of care (e.g., unlicensed providers, care or treatment provided by a family member, etc.);

(d) Exclusions and exceptions;

(e) Limitations.]

[This section should provide a brief specific description of any policy provisions which limit, exclude, restrict, reduce, delay, or in any other manner operate to qualify payment of the benefits described in Number 6 above.]

THIS POLICY MAY NOT COVER ALL THE EXPENSES ASSOCIATED WITH YOUR LONG-TERM CARE NEEDS.

11. RELATIONSHIP OF COST OF CARE AND BENEFITS. Because the costs of long-term care services will likely increase over time, you should consider whether and how the benefits of this plan may be adjusted. [As applicable, indicate the following:

(a) That the benefit level will not increase over time;

(b) Any automatic benefit adjustment provisions;

(c) Whether the insured will be guaranteed the option to buy additional benefits and the basis upon which benefits will be increased over time if not by a specified amount or percentage;

(d) If there is such a guarantee, include whether additional underwriting or health screening will be required, the frequency and amounts of the upgrade options, and any significant restrictions or limitations;

(e) And finally, describe whether there will be any additional premium charge imposed, and how that is to be calculated.]

12. ALZHEIMER'S DISEASE AND OTHER ORGANIC BRAIN DISORDERS.

[State that the policy provides coverage for insureds clinically diagnosed as having Alzheimer's disease or related degenerative and dementing illnesses. Specifically describe each benefit screen or other policy provision which provides preconditions to the availability of policy benefits for such an insured.]

13. PREMIUM.

[(a) State the total annual premium for the policy;

(b) If the premium varies with an applicant's choice among benefit options, indicate the portion of annual premium which corresponds to each benefit option.]

14. ADDITIONAL FEATURES.

[(a) Indicate if medical underwriting is used;

(b) Describe other important features.]

15. CONTACT THE STATE SENIOR HEALTH INSURANCE ASSISTANCE PROGRAM IF YOU HAVE GENERAL QUESTIONS REGARDING LONG-TERM CARE INSURANCE. CONTACT THE INSURANCE COMPANY IF YOU HAVE SPECIFIC QUESTIONS REGARDING YOUR LONG-TERM CARE INSURANCE POLICY OR CERTIFICATE.

§114-32-~~21~~ 30. Requirement to Deliver Shopper's Guide.

~~21.1.~~ 30.1. A long-term care insurance shopper's guide in the format developed by the National Association of Insurance Commissioners, or a guide developed or approved by the Commissioner, shall be provided to all prospective applicants of a long-term care insurance policy or certificate.

~~21.1.1.~~ a. In the case of t producer solicitations, a producer must deliver the shopper's guide prior to the presentation of an application or enrollment form.

~~21.1.2.~~ b. In the case of direct response solicitation, the shopper's guide must be presented in conjunction with any application or enrollment form.

~~21.2.~~ 30.2. Life insurance policies or riders containing accelerated long-term care benefits are not required to furnish the above-referenced guide, but shall furnish the policy summary required under W. Va. Code §33-15A-6.

§114-32-~~22~~ 31. Penalties.

In addition to any other penalties provided by the laws of this State, any insurer and any producer found to have violated any requirement of this State relating to the regulation of long-term care insurance or the marketing of such insurance shall be subject to a fine of up to three (3) times the amount of any commissions paid for each policy involved in the violation or up to $10,000, whichever is greater.

~~**§114-32-23. Severability.**~~

~~If any provision of this regulation or the application thereof to any person or circumstance is for any reason held to be invalid, the remainder of the regulation and the application of such provision to other persons or circumstances shall not be affected thereby.~~

~~Appendix A~~

~~RESCISSION REPORTING FORM FOR LONG-TERM CARE POLICIES FOR THE STATE OF WEST VIRGINIA FOR THE REPORTING YEAR 19[ ]~~

~~Company Name:~~ _____

~~Address:~~ _____

_____

~~Phone Number:~~ _____

~~Due: March 1 annually~~

~~Instructions:~~

~~The purpose of this form is to report all rescissions of long-term care insurance policies or certificates. Those rescissions voluntarily effectuated by an insured are not required to be included in this report. Please furnish one form per rescission.~~

~~Policy Form #~~	~~Policy and Certificate #~~	~~Date of Name of Insured~~	~~Date/s Policy Issuance~~	~~Claim/s Submitted~~	~~Date of Rescission~~

~~Detailed reason for rescission:~~ _____

_____

_____

_____

_____

~~Signature~~

_____

~~Name and Title (please type)~~

_____

~~Date~~

APPENDIX A

RESCISSION REPORTING FORM FOR LONG-TERM CARE POLICIES FOR THE STATE OF WEST VIRGINIA FOR THE REPORTING YEAR 20[ ]

Company Name:

Address:

Phone Number:

Due: March 1 annually

Instructions:
The purpose of this form is to report all rescissions of long-term care insurance policies or certificates. Those rescissions voluntarily effectuated by an insured are not required to be included in this report. Please furnish one form per rescission.

Policy Form #	Policy and Certificate #	Name of Insured	Date of Policy Issuance	Date/s Claim/s Submitted	Date of Rescission

Detailed reason for rescission:

_____
Signature

_____
Name and Title (please type)

_____
Date

~~Appendix B~~

~~**NOTICE TO APPLICANT REGARDING REPLACEMENT OF INDIVIDUAL ACCIDENT AND SICKNESS OR LONG-TERM CARE INSURANCE**~~

~~[Insurance company's name and address]~~

~~SAVE THIS NOTICE! IT MAY BE IMPORTANT TO YOU IN THE FUTURE.~~

~~According to [your application] [information you have furnished], you intend to lapse or otherwise terminate existing accident and sickness or long-term care insurance and replace it with an individual long-term care insurance policy to be issued by [company name] Insurance Company. Your new policy provides thirty (30) days within which you may decide, without cost, whether you desire to keep the policy. For your own information and protection, you should be aware of and seriously consider certain factors which may affect the insurance protection available to you under the new policy.~~

~~You should review this new coverage carefully, comparing it with all accident and sickness or long-term care insurance coverage you now have, and terminate your present policy only if, after due consideration, you find that purchase of this long-term care coverage is a wise decision.~~

~~STATEMENT TO APPLICANT BY AGENT [BROKER OR OTHER REPRESENTATIVE]: (Use additional sheets, as necessary.)~~

~~I have reviewed your current medical or health insurance coverage. I believe the replacement of insurance involved in this transaction materially improves your position. My conclusion has taken into account the following considerations, which I call to your attention:~~

~~1. Health conditions which you may presently have (preexisting conditions) may not be immediately or fully covered under the new policy. This could result in denial or delay in payment of benefits under the new policy, whereas a similar claim might have been payable under your present policy.~~

~~2. State law provides that your replacement policy or certificate may not contain new preexisting conditions or probationary or waiting periods. The insurer will waive any time periods applicable to preexisting conditions or probationary or waiting periods in the new policy (or coverage) for similar benefits to the extent such time was spent (depleted) under the original policy.~~

~~3. If you are replacing existing long-term care insurance coverage, you may wish to secure the advice of your present insurer or its agent regarding the proposed replacement of your present policy. This is not only your right, but it is also in your best interest to make sure you understand all the relevant factors involved in replacing your present coverage.~~

~~4. If, after due consideration, you still wish to terminate your present policy and replace it with new coverage, be certain to truthfully and completely answer all questions on the application concerning your medical health history. Failure to include all material medical information on an application may provide a basis for the company to deny any future claims and to refund your premium as though your policy had never been in force. After the application has been completed and before you sign it, reread it carefully to be certain that all information has been properly recorded.~~

~~_____~~

~~(Signature of Agent, Broker, or Other Representative)~~

~~[Typed Name and Address of Agent or Broker]~~

~~The above "Notice to Applicant" was delivered to me on:~~

_____

~~(Date)~~

_____

~~(Applicant's Signature)~~

APPENDIX B

Long Term Care Insurance
Personal Worksheet

People buy long-term care insurance for many reasons. Some don't want to use their own assets to pay for long-term care. Some buy insurance to make sure they can choose the type of care they get. Others don't want their family to have to pay for care or don't want to go on Medicaid. But long term care insurance may be expensive, and may not be right for everyone.

By state law, the insurance company must fill out part of the information on this worksheet and **ask** you to fill out the rest to help you and the company decide if you should buy this policy.

Premium Information

Policy Form Numbers_____

The premium for the coverage you are considering will be [$_____per month, or $_____per year,] [a one-time single premium of $_____.]

Type of Policy (noncancellable/guaranteed renewable):

The Company's Right to Increase Premiums:

[The company cannot raise your rates on this policy.] [The company has a right to increase premiums on this policy form in the future, provided it raises rates for all policies in the same class in this state.] [Insurers shall use appropriate bracketed statement. Rate guarantees shall not be shown on this form.]

Rate Increase History

The company has sold long-term care insurance since [year] and has sold this policy since [year]. [The company has never raised its rates for any long-term care policy it has sold in this state or any other state.] [The company has not raised its rates for this policy form or similar policy forms in this state or any other state in the last 10 years.] [The company has raised its premium rates on this policy form or similar policy forms in the last 10 years. Following is a summary of the rate increases.]

Questions Related to Your Income

How will you pay each year's premium?
□ From my Income □ From my Savings/Investments □ My Family will Pay

[Have you considered whether you could afford to keep this policy if the premiums went up, for example, by 20%?]

What is your annual income? (check one) □ Under $10,000 □ $[10-20,000] □ $[20-30,000] □ $[30-50,000] □ Over $50,000

How do you expect your income to change over the next 10 years? (check one)
□ No change □ Increase □ Decrease

If you will be paying premiums with money received only from your own income, a rule of thumb is

that you may not be able to afford this policy if the premiums will be more than 7% of your income.

Will you buy inflation protection? (check one) ☐ Yes ☐ No
If not, have you considered how you will pay for the difference between future costs and your daily benefit amount? ☐ From my Income ☐ From my Savings/Investments ☐ My Family will Pay

The national average annual cost of care in [insert year] was [insert $ amount], but this figure varies across the country. In ten years the national average annual cost would be about [insert $ amount] if costs increase 5% annually.

What elimination period are you considering? Number of days _____ Approximate cost $_____ for that period of care.

How are you planning to pay for your care during the elimination period? (check one)
☐ From my Income ☐ From my Savings/Investments ☐ My Family will Pay

Questions Related to Your Savings and Investments

Not counting your home, about how much are all of your assets (your savings and investments) worth? (check one)
☐ Under $20,000 ☐ $20,000-$30,000 ☐ $30,000-$50,000 ☐ Over $50,000

How do you expect your assets to change over the next ten years? (check one)
☐ Stay about the same ☐ Increase ☐ Decrease

If you are buying this policy to protect your assets and your assets are less than $30,000, you may wish to consider other options for financing your long-term care.

Disclosure Statement

☐	The answers to the questions above describe my financial situation. **Or** ☐ I choose not to complete this information. (Check one.)
☐	I acknowledge that the carrier or its producer (below) has reviewed this form with me including the premium, premium rate increase history and potential for premium increases in the future. [For direct mail situations, use the following: I acknowledge that I have reviewed this form including the premium, premium rate increase history and potential for premium increases in the future.] I understand the above disclosures. **I understand that the rates for this policy may increase in the future.** (This box must be checked).

Signed: _____
(Applicant) (Date)

[☐ I explained to the applicant the importance of completing this information.

Signed: _____ _____

(Producer) (Date)

Producer's Printed Name:]

[In order for us to process your application, please return this signed statement to [name of company], along with your application.]

[My producer has advised me that this policy does not seem to be suitable for me. However, I still want the company to consider my application.

Signed: _____ _____]
(Applicant) (Date)

The company may contact you to verify your answers.

~~Appendix C~~

~~NOTICE TO APPLICANT REGARDING REPLACEMENT OF ACCIDENT AND SICKNESS OR LONG-TERM CARE INSURANCE~~

~~[Insurance company's name and address]~~

~~SAVE THIS NOTICE! IT MAY BE IMPORTANT TO YOU IN THE FUTURE.~~

~~According to [your application] [information you have furnished], you intend to lapse or otherwise terminate existing accident and sickness or long-term care insurance and replace it with the long-term care insurance policy delivered herewith issued by [company name] Insurance Company. Your new policy provides thirty (30) days within which you may decide, without cost, whether you desire to keep the policy. For your own information and protection, you should be aware of and seriously consider certain factors which may affect the insurance protection available to you under the new policy.~~

~~You should review this new coverage carefully, comparing it with all accident and sickness or long-term care insurance coverage you now have, and terminate your present policy only if, after due consideration, you find that purchase of this long-term care coverage is a wise decision.~~

~~1. Health conditions which you may presently have (preexisting conditions), may not be immediately or fully covered under the new policy. This could result in denial or delay in payment of benefits under the new policy, whereas a similar claim might have been payable under your present policy.~~

~~2. State law provides that your replacement policy or certificate may not contain new preexisting conditions or probationary or waiting periods. Your insurer will waive any time periods applicable to preexisting conditions or probationary or waiting periods in the new policy (or coverage) for similar benefits to the extent such time was spent (depleted) under the original policy.~~

~~3. If you are replacing existing long-term care insurance coverage, you may wish to secure the advice of your present insurer or its agent regarding the proposed replacement of your present policy. This is not only your right, but it is also in your best interest to make sure you understand all the relevant factors involved in replacing your present coverage.~~

~~4. [To be included only if the application is attached to the policy.] If, after due consideration, you still wish to terminate your present policy and replace it with new coverage, read the copy of the application attached to your new policy and be sure that all questions are answered fully and correctly. Omissions or misstatements in the application could cause an otherwise valid claim to be denied. Carefully check the application and write to [company name and address] within thirty (30) days if any information is not correct and complete, or if any past medical history has been left out of the application.~~

~~_____~~

~~(Company Name)~~

UNITED STATES CODE SERVICE
TITLE 42. THE PUBLIC HEALTH AND WELFARE
CHAPTER 7. SOCIAL SECURITY ACT
TITLE XVIII. HEALTH INSURANCE FOR THE AGED AND DISABLED

Chapter 7, Title XVII can be found at:

http://www.ssa.gov/OP_Home/ssact/title18/1800.htm

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*** CURRENT THROUGH PL 111-2, APPROVED 1/29/2009 ***

TITLE 26. INTERNAL REVENUE CODE
SUBTITLE F. PROCEDURE AND ADMINISTRATION
CHAPTER 79. DEFINITIONS

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26 USCS § 7702B

§ 7702B. Treatment of qualified long-term care insurance [Caution: See prospective amendment note below.].

(a) In general. For purposes of this title--

(1) a qualified long-term care insurance contract shall be treated as an accident and health insurance contract,

(2) amounts (other than policyholder dividends, as defined in section 808 [*26 USCS § 808*], or premium refunds) received under a qualified long-term care insurance contract shall be treated as amounts received for personal injuries and sickness and shall be treated as reimbursement for expenses actually incurred for medical care (as defined in section 213(d) [*26 USCS § 213(d)*]),

(3) any plan of an employer providing coverage under a qualified long-term care insurance contract shall be treated as an accident and health plan with respect to such coverage,

(4) except as provided in subsection (e)(3), amounts paid for a qualified long-term care insurance contract providing the benefits described in subsection (b)(2)(A) shall be treated as payments made for insurance for purposes of section 213(d)(1)(D) [*26 USCS § 213(d)(1)(D)*], and

(5) a qualified long-term care insurance contract shall be treated as a guaranteed renewable contract subject to the rules of section 816(e) [*26 USCS § 816(e)*].

(b) Qualified long-term care insurance contract. For purposes of this title--

(1) In general. The term "qualified long-term care insurance contract" means any insurance contract if--

(A) the only insurance protection provided under such contract is coverage of qualified long-term care services,

(B) such contract does not pay or reimburse expenses incurred for services or items to the extent that such expenses are reimbursable under title XVIII of the Social Security Act [*42 USCS §§ 1395* et seq.] or would be so reimbursable but for the application of a deductible or coinsurance amount,

(C) such contract is guaranteed renewable,

(D) such contract does not provide for a cash surrender value or other money that can be--

(i) paid, assigned, or pledged as collateral for a loan, or

(ii) borrowed,

other than as provided in subparagraph (E) or paragraph (2)(C),

(E) all refunds of premiums, and all policyholder dividends or similar amounts, under such contract are to be applied as a reduction in future premiums or to increase future benefits, and

(F) such contract meets the requirements of subsection (g).

(2) Special rules.

(A) Per diem, etc. payments permitted. A contract shall not fail to be described in subparagraph (A) or (B) of paragraph (1) by reason of payments being made on a per diem or other periodic basis without regard to the expenses incurred during the period to which the payments relate.

(B) Special rules relating to medicare.

(i) Paragraph (1)(B) shall not apply to expenses which are reimbursable under title XVIII of the Social Security Act [*42 USCS §§ 1395* et seq.] only as a secondary payor.

(ii) No provision of law shall be construed or applied so as to prohibit the offering of a qualified long-term care insurance contract on the basis that the contract coordinates its benefits with those provided under such title.

(C) Refunds of premiums. Paragraph (1)(E) shall not apply to any refund on the death of the insured, or on a complete surrender or cancellation of the contract, which cannot exceed the aggregate premiums paid under the contract. Any refund on a complete surrender or cancellation of the contract shall be includible in gross income to the extent that any deduction or exclusion was allowable with respect to the premiums.

(c) Qualified long-term care services. For purposes of this section--

(1) In general. The term "qualified long-term care services" means necessary diagnostic, preventive, therapeutic, curing, treating, mitigating, and rehabilitative services, and maintenance or personal care services, which--

(A) are required by a chronically ill individual, and

(B) are provided pursuant to a plan of care prescribed by a licensed health care practitioner.

(2) Chronically ill individual.

(A) In general. The term "chronically ill individual" means any individual who has been certified by a licensed health care practitioner as--

(i) being unable to perform (without substantial assistance from another individual) at least 2 activities of daily living for a period of at least 90 days due to a loss of functional capacity,

(ii) having a level of disability similar (as determined under regulations prescribed by the Secretary in consultation with the Secretary of Health and Human Services) to the level of disability described in clause (i), or

(iii) requiring substantial supervision to protect such individual from threats to health and safety due to severe cognitive impairment.

Such term shall not include any individual otherwise meeting the requirements of the preceding sentence unless within the preceding 12-month period a licensed health care practitioner has certified that such individual meets such requirements.

(B) Activities of daily living. For purposes of subparagraph (A), each of the following is an activity of daily living:

(i) Eating.

(ii) Toileting.

(iii) Transferring.

(iv) Bathing.

(v) Dressing.

(vi) Continence.

A contract shall not be treated as a qualified long-term care insurance contract unless the determination of whether an individual is a chronically ill individual described in subparagraph (A)(i) takes into account at least 5 of such activities.

(3) Maintenance or personal care services. The term "maintenance or personal care services" means any care the primary purpose of which is the provision of needed assistance with any of the disabilities as a result of which the individual is a chronically ill individual (including the protection from threats to health and safety due to severe cognitive impairment).

(4) Licensed health care practitioner. The term "licensed health care practitioner" means any physician (as defined in section 1861(r)(1) of the Social Security Act [*42 USCS § 1395x(r)(1)*]) and any registered professional nurse, licensed social worker, or other individual who meets such requirements as may be prescribed by the Secretary.

(d) Aggregate payments in excess of limits.

(1) In general. If the aggregate of--

(A) the periodic payments received for any period under all qualified long-term care insurance contracts which are treated as made for qualified long-term care services for an insured, and

(B) the periodic payments received for such period which are treated under section 101(g) [*26 USCS § 101(g)*] as paid by reason of the death of such insured,

exceeds the per diem limitation for such period, such excess shall be includible in gross income without regard to section 72 [*26 USCS § 72*]. A payment shall not be taken into account under subparagraph (B) if the insured is a terminally ill individual (as defined in section 101(g) [*26 USCS § 101(g)*]) at the time the payment is received.

(2) Per diem limitation. For purposes of paragraph (1), the per diem limitation for any period is an amount equal to the excess (if any) of--

(A) the greater of--

(i) the dollar amount in effect for such period under paragraph (4), or

(ii) the costs incurred for qualified long-term care services provided for the insured for such period, over

(B) the aggregate payments received as reimbursements (through insurance or otherwise) for qualified long-term care services provided for the insured during such period.

(3) Aggregation rules. For purposes of this subsection--

(A) all persons receiving periodic payments described in paragraph (1) with respect to the same insured shall be treated as 1 person, and

(B) the per diem limitation determined under paragraph (2) shall be allocated first to the insured and any remaining limitation shall be allocated among the other such persons in such manner as the Secretary shall prescribe.

(4) Dollar amount [Caution: See § 3.40 of *Rev. Proc. 2007-66* (*26 USCS § 1* note) for provision that, for calendar year 2008, the stated dollar amount of the per diem limitation under this paragraph is $ 270.]. The dollar amount in effect under this subsection shall be $ 175 per day (or the equivalent amount in the case of payments on another periodic basis).

(5) Inflation adjustment. In the case of a calendar year after 1997, the dollar amount contained in paragraph (4) shall be increased at the same time and in the same manner as amounts are increased pursuant to section 213(d)(10) [*26 USCS § 213(d)(10)*].

(6) Periodic payments. For purposes of this subsection, the term "periodic payment" means any payment (whether on a periodic basis or otherwise) made without regard to the extent of the costs incurred by the payee for qualified long-term care services.

(e) Treatment of coverage provided as part of a life insurance contract. Except as otherwise provided in regulations prescribed by the Secretary, in the case of any long-term care insurance coverage (whether or not qualified) provided by a rider on or as part of a life insurance contract--

(1) In general. This title shall apply as if the portion of the contract providing such coverage is a separate contract.

(2) Application of section 7702. Section 7702(c)(2) [*26 USCS § 7702(c)(2)*] (relating to the guideline premium limitation) shall be applied by increasing the guideline premium limitation with respect to a life insurance contract, as of any date--

(A) by the sum of any charges (but not premium payments) against the life insurance contract's cash surrender value (within the meaning of section 7702(f)(2)(A) [*26 USCS § 7702(f)(2)(A)*]) for such coverage made to that date under the contract, less

(B) any such charges the imposition of which reduces the premiums paid for the contract (within the meaning of section 7702(f)(1) [*26 USCS § 7702(f)(1)*]).

(3) Application of section 213. No deduction shall be allowed under section 213(a) [*26 USCS § 213(a)*] for charges against the life insurance contract's cash surrender value described in paragraph (2), unless such charges are includible in income as a result of the application of section 72(e)(10) [*26 USCS § 72(e)(10)*] and the rider is a qualified long-term care insurance contract under subsection (b).

(4) Portion defined. For purposes of this subsection, the term "portion" means only the terms and benefits under a life insurance contract that are in addition to the terms and benefits under the contract without regard to long-term care insurance coverage.

(f) Treatment of certain State-maintained plans.

(1) In general. If--

(A) an individual receives coverage for qualified long-term care services under a State long-term care plan, and

(B) the terms of such plan would satisfy the requirements of subsection (b) were such plan an insurance contract, such plan shall be treated as a qualified long-term care insurance contract for purposes of this title.

(2) State long-term care plan. For purposes of paragraph (1), the term "State long-term care plan" means any plan--

(A) which is established and maintained by a State or an instrumentality of a State,

(B) which provides coverage only for qualified long-term care services, and

(C) under which such coverage is provided only to--

(i) employees and former employees of a State (or any political subdivision or instrumentality of a State),

(ii) the spouses of such employees, and

(iii) individuals bearing a relationship to such employees or spouses which is described in any of subparagraphs (A) through (G) of section 152(d)(2) [*26 USCS § 152(d)(2)*].

(g) Consumer protection provisions.

(1) In general. The requirements of this subsection are met with respect to any contract if the contract meets--

(A) the requirements of the model regulation and model Act described in paragraph (2),

(B) the disclosure requirement of paragraph (3), and

(C) the requirements relating to nonforfeitability under paragraph (4).

(2) Requirements of model regulation and Act.

(A) In general. The requirements of this paragraph are met with respect to any contract if such contract meets--

(i) Model regulation. The following requirements of the model regulation:

(I) Section 7A (relating to guaranteed renewal or noncancellability), and the requirements of section 6B of the model Act relating to such section 7A.

(II) Section 7B (relating to prohibitions on limitations and exclusions).

(III) Section 7C (relating to extension of benefits).

(IV) Section 7D (relating to continuation or conversion of coverage).

(V) Section 7E (relating to discontinuance and replacement of policies).

(VI) Section 8 (relating to unintentional lapse).

(VII) Section 9 (relating to disclosure), other than section 9F thereof.

(VIII) Section 10 (relating to prohibitions against post-claims underwriting).

(IX) Section 11 (relating to minimum standards).

(X) Section 12 (relating to requirement to offer inflation protection), except that any requirement for a signature on a rejection of inflation protection shall permit the signature to be on an application or on a separate form.

(XI) Section 23 (relating to prohibition against preexisting conditions and probationary periods in replacement policies or certificates).

(ii) Model Act. The following requirements of the model Act:

(I) Section 6C (relating to preexisting conditions).

(II) Section 6D (relating to prior hospitalization).

(B) Definitions. For purposes of this paragraph--

(i) Model provisions. The terms "model regulation" and "model Act" mean the long-term care insurance model regulation, and the long-term care insurance model Act, respectively, promulgated by the National Association of Insurance Commissioners (as adopted as of January 1993).

(ii) Coordination. Any provision of the model regulation or model Act listed under clause (i) or (ii) of subparagraph (A) shall be treated as including any other provision of such regulation or Act necessary to implement the provision.

(iii) Determination. For purposes of this section and section 4980C [*26 USCS § 4980C*], the determination of whether any requirement of a model regulation or the model Act has been met shall be made by the Secretary.

(3) Disclosure requirement. The requirement of this paragraph is met with respect to any contract if such contract meets the requirements of section 4980C(d) [*26 USCS § 4980C(d)*].

(4) Nonforfeiture requirements.

(A) In general. The requirements of this paragraph are met with respect to any level premium contract, if the issuer of such contract offers to the policyholder, including any group policyholder, a nonforfeiture provision meeting the requirements of subparagraph (B).

(B) Requirements of provision. The nonforfeiture provision required under subparagraph (A) shall meet the following requirements:

(i) The nonforfeiture provision shall be appropriately captioned.

(ii) The nonforfeiture provision shall provide for a benefit available in the event of a default in the payment of any premiums and the amount of the benefit may be adjusted subsequent to being initially granted only as necessary to reflect changes in claims, persistency, and interest as reflected in changes in rates for premium paying contracts approved by the appropriate State regulatory agency for the same contract form.

(iii) The nonforfeiture provision shall provide at least one of the following:

(I) Reduced paid-up insurance.

(II) Extended term insurance.

(III) Shortened benefit period.

(IV) Other similar offerings approved by the appropriate State regulatory agency.

(5) Cross reference. For coordination of the requirements of this subsection with State requirements, see section 4980C(f) [*26 USCS § 4980C(f)*].

HISTORY:

(Added Aug. 21, 1996, P.L. 104-191, Title III, §§ 321(a), 325, 110 Stat. 2054, 2063; Aug. 5, 1997, P.L. 105-34, Title XVI, § 1602(b), (e), 111 Stat. 1094; July 22, 1998, P.L. 105-206, Title VI, § 6023(28), 112 Stat. 826; Oct. 4, 2004, P.L. 108-311, Title II, § 207(25), 118 Stat. 1178; Aug. 17, 2006, P.L. 109-280, Title VIII, Subtitle D, § 844(c), (f), 120 Stat. 1011, 1013.)

HISTORY; ANCILLARY LAWS AND DIRECTIVES

Prospective amendment:

Amendment of subsec. (e), applicable to taxable years beginning after Dec. 31. 2009. Act Aug. 17, 2006, P.L. 109-280, Title VIII, Subtitle D, § 844(c), 120 Stat. 1011 (applicable to contracts issued after 12/31/1996, but only with respect to taxable years beginning after 12/31/2009, as provided by Sec. 844(g)(1) of P.L. 109-280, which appears as a note to Code Sec. 72), provides that subsec. (e) of this section is amended to read as follows:

"(e) Treatment of coverage provided as part of a life insurance or annuity contract. Except as otherwise provided in regulations prescribed by the Secretary, in the case of any long-term care insurance coverage (whether or not qualified) provided by a rider on or as part of a life insurance contract or an annuity contract--

"(1) In general. This title shall apply as if the portion of the contract providing such coverage is a separate contract.

"(2) Denial of deduction under section 213. No deduction shall be allowed under section 213(a) [*26 USCS § 213(a)*] for any payment made for coverage under a qualified long-term care insurance contract if such payment is made as a charge against the cash surrender value of a life insurance contract or the cash value of an annuity contract.

"(3) Portion defined. For purposes of this subsection, the term 'portion' means only the terms and benefits under a life insurance contract or annuity contract that are in addition to the terms and benefits under the contract without regard to long-term care insurance coverage.

"(4) Annuity contracts to which paragraph (1) does not apply. For purposes of this subsection, none of the following shall be treated as an annuity contract:

"(A) A trust described in section 401(a) [*26 USCS § 401(a)*] which is exempt from tax under section 501(a) [*26 USCS § 501(a)*].

"(B) A contract--

"(i) purchased by a trust described in subparagraph (A),

"(ii) purchased as part of a plan described in section 403(a) [*26 USCS § 403(a)*],

"(iii) described in section 403(b) [*26 USCS § 403(b)*],

"(iv) provided for employees of a life insurance company under a plan described in section 818(a)(3) [*26 USCS § 818(a)(3)*], or

"(v) from an individual retirement account or an individual retirement annuity.

"(C) A contract purchased by an employer for the benefit of the employee (or the employee's spouse).

Any dividend described in section 404(k) [*26 USCS § 404(k)*] which is received by a participant or beneficiary shall, for purposes of this paragraph, be treated as paid under a separate contract to which subparagraph (B)(i) applies.".

Amendments:

In 2006, P.L. 109-280, Sec. 844(f) (effective as if included in Sec. 321(a) of P.L. 104-191, as provided by Sec. 844(g)(5) of P.L. 109-280, which appears as a note to Code Sec. 72), amended subsec. (e)(1) by substituting "title" for "section".

In 2004, P.L. 108-311, Sec. 207(25) (applicable to taxable years beginning after 12/31/2004, as provided by Sec. 208 of P.L. 108-311, which appears as a note to Code Sec. 2), amended subsec. (f)(2)(C)(iii) by substituting "subparagraphs (A) through (G) of section 152(d)(2)" for "paragraphs (1) through (8) of section 152(a)".

In 1998, P.L. 105-206, Sec. 6023(28) (effective 7/22/98, pursuant to Sec. 6023(32) of P.L. 105-206, which appears as a note to Code Sec. 34), amended para. (2) of subsec. (e) by inserting "section" in the paragraph heading.

In 1997, P.L. 105-34, Sec. 1602(b), (e) (effective as if included in the provisions of P.L. 104-191 to which such amendments relate, as provided by Sec. 1602(i), which appears as a note to Code Sec. 26), amended subsec. (c)(2)(B) by inserting "described in subparagraph (A)(i)" in the concluding matter; and amended subsec. (g)(4)(B) by substituting "appropriate State regulatory agency" for "Secretary" in cls. (ii) and (iii)(IV).

In 1996. P.L. 104-191, Sec. 321(a) (applicable to contracts issued after 12/31/96, and as provided by Sec. 321(f), which appears as a note to this section), added Code Sec. 7702B.

--P.L. 104-191, Sec. 325, added subsec. (g).

Other provisions:

Application of amendments made by § 321 of Act Aug. 21, 1996. Act Aug. 21, 1996, P.L. 104-191, Title III, Subtitle C, Part I, § 321(f), 110 Stat. 2059, provides:

"(1) General effective date.

(A) In general. Except as provided in subparagraph (B), the amendments made by this section [for full classification, consult USCS Tables volumes] shall apply to contracts issued after December 31, 1996.

"(B) Reserve method. The amendment made by subsection (b) [amending *26 USCS 807(d)(3)(A)(iii)*] shall apply to contracts issued after December 31, 1997.

"(2) Continuation of existing policies. In the case of any contract issued before January 1, 1997, which met the long-term care insurance requirements of the State in which the contract was situsted at the time the contract was issued--

"(A) such contract shall be treated for purposes of the Internal Revenue Code of 1986 as a qualified long-term care insurance contract (as defined in section 7702B(b) of such Code), and

"(B) services provided under, or reimbursed by, such contract shall be treated for such purposes as qualified long-term care services (as defined in section 7702B(c) of such Code).

In the case of an individual who is covered on December 31, 1996, under a State long-term care plan (as defined in section 7702B(f)(2) of such Code), the terms of such plan on such date shall be treated for purposes of the preceding sentence as a contract issued on such date which met the long-term care insurance requirements of such State.

"(3) Exchanges of existing policies. If, after the date of enactment of this Act and before January 1, 1998, a contract providing for long-term care insurance coverage is exchanged solely for a qualified long-term care insurance contract (as defined in section 7702B(b) of such Code), no gain or loss shall be recognized on the exchange. If, in addition to a qualified long-term care insurance contract, money or other property is received in the exchange, then any gain shall be recognized to the extent of the sum of the money and the fair market value of the other property received. For purposes of this paragraph, the cancellation of a contract providing for long-term care insurance coverage and reinvestment of the cancellation proceeds in a qualified long-term care insurance contract within 60 days thereafter shall be treated as an exchange.

"(4) Issuance of certain riders permitted. For purposes of applying *sections 101(f), 7702*, and *7702A of the Internal Revenue Code of 1986* to any contract--

"(A) the issuance of a rider which is treated as a qualified long-term care insurance contract under section 7702B, and

"(B) the addition of any provision required to conform any other long-term care rider to be so treated,

shall not be treated as a modification or material change of such contract.

"(5) Application of per diem limitation to existing contracts. The amount of per diem payments made under a contract issued on or before July 31, 1996, with respect to an insured which are excludable from gross income by reason of *section 7702B of the Internal Revenue Code of 1986* (as added by this section) shall not be reduced under subsection (d)(2)(B) thereof by reason of reimbursements received under a contract issued on or before such date. The preceding sentence shall cease to apply as of the date (after July 31, 1996) such contract is exchanged or there is any contract modification which results in an increase in the amount of such per diem payments or the amount of such reimbursements.".

Long-term care study request. Act Aug. 21, 1996, P.L. 104-191, Title III, Subtitle C, Part I, § 321(g), 110 Stat. 2060, provides: "The Chairman of the Committee on Ways and Means of the House of Representatives and the Chairman of the Committee on Finance of the Senate shall jointly request the National Association of Insurance Commissioners, in consultation with representatives of the insurance industry and consumer organizations, to formulate, develop, and conduct a study to determine the marketing and other effects of per diem limits on certain types of long-term care policies. If the National Association of Insurance Commissioners agrees to the study request, the National Association of Insurance Commissioners shall report the results of its study to such committees not later than 2 years after accepting the request.".

NOTES:

Related Statutes & Rules:

This section is referred to in *5 USCS §§ 9001, 9002; 12 USCS § 1715z-20; 26 USCS §§ 101, 106, 162, 213, 220, 223, 807, 818, 4980B, 4980C; 42 USCS § 300bb-8.*

Research Guide:

Am Jur:
33A Am Jur 2d, Federal Taxation (2008) § 12848.
34 Am Jur 2d, Federal Taxation (2008) §§ 18808, 18812, 18813, 18815.

Labor and Employment:
6 Labor and Employment Law (Matthew Bender), ch 155, Continuation Coverage Under Group Health Plans (COBRA) § 155.05.

Law Review Articles:
McKenzie. Handling medical data? Think HIPAA now. 17 Computer Internet Law 15, November 2000.
Roach. HIPAA privacy: "individual rights" and the "minimum necessary" requirements. 33 J Health L 549, Fall 2000.

Interpretive Notes and Decisions:

In finding that exclusion of same-sex couples from designation of marriage violates California Constitution, court noted nine differences between marriage and domestic partnership statutes, including ineligibility of domestic partners for long-term care plans under *Cal. Fam. Code § 297.5(g)*; that provision protected federal tax-qualified status of California Public Employees' Retirement System under *26 USCS § 7702B(f)(2)(C). In re Marriage Cases (2008) 43 Cal 4th 757,* reported at (2008, Cal) *2008 Cal LEXIS 6155.*

STATE OF WEST VIRGINIA
Offices of the Insurance Commissioner
JOE MANCHIN III
Governor

JANE L. CLINE
Insurance Commissioner

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OFFICE WEST VIRGINIA
SECRETARY OF STATE

TO: Judy Cooper

FROM: Sarah Chapman

RE: Federal law to be filed with Title 114 CSR 32, Long-Term Care

DATE: February 23, 2009

Judy,

Please find enclosed a copy of United States Code, Title 42, Chapter 7, Title XVIII (Health Insurance for the Aged and Disabled) referenced in §114 CSR 32 filed with the Secretary of State's office February 17, 2009.

Thanks,

Sarah Chapman
Paralegal
1124 Smith St.
Charleston, WV 25301
(304) 558-6279 ext. 1181

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*** CURRENT THROUGH PL 111-2, APPROVED 1/29/2009 ***

TITLE 42. THE PUBLIC HEALTH AND WELFARE
CHAPTER 7. SOCIAL SECURITY ACT
TITLE XVIII. HEALTH INSURANCE FOR THE AGED AND DISABLED

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§ 1395. Prohibition against any Federal interference

Nothing in this *title [42 USCS §§ 1395* et seq.] shall be construed to authorize any Federal officer or employee to exercise any supervision or control over the practice of medicine or the manner in which medical services are provided, or over the selection, tenure, or compensation of any officer or employee of any institution, agency, or person providing health services; or to exercise any supervision or control over the administration or operation of any such institution, agency, or person.

HISTORY:
(Aug. 14, 1935, ch 531, Title XVIII, § 1801, as added July 30, 1965, P.L. 89-97, Title I, Part 1, § 102(a), 79 Stat. 291.)

§ 1395a. Free choice by patient guaranteed

(a) Basic freedom of choice. Any individual entitled to insurance benefits under this *title [42 USCS §§ 1395* et seq.] may obtain health services from any institution, agency, or person qualified to participate under this *title [42 USCS §§ 1395* et seq.] if such institution, agency, or person undertakes to provide him such services.

(b) Use of private contracts by medicare beneficiaries.
(1) In general. Subject to the provisions of this subsection, nothing in this *title [42 USCS §§ 1395* et seq.] shall prohibit a physician or practitioner from entering into a private contract with a medicare beneficiary for any item or service--
(A) for which no claim for payment is to be submitted under this *title [42 USCS §§ 1395* et seq.], and
(B) for which the physician or practitioner receives--
(i) no reimbursement under this *title [42 USCS §§ 1395* et seq.] directly or on a capitated basis, and
(ii) receives no amount for such item or service from an organization which receives reimbursement for such item or service under this *title [42 USCS §§ 1395* et seq.] directly or on a capitated basis.
(2) Beneficiary protections.
(A) In general. Paragraph (1) shall not apply to any contract unless--
(i) the contract is in writing and is signed by the medicare beneficiary before any item or service is provided pursuant to the contract;
(ii) the contract contains the items described in subparagraph (B); and
(iii) the contract is not entered into at a time when the medicare beneficiary is facing an emergency or urgent health care situation.
(B) Items required to be included in contract. Any contract to provide items and services to which paragraph (1) applies shall clearly indicate to the medicare beneficiary that by signing such contract the beneficiary--
(i) agrees not to submit a claim (or to request that the physician or practitioner submit a claim) under this *title [42 USCS §§ 1395* et seq.] for such items or services even if such items or services are otherwise covered by this *title [42 USCS §§ 1395* et seq.];

(ii) agrees to be responsible, whether through insurance or otherwise, for payment of such items or services and understands that no reimbursement will be provided under this *title [42 USCS §§ 1395* et seq.] for such items or services;

(iii) acknowledges that no limits under this *title [42 USCS §§ 1395* et seq.] (including the limits under section 1848(g) [*42 USCS § 1395w-4(g)*]) apply to amounts that may be charged for such items or services;

(iv) acknowledges that Medigap plans under section 1882 [*42 USCS § 1395ss*] do not, and other supplemental insurance plans may elect not to, make payments for such items and services because payment is not made under this *title [42 USCS §§ 1395* et seq.]; and

(v) acknowledges that the medicare beneficiary has the right to have such items or services provided by other physicians or practitioners for whom payment would be made under this *title [42 USCS §§ 1395* et seq.].

Such contract shall also clearly indicate whether the physician or practitioner is excluded from participation under the medicare program under section 1128 [*42 USCS § 1320a-7*].

(3) Physician or practitioner requirements.

(A) In general. Paragraph (1) shall not apply to any contract entered into by a physician or practitioner unless an affidavit described in subparagraph (B) is in effect during the period any item or service is to be provided pursuant to the contract.

(B) Affidavit. An affidavit is described in this subparagraph if--

(i) the affidavit identifies the physician or practitioner and is in writing and is signed by the physician or practitioner;

(ii) the affidavit provides that the physician or practitioner will not submit any claim under this *title [42 USCS §§ 1395* et seq.] for any item or service provided to any medicare beneficiary (and will not receive any reimbursement or amount described in paragraph (1)(B) for any such item or service) during the 2-year period beginning on the date the affidavit is signed; and

(iii) a copy of the affidavit is filed with the Secretary no later than 10 days after the first contract to which such affidavit applies is entered into.

(C) Enforcement. If a physician or practitioner signing an affidavit under subparagraph (B) knowingly and willfully submits a claim under this *title [42 USCS §§ 1395* et seq.] for any item or service provided during the 2-year period described in subparagraph (B)(ii) (or receives any reimbursement or amount described in paragraph (1)(B) for any such item or service) with respect to such affidavit--

(i) this subsection shall not apply with respect to any items and services provided by the physician or practitioner pursuant to any contract on and after the date of such submission and before the end of such period; and

(ii) no payment shall be made under this *title [42 USCS §§ 1395* et seq.] for any item or service furnished by the physician or practitioner during the period described in clause (i) (and no reimbursement or payment of any amount described in paragraph (1)(B) shall be made for any such item or service).

(4) Limitation on actual charge and claim submission requirement not applicable. Section 1848(g) [*42 USCS § 1395w-4(g)*] shall not apply with respect to any item or service provided to a medicare beneficiary under a contract described in paragraph (1).

(5) Definitions. In this subsection:

(A) Medicare beneficiary. The term "medicare beneficiary" means an individual who is entitled to benefits under part A [*42 USCS §§ 1395c* et seq.] or enrolled under part B [*42 USCS §§ 1395j* et seq.].

(B) Physician. The term "physician" has the meaning given such term by paragraphs (1), (2), (3), and (4) of section 1861(r) [*42 USCS § 1395x(r)*].

(C) Practitioner. The term "practitioner" has the meaning given such term by section 1842(b)(18)(C) [*42 USCS § 1395u(b)(18)(C)*].

HISTORY:

(Aug. 14, 1935, ch 531, Title XVIII, § 1802, as added July 30, 1965, P.L. 89-97, Title I, Part 1, § 102(a), 79 Stat. 291; Aug. 5, 1997, P.L. 105-33, Title IV, Subtitle F, Ch 1, Subch A, § 4507(a)(1), (2)(A), 111 Stat. 439, 441; Dec. 8, 2003, P.L. 108-173, Title VI, Subtitle A, § 603, 117 Stat. 2301.)

§ 1395b. Option to individuals to obtain other health insurance protection

Nothing contained in this *title [42 USCS §§ 1395* et seq.] shall be construed to preclude any State from providing, or any individual from purchasing or otherwise securing, protection against the cost of any health services.

HISTORY:

(Aug. 14, 1935, ch 531, Title XVIII, § 1803, as added July 30, 1965, P.L. 89-97, Title I, Part 1, § 102(a), 79 Stat. 291.)

§ 1395b-1. Incentives for economy while maintaining or improving quality in the provision of health services

(a) Grants and contracts to develop and engage in experiments and demonstration projects.

(1) The Secretary of Health, Education, and Welfare [Secretary of Health and Human Services] is authorized, either directly or through grants to public or private agencies, institutions, and organizations or contracts with public or private agencies, institutions, and organizations, to develop and engage in experiments and demonstration projects for the following purposes:

(A) to determine whether, and if so which, changes in methods of payment or reimbursement (other than those dealt with in section 222(a) of the Social Security Amendments of 1972 [note to this section]) for health care and services under health programs established by the Social Security Act, including a change to methods based on negotiated rates, would have the effect of increasing the efficiency and economy of health services under such programs through the creation of additional incentives to these ends without adversely affecting the quality of such services;

(B) to determine whether payments for services other than those for which payment may be made under such programs (and which are incidental to services for which payment may be made under such programs) would, in the judgment of the Secretary, result in more economical provision and more effective utilization of services for which payment may be made under such program, where such services are furnished by organizations and institutions which have the capability of providing--

(i) comprehensive health care services,

(ii) mental health care services (as defined by section 401(c) of the Mental Retardation Facilities and Community Health Centers Construction Act of 1963),

(iii) ambulatory health care services (including surgical services provided on an outpatient basis), or

(iv) institutional services which may substitute, at lower cost, for hospital care;

(C) to determine whether the rates of payment or reimbursement for health care services, approved by a State for purposes of the administration of one or more of its laws, when utilized to determine the amount to be paid for services furnished in such State under the health programs established by the Social Security Act, would have the effect of reducing the costs of such programs without adversely affecting the quality of such services;

(D) to determine whether payments under such programs based on a single combined rate of reimbursement or charge for the teaching activities and patient care which residents, interns, and supervising physicians render in connection with a graduate medical education program in a patient facility would result in more equitable and economical patient care arrangements without adversely affecting the quality of such care;

(E) to determine whether coverage of intermediate care facility services and homemaker services would provide suitable alternatives to posthospital benefits presently provided under title XVIII of the Social Security Act [*42 USCS §§ 1395* et seq.]; such experiment and demonstration projects may include:

(i) counting each day of care in an intermediate care facility as one day of care in a skilled nursing facility, if such care was for a condition for which the individual was hospitalized,

(ii) covering the services of homemakers for a maximum of 21 days, if institutional services are not medically appropriate,

(iii) determining whether such coverage would reduce long-range costs by reducing the lengths of stay in hospitals and skilled nursing facilities, and

(iv) establishing alternative eligibility requirements and determining the probable cost of applying each alternative, if the project suggests that such extension of coverage would be desirable;

(F) to determine whether, and if so which type of, fixed price or performance incentive contract would have the effect of inducing to the greatest degree effective, efficient, and economical performance of agencies and organizations making payment under agreements or contracts with the Secretary for health care and services under health programs established by the Social Security Act;

(G) to determine under what circumstances payment for services would be appropriate and the most appropriate, equitable, and noninflationary methods and amounts of reimbursement under health care programs established by the Social Security Act for services, which are performed independently by an assistant to a physician, including a nurse practitioner (whether or not performed in the office of or at a place at which such physician is physically present), and--

(i) which such assistant is legally authorized to perform by the State or political subdivision wherein such services are performed, and

(ii) for which such physician assumes full legal and ethical responsibility as to the necessity, propriety, and quality thereof;

(H) to establish an experimental program to provide day-care services, which consist of such personal care, supervision, and services as the Secretary shall by regulation prescribe, for individuals eligible to enroll in the supplemental medical insurance program established under part B of title XVIII and title XIX of the Social Security Act [*42 USCS §§ 1395j* et seq. and *1397* et seq.], in day-care centers which meet such standards as the Secretary shall by regulation establish;

(I) to determine whether the services of clinical psychologists may be made more generally available to persons eligible for services under titles XVIII and XIX of this Act [*42 USCS §§ 1395* et seq. and *1397* et seq.] in a manner consistent with quality of care and equitable and efficient administration;

(J) to develop or demonstrate improved methods for the investigation and prosecution of fraud in the provision of care or services under the health programs established by the Social Security Act; and

(K) to determine whether the use of competitive bidding in the awarding of contracts, or the use of other methods of reimbursement, under part B of title XI [*42 USCS §§ 1320c* et seq.] would be efficient and effective methods of furthering the purposes of that part [*42 USCS §§ 1320c* et seq.]

For purposes of this subsection, "health programs established by the Social Security Act" means the program established by title XVIII of such Act [*42 USCS §§ 1395* et seq.] and a program established by a plan of a State approved under title XIX of such Act [*42 USCS §§ 1396* et seq.].

(2) Grants, payments under contracts, and other expenditures made for experiments and demonstration projects under paragraph (1) shall be made in appropriate part from the Federal Hospital Insurance Trust Fund (established by section 1817 of the Social Security Act [*42 USCS § 1395i*]) and the Federal Supplementary Medical Insurance Trust Fund (established by section 1841 of the Social Security Act [*42 USCS § 1395t*]) and from funds appropriated under title XIX of such Act [*42 USCS §§ 1396* et seq.]. Grants and payments under contracts may be made either in advance or by way of reimbursement, as may be determined by the Secretary, and shall be made in such installments and on such conditions as the Secretary finds necessary to carry out the purpose of this section. With respect to any such grant, payment, or other expenditure, the amount to be paid from each of such trust funds (and from funds appropriated under such title XIX [*42 USCS §§ 1396* et seq.]) shall be determined by the Secretary, giving due regard to the purposes of the experiment or project involved.

(b) Waiver of certain payment or reimbursement requirements; advice and recommendations of specialists preceding experiments and demonstration projects. In the case of any experiment or demonstration project under subsection (a), the Secretary may waive compliance with the requirements of titles XVIII and XIX of the Social Security Act [*42 USCS §§ 1395* et seq. and *1396* et seq.] insofar as such requirements relate to reimbursement or payment on the basis of reasonable cost, or (in the case of physicians) on the basis of reasonable charge, or to reimbursement or payment only for such services or items as may be specified in the experiment [or demonstration project]; and costs incurred in such experiment or demonstration project in excess of the costs which would otherwise be reimbursed or paid under such titles may be reimbursed or paid to the extent that such waiver applies to them (with such excess being borne by the Secretary). No experiment or demonstration project shall be engaged in or developed under subsection (a) until the Secretary obtains the advice and recommendations of specialists who are competent to evaluate the proposed experiment or demonstration project as to the soundness of its objectives, the possibilities of securing productive results, the adequacy of resources to conduct the proposed experiment or demonstration project, and its relationship to other similar experiments and projects already completed or in process.

HISTORY:

(Jan. 2, 1968, P.L. 90-248, Title IV, § 402(a), (b), 81 Stat. 930, 931; Oct. 30, 1972, P.L. 92-603, Title II, §§ 222(b), 278(b)(2), 86 Stat. 1391, 1453; Oct. 25, 1977, P.L. 95-142, § 17(d), 91 Stat. 1202; Aug. 13, 1981, P.L. 97-35, Title XXI, Subtitle D, § 2193(d), 95 Stat. 828; Sept. 3, 1982, P.L. 97-248, Title I, Subtitle C, § 147, 96 Stat. 394; July 18, 1984, P.L. 98-369, Division B, Title III, Subtitle A, Part II, § 2331(b), 98 Stat. 1088.)

§ 1395b-2. Notice of medicare benefits; medicare and medigap information

(a) Notice of medicare benefits. The Secretary shall prepare (in consultation with groups representing the elderly and with health insurers) and provide for distribution of a notice containing--

(1) a clear, simple explanation of the benefits available under this *title [42 USCS §§ 1395* et seq.] and the major categories of health care for which benefits are not available under this *title [42 USCS §§ 1395* et seq.],

(2) the limitations on payment (including deductibles and coinsurance amounts) that are imposed under this *title [42 USCS §§ 1395* et seq.], and

(3) a description of the limited benefits for long-term care services available under this *title [42 USCS §§ 1395* et seq.] and generally available under State plans approved under title XIX [*42 USCS §§ 1396* et seq.].

Such notice shall be mailed annually to individuals entitled to benefits under part A [*42 USCS §§ 1395c* et seq.] or part B [*42 USCS §§ 1395j* et seq.] of this title and when an individual applies for benefits under part A [*42 USCS §§ 1395c* et seq.] or enrolls under part B [*42 USCS §§ 1395j* et seq.].

(b) Medicare and medigap information. The Secretary shall provide information via a toll-free telephone number on the programs under this *title [42 USCS §§ 1395* et seq.]. The Secretary shall provide, through the toll-free telephone number 1-800-MEDICARE, for a means by which individuals seeking information about, or assistance with, such programs who phone such toll-free number are transferred (without charge) to appropriate entities for the provision of such information or assistance. Such toll-free number shall be the toll-free number listed for general information and assistance in the annual notice under subsection (a) instead of the listing of numbers of individual contractors.

(c) Contents of notice. The notice provided under subsection (a) shall include--

(1) a statement which indicates that because errors do occur and because medicare fraud, waste, and abuse is a significant problem, beneficiaries should carefully check any explanation of benefits or itemized statement furnished pursuant to section 1806 [*42 USCS § 1395b-7*] for accuracy and report any errors or questionable charges by calling the toll-free phone number described in paragraph (4);

(2) a statement of the beneficiary's right to request an itemized statement for medicare items and services (as provided in section 1806(b) [*42 USCS § 1395b-7(b)*]);

(3) a description of the program to collect information on medicare fraud and abuse established under section 203(b) of the Health Insurance Portability and Accountability Act of 1996 [*42 USCS § 1395b-5*]; and

(4) a toll-free telephone number maintained by the Inspector General in the Department of Health and Human Services for the receipt of complaints and information about waste, fraud, and abuse in the provision or billing of services under this *title [42 USCS §§ 1395* et seq.].

HISTORY:

(Aug. 14, 1935, ch 531, Title XVIII, § 1804; as added July 1, 1988, P.L. 100-360, Title II, Subtitle C, § 223(a), 102 Stat. 747; Oct. 31, 1994, P.L. 103-432, Title I, Subtitle D, § 171(j)(1), 108 Stat. 4451; Aug. 5, 1997, P.L. 105-33, Title IV, Subtitle D, Ch 2, § 4311(a)(1), 111 Stat. 384; Dec. 8, 2003, P.L. 108-173, Title IX, Subtitle C, § 923(d)(1), 117 Stat. 2394.)

§ 1395b-3. Health insurance advisory service for medicare beneficiaries

(a) In general. The Secretary of Health and Human Services shall establish a health insurance advisory service program (in this section referred to as the "beneficiary assistance program") to assist medicare-eligible individuals with the receipt of services under the medicare and medicaid programs and other health insurance programs.

(b) Outreach elements. The beneficiary assistance program shall provide assistance--

(1) through operation using local Federal offices that provide information on the medicare program,

(2) using community outreach programs, and

(3) using a toll-free telephone information service.

(c) Assistance provided. The beneficiary assistance program shall provide for information, counseling, and assistance for medicare-eligible individuals with respect to at least the following:

(1) With respect to the medicare program--

(A) eligibility,

(B) benefits (both covered and not covered),

(C) the process of payment for services,

(D) rights and process for appeals of determinations,

(E) other medicare-related entities (such as peer review organizations, fiscal intermediaries, and carriers), and

(F) recent legislative and administrative changes in the medicare program.

(2) With respect to the medicaid program--

(A) eligibility, benefits, and the application process,

(B) linkages between the medicaid and medicare programs, and

(C) referral to appropriate State and local agencies involved in the medicaid program.

(3) With respect to medicare supplemental policies--

(A) the program under section 1882 of the Social Security Act [*42 USCS § 1395ss*] and standards required under such program,

(B) how to make informed decisions on whether to purchase such policies and on what criteria to use in evaluating different policies,

(C) appropriate Federal, State, and private agencies that provide information and assistance in obtaining benefits under such policies, and

(D) other issues deemed appropriate by the Secretary.

The beneficiary assistance program also shall provide such other services as the Secretary deems appropriate to increase beneficiary understanding of, and confidence in, the medicare program and to improve the relationship between beneficiaries and the program.

(d) Educational material. The Secretary, through the Administrator of the Centers for Medicare & Medicaid Services, shall develop appropriate educational materials and other appropriate techniques to assist employees in carrying out this section.

(e) Notice to beneficiaries. The Secretary shall take such steps as are necessary to assure that medicare-eligible beneficiaries and the general public are made aware of the beneficiary assistance program.

(f) Report. The Secretary shall include, in an annual report transmitted to the Congress, a report on the beneficiary assistance program and on other health insurance informational and counseling services made available to medicare-eligible individuals. The Secretary shall include in the report recommendations for such changes as may be desirable to improve the relationship between the medicare program and medicare-eligible individuals.

HISTORY:

(Nov. 5, 1990, P.L. 101-508, Title IV, Subtitle A, Part 4, § 4359, 104 Stat. 1388-137; Dec. 8, 2003, P.L. 108-173, Title IX, § 900(e)(6)(G), 117 Stat. 2374.)

§ 1395b-4. Health insurance information, counseling, and assistance grants

(a) Grants. The Secretary of Health and Human Services (in this section referred to as the "Secretary") shall make grants to States, with approved State regulatory programs under section 1882 of the Social Security Act [*42 USCS § 1395ss*], that submit applications to the Secretary that meet the requirements of this section for the purpose of providing information, counseling, and assistance relating to the procurement of adequate and appropriate health insurance coverage to individuals who are eligible to receive benefits under title XVIII of the Social Security Act [*42 USCS §§ 1395* et seq.] (in this section referred to as "eligible individuals"). The Secretary shall prescribe regulations to establish a minimum level of funding for a grant issued under this section.

(b) Grant applications.

(1) In submitting an application under this section, a State may consolidate and coordinate an application that consists of parts prepared by more than one agency or department of such State.

(2) As part of an application for a grant under this section, a State shall submit a plan for a State-wide health insurance information, counseling, and assistance program. Such program shall--

(A) establish or improve upon a health insurance information, counseling, and assistance program that provides counseling and assistance to eligible individuals in need of health insurance information, including--

(i) information that may assist individuals in obtaining benefits and filing claims under titles XVIII and XIX of the Social Security Act [*42 USCS §§ 1395* et seq. and *1396* et seq.];

(ii) policy comparison information for medicare supplemental policies (as described in section 1882(g)(1) of the Social Security Act [*42 USCS § 1395ss(g)(1)*]) and information that may assist individuals in filing claims under such medicare supplemental policies;

(iii) information regarding long-term care insurance; and

(iv) information regarding other types of health insurance benefits that the Secretary determines to be appropriate;

(B) in conjunction with the health insurance information, counseling, and assistance program described in subparagraph (A), establish a system of referral to appropriate Federal or State departments or agencies for assistance with problems related to health insurance coverage (including legal problems), as determined by the Secretary;

(C) provide for a sufficient number of staff positions (including volunteer positions) necessary to provide the services of the health insurance information, counseling, and assistance program;

(D) provide assurances that staff members (including volunteer staff members) of the health insurance information, counseling, and assistance program have no conflict of interest in providing the counseling described in subparagraph (A);

(E) provide for the collection and dissemination of timely and accurate health care information to staff members;

(F) provide for training programs for staff members (including volunteer staff members);

(G) provide for the coordination of the exchange of health insurance information between the staff of departments and agencies of the State government and the staff of the health insurance information, counseling, and assistance program;

(H) make recommendations concerning consumer issues and complaints related to the provision of health care to agencies and departments of the State government and the Federal Government responsible for providing or regulating health insurance;

(I) establish an outreach program to provide the health insurance information and counseling described in subparagraph (A) and the referrals described in subparagraph (B) to eligible individuals; and

(J) demonstrate, to the satisfaction of the Secretary, an ability to provide the counseling and assistance required under this section.

(c) Special grants.

(1) A State that is conducting a health insurance information, counseling, and assistance program that is substantially similar to a program described in subsection (b)(2) shall, as a requirement for eligibility for a grant under this section, demonstrate, to the satisfaction of the Secretary, that such State shall maintain the activities of such program at least at the level that such activities were conducted immediately preceding the date of the issuance of any grant during the period of time covered by such grant under this section.

(2) If the Secretary determines that the existing health insurance information, counseling, and assistance program is substantially similar to a program described in subsection (b)(2), the Secretary may waive some or all of the requirements described in such subsection and issue a grant to the State for the purpose of increasing the number of services offered by the health insurance information, counseling, and assistance program, experimenting with new methods of outreach in conducting such program, or expanding such program to geographic areas of the State not previously served by the program.

(d) Criteria for issuing grants. In issuing a grant under this section, the Secretary shall consider--

(1) the commitment of the State to carrying out the health insurance information, counseling, and assistance program described in subsection (b)(2), including the level of cooperation demonstrated--

(A) by the office of the chief insurance regulator of the State, or the equivalent State entity;

(B) other officials of the State responsible for overseeing insurance plans issued by nonprofit hospital and medical service associations; and

(C) departments and agencies of such State responsible for--

(i) administering funds under title XIX of the Social Security Act [*42 USCS §§ 1396* et seq.], and

(ii) administering funds appropriated under the Older Americans Act;

(2) the population of eligible individuals in such State as a percentage of the population of such State; and

(3) in order to ensure the needs of rural areas in such State, the relative costs and special problems associated with addressing the special problems of providing health care information, counseling, and assistance [to] eligible individuals residing in rural areas of such State.

(e) Annual State report. A State that receives a grant under this section shall, not later than 180 days after receiving such grant, and annually thereafter during the period of the grant, issue a report to the Secretary that includes information, concerning--

(1) the number of individuals served by the health insurance information, counseling and assistance program of such State;

(2) an estimate of the amount of funds saved by the State, and by eligible individuals in the State, in the implementation of such program; and

(3) the problems that eligible individuals in such State encounter in procuring adequate and appropriate health care coverage.

(f) Report to Congress. Beginning with 1992, and annually thereafter, the Secretary shall issue a report to the Committee on Finance of the Senate, the Special Committee on Aging of the Senate, the Committee on Ways and Means of the House of Representatives, and the Committee on Energy and Commerce of the House of Representatives that--

(1) summarizes the allocation of funds authorized for grants under this section and the expenditure of such funds;

(2) outlines the problems that eligible individuals encounter in procuring adequate and appropriate health care coverage;

(3) makes recommendations that the Secretary determines to be appropriate to address the problems described in paragraph (3) [paragraph (2)]; and

(4) in the case of the report issued 2 years after the date of enactment of this section, evaluates the effectiveness of counseling programs established under this program, and makes recommendations regarding continued authorization of funds for these purposes.

(g) Authorization of appropriations for grants. There are authorized to be appropriated, in equal parts from the Federal Hospital Insurance Trust Fund and from the Federal Supplementary Medical Insurance Trust Fund, $ 10,000,000 for each of fiscal years 1991, 1992, 1993, 1994, 1995, and 1996, to fund the grant programs described in this section.

HISTORY:

(Nov. 5, 1990, P.L. 101-508, Title IV, Subtitle A, Part 4, § 4360, 104 Stat. 1388-138; Oct. 31, 1994, P.L. 103-432, Title I, Subtitle D, § 171(i), 108 Stat. 4450; Nov. 2, 1994, P.L. 103-437, § 15(b), 108 Stat. 4591; Nov. 10, 1998, P.L. 105-362, Title VI, § 602(b)(2), 112 Stat. 3286.)

§ 1395b-5. Beneficiary incentive programs

(a) [Repealed]

(b) Program to collect information on fraud and abuse.

(1) Establishment of program. Not later than 3 months after the date of the enactment of this Act [enacted Aug. 21, 1996], the Secretary shall establish a program under which the Secretary shall encourage individuals to report to the Secretary information on individuals and entities who are engaging in or who have engaged in acts or omissions which constitute grounds for the imposition of a sanction under section 1128, 1128A, or 1128B of the Social Security Act [*42 USCS § 1320a-7, 1320a-7a*, or *1320a-7b*], or who have otherwise engaged in fraud and abuse against the Medicare program under title XVIII of such act [*42 USCS §§ 1395* et seq.] for which there is a sanction provided under law. The program shall discourage provision of, and not consider, information which is frivolous or otherwise not relevant or material to the imposition of such a sanction.

(2) Payment of portion of amounts collected. If an individual reports information to the Secretary under the program established under paragraph (1) which serves as the basis for the collection by the Secretary or the Attorney General of any amount of at least $ 100 (other than any amount paid as a penalty under section 1128B of the Social Security Act [*42 USCS § 1320a-7b*]), the Secretary may pay a portion of the amount collected to the individual (under procedures similar to those applicable under *section 7623 of the Internal Revenue Code of 1986* [*26 USCS § 7623*] to payments to individuals providing information on violations of such Code).

(c) Program to collect information on program efficiency.

(1) Establishment of program. Not later than 3 months after the date of the enactment of this Act [enacted Aug. 21, 1996], the Secretary shall establish a program under which the Secretary shall encourage individuals to submit to the Secretary suggestions on methods to improve the efficiency of the Medicare program.

(2) Payment of portion of program savings. If an individual submits a suggestion to the Secretary under the program established under paragraph (1) which is adopted by the Secretary and which results in savings to the program, the Secretary may make a payment to the individual of such amount as the Secretary considers appropriate.

HISTORY:

(Aug. 21, 1996, P.L. 104-191, Title II, Subtitle A, § 203, 110 Stat. 1998; Aug. 5, 1997, P.L. 105-33, Title IV, Subtitle D, Ch 2, § 4311(b)(2), 111 Stat. 386.)

§ 1395b-6. Medicare Payment Advisory Commission

(a) Establishment. There is hereby established as an agency of Congress the Medicare Payment Advisory Commission (in this section referred to as the "Commission").

(b) Duties.

(1) Review of payment policies and annual reports. The Commission shall--

(A) review payment policies under this *title [42 USCS §§ 1395* et seq.], including the topics described in paragraph (2);

(B) make recommendations to Congress concerning such payment policies;

(C) by not later than March 1 of each year (beginning with 1998), submit a report to Congress containing the results of such reviews and its recommendations concerning such policies; and

(D) by not later than June 15 of each year, submit a report to Congress containing an examination of issues affecting the medicare program, including the implications of changes in health care delivery in the United States and in the market for health care services on the medicare program and including a review of the estimate of the conversion factor submitted under section 1848(d)(1)(E)(ii) [*42 USCS § 1395w-4(d)(1)(E)(ii)*].

(2) Specific topics to be reviewed.

(A) Medicare + Choice program. Specifically, the Commission shall review, with respect to the Medicare + Choice program under part C [*42 USCS §§ 1395w-21* et seq.], the following:

(i) The methodology for making payment to plans under such program, including the making of differential payments and the distribution of differential updates among different payment areas.

(ii) The mechanisms used to adjust payments for risk and the need to adjust such mechanisms to take into account health status of beneficiaries.

(iii) The implications of risk selection both among Medicare + Choice organizations and between the Medicare + Choice option and the original medicare fee-for-service option.

(iv) The development and implementation of mechanisms to assure the quality of care for those enrolled with Medicare + Choice organizations.

(v) The impact of the Medicare + Choice program on access to care for medicare beneficiaries.

(vi) Other major issues in implementation and further development of the Medicare + Choice program.

(B) Original medicare fee-for-service system. Specifically, the Commission shall review payment policies under parts A and B [*42 USCS §§ 1395c* et seq. and *1395j* et seq.], including--

(i) the factors affecting expenditures for the efficient provision of services in different sectors, including the process for updating hospital, skilled nursing facility, physician, and other fees,

(ii) payment methodologies, and

(iii) their relationship to access and quality of care for medicare beneficiaries.

(C) Interaction of medicare payment policies with health care delivery generally. Specifically, the Commission shall review the effect of payment policies under this *title [42 USCS §§ 1395* et seq.] on the delivery of health care services other than under this *title [42 USCS §§ 1395* et seq.] and assess the implications of changes in health care delivery in the United States and in the general market for health care services on the medicare program.

(3) Comments on certain secretarial reports. If the Secretary submits to Congress (or a committee of Congress) a report that is required by law and that relates to payment policies under this *title [42 USCS §§ 1395* et seq.], the Secretary shall transmit a copy of the report to the Commission. The Commission shall review the report and, not later than 6 months after the date of submittal of the Secretary's report to Congress, shall submit to the appropriate committees of Congress written comments on such report. Such comments may include such recommendations as the Commission deems appropriate.

(4) Agenda and additional reviews. The Commission shall consult periodically with the chairmen and ranking minority members of the appropriate committees of Congress regarding the Commission's agenda and progress towards achieving the agenda. The Commission may conduct additional reviews, and submit additional reports to the appropriate committees of Congress, from time to time on such topics relating to the program under this *title [42 USCS §§ 1395* et seq.] as may be requested by such chairmen and members and as the Commission deems appropriate.

(5) Availability of reports. The Commission shall transmit to the Secretary a copy of each report submitted under this subsection and shall make such reports available to the public.

(6) Appropriate committees of Congress. For purposes of this section, the term "appropriate committees of Congress" means the Committees on Ways and Means and Commerce of the House of Representatives and the Committee on Finance of the Senate.

(7) Voting and reporting requirements. With respect to each recommendation contained in a report submitted under paragraph (1), each member of the Commission shall vote on the recommendation, and the Commission shall include, by member, the results of that vote in the report containing the recommendation.

(8) Examination of budget consequences. Before making any recommendations, the Commission shall examine the budget consequences of such recommendations, directly or through consultation with appropriate expert entities.

(c) Membership.

(1) Number and appointment. The Commission shall be composed of 17 members appointed by the Comptroller General.

(2) Qualifications.

(A) In general. The membership of the Commission shall include individuals with national recognition for their expertise in health finance and economics, actuarial science, health facility management, health plans and integrated delivery systems, reimbursement of health facilities, allopathic and osteopathic physicians, and other providers of health services, and other related fields, who provide a mix of different professionals, broad geographic representation, and a balance between urban and rural representatives.

(B) Inclusion. The membership of the Commission shall include (but not be limited to) physicians and other health professionals, experts in the area of pharmaco-economics or prescription drug benefit programs, employers, third-party payers, individuals skilled in the conduct and interpretation of biomedical, health services, and health economics research and expertise in outcomes and effectiveness research and technology assessment. Such membership shall also include representatives of consumers and the elderly.

(C) Majority nonproviders. Individuals who are directly involved in the provision, or management of the delivery, of items and services covered under this *title [42 USCS §§ 1395* et seq.] shall not constitute a majority of the membership of the Commission.

(D) Ethical disclosure. The Comptroller General shall establish a system for public disclosure by members of the Commission of financial and other potential conflicts of interest relating to such members. Members of the Commission shall be treated as employees of Congress for purposes of applying title I of the Ethics in Government Act of 1978 (Public Law 95-521) [5 USCS Appx].

(3) Terms.

(A) In general. The terms of members of the Commission shall be for 3 years except that the Comptroller General shall designate staggered terms for the members first appointed.

(B) Vacancies. Any member appointed to fill a vacancy occurring before the expiration of the term for which the member's predecessor was appointed shall be appointed only for the remainder of that term. A member may serve after the expiration of that member's term until a successor has taken office. A vacancy in the Commission shall be filled in the manner in which the original appointment was made.

(4) Compensation. While serving on the business of the Commission (including traveltime), a member of the Commission shall be entitled to compensation at the per diem equivalent of the rate provided for level IV of the Executive Schedule under *section 5315 of title 5, United States Code*; and while so serving away from home and the member's regular place of business, a member may be allowed travel expenses, as authorized by the Chairman of the Commission. Physicians serving as personnel of the Commission may be provided a physician comparability allowance by the Commission in the same manner as Government physicians may be provided such an allowance by an agency under *section 5948 of title 5, United States Code*, and for such purpose subsection (i) of such section shall apply to the Commission in the same manner as it applies to the Tennessee Valley Authority. For purposes of pay (other than pay of members of the Commission) and employment benefits, rights, and privileges, all personnel of the Commission shall be treated as if they were employees of the United States Senate.

(5) Chairman; Vice Chairman. The Comptroller General shall designate a member of the Commission, at the time of appointment of the member as Chairman and a member as Vice Chairman for that term of appointment, except that in the case of vacancy of the Chairmanship or Vice Chairmanship, the Comptroller General may designate another member for the remainder of that member's term.

(6) Meetings. The Commission shall meet at the call of the Chairman.

(d) Director and staff; experts and consultants. Subject to such review as the Comptroller General deems necessary to assure the efficient administration of the Commission, the Commission may--

(1) employ and fix the compensation of an Executive Director (subject to the approval of the Comptroller General) and such other personnel as may be necessary to carry out its duties (without regard to the provisions of title 5, United States Code, governing appointments in the competitive service);

(2) seek such assistance and support as may be required in the performance of its duties from appropriate Federal departments and agencies;

(3) enter into contracts or make other arrangements, as may be necessary for the conduct of the work of the Commission (without regard to section 3709 of the Revised Statutes (*41 U.S.C. 5*));

(4) make advance, progress, and other payments which relate to the work of the Commission;

(5) provide transportation and subsistence for persons serving without compensation; and

(6) prescribe such rules and regulations as it deems necessary with respect to the internal organization and operation of the Commission.

(e) Powers.

(1) Obtaining official data. The Commission may secure directly from any department or agency of the United States information necessary to enable it to carry out this section. Upon request of the Chairman, the head of that department or agency shall furnish that information to the Commission on an agreed upon schedule.

(2) Data collection. In order to carry out its functions, the Commission shall--

(A) utilize existing information, both published and unpublished, where possible, collected and assessed either by its own staff or under other arrangements made in accordance with this section,

(B) carry out, or award grants or contracts for, original research and experimentation, where existing information is inadequate, and

(C) adopt procedures allowing any interested party to submit information for the Commission's use in making reports and recommendations.

(3) Access of GAO to information. The Comptroller General shall have unrestricted access to all deliberations, records, and nonproprietary data of the Commission, immediately upon request.

(4) Periodic audit. The Commission shall be subject to periodic audit by the Comptroller General.

(f) Authorization of appropriations.

(1) Request for appropriations. The Commission shall submit requests for appropriations in the same manner as the Comptroller General submits requests for appropriations, but amounts appropriated for the Commission shall be separate from amounts appropriated for the Comptroller General.

(2) Authorization. There are authorized to be appropriated such sums as may be necessary to carry out the provisions of this section. Sixty percent of such appropriation shall be payable from the Federal Hospital Insurance Trust Fund, and 40 percent of such appropriation shall be payable from the Federal Supplementary Medical Insurance Trust Fund.

HISTORY:

(Aug. 14, 1935, ch 531, Title XVIII, § 1805, as added Aug. 5, 1997, P.L. 105-33, Title IV, Subtitle A, Ch 3, § 4022(a), 111 Stat. 350; Oct. 21, 1998, P.L. 105-277, Div J, Title V, Subtitle B, § 5202(a), 112 Stat. 2681-917; Nov. 29, 1999, P.L. 106-113, Div B, § 1000(a)(6), 113 Stat. 1536; Dec. 21, 2000, P.L. 106-554, § 1(a)(6), 114 Stat. 2763; Dec. 8, 2003, P.L. 108-173, Title VII, Subtitle D, § 735(a), (b), (c)(1), (e)(1), 117 Stat. 2353, 2354.)

(As amended Dec. 29, 2007, P.L. 110-173, Title III, § 301, 121 Stat. 2514.)

§ 1395b-7. Explanation of Medicare benefits

(a) In general. The Secretary shall furnish to each individual for whom payment has been made under this *title [42 USCS §§ 1395* et seq.] (or would be made without regard to any deductible) a statement which--

(1) lists the item or service for which payment has been made and the amount of such payment for each item or service; and

(2) includes a notice of the individual's right to request an itemized statement (as provided in subsection (b)).

(b) Request for itemized statement for Medicare items and services.

(1) In general. An individual may submit a written request to any physician, provider, supplier, or any other person (including an organization, agency, or other entity) for an itemized statement for any item or service provided to such individual by such person with respect to which payment has been made under this *title [42 USCS §§ 1395* et seq.].

(2) 30-day period to furnish statement.

(A) In general. Not later than 30 days after the date on which a request under paragraph (1) has been made, a person described in such paragraph shall furnish an itemized statement describing each item or service provided to the individual requesting the itemized statement.

(B) Penalty. Whoever knowingly fails to furnish an itemized statement in accordance with subparagraph (A) shall be subject to a civil money penalty of not more than $ 100 for each such failure. Such penalty shall be imposed and collected in the same manner as civil money penalties under subsection (a) of section 1128A [*42 USCS § 1320a-7a(a)*] are imposed and collected under that section.

(3) Review of itemized statement.

(A) In general. Not later than 90 days after the receipt of an itemized statement furnished under paragraph (1), an individual may submit a written request for a review of the itemized statement to the Secretary.

(B) Specific allegations. A request for a review of the itemized statement shall identify--

(i) specific items or services that the individual believes were not provided as claimed, or

(ii) any other billing irregularity (including duplicate billing).

(4) Findings of Secretary. The Secretary shall, with respect to each written request submitted under paragraph (3), determine whether the itemized statement identifies specific items or services that were not provided as claimed or any

other billing irregularity (including duplicate billing) that has resulted in unnecessary payments under this *title [42 USCS §§ 1395* et seq.].

(5) Recovery of amounts. The Secretary shall take all appropriate measures to recover amounts unnecessarily paid under this *title [42 USCS §§ 1395* et seq.] with respect to a statement described in paragraph (4).

HISTORY:

(Aug. 14, 1935, ch 531, Title XVIII, § 1806, as added Aug. 5, 1997, P.L. 105-33, Title IV, Subtitle D, Ch 2, § 4311(b)(1), 111 Stat. 385.)

§ 1395b-8. Chronic care improvement

(a) Implementation of chronic care improvement programs.

(1) In general. The Secretary shall provide for the phased-in development, testing, evaluation, and implementation of chronic care improvement programs in accordance with this section. Each such program shall be designed to improve clinical quality and beneficiary satisfaction and achieve spending targets with respect to expenditures under this *title [42 USCS §§ 1395* et seq.] for targeted beneficiaries with one or more threshold conditions.

(2) Definitions. For purposes of this section:

(A) Chronic care improvement program. The term "chronic care improvement program" means a program described in paragraph (1) that is offered under an agreement under subsection (b) or (c).

(B) Chronic care improvement organization. The term "chronic care improvement organization" means an entity that has entered into an agreement under subsection (b) or (c) to provide, directly or through contracts with subcontractors, a chronic care improvement program under this section. Such an entity may be a disease management organization, health insurer, integrated delivery system, physician group practice, a consortium of such entities, or any other legal entity that the Secretary determines appropriate to carry out a chronic care improvement program under this section.

(C) Care management plan. The term "care management plan" means a plan established under subsection (d) for a participant in a chronic care improvement program.

(D) Threshold condition. The term "threshold condition" means a chronic condition, such as congestive heart failure, diabetes, chronic obstructive pulmonary disease (COPD), or other diseases or conditions, as selected by the Secretary as appropriate for the establishment of a chronic care improvement program.

(E) Targeted beneficiary. The term "targeted beneficiary" means, with respect to a chronic care improvement program, an individual who--

(i) is entitled to benefits under part A [*42 USCS §§ 1395c* et seq.] and enrolled under part B [*42 USCS §§ 1395j* et seq.], but not enrolled in a plan under part C [*42 USCS §§ 1395w-21* et seq.];

(ii) has one or more threshold conditions covered under such program; and

(iii) has been identified under subsection (d)(1) as a potential participant in such program.

(3) Construction. Nothing in this section shall be construed as--

(A) expanding the amount, duration, or scope of benefits under this *title [42 USCS §§ 1395* et seq.];

(B) providing an entitlement to participate in a chronic care improvement program under this section;

(C) providing for any hearing or appeal rights under section 1869 [*42 USCS § 1395ff*], 1878 [*42 USCS § 1395oo*], or otherwise, with respect to a chronic care improvement program under this section; or

(D) providing benefits under a chronic care improvement program for which a claim may be submitted to the Secretary by any provider of services or supplier (as defined in section 1861(d) [*42 USCS § 1395x(d)*]).

(b) Developmental phase (Phase I).

(1) In general. In carrying out this section, the Secretary shall enter into agreements consistent with subsection (f) with chronic care improvement organizations for the development, testing, and evaluation of chronic care improvement programs using randomized controlled trials. The first such agreement shall be entered into not later than 12 months after the date of the enactment of this section [enacted Dec. 8, 2003].

(2) Agreement period. The period of an agreement under this subsection shall be for 3 years.

(3) Minimum participation.

(A) In general. The Secretary shall enter into agreements under this subsection in a manner so that chronic care improvement programs offered under this section are offered in geographic areas that, in the aggregate, consist of areas in which at least 10 percent of the aggregate number of medicare beneficiaries reside.

(B) Medicare beneficiary defined. In this paragraph, the term "medicare beneficiary" means an individual who is entitled to benefits under part A [*42 USCS §§ 1395c* et seq.], enrolled under part B [*42 USCS §§ 1395j* et seq.], or both, and who resides in the United States.

(4) Site selection. In selecting geographic areas in which agreements are entered into under this subsection, the Secretary shall ensure that each chronic care improvement program is conducted in a geographic area in which at least 10,000 targeted beneficiaries reside among other individuals entitled to benefits under part A [*42 USCS §§ 1395c* et seq.], enrolled under part B [*42 USCS §§ 1395j* et seq.], or both to serve as a control population.

(5) Independent evaluations of Phase I programs. The Secretary shall contract for an independent evaluation of the programs conducted under this subsection. Such evaluation shall be done by a contractor with knowledge of chronic care management programs and demonstrated experience in the evaluation of such programs. Each evaluation shall include an assessment of the following factors of the programs:

(A) Quality improvement measures, such as adherence to evidence-based guidelines and rehospitalization rates.

(B) Beneficiary and provider satisfaction.

(C) Health outcomes.

(D) Financial outcomes, including any cost savings to the program under this *title [42 USCS §§ 1395* et seq.].

(c) Expanded implementation phase (Phase II).

(1) In general. With respect to chronic care improvement programs conducted under subsection (b), if the Secretary finds that the results of the independent evaluation conducted under subsection (b)(6) indicate that the conditions specified in paragraph (2) have been met by a program (or components of such program), the Secretary shall enter into agreements consistent with subsection (f) to expand the implementation of the program (or components) to additional geographic areas not covered under the program as conducted under subsection (b), which may include the implementation of the program on a national basis. Such expansion shall begin not earlier than 2 years after the program is implemented under subsection (b) and not later than 6 months after the date of completion of such program.

(2) Conditions for expansion of programs. The conditions specified in this paragraph are, with respect to a chronic care improvement program conducted under subsection (b) for a threshold condition, that the program is expected to--

(A) improve the clinical quality of care;

(B) improve beneficiary satisfaction; and

(C) achieve targets for savings to the program under this *title [42 USCS §§ 1395* et seq.] specified by the Secretary in the agreement within a range determined to be appropriate by the Secretary, subject to the application of budget neutrality with respect to the program and not taking into account any payments by the organization under the agreement under the program for risk under subsection (f)(3)(B).

(3) Independent evaluations of Phase II programs. The Secretary shall carry out evaluations of programs expanded under this subsection as the Secretary determines appropriate. Such evaluations shall be carried out in the similar manner as is provided under subsection (b)(5).

(d) Identification and enrollment of prospective program participants.

(1) Identification of prospective program participants. The Secretary shall establish a method for identifying targeted beneficiaries who may benefit from participation in a chronic care improvement program.

(2) Initial contact by Secretary. The Secretary shall communicate with each targeted beneficiary concerning participation in a chronic care improvement program. Such communication may be made by the Secretary and shall include information on the following:

(A) A description of the advantages to the beneficiary in participating in a program.

(B) Notification that the organization offering a program may contact the beneficiary directly concerning such participation.

(C) Notification that participation in a program is voluntary.

(D) A description of the method for the beneficiary to participate or for declining to participate and the method for obtaining additional information concerning such participation.

(3) Voluntary participation. A targeted beneficiary may participate in a chronic care improvement program on a voluntary basis and may terminate participation at any time.

(e) Chronic care improvement programs.

(1) In general. Each chronic care improvement program shall--

(A) have a process to screen each targeted beneficiary for conditions other than threshold conditions, such as impaired cognitive ability and co-morbidities, for the purposes of developing an individualized, goal-oriented care management plan under paragraph (2);

(B) provide each targeted beneficiary participating in the program with such plan; and

(C) carry out such plan and other chronic care improvement activities in accordance with paragraph (3).

(2) Elements of care management plans. A care management plan for a targeted beneficiary shall be developed with the beneficiary and shall, to the extent appropriate, include the following:

(A) A designated point of contact responsible for communications with the beneficiary and for facilitating communications with other health care providers under the plan.

(B) Self-care education for the beneficiary (through approaches such as disease management or medical nutrition therapy) and education for primary caregivers and family members.

(C) Education for physicians and other providers and collaboration to enhance communication of relevant clinical information.

(D) The use of monitoring technologies that enable patient guidance through the exchange of pertinent clinical information, such as vital signs, symptomatic information, and health self-assessment.

(E) The provision of information about hospice care, pain and palliative care, and end-of-life care.

(3) Conduct of programs. In carrying out paragraph (1)(C) with respect to a participant, the chronic care improvement organization shall--

(A) guide the participant in managing the participant's health (including all co-morbidities, relevant health care services, and pharmaceutical needs) and in performing activities as specified under the elements of the care management plan of the participant;

(B) use decision-support tools such as evidence-based practice guidelines or other criteria as determined by the Secretary; and

(C) develop a clinical information database to track and monitor each participant across settings and to evaluate outcomes.

(4) Additional responsibilities.

(A) Outcomes report. Each chronic care improvement organization offering a chronic care improvement program shall monitor and report to the Secretary, in a manner specified by the Secretary, on health care quality, cost, and outcomes.

(B) Additional requirements. Each such organization and program shall comply with such additional requirements as the Secretary may specify.

(5) Accreditation. The Secretary may provide that chronic care improvement programs and chronic care improvement organizations that are accredited by qualified organizations (as defined by the Secretary) may be deemed to meet such requirements under this section as the Secretary may specify.

(f) Terms of agreements.

(1) Terms and conditions.

(A) In general. An agreement under this section with a chronic care improvement organization shall contain such terms and conditions as the Secretary may specify consistent with this section.

(B) Clinical, quality improvement, and financial requirements. The Secretary may not enter into an agreement with such an organization under this section for the operation of a chronic care improvement program unless--

(i) the program and organization meet the requirements of subsection (e) and such clinical, quality improvement, financial, and other requirements as the Secretary deems to be appropriate for the targeted beneficiaries to be served; and

(ii) the organization demonstrates to the satisfaction of the Secretary that the organization is able to assume financial risk for performance under the agreement (as applied under paragraph (3)(B)) with respect to payments made to the organization under such agreement through available reserves, reinsurance, withholds, or such other means as the Secretary determines appropriate.

(2) Manner of payment. Subject to paragraph (3)(B), the payment under an agreement under--

(A) subsection (b) shall be computed on a per-member per-month basis; or

(B) subsection (c) may be on a per-member per-month basis or such other basis as the Secretary and organization may agree.

(3) Application of performance standards.

(A) Specification of performance standards. Each agreement under this section with a chronic care improvement organization shall specify performance standards for each of the factors specified in subsection (c)(2), including clinical quality and spending targets under this *title [42 USCS §§ 1395* et seq.], against which the performance of the chronic care improvement organization under the agreement is measured.

(B) Adjustment of payment based on performance.

(i) In general. Each such agreement shall provide for adjustments in payment rates to an organization under the agreement insofar as the Secretary determines that the organization failed to meet the performance standards specified in the agreement under subparagraph (A).

(ii) Financial risk for performance. In the case of an agreement under subsection (b) or (c), the agreement shall provide for a full recovery for any amount by which the fees paid to the organization under the agreement exceed the estimated savings to the programs under this *title [42 USCS §§ 1395* et seq.] attributable to implementation of such agreement.

(4) Budget neutral payment condition. Under this section, the Secretary shall ensure that the aggregate sum of medicare program benefit expenditures for beneficiaries participating in chronic care improvement programs and funds paid to chronic care improvement organizations under this section, shall not exceed the medicare program benefit expenditures that the Secretary estimates would have been made for such targeted beneficiaries in the absence of such programs.

(g) Funding.

(1) Subject to paragraph (2), there are appropriated to the Secretary, in appropriate part from the Federal Hospital Insurance Trust Fund and the Federal Supplementary Medical Insurance Trust Fund, such sums as may be necessary to provide for agreements with chronic care improvement programs under this section.

(2) In no case shall the funding under this section exceed $ 100,000,000 in aggregate increased expenditures under this *title [42 USCS §§ 1395* et seq.] (after taking into account any savings attributable to the operation of this section) over the 3-fiscal-year period beginning on October 1, 2003.

HISTORY:

(Aug. 14, 1935, ch 531, Title XVIII, § 1807, as added Dec. 8, 2003, P.L. 108-173, Title VII, Subtitle C, § 721(a), 117 Stat. 2341.)

§ 1395b-9. Provisions relating to administration

(a) Coordinated administration of medicare prescription drug and Medicare Advantage programs.

(1) In general. There is within the Centers for Medicare & Medicaid Services a center to carry out the duties described in paragraph (3).

(2) Director. Such center shall be headed by a director who shall report directly to the Administrator of the Centers for Medicare & Medicaid Services.

(3) Duties. The duties described in this paragraph are the following:

(A) The administration of parts C and D [*42 USCS §§ 1395w-21* et seq. and *1395w-101* et seq.].

(B) The provision of notice and information under section 1804 [*42 USCS § 1395b-2*].

(C) Such other duties as the Secretary may specify.

(4) Deadline. The Secretary shall ensure that the center is carrying out the duties described in paragraph (3) by not later than January 1, 2008.

(b) Employment of management staff.

(1) In general. The Secretary may employ, within the Centers for Medicare & Medicaid Services, such individuals as management staff as the Secretary determines to be appropriate. With respect to the administration of parts C and D [*42 USCS §§ 1395w-21* et seq. and *1395w-101* et seq.], such individuals shall include individuals with private sector expertise in negotiations with health benefits plans.

(2) Eligibility. To be eligible for employment under paragraph (1) an individual shall be required to have demonstrated, by their education and experience (either in the public or private sector), superior expertise in at least one of the following areas:

(A) The review, negotiation, and administration of health care contracts.

(B) The design of health care benefit plans.

(C) Actuarial sciences.

(D) Compliance with health plan contracts.

(E) Consumer education and decision making.

(F) Any other area specified by the Secretary that requires specialized management or other expertise.

(3) Rates of payment.

(A) Performance-related pay. Subject to subparagraph (B), the Secretary shall establish the rate of pay for an individual employed under paragraph (1). Such rate shall take into account expertise, experience, and performance.

(B) Limitation. In no case may the rate of compensation determined under subparagraph (A) exceed the highest rate of basic pay for the Senior Executive Service under *section 5382(b) of title 5, United States Code.*

(c) Medicare beneficiary ombudsman.

(1) In general. The Secretary shall appoint within the Department of Health and Human Services a Medicare Beneficiary Ombudsman who shall have expertise and experience in the fields of health care and education of (and assistance to) individuals entitled to benefits under this *title [42 USCS §§ 1395* et seq.].

(2) Duties. The Medicare Beneficiary Ombudsman shall--

(A) receive complaints, grievances, and requests for information submitted by individuals entitled to benefits under part A [*42 USCS §§ 1395c* et seq.] or enrolled under part B [*42 USCS §§ 1395j* et seq.], or both, with respect to any aspect of the medicare program;

(B) provide assistance with respect to complaints, grievances, and requests referred to in subparagraph (A), including--

(i) assistance in collecting relevant information for such individuals, to seek an appeal of a decision or determination made by a fiscal intermediary, carrier, MA organization, or the Secretary;

(ii) assistance to such individuals with any problems arising from disenrollment from an MA plan under part C [*42 USCS §§ 1395w-21* et seq.]; and

(iii) assistance to such individuals in presenting information under section 1839(i)(4)(C) [*42 USCS § 1395r(i)(4)(C)*] (relating to income-related premium adjustment; and

(C) submit annual reports to Congress and the Secretary that describe the activities of the Office and that include such recommendations for improvement in the administration of this title as the Ombudsman determines appropriate.

The Ombudsman shall not serve as an advocate for any increases in payments or new coverage of services, but may identify issues and problems in payment or coverage policies.

(3) Working with health insurance counseling programs. To the extent possible, the Ombudsman shall work with health insurance counseling programs (receiving funding under section 4360 of Omnibus Budget Reconciliation Act of 1990 [*42 USCS § 1395b-4*]) to facilitate the provision of information to individuals entitled to benefits under part A [*42 USCS §§ 1395c* et seq.] or enrolled under part B [*42 USCS §§ 1395j* et seq.], or both regarding MA plans and changes to those plans. Nothing in this paragraph shall preclude further collaboration between the Ombudsman and such programs.

HISTORY:

(Aug. 14, 1935, ch 531, Title XVIII, § 1808, as added and amended Dec. 8, 2003, P.L. 108-173, Title IX, § 900(a), (b), Subtitle C, § 923(a), 117 Stat. 2369, 2393.)

§ 1395b-10. Addressing health care disparities

(a) Evaluating data collection approaches. The Secretary shall evaluate approaches for the collection of data under this *title [42 USCS §§ 1395* et seq.], to be performed in conjunction with existing quality reporting requirements and programs under this title, that allow for the ongoing, accurate, and timely collection and evaluation of data on disparities in health care services and performance on the basis of race, ethnicity, and gender. In conducting such evaluation, the Secretary shall consider the following objectives:

(1) Protecting patient privacy.

(2) Minimizing the administrative burdens of data collection and reporting on providers and health plans participating under this *title [42 USCS §§ 1395* et seq.].

(3) Improving Medicare program data on race, ethnicity, and gender.

(b) Reports to Congress.

(1) Report on evaluation. Not later than 18 months after the date of the enactment of this section [enacted July 15, 2008], the Secretary shall submit to Congress a report on the evaluation conducted under subsection (a). Such report shall, taking into consideration the results of such evaluation--

(A) identify approaches (including defining methodologies) for identifying and collecting and evaluating data on health care disparities on the basis of race, ethnicity, and gender for the original Medicare fee-for-service program under parts A and B [*42 USCS §§ 1395c* et seq. and *1395j* et seq.], the Medicare Advantage program under part C [*42 USCS §§ 1395w-21* et seq.], and the Medicare prescription drug program under part D [*42 USCS §§ 1395w-101* et seq.]; and

(B) include recommendations on the most effective strategies and approaches to reporting HEDIS quality measures as required under section 1852(e)(3) [*42 USCS § 1395w-22(e)(3)*] and other nationally recognized quality performance measures, as appropriate, on the basis of race, ethnicity, and gender.

(2) Reports on data analyses. Not later than 4 years after the date of the enactment of this section [enacted July 15, 2008], and 4 years thereafter, the Secretary shall submit to Congress a report that includes recommendations for improving the identification of health care disparities for Medicare beneficiaries based on analyses of the data collected under subsection (c).

(c) Implementing effective approaches. Not later than 24 months after the date of the enactment of this section [enacted July 15, 2008], the Secretary shall implement the approaches identified in the report submitted under subsection (b)(1) for the ongoing, accurate, and timely collection and evaluation of data on health care disparities on the basis of race, ethnicity, and gender.

HISTORY:

(Aug. 14, 1935, ch 531, Title XVIII, § 1809, as added July 15, 2008, P.L. 110-275, Title I, Subtitle F, § 185, 122 Stat. 2587.)

§ 1395c. Description of program

The insurance program for which entitlement is established by sections 226 and 226A [*42 USCS §§ 426* and *426-1*] provides basic protection against the costs of hospital, related post-hospital, home health services, and hospice care in accordance with this part [*42 USCS §§ 1395c* et seq.] for (1) individuals who are age 65 or over and are eligible for retirement benefits under title II of this Act [*42 USCS §§ 401* et seq.] (or would be eligible for such benefits if certain government employment were covered employment under such title) or under the railroad retirement system, (2) individuals under age 65 who have been entitled for not less than 24 months to benefits under title II of this Act [*42 USCS §§ 401* et seq.] (or would have been so entitled to such benefits if certain government employment were covered employment under such title) or under the railroad retirement system on the basis of a disability, and (3) certain individuals who do not meet the conditions specified in either clause (1) or (2) but who are medically determined to have end stage renal disease.

HISTORY:

(Aug. 14, 1935, ch 531, Title XVIII, Part A, § 1811, as added July 30, 1965, P.L. 89-97, Title I, Part 1, § 102(a), 79 Stat. 291; Oct. 30, 1972, P.L. 92-603, Title II, § 201(a)(2), 86 Stat. 1371; June 13, 1978, P.L. 95-292, § 4(a), 92 Stat. 315; June 9, 1980, P.L. 96-265, Title I, § 103(a)(2), 94 Stat. 444; Oct. 19, 1980, P.L. 96-473, § 2(b), 94 Stat. 2263; Dec. 5, 1980, P.L. 96-499, Title IX, Part B, Subpart I, § 930(a), 94 Stat. 2631; Sept. 3, 1982, P.L. 97-248, Title I, Subtitle A, Part II, § 122(a)(1), Title II, Subtitle E, Part III, § 278(b)(3), 96 Stat. 356, 561; April 7, 1986, P.L. 99-272, Title XIII, Subtitle B, § 13205(b)(2)(C)(i), 100 Stat. 317; July 1, 1988, P.L. 100-360, Title I, Subtitle A, § 104(d)(1), 102 Stat. 688; Dec. 13, 1989, P.L. 101-234, Title I, § 101(a)(1), 103 Stat. 1979.)

§ 1395d. Scope of benefits

(a) Entitlement to payment for inpatient hospital services, post-hospital extended care services, home health services, and hospice care. The benefits provided to an individual by the insurance program under this part [*42 USCS §§ 1395c* et seq.] shall consist of entitlement to have payment made on his behalf or, in the case of payments referred to in section 1814(d)(2) [*42 USCS § 1395f(d)(2)*] to him (subject to the provisions of this part [*42 USCS §§ 1395c* et seq.]) for--

(1) inpatient hospital services or inpatient critical access hospital services for up to 150 days during any spell of illness minus 1 day for each day of such services in excess of 90 received during any preceding spell of illness (if such individual was entitled to have payment for such services made under this part [*42 USCS §§ 1395c* et seq.] unless he specifies in accordance with regulations of the Secretary that he does not desire to have such payment made);

(2) (A) post-hospital extended care services for up to 100 days during any spell of illness, and (B) to the extent provided in subsection (f), extended care services that are not post-hospital extended care services;

(3) in the case of individuals not enrolled in part B [*42 USCS §§ 1395j* et seq.], home health services, and in the case of individuals so enrolled, post-institutional home health services furnished during a home health spell of illness for up to 100 visits during such spell of illness;

(4) in lieu of certain other benefits, hospice care with respect to the individual during up to two periods of 90 days each and an unlimited number of subsequent periods of 60 days each with respect to which the individual makes an election under subsection (d)(1); and

(5) **[Caution: This paragraph applies to services provided by a hospice program on or after January 1, 2005, pursuant to § 512(d) of Act Dec. 8, 2003, P.L. 108-173, which appears as a note to this section.]** for individuals who are terminally ill, have not made an election under subsection (d)(1), and have not previously received services under this paragraph, services that are furnished by a physician (as defined in section 1861(r)(1) [*42 USCS § 1395x(r)(1)*]) who is either the medical director or an employee of a hospice program and that--

(A) consist of--

(i) an evaluation of the individual's need for pain and symptom management, including the individual's need for hospice care; and

(ii) counseling the individual with respect to hospice care and other care options; and

(B) may include advising the individual regarding advanced care planning.

(b) Services not covered. Payment under this part [*42 USCS §§ 1395c* et seq.] for services furnished an individual during a spell of illness may not (subject to subsection (c)) be made for--

(1) inpatient hospital services furnished to him during such spell after such services have been furnished to him for 150 days during such spell minus 1 day for each day of inpatient hospital services in excess of 90 received during any preceding spell of illness (if such individual was entitled to have payment for such services made under this part [*42 USCS §§ 1395c* et seq.] unless he specifies in accordance with regulations of the Secretary that he does not desire to have such payment made);

(2) post-hospital extended care services furnished to him during such spell after such services have been furnished to him for 100 days during such spell; or

(3) inpatient psychiatric hospital services furnished to him after such services have been furnished to him for a total of 190 days during his lifetime.

Payment under this part [*42 USCS §§ 1395c* et seq.] for post-institutional home health services furnished an individual during a home health spell of illness may not be made for such services beginning after such services have been furnished for a total of 100 visits during such spell.

(c) Inpatients of psychiatric hospitals. If an individual is an inpatient of a psychiatric hospital on the first day of the first month for which he is entitled to benefits under this part [*42 USCS §§ 1395c* et seq.], the days on which he was an inpatient of such a hospital in the 150-day period immediately before such first day shall be included in determining the number of days limit under subsection (b)(1) insofar as such limit applies to (1) inpatient psychiatric hospital services, or (2) inpatient hospital services for an individual who is an inpatient primarily for the diagnosis or treatment of mental illness (but shall not be included in determining such number of days limit insofar as it applies to other inpatient hospital services or in determining the 190-day limit under subsection (b)(3)).

(d) Hospice care; election; waiver of rights; revocation; change of election.

(1) Payment under this part [*42 USCS §§ 1395c* et seq.] may be made for hospice care provided with respect to an individual only during two periods of 90 days each, a subsequent period of 30 days and an unlimited number of subsequent periods of 60 days each, if the individual makes an election under this paragraph to receive hospice care under this part [*42 USCS §§ 1395c* et seq.] provided by, or under arrangements made by, a particular hospice program instead of certain other benefits under this *title [42 USCS §§ 1395* et seq.].

(2) (A) Except as provided in subparagraphs (B) and (C) and except in such exceptional and unusual circumstances as the Secretary may provide, if an individual makes such an election for a period with respect to a particular hospice program, the individual shall be deemed to have waived all rights to have payment made under this *title [42 USCS §§ 1395* et seq.] with respect to--

(i) hospice care provided by another hospice program (other than under arrangements made by the particular hospice program) during the period, and

(ii) services furnished during the period that are determined (in accordance with guidelines of the Secretary) to be--

(I) related to the treatment of the individual's condition with respect to which a diagnosis of terminal illness has been made or

(II) equivalent to (or duplicative of) hospice care;

except that clause (ii) shall not apply to physicians' services furnished by the individual's attending physician (if not an employee of the hospice program) or to services provided by (or under arrangements made by) the hospice program.

(B) After an individual makes such an election with respect to a 90-day period or a subsequent 60-day period, the individual may revoke the election during the period, in which case--

(i) the revocation shall act as a waiver of the right to have payment made under this part [*42 USCS §§ 1395c* et seq.] for any hospice care benefits for the remaining time in such period and (for purposes of subsection (a)(4) and subparagraph (A)) the individual shall be deemed to have been provided such benefits during such entire period, and

(ii) the individual may at any time after the revocation execute a new election for a subsequent period, if the individual otherwise is entitled to hospice care benefits with respect to such a period.

(C) An individual may, once in each such period, change the hospice program with respect to which the election is made and such change shall not be considered a revocation of an election under subparagraph (B).

(D) For purposes of this *title [42 USCS §§ 1395* et seq.], an individual's election with respect to a hospice program shall no longer be considered to be in effect with respect to that hospice program after the date the individual's revocation or change of election with respect to that election takes effect.

(e) Services taken into account. For purposes of subsections (b) and (c), inpatient hospital services, inpatient psychiatric hospital services, and post-hospital extended care services shall be taken into account only if payment is or would be, except for this section or the failure to comply with the request and certification requirements of or under section 1814(a) [*42 USCS § 1395f(a)*], made with respect to such services under this part [*42 USCS §§ 1395c* et seq.].

(f) Coverage of extended care services without regard to three-day prior hospitalization requirement.

(1) The Secretary shall provide for coverage, under clause (B) of subsection (a)(2), of extended care services which are not post-hospital extended care services at such time and for so long as the Secretary determines, and under such terms and conditions (described in paragraph (2)) as the Secretary finds appropriate, that the inclusion of such services will not result in any increase in the total of payments made under this *title [42 USCS §§ 1395* et seq.] and will not alter the acute care nature of the benefit described in subsection (a)(2).

(2) The Secretary may provide--

(A) for such limitations on the scope and extent of services described in subsection (a)(2)(B) and on the categories of individuals who may be eligible to receive such services, and

(B) notwithstanding sections 1814, 1861(v), and 1866 [*42 USCS §§ 1395f, 1395x(v)*, and *1395ww*], for such restrictions and alternatives on the amounts and methods of payment for services described in such subsection,

as may be necessary to carry out paragraph (1).

(g) "Spell of illness" defined. For definition of "spell of illness", and for definitions of other terms used in this part [*42 USCS §§ 1395c* et seq.], see section 1861 [*42 USCS § 1395x*].

HISTORY:

(Aug. 14, 1935, ch 531, Title XVIII, Part A, § 1812, as added July 30, 1965, P.L. 89-97, Title I, Part 1, § 102(a), 79 Stat. 291; Jan. 2, 1968, P.L. 90-248, Title I, Part 3, §§ 129(c)(2), 137(a), 138(a), 143(b), 146(a), 81 Stat. 847, 853, 854, 857, 859; Dec. 5, 1980, P.L. 96-499, Title IX, Part B, Subpart I, §§ 930(b)-(d), 931(a), 94 Stat. 2631, 2633; Aug. 13, 1981, P.L. 97-35, Title XXI, Subtitle B, ch 1, § 2121(a), 95 Stat. 796; Sept. 3, 1982, P.L. 97-248, Title I, Subtitle A, Part II, §§ 122(b), 123, 96 Stat. 356, 364; Jan. 12, 1983, P.L. 97-448, Title III, § 309(b)(5), 96 Stat. 2409; July 1, 1988, P.L. 100-360, Title I, Subtitle A, § 101, 102 Stat. 684; Dec. 13, 1989, P.L. 101-234, Title I, § 101(a)(1), 103 Stat. 1979; Dec. 19, 1989, P.L. 101-239, Title VI, Subtitle A, Part 1, Subpart A, § 6003(g)(3)(B)(i), 103 Stat. 2152; Nov. 5, 1990, P.L. 101-508, Title IV, Subtitle A, Part 1, § 4006(a), 104 Stat. 1388-43; Oct. 31, 1994, P.L. 103-432, Title I, Subtitle A, § 102(g)(1), 108 Stat. 4404; Aug. 5, 1997, P.L. 105-33, Title IV, Subtitle C, § 4201(c)(1), Subtitle E, Ch 4, § 4443(a), (b)(1), Subtitle G, Ch 1, Subch B, § 4611(a), 111 Stat. 373, 423, 472; Nov. 29, 1999, P.L. 106-113, Div B, § 1000(a)(6), 113 Stat. 1536; Dec. 8, 2003, P.L. 108-173, Title V, Subtitle B, § 512(a), Title VII, Subtitle D, § 736(c)(1), 117 Stat. 2299, 2356.)

§ 1395e. Deductibles and coinsurance

(a) Inpatient hospital services or inpatient critical access hospital services; outpatient hospital diagnostic services; blood; post-hospital extended care services.

(1) The amount payable for inpatient hospital services or inpatient critical access hospital services furnished an individual during any spell of illness shall be reduced by a deduction equal to the inpatient hospital deductible or, if less, the charges imposed with respect to such individual for such services, except that, if the customary charges for such services are greater than the charges so imposed, such customary charges shall be considered to be the charges so imposed. Such amount shall be further reduced by a coinsurance amount equal to--

(A) one-fourth of the inpatient hospital deductible for each day (before the 91st day) on which such individual is furnished such services during such spell of illness after such services have been furnished to him for 60 days during such spell; and

(B) one-half of the inpatient hospital deductible for each day (before the day following the last day for which such individual is entitled under section 1812(a)(1) [*42 USCS § 1395d(a)(1)*] to have payment made on his behalf for inpatient hospital services or inpatient critical access hospital services during such spell of illness) on which such individual is furnished such services during such spell of illness after such services have been furnished to him for 90 days during such spell;

except that the reduction under this sentence for any day shall not exceed the charges imposed for that day with respect to such individual for such services (and for this purpose, if the customary charges for such services are greater than the charges so imposed, such customary charges shall be considered to be the charges so imposed).

(2) (A) The amount payable to any provider of services under this part [*42 USCS § 1395c* et seq.] for services furnished an individual shall be further reduced by a deduction equal to the expenses incurred for the first three pints of whole blood (or equivalent quantities of packed red blood cells, as defined under regulations) furnished to the individual during each calendar year, except that such deductible for such blood shall in accordance with regulations be appropriately reduced to the extent that there has been a replacement of such blood (or equivalent quantities of packed red blood cells, as so defined); and for such purposes blood (or equivalent quantities of packed red blood cells, as so defined) furnished such individual shall be deemed replaced when the institution or other person furnishing such blood (or such equivalent quantities of packed red blood cells, as so defined) is given one pint of blood for each pint of blood (or equivalent quantities of packed red blood cells, as so defined) furnished such individual with respect to which a deduction is made under this sentence.

(B) The deductible under subparagraph (A) for blood or blood cells furnished an individual in a year shall be reduced to the extent that a deductible has been imposed under section 1833(b) [*42 USCS § 1395l(b)*] to blood or blood cells furnished the individual in the year.

(3) The amount payable for post-hospital extended care services furnished an individual during any spell of illness shall be reduced by a coinsurance amount equal to one-eighth of the inpatient hospital deductible for each day (before the 101st day) on which he is furnished such services after such services have been furnished to him for 20 days during such spell.

(4) (A) The amount payable for hospice care shall be reduced--

(i) in the case of drugs and biologicals provided on an outpatient basis by (or under arrangements made by) the hospice program, by a coinsurance amount equal to an amount (not to exceed $ 5 per prescription) determined in accordance with a drug copayment schedule (established by the hospice program) which is related to, and approximates 5 percent of, the cost of the drug or biological to the program, and

(ii) in the case of respite care provided by (or under arrangements made by) the hospice program, by a coinsurance amount equal to 5 percent of the amount estimated by the hospice program (in accordance with regulations of the Secretary) to be equal to the amount of payment under section 1814(i) [*42 USCS § 1395f(i)*] to that program for respite care;

except that the total of the coinsurance required under clause (ii) for an individual may not exceed for a hospice coinsurance period the inpatient hospital deductible applicable for the year in which the period began. For purposes of this subparagraph, the term "hospice coinsurance period" means, for an individual, a period of consecutive days beginning with the first day for which an election under section 1812(d) [*42 USCS § 1395d(d)*] is in effect for the individual and ending with the close of the first period of 14 consecutive days on each of which such an election is not in effect for the individual.

(B) During the period of an election by an individual under section 1812(d)(1) [*42 USCS § 1395d(d)(1)*], no copayments or deductibles other than those under subparagraph (A) shall apply with respect to services furnished to such individual which constitute hospice care, regardless of the setting in which such services are furnished.

(b) Inpatient hospital deductible; application.

(1) The inpatient hospital deductible for 1987 shall be $ 520. The inpatient hospital deductible for any succeeding year shall be an amount equal to the inpatient hospital deductible for the preceding calendar year, changed by the Secretary's best estimate of the payment-weighted average of the applicable percentage increases (as defined in section 1886(b)(3)(B) [*42 USCS § 1395ww(b)(3)(B)*]) which are applied under section 1886(d)(3)(A) [*42 USCS § 1395ww(d)(3)(A)*] for discharges in the fiscal year that begins on October 1 of such preceding calendar year, and adjusted to reflect changes in real case mix (determined on the basis of the most recent case mix data available). Any amount determined under the preceding sentence which is not a multiple of $ 4 shall be rounded to the nearest multiple of $ 4 (or, if it is midway between two multiples of $ 4, to the next higher multiple of $ 4).

(2) The Secretary shall promulgate the inpatient hospital deductible and all coinsurance amounts under this section between September 1 and September 15 of the year preceding the year to which they will apply.

(3) The inpatient hospital deductible for a year shall apply to--

(A) the deduction under the first sentence of subsection (a)(1) for the year in which the first day of inpatient hospital services or inpatient critical access hospital services occurs in a spell of illness, and

(B) to the coinsurance amounts under subsection (a) for inpatient hospital services, inpatient critical access hospital services and post-hospital extended care services furnished in that year.

HISTORY:

(Aug. 14, 1935, ch 531, Title XVIII, Part A, § 1813, as added July 30, 1965, P.L. 89-97, Title I, Part 1, § 102(a), 79 Stat. 292; Jan. 2, 1968, P.L. 90-248, Title I, Part 3, §§ 129(c)(3), (4), 135(a), 137(b), 81 Stat. 847, 848, 852, 854; Aug. 13, 1981, P.L. 97-35, Title XXI, Subtitle B, ch 2, §§ 2131(a), 2132(a), 95 Stat. 797; Sept. 3, 1982, P.L. 97-248, Title I, Subtitle A, Part II, § 122(e), 96 Stat. 361; April 7, 1986, P.L. 99-272, Title IX, Subtitle A, Part 1, Subpart B, § 9125(a), 100 Stat. 168; Oct. 21, 1986, P.L. 99-509, Title IX, Subtitle D, Part 1, § 9301(a), 100 Stat. 1981; Dec. 22, 1987, P.L. 100-203, Title IV, Subtitle A, Part 1, § 4002(f)(3), 101 Stat. 1330-45; July 1, 1988, P.L. 100-360, Title I, Subtitle A, § 102, Title IV, Subtitle B, § 411(b)(1)(H)(ii), 102 Stat. 685, 769; Dec. 13, 1989, P.L. 101-234, Title I, § 101(a)(1), 103 Stat. 1979; Oct. 31, 1994, P.L. 103-432, Title I, Subtitle A, § 102(g)(2), (3), 108 Stat. 4404; Aug. 5, 1997, P.L. 105-33, Title IV, Subtitle C, § 4201(c)(1), 111 Stat. 373.)

§ 1395f. Conditions of and limitations on payment for services

(a) Requirement of requests and certifications. Except as provided in subsections (d) and (g) and in section 1876 [*42 USCS § 1395mm*], payment for services furnished an individual may be made only to providers of services which are eligible therefor under section 1866 [*42 USCS § 1395cc*] and only if--

(1) written request, signed by such individual, except in cases in which the Secretary finds it impracticable for the individual to do so, is filed for such payment in such form, in such manner, and by such person or persons as the Secretary may be regulation prescribe, no later than the close of the period of 3 calendar years following the year in which such services are furnished (deeming any services furnished in the last 3 calendar months of any calendar year to have been furnished in the succeeding calendar year) except that where the Secretary deems that efficient administration so requires, such period may be reduced to not less than 1 calendar year;

(2) a physician, or, in the case of services described in subparagraph (B), a physician, or a nurse practitioner or clinical nurse specialist who does not have a direct or indirect employment relationship with the facility but is working in collaboration with a physician, certifies (and recertifies, where such services are furnished over a period of time, in such cases, with such frequency, and accompanied by such supporting material, appropriate to the case involved, as may be provided by regulations, except that the first of such recertifications shall be required in each case of inpatient hospital services not later than the 20th day of such period) that--

(A) in the case of inpatient psychiatric hospital services, such services are or were required to be given on an inpatient basis, by or under the supervision of a physician, for the psychiatric treatment of an individual; and (i) such treatment can or could reasonably be expected to improve the condition for which such treatment is or was necessary or (ii) inpatient diagnostic study is or was medically required and such services are or were necessary for such purposes;

(B) in the case of post-hospital extended care services, such services are or were required to be given because the individual needs or needed on a daily basis skilled nursing care (provided directly by or requiring the supervision of skilled nursing personnel) or other skilled rehabilitation services, which as a practical matter can only be provided in a skilled nursing facility on an inpatient basis, for any of the conditions with respect to which he was receiving inpatient hospital services (or services which would constitute inpatient hospital services if the institution met the requirements of paragraphs (6) and (9) of section 1861(e) [*42 USCS § 1395x(e)(6)* and (9)] prior to transfer to the skilled nursing facility or for a condition requiring such extended care services which arose after such transfer and while he was still in the facility for treatment of the condition or conditions for which he was receiving such inpatient hospital services;

(C) in the case of home health services, such services are or were required because the individual is or was confined to his home (except when receiving items and services referred to in section 1861(m)(7) [*42 USCS § 1395x(m)(7)*]) and needs or needed skilled nursing care (other than solely venipuncture for the purpose of obtaining a blood sample) on an intermittent basis or physical or speech therapy or, in the case of an individual who has been furnished home health services based on such a need and who no longer has such a need for such care or therapy, continues or continued to need occupational therapy; a plan for furnishing such services to such individual has been established and is periodically reviewed by a physician; and such services are or were furnished while the individual was under the care of a physician; or

(D) in the case of inpatient hospital services in connection with the care, treatment, filling, removal, or replacement of teeth or structures directly supporting teeth, the individual, because of his underlying medical condition and clinical status or because of the severity of the dental procedure, requires hospitalization in connection with the provision of such services;

(3) with respect to inpatient hospital services (other than inpatient psychiatric hospital services) which are furnished over a period of time, a physician certifies that such services are required to be given on an inpatient basis for such individual's medical treatment, or that inpatient diagnostic study is medically required and such services are necessary for such purpose, except that (A) such certification shall be furnished only in such cases, with such frequency, and accompanied by such supporting material, appropriate to the cases involved, as may be provided by regulations, and (B)

the first such certification required in accordance with clause (A) shall be furnished no later than the 20th day of such period;

(4) in the case of inpatient psychiatric hospital services, the services are those which the records of the hospital indicate were furnished to the individual during periods when he was receiving (A) intensive treatment services, (B) admission and related services necessary for a diagnostic study, or (C) equivalent services;

(5) with respect to inpatient hospital services furnished such individual after the 20th day of a continuous period of such services , there was not in effect, at the time of admission of such individual to the hospital, a decision under section 1866(d) [*42 USCS § 1395cc(d)*] (based on a finding that utilization review of long-stay cases is not being made in such hospital);

(6) with respect to inpatient hospital services or post-hospital extended care services furnished such individual during a continuous period, a finding has not been made (by the physician members of the committee or group, as described in section 1861(k)(4) [*42 USCS § 1395x(k)(4)*], including any finding made in the course of a sample or other review of admissions to the institution) pursuant to the system of utilization review that further inpatient hospital services or further post-hospital extended care services, as the case may be, are not medically necessary; except that, if such a finding has been made, payment may be made for such services furnished before the 4th day after the date on which the hospital or skilled nursing facility, as the case may be, received notice of such finding;

(7) in the case of hospice care provided an individual--

(A) (i) in the first 90-day period--

(I) the individual's attending physician (as defined in section 1861(dd)(3)(B) [*42 USCS § 1395x(dd)(3)(B)*]) (which for purposes of this subparagraph does not include a nurse practitioner), and

(II) the medical director (or physician member of the interdisciplinary group described in section 1861(dd)(2)(B) [*42 USCS § 1395x(dd)(2)(B)*]) of the hospice program providing (or arranging for) the care,

each certify in writing at the beginning of the period, that the individual is terminally ill (as defined in section 1861(dd)(3)(A) [*42 USCS § 1395x(dd)(3)(A)*]) based on the physician's or medical director's clinical judgment regarding the normal course of the individual's illness, and

(ii) in a subsequent 90- or 60-day period, the medical director or physician described in clause (i)(II) recertifies at the beginning of the period that the individual is terminally ill based on such clinical judgment;

(B) a written plan for providing hospice care with respect to such individual has been established (before such care is provided by, or under arrangements made by, that hospice program) and is periodically reviewed by the individual's attending physician and by the medical director (and the interdisciplinary group described in section 1861(dd)(2)(B) [*42 USCS § 1395x(dd)(2)(B)*]) of the hospice program; and

(C) such care is being or was provided pursuant to such plan of care; and

(8) in the case of inpatient critical access hospital services, a physician certifies that the individual may reasonably be expected to be discharged or transferred to a hospital within 96 hours after admission to the critical access hospital.

To the extent provided by regulations, the certification and recertification requirements of paragraph (2) shall be deemed satisfied where, at a later date, a physician, nurse practitioner, or clinical nurse specialist (as the case may be) makes certification of the kind provided in subparagraph (A), (B), (C), or (D) of paragraph (2) (whichever would have applied), but only where such certification is accompanied by such medical and other evidence as may be required by such regulations. With respect to the physician certification required by paragraph (2) for home health services furnished to any individual by a home health agency (other than an agency which is a governmental entity) and with respect to the establishment and review of a plan for such services, the Secretary shall prescribe regulations which shall become effective no later than July 1, 1981, and which prohibit a physician who has a significant ownership interest in, or a significant financial or contractual relationship with, such home health agency from performing such certification and from establishing or reviewing such plan, except that such prohibition shall not apply with respect to a home health agency which is a sole community home health agency (as determined by the Secretary). For purposes of the preceding sentence, service by a physician as an uncompensated officer or director of a home health agency shall not constitute having a significant ownership interest in, or a significant financial or contractual relationship with, such agency. For purposes of paragraph (2)(C), an individual shall be considered to be "confined to his home" if the individual has a condition, due to an illness or injury, that restricts the ability of the individual to leave his or her home except with the assistance of another individual or the aid of a supportive device (such as crutches, a cane, a wheelchair, or a walker), or if the individual has a condition such that leaving his or her home is medically contraindicated. While an individual does not have to be bedridden to be considered "confined to his home", the condition of the individual should be such that there exists a normal inability to leave home and that leaving home requires a considerable and taxing effort by the individual. Any absence of an individual from the home attributable to the need to receive health care treatment, including regular absences for the purpose of participating in therapeutic, psychosocial, or medical treatment in an adult day-care program that is licensed or certified by a State, or accredited, to furnish adult day-care services in the State shall not disqualify an individual from being considered to be "confined to his home". Any other absence of an

individual from the home shall not so disqualify an individual if the absence is of infrequent or of relatively short duration. For purposes of the preceding sentence, any absence for the purpose of attending a religious service shall be deemed to be an absence of infrequent or short duration.

(b) Amount paid to provider of services. The amount paid to any provider of services (other than a hospice program providing hospice care, other than a critical access hospital providing inpatient critical access hospital services, and other than a home health agency with respect to durable medical equipment) with respect to services for which payment may be made under this part [*42 USCS §§ 1395c* et seq.] shall, subject to the provisions of sections 1813, 1886, and 1895 [*42 USCS §§ 1395e, 1395ww*, and *1395fff*], be--

(1) except as provided in paragraph (3), the lesser of (A) the reasonable cost of such services, as determined under section 1861(v) [*42 USCS § 1395x(v)*] and as further limited by section 1881(b)(2)(B) [*42 USCS § 1395rr(b)(2)(B)*], or (B) the customary charges with respect to such services;

(2) if such services are furnished by a public provider of services, or by another provider which demonstrates to the satisfaction of the Secretary that a significant portion of its patients are low-income (and requests that payment be made under this paragraph), free of charge or at nominal charges to the public, the amount determined on the basis of those items (specified in regulations prescribed by the Secretary) included in the determination of such reasonable cost which the Secretary finds will provide fair compensation to such provider for such services; or

(3) if some or all of the hospitals in a State have been reimbursed for services (for which payment may be made under this part [*42 USCS §§ 1395c* et seq.]) pursuant to a reimbursement system approved as a demonstration project under section 402 of the Social Security Amendments of 1967 [*42 USCS §§ 1395b-1* and *1395ll*] or section 222 of the Social Security Amendments of 1972 [*42 USCS §§ 1395b-1* and note and 1395ll], if the rate of increase in such hospitals in their costs per hospital inpatient admission of individuals entitled to benefits under this part [*42 USCS §§ 1395c* et seq.] over the duration of such project was equal to or less than such rate of increase for admissions of such individuals with respect to all hospitals in the United States during such period, and if either the State has legislative authority to operate such system and the State elects to have reimbursement to such hospitals made in accordance with this paragraph or the system is operated through a voluntary agreement of hospitals and such hospitals elect to have reimbursement to those hospitals made in accordance with this paragraph, then the Secretary may provide for continuation of reimbursement to such hospitals under such system until the Secretary determines that--

(A) a third-party payor reimburses such a hospital on a basis other than under such system, or

(B) the aggregate rate of increase from January 1, 1981, to the most recent date for which annual data are available in such hospitals in costs per hospital inpatient admission of individuals entitled to benefits under this part [*42 USCS §§ 1395c* et seq.] is greater than such rate of increase for admissions of such individuals with respect to all hospitals in the United States for such period.

In the case of any State which has had such a demonstration project reimbursement system in continuous operation since July 1, 1977, the Secretary shall provide under paragraph (3) for continuation of reimbursement to hospitals in the State under such system until the first day of the 37th month beginning after the date the Secretary determines and notifies the Governor of the State that either of the conditions described in subparagraph (A) or (B) of such paragraph has occurred. If, by the end of such 36-month period, the Secretary determines, based on evidence submitted by the Governor of the State, that neither of the conditions described in subparagraph (A) or (B) of paragraph (3) continues to apply, the Secretary shall continue without interruption payment to hospitals in the State under the State's system. If, by the end of such 36-month period, the Secretary determines, based on such evidence, that either of the conditions described in subparagraph (A) or (B) of such paragraph continues to apply, the Secretary shall (i) collect any net excess reimbursement to hospitals in the State during such 36-month period (basing such net excess reimbursement on the net difference, if any, in the rate of increase in costs per hospital inpatient admission under the State system compared to the rate of increase in such costs with respect to all hospitals in the United States over the 36-month period, as measured by including the cumulative savings under the State system based on the difference in the rate of increase in costs per hospital inpatient admission under the State system as compared to the rate of increase in such costs with respect to all hospitals in the United States between January 1, 1981, and the date of the Secretary's initial notice), and (ii) provide a reasonable period, not to exceed 2 years, for transition from the State system to the national payment system.

(c) No payments to Federal providers of services. Subject to section 1880 [*42 USCS § 1395qq*], no payment may be made under this part [*42 USCS §§ 1395c* et seq.] (except under subsection (d) or subsection (h)) to any Federal provider of services, except a provider of services which the Secretary determines is providing services to the public generally as a community institution or agency; and no such payment may be made to any provider of services for any item or service which such provider is obligated by a law of, or a contract with, the United States to render at public expense.

(d) Payments for emergency hospital services.

(1) Payments shall also be made to any hospital for inpatient hospital services furnished in a calendar year, by the hospital or under arrangements (as defined in section 1861(w) [*42 USCS § 1395x(w)*]) with it, to an individual entitled to hospital insurance benefits under section 226 [*42 USCS § 426*] even though such hospital does not have an agreement in effect under this *title [42 USCS §§ 1395* et seq.] if (A) such services were emergency services, (B) the Secretary would be required to make such payment if the hospital had such an agreement in effect and otherwise met the conditions of payment hereunder, and (C) such hospital has elected to claim payments for all such inpatient emergency services and for the emergency outpatient services referred to in section 1835(b) [*42 USCS § 1395n(b)*] furnished during such year. Such payments shall be made only in the amounts provided under subsection (b) and then only if such hospital agrees to comply, with respect to the emergency services provided, with the provisions of section 1866(a) [*42 USCS § 1395cc(a)*].

(2) Payment may be made on the basis of an itemized bill to an individual entitled to hospital insurance benefits under section 226 [*42 USCS § 426*] for services described in paragraph (1) which are emergency services if (A) payment cannot be made under paragraph (1) solely because the hospital does not elect to claim such payment, and (B) such individual files application (submitted within such time and in such form and manner and by such person, and containing and supported by such information as the Secretary shall by regulations prescribe) for reimbursement.

(3) The amounts payable under the preceding paragraph with respect to services described therein shall, subject to the provisions of section 1813 [*42 USCS § 1395e*], be equal to 60 percent of the hospital's reasonable charges for routine services furnished in the accommodations occupied by the individual or in semiprivate accommodations (as defined in section 1861(v)(4) [*42 USCS § 1395x(v)(4)*]), whichever is less, plus 80 percent of the hospital's reasonable charges for ancillary services. If separate charges for routine and ancillary services are not made by the hospital, reimbursement may be based on two-thirds of the hospital's reasonable charges for the services received but not to exceed the charges which would have been made if the patient had occupied semiprivate accommodations. For purposes of the preceding provisions of this paragraph, the term "routine services" shall mean the regular room, dietary, and nursing services, minor medical and surgical supplies and the use of equipment and facilities for which a separate charge is not customarily made; the term "ancillary services" shall mean those special services for which charges are customarily made in addition to routine services.

(e) Payment for inpatient hospital services prior to notification of noneligibility. Notwithstanding that an individual is not entitled to have payment made under this part [*42 USCS §§ 1395c* et seq.] for inpatient hospital services furnished by any hospital, payment shall be made to such hospital (unless it elects not to receive such payment or, if payment has already been made by or on behalf of such individual, fails to refund such payment within the time specified by the Secretary) for such services which are furnished to the individual prior to notification to such hospital from the Secretary of his lack of entitlement, if such payments are precluded only by reason of section 1812 [*42 USCS § 1395d*] and if such hospital complies with the requirements of and regulations under this *title [42 USCS §§ 1395* et seq.] with respect to such payments, has acted in good faith and without knowledge of such lack of entitlement, and has acted reasonably in assuming entitlement existed. Payment under the preceding sentence may not be made for services furnished an individual pursuant to any admission after the 6th elapsed day (not including as an elapsed day Saturday, Sunday, or a legal holiday) after the day on which such admission occurred.

(f) Payment for certain inpatient hospital services furnished outside the United States.

(1) Payment shall be made for inpatient hospital services furnished to an individual entitled to hospital insurance benefits under section 226 [*42 USCS § 426*] by a hospital located outside the United States, or under arrangements (as defined in section 1861(w) [*42 USCS § 1395x(w)*]) with it, if--

(A) such individual is a resident of the United States, and

(B) such hospital was closer to, or substantially more accessible from, the residence of such individual than the nearest hospital within the United States which was adequately equipped to deal with, and was available for the treatment of, such individual's illness or injury.

(2) Payment may also be made for emergency inpatient hospital services furnished to an individual entitled to hospital insurance benefits under section 226 [*42 USCS § 426*] by a hospital located outside the United States if--

(A) such individual was physically present--

(i) in a place within the United States; or

(ii) at a place within Canada while traveling without unreasonable delay by the most direct route (as determined by the Secretary) between Alaska and another State;

at the time the emergency which necessitated such inpatient hospital services occurred, and

(B) such hospital was closer to, or substantially more accessible from, such place than the nearest hospital within the United States which was adequately equipped to deal with, and was available for the treatment of, such individual's illness or injury.

(3) Payment shall be made in the amount provided under subsection (b) to any hospital for the inpatient hospital services described in paragraph (1) or (2) furnished to an individual by the hospital or under arrangements (as defined in section 1861(w) [*42 USCS § 1395x(w)*]) with it if (A) the Secretary would be required to make such payment if the hospital had an agreement in effect under this *title [42 USCS §§ 1395* et seq.] and otherwise met the conditions of payment hereunder, (B) such hospital elects to claim such payment, and (C) such hospital agrees to comply, with respect to such services, with the provisions of section 1866(a) [*42 USCS § 1395cc(a)*].

(4) Payment for the inpatient hospital services described in paragraph (1) or (2) furnished to an individual entitled to hospital insurance benefits under section 226 [*42 USCS § 426*] may be made on the basis of an itemized bill to such individual if (A) payment for such services cannot be made under paragraph (3) solely because the hospital does not elect to claim such payment, and (B) such individual files application (submitted within such time and in such form and manner and by such person, and continuing and supported by such information as the Secretary shall by regulations prescribe) for reimbursement. The amount payable with respect to such services shall, subject to the provisions of section 1813 [*42 USCS § 1395e*], be equal to the amount which would be payable under subsection (d)(3).

(g) Payment to physicians for services rendered in teaching hospital. For purposes of services for which the reasonable cost thereof is determined under section 1861(v)(1)(D) [*42 USCS § 1395x(v)(1)(D)*] (or would be if section 1886 [*42 USCS § 1395ww*] did not apply), payment under this part [*42 USCS §§ 1395c* et seq.] shall be made to such fund as may be designated by the organized medical staff of the hospital in which such services were furnished or, if such services were furnished in such hospital by the faculty of a medical school, to such fund as may be designated by such faculty, but only if--

(1) such hospital has an agreement with the Secretary under section 1866 [*42 USCS § 1395cc*], and

(2) the Secretary has received written assurances that (A) such payment will be used by such fund solely for the improvement of care of hospital patients or for educational or charitable purposes and (B) the individuals who were furnished such services or any other persons will not be charged for such services (or if charged, provision will be made for return of any moneys incorrectly collected).

(h) Payment for specified hospital services provided in Department of Veterans Affairs hospitals; amount of payment.

(1) Payments shall also be made to any hospital operated by the Department of Veterans Affairs for inpatient hospital services furnished in a calendar year by the hospital, or under arrangements (as defined in section 1861(w) [*42 USCS § 1395x(w)*]) with it, to an individual entitled to hospital benefits under section 226 [*42 USCS § 426*] even though the hospital is a Federal provider of services if (A) the individual was not entitled to have the services furnished to him free of charge by the hospital, (B) the individual was admitted to the hospital in the reasonable belief on the part of the admitting authorities that the individual was a person who was entitled to have the services furnished to him free of charge, (C) the authorities of the hospital, in admitting the individual, and the individual, acted in good faith, and (D) the services were furnished during a period ending with the close of the day on which the authorities operating the hospital first became aware of the fact that the individual was not entitled to have the services furnished to him by the hospital free of charge, or (if later) ending with the first day on which it was medically feasible to remove the individual from the hospital by discharging him therefrom or transferring him to a hospital which has in effect an agreement under this *title [42 USCS §§ 1395* et seq.].

(2) Payment for services described in paragraph (1) shall be in an amount equal to the charge imposed by the Secretary of Veterans Affairs for such services, or (if less) the amount that would be payable for such services under subsection (b) and section 1886 [*42 USCS § 1395ww*] (as estimated by the Secretary). Any such payment shall be made to the entity to which payment for the services involved would have been payable, if payment for such services had been made by the individual receiving the services involved (or by another private person acting on behalf of such individual).

(i) Payment for hospice care.

(1) (A) Subject to the limitation under paragraph (2) and the provisions of section 1813(a)(4) [*42 USCS § 1395e(a)(4)*] and except as otherwise provided in this paragraph the amount paid to a hospice program with respect to hospice care for which payment may be made under this part [*42 USCS §§ 1395c* et seq.] shall be an amount equal to the costs which are reasonable and related to the cost of providing hospice care or which are based on such other tests of reasonableness as the Secretary may prescribe in regulations (including those authorized under section 1861(v)(1)(A) [*42 USCS § 1395x(v)(1)(A)*]), except that no payment may be made for bereavement counseling and no reimbursement may be made for other counseling services (including nutritional and dietary counseling) as separate services.

(B) Notwithstanding subparagraph (A), for hospice care furnished on or after April 1, 1986, the daily rate of payment per day for routine home care shall be $ 63.17 and the daily rate of payment for other services included in hospice care shall be the daily rate of payment recognized under subparagraph (A) as of July 1, 1985, increased by $ 10.

(C) (i) With respect to routine home care and other services included in hospice care furnished on or after January 1, 1990, and on or before September 30, 1990, the payment rates for such care and services shall be 120 percent of such rates in effect as of September 30, 1989.

(ii) With respect to routine home care and other services included in hospice care furnished during a subsequent fiscal year, the payment rates for such care and services shall be the payment rates in effect under this subparagraph during the previous fiscal year increased by--

(I) for a fiscal year ending on or before September 30, 1993, the market basket percentage increase (as defined in section 1886(b)(3)(B)(iii) [*42 USCS § 1395ww(b)(3)(B)(iii)*]) for the fiscal year;

(II) for fiscal year 1994, the market basket percentage increase for the fiscal year minus 2.0 percentage points;

(III) for fiscal year 1995, the market basket percentage increase for the fiscal year minus 1.5 percentage points;

(IV) for fiscal year 1996, the market basket percentage increase for the fiscal year minus 1.5 percentage points;

(V) for fiscal year 1997, the market basket percentage increase for the fiscal year minus 0.5 percentage point;

(VI) for each of fiscal years 1998 through 2002, the market basket percentage increase for the fiscal year involved minus 1.0 percentage points, plus, in the case of fiscal year 2001, 5.0 percentage points; and

(VII) for a subsequent fiscal year, the market basket percentage increase for the fiscal year.

(2) (A) The amount of payment made under this part [*42 USCS §§ 1395c* et seq.] for hospice care provided by (or under arrangements made by) a hospice program for an accounting year may not exceed the "cap amount" for the year (computed under subparagraph (B)) multiplied by the number of medicare beneficiaries in the hospice program in that year (determined under subparagraph (C)).

(B) For purposes of subparagraph (A), the "cap amount" for a year is $ 6,500, increased or decreased, for accounting years that end after October 1, 1984, by the same percentage as the percentage increase or decrease, respectively, in the medical care expenditure category of the Consumer Price Index for All Urban Consumers (United States city average), published by the Bureau of Labor Statistics, from March 1984 to the fifth month of the accounting year.

(C) For purposes of subparagraph (A), the "number of medicare beneficiaries" in a hospice program in an accounting year is equal to the number of individuals who have made an election under subsection (d) with respect to the hospice program and have been provided hospice care by (or under arrangements made by) the hospice program under this part [*42 USCS §§ 1395c* et seq.] in the accounting year, such number reduced to reflect the proportion of hospice care that each such individual was provided in a previous or subsequent accounting year or under a plan of care established by another hospice program.

(D) A hospice program shall submit claims for payment for hospice care furnished in an individual's home under this *title [42 USCS §§ 1395* et seq.] only on the basis of the geographic location at which the service is furnished, as determined by the Secretary.

(3) Hospice programs providing hospice care for which payment is made under this subsection shall submit to the Secretary such data with respect to the costs for providing such care for each fiscal year, beginning with fiscal year 1999, as the Secretary determines necessary.

(4) **[Caution: This paragraph applies to services provided by a hospice program on or after January 1, 2005, as provided by § 512(d) of Act Dec. 8, 2003, P.L. 108-173, which appears as *42 USCS § 1395d* note.]** The amount paid to a hospice program with respect to the services under section 1812(a)(5) [*42 USCS § 1395d(a)(5)*] for which payment may be made under this part shall be equal to an amount established for an office or other outpatient visit for evaluation and management associated with presenting problems of moderate severity and requiring medical decisionmaking of low complexity under the fee schedule established under section 1848(b) [*42 USCS § 1395w-4(b)*], other than the portion of such amount attributable to the practice expense component.

(5) In the case of hospice care provided by a hospice program under arrangements under section 1861(dd)(5)(D) [*42 USCS § 1395x(dd)(5)(D)*] made by another hospice program, the hospice program that made the arrangements shall bill and be paid for the hospice care.

(j) Elimination of lesser-of-cost-or-charges provision.

(1) The lesser-of-cost-or-charges provisions (described in paragraph (2)) will not apply in the case of services provided by a class of provider of services if the Secretary determines and certifies to Congress that the failure of such provisions to apply to the services provided by that class of providers will not result in any increase in the amount of payments made for those services under this *title [42 USCS §§ 1395* et seq.]. Such change will take effect with respect to services furnished, or cost reporting periods of providers, on or after such date as the Secretary shall provide in the certification. Such change for a class of provider shall be discontinued if the Secretary determines and notifies Congress

that such change has resulted in an increase in the amount of payments made under this *title [42 USCS §§ 1395* et seq.] for services provided by that class of provider.

(2) The lesser-of-cost-or-charges provisions referred to in paragraph (1) are as follows:

(A) Clause (B) of paragraph (1) and paragraph (2) of subsection (b).

(B) Section 1834(a)(1)(B) [*42 USCS § 1395m(a)(1)(B)*].

(C) So much of subparagraph (A) of section 1833(a)(2) [*42 USCS § 1395l(a)(2)(A)*] as provides for payment other than of the reasonable cost of such services, as determined under section 1861(v) [*42 USCS § 1395x(v)*].

(D) Subclause (II) of clause (i) and clause (ii) of section 1833(a)(2)(B) [*42 USCS § 1395* l(a)(2)(B)(i)(II) and (ii)].

(k) Payments to home health agencies for durable medical equipment. The amount paid to any home health agency with respect to durable medical equipment for which payment may be made under this part [*42 USCS §§ 1395c* et seq.] shall be the amount described in section 1834(a)(1) [*42 USCS § 1395m(a)(1)*].

(l) Payment for inpatient critical access hospital services.

(1) Except as provided in paragraph (2), the amount of payment under this part [*42 USCS §§ 1395c* et seq.] for inpatient critical access hospital services is equal to 101 percent of the reasonable costs of the critical access hospital in providing such services.

(2) In the case of a distinct part psychiatric or rehabilitation unit of a critical access hospital described in section 1820(c)(2)(E) [*42 USCS § 1395i-4(c)(2)(E)*], the amount of payment for inpatient critical access hospital services of such unit shall be equal to the amount of the payment that would otherwise be made if such services were inpatient hospital services of a distinct part psychiatric or rehabilitation unit, respectively, described in the matter following clause (v) of section 1886(d)(1)(B) [*42 USCS § 1395ww(d)(1)(B)*].

HISTORY:

(Aug. 14, 1935, ch 531, Title XVIII, Part A, § 1814, as added July 30, 1965, P.L. 89-97, Title I, Part 1, § 102(a), 79 Stat. 294; Jan. 2, 1968, P.L. 90-248, Title I, Part 3, §§ 126(a), 129(c)(5), (6)(A), 143(c), 81 Stat. 846, 848, 857; Oct. 30, 1972, P.L. 92-603, Title II, §§ 211(a), 226(c)(1), 227(b), 228(a), 233(a), 234(g)(1), 238(a), 247(a), 256(a), 278(a)(1)-(3), (b)(4), (17), 281(e), 86 Stat. 1382, 1404, 1405, 1407, 1411, 1413, 1416, 1425, 1447, 1453, 1454, 1456; Dec. 31, 1973, P.L. 93-233, § 18(k)(1), (2), 87 Stat. 970; Sept. 30, 1976, P.L. 94-437, Title IV, § 401(a), 90 Stat. 1408; Oct. 25, 1977, P.L. 95-142, § 23(a), (b), 91 Stat. 1208; June 13, 1978, P.L. 95-292, § 4 (f), 92 Stat. 315; Dec. 5, 1980, P.L. 96-499, Title IX, Part A, Subpart I, §§ 903(a), 930(e), (f), 931(b), 936(b), Subpart II, § 941(a), (b), 94 Stat. 2614, 2631, 2633, 2640, 2641; Aug. 13, 1981, P.L. 97-35, Title XXI, Subtitle B, Ch 1, §§ 2121(b), 2122(a)(1), 95 Stat. 796; Sept. 3, 1982, P.L. 97-248, Title I, Subtitle A, Part I, Subpart A, § 101(c)(1), Part II, § 122(c)(1), (2), 96 Stat. 335, 357; Jan. 12, 1983, P.L. 97-448, Title III, § 309(b)(7), 96 Stat. 2409; April 20, 1983, P.L. 98-21, Title VI, §§ 601(d), 602(b) in part, (c), 97 Stat. 152, 163; Aug. 29, 1983, P.L. 98-90, § 1, 97 Stat. 606; July 18, 1984, P.L. 98-369, Division B, Title III, Subtitle A, Part I, §§ 2308(b)(2)(A), 2321(a), (f), Part II, §§ 2335(a), 2336(a), (b), 2354(b)(1), 98 Stat. 1074, 1084, 1085, 1090, 1091, 1100; Nov. 8, 1984, P.L. 98-617, §§ 1, 3(a)(3), (b)(1), 98 Stat. 3294, 3296; April 7, 1986, P.L. 99-272, Title IX, Subtitle A, Part 1, Subpart B, § 9123(b), 100 Stat. 168; Dec. 22, 1987, P.L. 100-203, Title IV, Subtitle A, Part 1, § 4008(b)(1), Part 2, Subpart B, § 4024(a), Part 3, Subpart B, § 4062(d)(1), 101 Stat. 1330-55, 1330-73, 1330-108; July 1, 1988, P.L. 100-360, Title I, Subtitle A, § 104(d)(2), 102 Stat. 688; Dec. 13, 1989, P.L. 101-234, Title I, § 101(a)(1), 103 Stat. 1979; Dec. 19, 1989, P.L. 101-239, Title VI, Subtitle A, Part 1, Subpart A, § 6003(g)(3)(B)(ii), (iii), 6005(a),(b), Subpart B, § 6028, 103 Stat. 2152, 2160, 2168; Nov. 5, 1990, P.L. 101-508, Title IV, Subtitle A, Part 1, §§ 4006(b), 4008(i)(3), (m)(3)(A), 104 Stat. 1388-43, 1388a-51; June 13, 1991, P.L. 102-54, § 13(q)(3)(A)(iii), (iv), (B)(iv), 105 Stat. 279; Aug. 10, 1993, P.L. 103-66, Title XIII, Ch 2, Subch A, Part I, § 13504, 107 Stat. 579; Oct. 31, 1994, P.L. 103-432, Title I, Subtitle A, §§ 102(a)(3), (d), 106(b)(1)(A), 110(d)(1), 108 Stat. 4402, 4403, 4405, 4408; Aug. 5, 1997, P.L. 105-33, Title IV, Subtitle C, § 4201(c)(1), (3), Subtitle E, Ch 4, §§ 4441, 4442(a), 4443(b)(2), 4448, Subtitle G, Ch 1, Subch A, § 4603(c)(1), Subch B, § 4615(a), 111 Stat. 373, 422, 423, 424, 470, 475; Dec. 21, 2000, P.L. 106-554, § 1(a)(6), 114 Stat. 2763; Dec. 8, 2003, P.L. 108-173, Title IV, Subtitle A, §§ 405(a)(1), (g)(2), 408(b), Title V, Subtitle B, § 512(b), Title VII, Subtitle D, § 736(a)(1), (2), (c)(2)(A), Title IX, Subtitle E, § 946(b), 117 Stat. 2266, 2269, 2270, 2299, 2354, 2356, 2425.)

§ 1395g. Payment to providers of services

(a) Determination of amount. The Secretary shall periodically determine the amount which should be paid under this part [*42 USCS §§ 1395c* et seq.] to each provider of services with respect to the services furnished by it, and the provider of services shall be paid, at such time or times as the Secretary believes appropriate (but not less often than monthly) and prior to audit or settlement by the General Accounting Office [Government Accountability Office], from

the Federal Hospital Insurance Trust Fund, the amounts so determined, with necessary adjustments on account of previously made overpayments or underpayments; except that no such payments shall be made to any provider unless it has furnished such information as the Secretary may request in order to determine the amounts due such provider under this part [*42 USCS §§ 1395c* et seq.] for the period with respect to which the amounts are being paid or any prior period.

(b) Conditions. No payment shall be made to a provider of services which is a hospital for or with respect to services furnished by it for any period with respect to which it is deemed, under section 1861(w)(2) [*42 USCS § 1395x(w)(2)*], to have in effect an arrangement with a quality control and peer review organization for the conduct of utilization review activities by such organization unless such hospital has paid to such organization the amount due (as determined pursuant to such section) to such organization for the review activities conducted by it pursuant to such arrangements or such hospital has provided assurances satisfactory to the Secretary that such organization will promptly be paid the amount so due to it from the proceeds of the payment claimed by the hospital. Payment under this *title [42 USCS §§ 1395* et seq.] for utilization review activities provided by a quality control and peer review organization pursuant to an arrangement or deemed arrangement with a hospital under section 1861(w)(2) [*42 USCS § 1395x(w)(2)*] shall be calculated without any requirement that the reasonable cost of such activities be apportioned among the patients of such hospital, if any, to whom such activities were not applicable.

(c) Payments under assignment or power of attorney. No payment which may be made to a provider of services under this *title [42 USCS §§ 1395* et seq.] for any service furnished to an individual shall be made to any other person under an assignment or power of attorney; but nothing in this subsection shall be construed (1) to prevent the making of such a payment in accordance with an assignment from the provider if such assignment is made to a governmental agency or entity or is established by or pursuant to the order of a court of competent jurisdiction, or (2) to preclude an agent of the provider of services from receiving any such payment if (but only if) such agent does so pursuant to an agency agreement under which the compensation to be paid to the agent for his services for or in connection with the billing or collection of payments due such provider under this *title [42 USCS §§ 1395* et seq.] is unrelated (directly or indirectly) to the amount of such payments or the billings therefor, and is not dependent upon the actual collection of any such payment.

(d) Accrual of interest on balance of excess or deficit not paid. Whenever a final determination is made that the amount of payment made under this part [*42 USCS §§ 1395c* et seq.] to a provider of services was in excess of or less than the amount of payment that is due, and payment of such excess of deficit is not made (or effected by offset) within 30 days of the date of the determination, interest shall accrue on the balance of such excess or deficit not paid or offset (to the extent that the balance is owed by or owing to the provider) at a rate determined in accordance with the regulations of the Secretary of the Treasury applicable to charges for late payment.

(e) Periodic interim payments.

(1) The Secretary shall provide payment under this part for inpatient hospital services furnished by a subsection (d) hospital (as defined in section 1886(d)(1)(B) [*42 USCS § 1395ww(d)(1)(B)*], and including a distinct psychiatric or rehabilitation unit of such a hospital) and a subsection (d) Puerto Rico hospital (as defined in section 1886(d)(9)(A) [*42 USCS § 1395ww(d)(9)(A)*]) on a periodic interim payment basis (rather than on the basis of bills actually submitted) in the following cases:

(A) Upon the request of a hospital which is paid through an agency or organization with an agreement with the Secretary under section 1816 [*42 USCS § 1395h*], if the agency or organization, for three consecutive calendar months, fails to meet the requirements of subsection (c)(2) of such section and if the hospital meets the requirements (in effect as of October 1, 1986) applicable to payment on such a basis, until such time as the agency or organization meets such requirements for three consecutive calendar months.

(B) In the case of a hospital that--

(i) has a disproportionate share adjustment percentage (as established in clause (iv) of such section) of at least 5.1 percent (as computed for purposes of establishing the average standardized amounts for discharges occurring during fiscal year 1987), and

(ii) requests payment on such basis,

but only if the hospital was being paid for inpatient hospital services on such a periodic interim payment basis as of June 30, 1987, and continues to meet the requirements (in effect as of October 1, 1986) applicable to payment on such a basis.

(C) In the case of a hospital that--

(i) is located in a rural area,

(ii) has 100 or fewer beds, and

(iii) requests payment on such basis,

but only if the hospital was being paid for inpatient hospital services on such a periodic interim payment basis as of June 30, 1987, and continues to meet the requirements (in effect as of October 1, 1986) applicable to payment on such a basis.

(2) The Secretary shall provide (or continue to provide) for payment on a periodic interim payment basis (under the standards established under section 405.454(j) of title 42, Code of Federal Regulations, as in effect on October 1, 1986, in the cases described in subparagraphs (A) through (D)) with respect to--

(A) inpatient hospital services of a hospital that is not a subsection (d) hospital (as defined in section 1886(d)(1)(B) [*42 USCS § 1395ww(d)(1)(B)*]);

(B) a hospital which is receiving payment under a State hospital reimbursement system under section 1814(b)(3) [*42 USCS § 1395f(b)(3)*] or *1886(c)* [*42 USCS § 1395ww(c)*], if payment on a periodic interim payment basis is an integral part of such reimbursement system;

(C) extended care services;

(D) hospice care; and

(E) inpatient critical access hospital services;

if the provider of such services elects to receive, and qualifies for, such payments.

(3) In the case of a subsection (d) hospital or a subsection (d) Puerto Rico hospital (as defined for purposes of section 1886 [*42 USCS § 1395ww*]) which has significant cash flow problems resulting from operations of its intermediary or from unusual circumstances of the hospital's operation, the Secretary may make available appropriate accelerated payments.

(4) A hospital created by the merger or consolidation of 2 or more hospitals or hospital campuses shall be eligible to receive periodic interim payment on the basis described in paragraph (1)(B) if--

(A) at least one of the hospitals or campuses received periodic interim payment on such basis prior to the merger or consolidation; and

(B) the merging or consolidating hospitals or campuses would each meet the requirement of paragraph (1)(B)(i) if such hospitals or campuses were treated as independent hospitals for purposes of this *title [42 USCS §§ 1395* et seq.].

HISTORY:

(Aug. 14, 1935, ch 531, Title XVIII, Part A, § 1815, as added July 30, 1965, P.L. 89-97, Title I, Part 1, § 102(a), 79 Stat. 297; Dec. 31, 1975, P.L. 94-182, Title I, § 112(a)(2), 89 Stat. 1055; Oct. 25, 1977, P.L. 95-142, § 2(a)(2), 91 Stat. 1175; Oct. 19, 1980, P.L. 96-473, § 6(i), 94 Stat. 2266; Sept. 3, 1982, P.L. 97-248, Title I, Subtitle A, Part I, § 117(a)(1), Subtitle C, § 148(b), 96 Stat. 254, 394; Oct. 21, 1986, P.L. 99-509, P.L. 99-509, Title IX, Subtitle D, Part 2, § 9311(a)(1), 100 Stat. 1966; Dec. 19, 1989, P.L. 101-239, Title VI, Subtitle A, Part 1, Subpart 3, § 6021(a), 103 Stat. 2167; Aug. 5, 1997, P.L. 105-33, Title IV, Subtitle G, Ch 1, Subch A, § 4603(b), 111 Stat. 470; Dec. 8, 2003, P.L. 108-173, Title IV, Subtitle A, § 405(c)(1), Title VII, Subtitle D, § 736(a)(3), 117 Stat. 2266, 2354.)

§ 1395h. Provisions relating to the administration of part A

(a) The administration of this part [*42 USCS §§ 1395c* et seq.] shall be conducted through contracts with medicare administrative contractors under section 1874A [*42 USCS § 1395kk-1*].

(b) [Repealed]

(c) Terms and conditions of agreements; prompt payment of claims.

(1) [Deleted]

(2) (A) Each contract under section 1874A [*42 USCS § 1395kk-1*] that provides for making payments under this part [*42 USCS §§ 1395c* et seq.] shall provide that payment shall be issued, mailed, or otherwise transmitted with respect to not less than 95 percent of all claims submitted under this *title [42 USCS §§ 1395* et seq.]--

(i) which are clean claims, and

(ii) for which payment is not made on a periodic interim payment basis,

within the applicable number of calendar days after the date on which the claim is received.

(B) In this paragraph:

(i) The term "clean claim" means a claim that has no defect or impropriety (including any lack of any required substantiating documentation) or particular circumstance requiring special treatment that prevents timely payment from being made on the claim under this *title [42 USCS §§ 1395* et seq.].

(ii) The term "applicable number of calendar days" means--

(I) with respect to claims received in the 12-month period beginning October 1, 1986, 30 calendar days,

(II) with respect to claims received in the 12-month period beginning October 1, 1987, 26 calendar days,

(III) with respect to claims received in the 12-month period beginning October 1, 1988, 25 calendar days,

(IV) with respect to claims received in the 12-month period beginning October 1, 1989, and claims received in any succeeding 12-month period ending on or before September 30, 1993, 24 calendar days, and

(V) with respect to claims received in the 12-month period beginning October 1, 1993, and claims received in any succeeding 12-month period, 30 calendar days.

(C) If payment is not issued, mailed, or otherwise transmitted within the applicable number of calendar days (as defined in clause (ii) of subparagraph (B)) after a clean claim (as defined in clause (i) of such subparagraph) is received from a hospital, critical access hospital, skilled nursing facility, home health agency, hospice program, comprehensive outpatient rehabilitation facility, or rehabilitation agency that is not receiving payments on a periodic interim payment basis with respect to such services, interest shall be paid at the rate used for purposes of *section 3902(a) of title 31, United States Code* (relating to interest penalties for failure to make prompt payments) for the period beginning on the day after the required payment date and ending on the date on which payment is made.

(3)

(A) Each contract under section 1874A [*42 USCS § 1395kk-1*] that provides for making payments under this part [*42 USCS §§ 1395c* et seq.] shall provide that no payment shall be issued, mailed, or otherwise transmitted with respect to any claim submitted under this *title [42 USCS §§ 1395* et seq.] within the applicable number of calendar days after the date on which the claim is received.

(B) In this paragraph, the term "applicable number of calendar days" means--

(i) with respect to claims submitted electronically as prescribed by the Secretary, 13 days, and

(ii) with respect to claims submitted otherwise, 28 days.

(d)--(i) [Repealed]

(j) Denial of claim; notification and reconsideration. A contract with a medicare administrative contractor under section 1874A [*42 USCS § 1395kk-1*] with respect to the administration of this part [*42 USCS §§ 1395c* et seq.] shall require that, with respect to a claim for home health services, extended care services, or post-hospital extended care services submitted by a provider to such medicare administrative contractor that is denied such agency or organization--

(1) furnish the provider and the individual with respect to whom the claim is made with a written explanation of the denial and of the statutory or regulatory basis for the denial; and

(2) in the case of a request for reconsideration of a denial promptly notify such individual and the provider of the disposition of such reconsideration.

(k) Reports on efforts to recover erroneous payments. A contract with a medicare administrative contractor under section 1874A [*42 USCS § 1395kk-1*] with respect to the administration of this part [*42 USCS §§ 1395c* et seq.] shall require that such medicare administrative contractor submit an annual report to the Secretary describing the steps taken to recover payments made for items or services for which payment has been or could be made under a primary plan (as defined in section 1862(b)(2)(A) *[42 USCS § 1385y*(b)(2)(A)]).

(l) [Repealed]

HISTORY:

(Aug. 14, 1935, ch 531, Title XVIII, Part A, § 1816, as added July 30, 1965, P.L. 89-97, Title I, Part 1, § 102(a), 79 Stat. 297; Oct. 30, 1972, P.L. 92-603, Title II, § 243(b), 86 Stat. 1422; Oct. 25, 1977, P.L. 95-142, § 14(a), 91 Stat. 1198; Dec. 5, 1980, P.L. 96-499, Title IX, Part B, Subpart I, § 930(o), 94 Stat. 2632; Sept. 3, 1982, P.L. 97-248, Title I, Subtitle A, Part II, § 122(c)(3), 96 Stat. 359; July 18, 1984, P.L. 98-369, Division B, Title III, Subtitle A, Part I, § 2326(b), (c)(1), (d)(1), 98 Stat. 1087; Oct. 21, 1986, P.L. 99-509, Title IX, Subtitle D, Part 2, § 9311(b) Part 4, § 9352(a)(2), 100 Stat. 1997, 2043; Dec. 22, 1987, P.L. 100-203, Title IV, Subtitle A, Part 2, Subpart C, §§ 4031(a)(1), 4032(a), (b), Part 3, Subpart D, § 4085(d)(1), 101 Stat. 1330-75, 1330-76, 1330-77, 1330-130; July 1, 1988, P.L. 100-360, Title II, Subtitle A, § 203(f), Title IV, Subtitle B, § 411(e)(1)(B), 102 Stat. 725, 775; Dec. 13, 1989, P.L. 101-234, Title II, § 201(a)(1), 103 Stat. 1981; Dec. 19, 1989, P.L. 101-239, Title VI, Subtitle A, Part 1, Subpart A, § 6003(g)(3)(D)(vi), Part 3, Subpart A, § 6202(d)(1), 103 Stat. 2153, 2234; Nov. 5, 1990, P.L. 101-508, Title IV, Subtitle A, Part 1, § 4005(c)(1)(A), 104 Stat. 1388-41; Aug. 10, 1993, P.L. 103-66, Title XIII, Ch 2, Subch A, Part III, § 13568(a), (b), 107 Stat. 608; Oct. 31, 1994, P.L. 103-432, Title I, Subtitle A, § 110(d)(2), Subtitle C, § 151(b)(1)(A), (2)(A), 108 Stat. 4408, 4433, 4434; Aug. 21, 1996, P.L. 104-191, Title II, Subtitle A, § 202(b)(1), 110 Stat. 1998; Aug. 5, 1997, P.L. 105-33, Title IV, Subtitle C, § 4201(c)(1), 111 Stat. 373; Dec. 8, 2003, P.L. 108-173, Title VII, Subtitle D, § 736(a)(4), Title IX, Subtitle B, § 911(b), 117 Stat. 2355, 2383.)

(As amended Feb. 8, 2006, P.L. 109-171, Title V, Subtitle C, § 5202(a)(1), 120 Stat. 47.)

§ 1395i. Federal Hospital Insurance Trust Fund

(a) Creation; deposits; transfers from Treasury. There is hereby created on the books of the Treasury of the United States a trust fund to be known as the "Federal Hospital Insurance Trust Fund" (hereinafter in this section referred to as the "Trust Fund"). The Trust Fund shall consist of such gifts and bequests as may be made as provided in section 201(i)(1) [*42 USCS § 401(i)(1)*], and such amounts as may be deposited in, or appropriated to, such fund as provided in this part [*42 USCS §§ 1395c* et seq.]. There are hereby appropriated to the Trust Fund for the fiscal year ending June 30, 1966, and for each fiscal year thereafter, out of any moneys in the Treasury not otherwise appropriated, amounts equivalent to 100 per centum of--

(1) the taxes imposed by *sections 3101(b)* and *3111(b) of the Internal Revenue Code of 1954* [1986] [*26 USCS §§ 3101(b)* and *3111(b)*] with respect to wages reported to the Secretary of the Treasury or his delegate pursuant to subtitle F of such Code [*26 USCS §§ 6001* et seq.] after December 31, 1965, as determined by the Secretary of the Treasury by applying the applicable rates of tax under such sections to such wages, which wages shall be certified by the Commissioner of Social Security on the basis of records of wages established and maintained by the Commissioner of Social Security in accordance with such reports; and

(2) the taxes imposed by *section 1401(b) of the Internal Revenue Code of 1954* [1986] [*26 USCS § 1401(b)*] with respect to self-employment income reported to the Secretary of the Treasury or his delegate on tax returns under subtitle F of such Code [*26 USCS §§ 6001* et seq.], as determined by the Secretary of the Treasury by applying the applicable rate of tax under such section to such self-employment income, which self-employment income shall be certified by the Commissioner of Social Security on the basis of records of self-employment established and maintained by the Commissioner of Social Security in accordance with such returns.

The amounts appropriated by the preceding sentence shall be transferred from time to time from the general fund in the Treasury to the Trust Fund, such amounts to be determined on the basis of estimates by the Secretary of the Treasury of the taxes, specified in the preceding sentence, paid to or deposited into the Treasury; and proper adjustments shall be made in amounts subsequently transferred to the extent prior estimates were in excess of or were less than the taxes specified in such sentence.

(b) Board of Trustees; composition; meetings; duties. With respect to the Trust Fund, there is hereby created a body to be known as the Board of Trustees of the Trust Fund (hereinafter in this section referred to as the "Board of Trustees") composed of the Commissioner of Social Security, the Secretary of the Treasury, the Secretary of Labor, and the Secretary of Health and Human Services, all ex officio, and of two members of the public (both of whom may not be from the same political party), who shall be nominated by the President for a term of four years and subject to confirmation by the Senate. A member of the Board of Trustees serving as a member of the public and nominated and confirmed to fill a vacancy occurring during a term shall be nominated and confirmed only for the remainder of such term. An individual nominated and confirmed as a member of the public may serve in such position after the expiration of such member's term until the earlier of the time at which the member's successor takes office or the time at which a report of the Board is first issued under paragraph (2) after the expiration of the member's term. The Secretary of the Treasury shall be the Managing Trustee of the Board of Trustees (hereinafter in this section referred to as the "Managing Trustee"). The Administrator of the Centers for Medicare & Medicaid Services shall serve as the Secretary of the Board of Trustees. The Board of Trustees shall meet not less frequently than once each calendar year. It shall be the duty of the Board of Trustees to--

(1) Hold the Trust Fund;

(2) Report to the Congress not later than the first day of April of each year on the operation and status of the Trust Fund during the preceding fiscal year and on its expected operation and status during the current fiscal year and the next 2 fiscal years;

(3) Report immediately to the Congress whenever the Board is of the opinion that the amount of the Trust Fund is unduly small; and

(4) Review the general policies followed in managing the Trust Fund, and recommend changes in such policies, including necessary changes in the provisions of law which govern the way in which the Trust Fund is to be managed.

The report provided for in paragraph (2) shall include a statement of the assets of, and the disbursements made from, the Trust Fund during the preceding fiscal year, an estimate of the expected income to, and disbursements to be made from, the Trust Fund during the current fiscal year and each of the next 2 fiscal years, and a statement of the actuarial status of the Trust Fund. Such report shall also include an actuarial opinion by the Chief Actuary of the Centers for

Medicare & Medicaid Services certifying that the techniques and methodologies used are generally accepted within the actuarial profession and that the assumptions and cost estimates used are reasonable. Such report shall be printed as a House document of the session of the Congress to which the report is made. A person serving on the Board of Trustees shall not be considered to be a fiduciary and shall not be personally liable for actions taken in such capacity with respect to the Trust Fund. Each report provided under paragraph (2) beginning with the report in 2005 shall include the information specified in section 801(a) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 [note to this section].

(c) Investment of Trust Fund by Managing Trustee. It shall be the duty of the Managing Trustee to invest such portion of the Trust Fund as is not, in his judgment, required to meet current withdrawals. Such investments may be made only in interest-bearing obligations of the United States or in obligations guaranteed as to both principal and interest by the United States. For such purpose such obligations may be acquired (1) on original issue at the issue price, or (2) by purchase of outstanding obligations at the market price. The purposes for which obligations of the United States may be issued under chapter 31 of title 31, United States Code [*31 USCS §§ 3101* et seq.], are hereby extended to authorize the issuance at par of public-debt obligations for purchase by the Trust Fund. Such obligations issued for purchase by the Trust Fund shall have maturities fixed with due regard for the needs of the Trust Fund and shall bear interest at a rate equal to the average market yield (computed by the Managing Trustee on the basis of market quotations as of the end of the calendar month next preceding the date of such issue) on all marketable interest-bearing obligations of the United States then forming a part of the public debt which are not due or callable until after the expiration of 4 years from the end of such calendar month; except that where such average market yield is not a multiple of one-eighth of 1 per centum, the rate of interest on such obligations shall be the multiple of one-eighth of 1 per centum nearest such market yield. The Managing Trustee may purchase other interest-bearing obligations of the United States or obligations guaranteed as to both principal and interest by the United States, on original issue or at the market price, only where he determines that the purchase of such other obligations is in the public interest.

(d) Authority of Managing Trustee to sell obligations. Any obligations acquired by the Trust Fund (except public-debt obligations issued exclusively to the Trust Fund) may be sold by the Managing Trustee at the market price, and such public-debt obligations may be redeemed at par plus accrued interest.

(e) Interest on and proceeds from sale or redemption of obligations. The interest on, and the proceeds from the sale or redemption of, any obligations held in the Trust Fund shall be credited to and form a part of the Trust Fund.

(f) Payment of estimated taxes.

(1) The Managing Trustee is directed to pay from time to time from the Trust Fund into the Treasury the amount estimated by him as taxes imposed under section 3101(b) [*26 USCS § 3101(b)*] which are subject to refund under *section 6413(c) of the Internal Revenue Code of 1954* [1986] [*26 USCS § 6413(c)*] with respect to wages paid after December 31, 1965. Such taxes shall be determined on the basis of the records of wages established and maintained by the Commissioner of Social Security in accordance with the wages reported to the Secretary of the Treasury or his delegate pursuant to subtitle F of the Internal Revenue Code of 1954 [1986] [*26 USCS §§ 6001* et seq.], and the Commissioner of Social Security shall furnish the Managing Trustee such information as may be required by the Managing Trustee for such purpose. The payments by the Managing Trustee shall be covered into the Treasury as repayments to the account for refunding internal revenue collections.

(2) Repayments made under paragraph (1) shall not be available for expenditures but shall be carried to the surplus fund of the Treasury. If it subsequently appears that the estimates under such paragraph in any particular period were too high or too low, appropriate adjustments shall be made by the Managing Trustee in future payments.

(g) Transfers from other Funds. There shall be transferred periodically (but not less often than once each fiscal year) to the Trust Fund from the Federal Old-Age and Survivors Insurance Trust Fund and from the Federal Disability Insurance Trust Fund amounts equivalent to the amounts not previously so transferred which the Secretary of Health and Human Services shall have certified as overpayments (other than amounts so certified to the Railroad Retirement Board) pursuant to section 1870(b) of this Act [*42 USCS § 1395gg(b)*]. There shall be transferred periodically (but not less often than once each fiscal year) to the Trust Fund from the Railroad Retirement Account amounts equivalent to the amounts not previously so transferred which the Secretary of Health and Human Services shall have certified as overpayments to the Railroad Retirement Board pursuant to section 1870(b) of this Act [*42 USCS § 1395gg(b)*].

(h) Payments from Trust Fund amounts certified by Secretary. The Managing Trustee shall also pay from time to time from the Trust Fund such amounts as the Secretary of Health and Human Services certifies are necessary to make the

payments provided for by this part [*42 USCS §§ 1395c* et seq.], and the payments with respect to administrative expenses in accordance with section 201(g)(1) [*42 USCS § 401(g)(1)*].

(i) Payment of travel expenses for travel within United States; reconsideration interviews and proceedings before administrative law judges. There are authorized to be made available for expenditure out of the Trust Fund such amounts as are required to pay travel expenses, either on an actual cost or commuted basis, to parties, their representatives, and all reasonably necessary witnesses for travel within the United States (as defined in section 210(i) [*42 USCS § 410(i)*]) to attend reconsideration interviews and proceedings before administrative law judges with respect to any determination under this *title [42 USCS §§ 1395* et seq.]. The amount available under the preceding sentence for payment for air travel by any person shall not exceed the coach fare for air travel between the points involved unless the use of first-class accommodations is required (as determined under regulations of the Secretary) because of such person's health condition or the unavailability of alternative accommodations; and the amount available for payment for other travel by any person shall not exceed the cost of travel (between the points involved) by the most economical and expeditious means of transportation appropriate to such person's health condition, as specified in such regulations. The amount available for payment under this subsection for travel by a representative to attend an administrative proceeding before an administrative law judge or other adjudicator shall not exceed the maximum amount allowable under this subsection for such travel originating within the geographic area of the office having jurisdiction over such proceeding.

(j) Loans from other Funds; interest; repayment; report to Congress.

(1) If at any time prior to January 1988 the Managing Trustee determines that borrowing authorized under this subsection is appropriate in order to best meet the need for financing the benefit payments from the Federal Hospital Insurance Trust Fund, the Managing Trustee may, subject to paragraph (5), borrow such amounts as he determines to be appropriate from either the Federal Old-Age and Survivors Insurance Trust Fund or the Federal Disability Insurance Trust Fund for transfer to and deposit in the Federal Hospital Insurance Trust Fund.

(2) In any case where a loan has been made to the Federal Hospital Insurance Trust Fund under paragraph (1), there shall be transferred on the last day of each month after such loan is made, from such Trust Fund to the lending Trust Fund, the total interest accrued to such day with respect to the unrepaid balance of such loan at a rate equal to the rate which the lending Trust Fund would earn on the amount involved if the loan were an investment under subsection (c) (even if such an investment would earn interest at a rate different than the rate earned by investments redeemed by the lending fund in order to make the loan).

(3) (A) If in any month after a loan has been made to the Federal Hospital Insurance Trust Fund under paragraph (1), the Managing Trustee determines that the assets of such Trust Fund are sufficient to permit repayment of all or part of any loans made to such Fund under paragraph (1), he shall make such repayments as he determines to be appropriate.

(B) (i) If on the last day of any year after a loan has been made under paragraph (1) by the Federal Old-Age and Survivors Insurance Trust Fund or the Federal Disability Insurance Trust Fund to the Federal Hospital Insurance Trust Fund, the Managing Trustee determines that the Hospital Insurance Trust Fund ratio exceeds 15 percent, he shall transfer from such Trust Fund to the lending trust fund an amount that--

(I) together with any amounts transferred to another lending trust fund under this paragraph for such year, will reduce the Hospital Insurance Trust Fund ratio to 15 percent; and

(II) does not exceed the outstanding balance of such loan.

(ii) Amounts required to be transferred under clause (i) shall be transferred on the last day of the first month of the year succeeding the year in which the determination described in clause (i) is made.

(iii) For purposes of this subparagraph, the term "Hospital Insurance Trust Fund ratio" means, with respect to any calendar year, the ratio of--

(I) the balance in the Federal Hospital Insurance Trust Fund, as of the last day of such calendar year; to

(II) the amount estimated by the Secretary to be the total amount to be paid from the Federal Hospital Insurance Trust Fund during the calendar year following such calendar year (other than payments of interest on, and repayments of, loans from the Federal Old-Age and Survivors Insurance Trust Fund and the Federal Disability Insurance Trust Fund under paragraph (1)), and reducing the amount of any transfer to the Railroad Retirement Account by the amount of any transfers into such Trust Fund from the Railroad Retirement Account.

(C) (i) The full amount of all loans made under paragraph (1) (whether made before or after January 1, 1983) shall be repaid at the earliest feasible date and in any event no later than December 31, 1989.

(ii) For the period after December 31, 1987 and before January 1, 1990, the Managing Trustee shall transfer each month from the Federal Hospital Insurance Trust Fund to any Trust Fund that is owed any amount by the Federal Hospital Insurance Trust Fund on a loan made under paragraph (1), an amount not less than an amount equal to (I) the amount owed to such Trust Fund by the Federal Hospital Insurance Trust Fund at the beginning of such month (plus the interest accrued on the outstanding balance of such loan during such month), divided by (II) the number of months

elapsing after the preceding month and before January 1990. The Managing Trustee may, during this period, transfer larger amounts than prescribed by the preceding sentence.

(4) The Board of Trustees shall make a timely report to the Congress of any amounts transferred (including interest payments) under this subsection.

(5) (A) No amounts may be loaned by the Federal Old-Age and Survivors Insurance Trust Fund or the Federal Disability Insurance Trust Fund under paragraph (1) during any month if the OASDI trust fund ratio for such month is less than 10 percent.

(B) For purposes of this paragraph, the term "OASDI trust fund ratio" means, with respect to any month, the ratio of--

(i) the combined balance in the Federal Old-Age and Survivors Insurance Trust Fund and the Federal Disability Insurance Trust Fund, reduced by the outstanding amount of any loan (including interest thereon) theretofore made to either such Trust Fund from the Federal Hospital Insurance Trust Fund under section 201(l) [*42 USCS § 401(l)*], as of the last day of the second month preceding such month, to

(ii) the amount obtained by multiplying by twelve the total amount which (as estimated by the Secretary) will be paid from the Federal Old-Age and Survivors Insurance Trust Fund and the Federal Disability Insurance Trust Fund during the month for which such ratio is to be determined for all purposes authorized by section 201 [*42 USCS § 401*] (other than payments of interest on, or repayments of, loans from the Federal Hospital Insurance Trust Fund under section 201(l) [*42 USCS § 401(l)*], but excluding any transfer payments between such trust funds and reducing the amount of any transfers to the Railroad Retirement Account by the amount of any transfers into either such trust fund from that Account.

(k) Health Care Fraud and Abuse Control Account.

(1) Establishment. There is hereby established in the Trust Fund an expenditure account to be known as the "Health Care Fraud and Abuse Control Account" (in this subsection referred to as the "Account").

(2) Appropriated amounts to Trust Fund.

(A) In general. There are hereby appropriated to the Trust Fund--

(i) such gifts and bequests as may be made as provided in subparagraph (B);

(ii) such amounts as may be deposited in the Trust Fund as provided in sections 242(b) and 249(c) of the Health Insurance Portability and Accountability Act of 1996 [notes to this section], and title XI [*42 USCS §§ 1301* et seq.]; and

(iii) such amounts as are transferred to the Trust Fund under subparagraph (C).

(B) Authorization to accept gifts. The Trust Fund is authorized to accept on behalf of the United States money gifts and bequests made unconditionally to the Trust Fund, for the benefit of the Account or any activity financed through the Account.

(C) Transfer of amounts. The Managing Trustee shall transfer to the Trust Fund, under rules similar to the rules in *section 9601 of the Internal Revenue Code of 1986* [*26 USCS § 9601*], an amount equal to the sum of the following:

(i) Criminal fines recovered in cases involving a Federal health care offense (as defined in *section 24(a) of title 18, United States Code*).

(ii) Civil monetary penalties and assessments imposed in health care cases, including amounts recovered under titles XI, XVIII, and XIX [*42 USCS §§ 1301* et seq., *1395* et seq., *1396* et seq.], and chapter 38 of title 31, United States Code [*31 USCS §§ 3801* et seq.] (except as otherwise provided by law).

(iii) Amounts resulting from the forfeiture of property by reason of a Federal health care offense.

(iv) Penalties and damages obtained and otherwise creditable to miscellaneous receipts of the general fund of the Treasury obtained under sections 3729 through 3733 of title 31, United States Code (known as the False Claims Act), in cases involving claims related to the provision of health care items and services (other than funds awarded to a relator, for restitution or otherwise authorized by law).

(D) Application. Nothing in subparagraph (C)(iii) shall be construed to limit the availability of recoveries and forfeitures obtained under title I of the Employee Retirement Income Security Act of 1974 for the purpose of providing equitable or remedial relief for employee welfare benefit plans, and for participants and beneficiaries under such plans, as authorized under such title.

(3) Appropriated amounts to account for fraud and abuse control program, etc.

(A) Departments of Health and Human Services and Justice.

(i) In general. There are hereby appropriated to the Account from the Trust Fund such sums as the Secretary and the Attorney General certify are necessary to carry out the purposes described in subparagraph (C), to be available without further appropriation until expended, in an amount not to exceed--

(I) for fiscal year 1997, $ 104,000,000;

(II) for each of the fiscal years 1998 through 2003, the limit for the preceding fiscal year, increased by 15 percent;

(III) for each of fiscal years 2004, 2005, and 2006, the limit for fiscal year 2003;

(IV) for each of fiscal years 2007, 2008, 2009, and 2010, the limit under this clause for the preceding fiscal year, increased by the percentage increase in the consumer price index for all urban consumers (all items; United States city average) over the previous year; and

(V) for each fiscal year after fiscal year 2010, the limit under this clause for fiscal year 2010.

(ii) Medicare and medicaid activities. For each fiscal year, of the amount appropriated in clause (i), the following amounts shall be available only for the purposes of the activities of the Office of the Inspector General of the Department of Health and Human Services with respect to the programs under this title and title XIX [*42 USCS §§ 1395* et seq. and *1396* et seq.]--

(I) for fiscal year 1997, not less than $ 60,000,000 and not more than $ 70,000,000;

(II) for fiscal year 1998, not less than $ 80,000,000 and not more than $ 90,000,000;

(III) for fiscal year 1999, not less than $ 90,000,000 and not more than $ 100,000,000;

(IV) for fiscal year 2000, not less than $ 110,000,000 and not more than $ 120,000,000;

(V) for fiscal year 2001, not less than $ 120,000,000 and not more than $ 130,000,000;

(VI) for fiscal year 2002, not less than $ 140,000,000 and not more than $ 150,000,000;

(VII) for each of fiscal years 2003, 2004, 2005, and 2006, not less than $ 150,000,000 and not more than $ 160,000,000;

(VIII) for fiscal year 2007, not less than $ 160,000,000, increased by the percentage increase in the consumer price index for all urban consumers (all items; United States city average) over the previous year;

(IX) for each of fiscal years 2008, 2009, and 2010, not less than the amount required under this clause for the preceding fiscal year, increased by the percentage increase in the consumer price index for all urban consumers (all items; United States city average) over the previous year; and

(X) for each fiscal year after fiscal year 2010, not less than the amount required under this clause for fiscal year 2010.

(B) Federal Bureau of Investigation. There are hereby appropriated from the general fund of the United States Treasury and hereby appropriated to the Account for transfer to the Federal Bureau of Investigation to carry out the purposes described in subparagraph (C), to be available without further appropriation until expended--

(i) for fiscal year 1997, $ 47,000,000;

(ii) for fiscal year 1998, $ 56,000,000;

(iii) for fiscal year 1999, $ 66,000,000;

(iv) for fiscal year 2000, $ 76,000,000;

(v) for fiscal year 2001, $ 88,000,000;

(vi) for fiscal year 2002, $ 101,000,000;

(vii) for each of fiscal years 2003, 2004, 2005, and 2006, $ 114,000,000;

(viii) for each of fiscal years 2007, 2008, 2009, and 2010, the amount to be appropriated under this subparagraph for the preceding fiscal year, increased by the percentage increase in the consumer price index for all urban consumers (all items; United States city average) over the previous year; and

(ix) for each fiscal year after fiscal year 2010, the amount to be appropriated under this subparagraph for fiscal year 2010.

(C) Use of funds. The purposes described in this subparagraph are to cover the costs (including equipment, salaries and benefits, and travel and training) of the administration and operation of the health care fraud and abuse control program established under section 1128C(a) [*42 USCS § 1320a-7c(a)*], including the costs of--

(i) prosecuting health care matters (through criminal, civil, and administrative proceedings);

(ii) investigations;

(iii) financial and performance audits of health care programs and operations;

(iv) inspections and other evaluations; and

(v) provider and consumer education regarding compliance with the provisions of title XI [*42 USCS §§ 1301* et seq.].

(4) Appropriated amounts to account for Medicare Integrity Program.

(A) In general. There are hereby appropriated to the Account from the Trust Fund for each fiscal year such amounts as are necessary to carry out the Medicare Integrity Program under section 1893 [*42 USCS § 1395ddd*], subject to subparagraphs (B), (C), and (D) and to be available without further appropriation.

(B) Amounts specified. Subject to subparagraph (C), the amount appropriated under subparagraph (A) for a fiscal year is as follows:

(i) For fiscal year 1997, such amount shall be not less than $ 430,000,000 and not more than $ 440,000,000.

(ii) For fiscal year 1998, such amount shall be not less than $ 490,000,000 and not more than $ 500,000,000.

(iii) For fiscal year 1999, such amount shall be not less than $ 550,000,000 and not more than $ 560,000,000.

(iv) For fiscal year 2000, such amount shall be not less than $ 620,000,000 and not more than $ 630,000,000.

(v) For fiscal year 2001, such amount shall be not less than $ 670,000,000 and not more than $ 680,000,000.

(vi) For fiscal year 2002, such amount shall be not less than $ 690,000,000 and not more than $ 700,000,000.

(vii) For each fiscal year after fiscal year 2002, such amount shall be not less than $ 710,000,000 and not more than $ 720,000,000.

(C) Adjustments. The amount appropriated under subparagraph (A) for a fiscal year is increased as follows:

(i) For fiscal year 2006, $ 100,000,000.

(D) Expansion of the Medicare-Medicaid Data Match Program. The amount appropriated under subparagraph (A) for a fiscal year is further increased as follows for purposes of carrying out section 1893(b)(6) [*42 USCS § 1395ddd(b)(6)*] for the respective fiscal year:

(i) $ 12,000,000 for fiscal year 2006.

(ii) $ 24,000,000 for fiscal year 2007.

(iii) $ 36,000,000 for fiscal year 2008.

(iv) $ 48,000,000 for fiscal year 2009.

(v) $ 60,000,000 for fiscal year 2010 and each fiscal year thereafter.

(5) Annual report. Not later than January 1, the Secretary and the Attorney General shall submit jointly a report to Congress which identifies--

(A) the amounts appropriated to the Trust Fund for the previous fiscal year under paragraph (2)(A) and the source of such amounts; and

(B) the amounts appropriated from the Trust Fund for such year under paragraph (3) and the justification for the expenditure of such amounts.

(6) GAO report. Not later than June 1, 1998, and January 1 of 2000, 2002, and 2004, the Comptroller General of the United States shall submit a report to Congress which--

(A) identifies--

(i) the amounts appropriated to the Trust Fund for the previous two fiscal years under paragraph (2)(A) and the source of such amounts; and

(ii) the amounts appropriated from the Trust Fund for such fiscal years under paragraph (3) and the justification for the expenditure of such amounts;

(B) identifies any expenditures from the Trust Fund with respect to activities not involving the program under this *title [42 USCS §§ 1395* et seq.];

(C) identifies any savings to the Trust Fund, and any other savings, resulting from expenditures from the Trust Fund; and

(D) analyzes such other aspects of the operation of the Trust Fund as the Comptroller General of the United States considers appropriate.

HISTORY:

(Aug. 14, 1935, ch 531, Title XVIII, Part A, § 1817, as added July 30, 1965, P.L. 89-97, Title I, Part 1, § 102(a), 79 Stat. 299; Jan. 2, 1968, P.L. 90-248, Title I, Part 4, § 169(a), 81 Stat. 875; Oct. 30, 1972, P.L. 92-603, Title I, § 132(d), 86 Stat. 1361; June 13, 1978, P.L. 95-292, § 5, 92 Stat. 315; June 9, 1980, P.L. 96-265, Title III, § 310(c), 94 Stat. 460; Dec. 29, 1981, P.L. 97-123, Title II, § 1(b), 95 Stat. 1659; April 20, 1983, P.L. 98-21, Title I, Part E, §§ 141(b), 142(b)(1), (2)(A), (3), (4), Part F, § 154(b), Title III, Part C, § 341(b), 97 Stat. 98, 100, 101, 107, 135; July 18, 1984, P.L. 98-369, Division B, Title III, Subtitle A, Part II, §§ 2337(a), 2354(b)(2), Title VI, Subtitle D, § 2663(j)(2)(F)(i), 98 Stat. 1091, 1100, 1160; April 7, 1986, P.L. 99-272, Title IX, Subtitle A, Part 2, Subpart B, § 9213(b) in part, 100 Stat. 180; July 1, 1988, P.L. 100-360, Title II, Subtitle B, § 212(c)(3), 102 Stat. 741; Nov. 10, 1988, P.L. 100-647, Title VIII, Subtitle A, § 8005(a), 102 Stat. 3781; Dec. 13, 1989, P.L. 101-234, Title II, § 202(a), 103 Stat. 1981; Nov. 5, 1990, P.L. 101-508, Title V, Subtitle B, § 5106(c), 104 Stat. 1388-268; Aug. 15, 1994, P.L. 103-296, Title I, § 108(c)(1), 108 Stat. 1485; Aug. 21, 1996, P.L. 104-191, Title II, Subtitle A, § 201(b), 110 Stat. 1993; Aug. 5, 1997, P.L. 105-33, Title IV, Subtitle D, Ch 2, § 4318, 111 Stat. 392; Nov. 29, 1999, P.L. 106-113, Div B, § 1000(a)(6), 113 Stat. 1536; Dec. 8, 2003, P.L. 108-173, Title VII, Subtitle D, § 736(a)(5), (6), Title VIII, Subtitle A, § 801(d)(1), Title IX, § 900(e)(1)(D), 117 Stat. 2355, 2359, 2371.)

(As amended Feb. 8, 2006, P.L. 109-171, Title V, Subtitle C, § 5204, Title VI, Subtitle A, Ch. 3, § 6034(d)(2), 120 Stat. 48, 78; Dec. 20, 2006, P.L. 109-432, Div B, Title III, § 303, 120 Stat. 2992.)

§ 1395i-1. Authorization of appropriations

There are authorized to be appropriated to the Federal Hospital Insurance Trust Fund (established by section 1817 of the Social Security Act [*42 USCS § 1395i*]) from time to time such sums as the Secretary deems necessary for any fiscal year, on account of--

(1) payments made or to be made during such fiscal year from such Trust Fund under part A of title XVIII of such Act [*42 USCS §§ 1395c* et seq.] with respect to individuals who are qualified railroad retirement beneficiaries (as defined in section 226(c) of such Act [*42 USCS § 426(c)*]) and who are not, and upon filing application for monthly insurance benefits under section 202 of such Act [*42 USCS § 402*] would not be, entitled to such benefits if service as an employee (as defined in the Railroad Retirement Act of 1937) after December 31, 1936, had been included in the term "employment" as defined in the Social Security Act,

(2) the additional administrative expenses resulting or expected to result therefrom, and

(3) any loss of interest to such Trust Fund resulting from the payment of such amounts,

in order to place such Trust Fund in the same position at the end of such fiscal year in which it would have been if the individuals described in paragraph (1) had not been entitled to benefits under part A of title XVIII of the Social Security Act [*42 USCS §§ 1395c* et seq.].

HISTORY:

(July 30, 1965, P.L. 89-97, Title I, Part 1, § 111(d), 79 Stat. 343.)

§ 1395i-1a. [Repealed]

§ 1395i-2. Hospital insurance benefits for uninsured elderly individuals not otherwise eligible

(a) Individuals eligible to enroll. Every individual who--

(1) has attained the age of 65,

(2) is enrolled under part B of this *title [42 USCS §§ 1395j* et seq.],

(3) is a resident of the United States, and is either (A) a citizen or (B) an alien lawfully admitted for permanent residence who has resided in the United States continuously during the 5 years immediately preceding the month in which he applies for enrollment under this section, and

(4) is not otherwise entitled to benefits under this part [*42 USCS §§ 1395c* et seq.],

shall be eligible to enroll in the insurance program established by this part [*42 USCS §§ 1395c* et seq.]. Except as otherwise provided, any reference to an individual entitled to benefits under this part [*42 USCS §§ 1395c* et seq.] includes an individual entitled to benefits under this part [*42 USCS §§ 1395c* et seq.] pursuant to an enrollment under this section or section 1818A [*42 USCS § 1395i-2a*].

(b) Time, manner, and form of enrollment. An individual may enroll under this section only in such manner and form as may be prescribed in regulations, and only during an enrollment period prescribed in or under this section.

(c) Period of enrollment; scope of coverage. The provisions of section 1837 (except subsection (f) thereof), section 1838, subsection (b) of section 1839, and subsections (f) and (h) of section 1840 [*42 USCS §§ 1395p* (except (f)), 1395q, 1395r(b), 1395s(f) and (h)] shall apply to persons authorized to enroll under this section except that--

(1) individuals who meet the conditions of subsection (a)(1), (3), and (4) on or before the last day of the seventh month after the month in which this section is enacted [enacted Oct. 30, 1972] may enroll under this part [*42 USCS §§ 1395c* et seq.] and (if not already so enrolled) may also enroll under part B [*42 USCS §§ 1395j* et seq.] during an initial general enrollment period which shall begin on the first day of the second month which begins after the date on which this section is enacted [enacted Oct. 30, 1972] and shall end on the last day of the tenth month after the month in which this section is enacted [enacted Oct. 30, 1972];

(2) in the case of an individual who first meets the conditions of eligibility under this section on or after the first day of the eighth month after the month in which this section is enacted [enacted Oct. 30, 1972], the initial enrollment period shall begin on the first day of the third month before the month in which he first becomes eligible and shall end 7 months later;

(3) in the case of an individual who enrolls pursuant to paragraph (1) of this subsection, entitlement to benefits shall begin on--

(A) the first day of the second month after the month in which he enrolls,

(B) July 1, 1973, or

(C) the first day of the first month in which he meets the requirements of subsection (a),

whichever is the latest;

(4) an individual's entitlement under this section shall terminate with the month before the first month in which he becomes eligible for hospital insurance benefits under section 226 of this Act [*42 USCS § 426*] or section 103 of the Social Security Amendments of 1965 [*42 USCS § 426a*]; and upon such termination, such individual shall be deemed, solely for purposes of hospital insurance entitlement, to have filed in such first month the application required to establish such entitlement;

(5) termination of coverage for supplementary medical insurance shall result in simultaneous termination of hospital insurance benefits for uninsured individuals who are not otherwise entitled to benefits under this Act;

(6) any percent increase effected under section 1839(b) [*42 USCS § 1395r(b)*] in an individual's monthly premium may not exceed 10 percent and shall only apply to premiums paid during a period equal to twice the number of months in the full 12-month periods described in that section and shall be subject to reduction in accordance with subsection (d)(6);

(7) an individual who meets the conditions of subsection (a) may enroll under this part [*42 USCS §§ 1395c* et seq.] during a special enrollment period that includes any month during any part of which the individual is enrolled under section 1876 [*42 USCS § 1395mm*] with an eligible organization and ending with the last day of the 8th consecutive month in which the individual is at no time so enrolled;

(8) in the case of an individual who enrolls during a special enrollment period under paragraph (7)--

(A) in any month of the special enrollment period in which the individual is at any time enrolled under section 1876 [*42 USCS § 1395mm*] with an eligible organization or in the first month following such a month, the coverage period shall begin on the first day of the month in which the individual so enrolls (or, at the option of the individual, on the first day of any of the following three months), or

(B) in any other month of the special enrollment period, the coverage period shall begin on the first day of the month following the month in which the individual so enrolls; and

(9) in applying the provisions of section 1839(b) [*42 USCS § 1395r(b)*], there shall not be taken into account months for which the individual can demonstrate that the individual was enrolled under section 1876 [*42 USCS § 1395mm*] with an eligible organization.

(d) Monthly actuarial rate and premiums.

(1) The Secretary shall, during September of each year (beginning with 1988), estimate the monthly actuarial rate for months in the succeeding year. Such actuarial rate shall be one-twelfth of the amount which the Secretary estimates (on an average, per capita basis) is equal to 100 percent of the benefits and administrative costs which will be payable from the Federal Hospital Insurance Trust Fund for services performed and related administrative costs incurred in the succeeding year with respect to individuals age 65 and over who will be entitled to benefits under this part [*42 USCS §§ 1395c* et seq.] during that year.

(2) The Secretary shall, during September of each year[,] determine and promulgate the dollar amount which shall be applicable for premiums for months occurring in the following year. Subject to paragraphs (4) and (5), the amount of an individual's monthly premium under this section shall be equal to the monthly actuarial rate determined under paragraph (1) for that following year. Any amount determined under the preceding sentence which is not a multiple of $ 1 shall be rounded to the nearest multiple of $ 1 (or, if it is a multiple of 50 cents but not a multiple of $ 1, to the next higher multiple of $ 1).

(3) Whenever the Secretary promulgates the dollar amount which shall be applicable as the monthly premium under this section, he shall, at the time such promulgation is announced, issue a public statement setting forth the actuarial assumptions and bases employed by him in arriving at the amount of an adequate actuarial rate for individuals 65 and older as provided in paragraph (1).

(4) (A) In the case of an individual described in subparagraph (B), the monthly premium for a month shall be reduced by the applicable reduction percent specified in the following table:

For a month in:	The applicable reduction percent is:
1994	25 percent
1995	30 percent

1996 ..... 35 percent
1997 ..... 40 percent
1998 or subsequent year ..... 45 percent.

(B) An individual described in this subparagraph with respect to a month is an individual who establishes to the satisfaction of the Secretary that, as of the last day of the previous month, the individual--

(i) had at least 30 quarters of coverage under title II [*42 USCS §§ 401* et seq.];

(ii) was married (and had been married for the previous 1-year period) to an individual who had at least 30 quarters of coverage under such title;

(iii) had been married to an individual for a period of at least 1 year (at the time of such individual's death) if at such time the individual had at least 30 quarters of coverage under such title; or

(iv) is divorced from an individual and had been married to the individual for a period of at least 10 years (at the time of the divorce) if at such time the individual had at least 30 quarters of coverage under such title; or

(5) (A) The amount of the monthly premium shall be zero in the case of an individual who is a person described in subparagraph (B) for a month, if--

(i) the individual's premium under this section for the month is not (and will not be) paid for, in whole or in part, by a State (under title XIX [*42 USCS §§ 1396* et seq.] or otherwise), a political subdivision of a State, or an agency or instrumentality of one or more States or political subdivisions thereof; and

(ii) in each of 84 months before such month, the individual was enrolled in this part under this section and the payment of the individual's premium under this section for the month was not paid for, in whole or in part, by a State (under title XIX [*42 USCS §§ 1396* et seq.] or otherwise), a political subdivision of a State, or an agency or instrumentality of one or more States or political subdivisions thereof.

(B) A person described in this subparagraph for a month is a person who establishes to the satisfaction of the Secretary that, as of the last day of the previous month--

(i) (I) the person was receiving cash benefits under a qualified State or local government retirement system (as defined in subparagraph (C)) on the basis of the person's employment in one or more positions covered under any such system, and

(II) the person would have at least 40 quarters of coverage under title II [*42 USCS §§ 401* et seq.] if remuneration for medicare qualified government employment (as defined in paragraph (1) of section 210(p) [*42 USCS § 410(p)*], but determined without regard to paragraph (3) of such section) paid to such person were treated as wages paid to such person and credited for purposes of determining quarters of coverage under section 213 [*42 USCS § 413*];

(ii) (I) the person was married (and had been married for the previous 1-year period) to an individual who is described in clause (i), or

(II) the person met the requirement of clause (i)(II) and was married (and had been married for the previous 1-year period) to an individual described in clause (i)(I);

(iii) the person had been married to an individual for a period of at least 1 year (at the time of such individual's death) if --

(I) the individual was described in clause (i) at the time of the individual's death, or

(II) the person met the requirement of clause (i)(II) and the individual was described in clause (i)(I) at the time of the individual's death; or

(iv) the person is divorced from an individual and had been married to the individual for a period of at least 10 years (at the time of the divorce) if --

(I) the individual was described in clause (i) at the time of the divorce, or

(II) the person met the requirement of clause (i)(II) and the individual was described in clause (i)(I) at the time of the divorce.

(C) For purposes of subparagraph (B)(i)(I), the term "qualified State or local government retirement system" means a retirement system that--

(i) is established or maintained by a State or political subdivision thereof, or an agency or instrumentality of one or more States or political subdivisions thereof;

(ii) covers positions of some or all employees of such a State, subdivision, agency, or instrumentality; and

(iii) does not adjust cash retirement benefits based on eligibility for a reduction in premium under this paragraph.

(6) (A) In the case where a State, a political subdivision of a State, or an agency or instrumentality of a State or political subdivision thereof determines to pay, for the life of each individual, the monthly premiums due under paragraph (1) on behalf of each of the individuals in a qualified State or local government retiree group who meets the conditions of subsection (a), the amount of any increase otherwise applicable under section 1839(b) [*42 USCS § 1395r(b)*] (as applied and modified by subsection (c)(6) of this section) with respect to the monthly premium for benefits under this part for an individual who is a member of such group shall be reduced by the total amount of taxes

paid under *section 3101(b) of the Internal Revenue Code of 1986* [*26 USCS § 3101(b)*] by such individual and under section 3111(b) of such Code [*26 USCS § 3111(b)*] by the employers of such individual on behalf of such individual with respect to employment (as defined in section 3121(b) of such Code [*26 USCS § 3121(b)*]).

(B) For purposes of this paragraph, the term "qualified State or local government retiree group" means all of the individuals who retire prior to a specified date that is before January 1, 2002, from employment in 1 or more occupations or other broad classes of employees of--

(i) the State;

(ii) a political subdivision of the State; or

(iii) an agency or instrumentality of the State or political subdivision of the State.

(e) Contract or other arrangement for payment of monthly premiums. Payment of the monthly premiums on behalf of any individual who meets the conditions of subsection (a) may be made by any public or private agency or organization under a contract or other arrangement entered into between it and the Secretary if the Secretary determines that payment of such premiums under such contract or arrangement is administratively feasible.

(f) Deposit of amounts into Treasury. Amounts paid to the Secretary for coverage under this section shall be deposited in the Treasury to the credit of the Federal Hospital Insurance Trust Fund.

(g) Buy-in under this part for qualified medicare beneficiaries.

(1) The Secretary shall, at the request of a State made after 1989, enter into a modification of an agreement entered into with the State pursuant to section 1843(a) [*42 USCS § 1395v(a)*] under which the agreement provides for enrollment in the program established by this part [*42 USCS §§ 1395c* et seq.] of qualified medicare beneficiaries (as defined in section 1905(p)(1) [*42 USCS § 1396d(p)(1)*]).

(2) (A) Except as provided in subparagraph (B), the provisions of subsections (c), (d), (e), and (f) of section 1843 [*42 USCS § 1395v(c)*, (d), (e), and (f)] shall apply to qualified medicare beneficiaries enrolled, pursuant to such agreement, in the program established by this part in the same manner and to the same extent as they apply to qualified medicare beneficiaries enrolled, pursuant to such agreement, in part B [*42 USCS §§ 1395j* et seq.]

(B) For purposes of this subsection, section 1843(d)(1) [*42 USCS § 1395v(d)(1)*] shall be applied by substituting "section 1818 [*42 USCS § 1395i-2*]" for "section 1839 [*42 USCS § 1395r*]" and "subsection (c)(6) (with reference to subsection (b) of section 1839 [*42 USCS § 1395r*])" for "subsection (b)".

HISTORY:

(Aug. 14, 1935, ch 531, Title XVIII, Part A, § 1818, as added Oct. 30, 1972, P.L. 92-603, Title II, § 202, 86 Stat. 1374; April 20, 1983, P.L. 98-21, Title VI, § 606(a)(3)(D), (b), 97 Stat. 170, 171; July 18, 1984, P.L. 98-369, Division B, Title III, Subtitle A, Part I, § 2315(e), Part II, § 2354(b)(3), (4), 98 Stat. 1080, 1100; April 7, 1986, P.L. 99-272, Title IX, Subtitle A, Part 1, Subpart B, § 9124(a), 100 Stat. 168; Dec. 22, 1987, P.L. 100-203, Title IV, Subtitle A, Part 1, § 4009(j)(9), 101 Stat. 1330-59; July 1, 1988, P.L. 100-360, Title I, Subtitle A, § 103, Title IV, Subtitle B, § 411(b)(8)(D), 102 Stat. 687, 772; Oct. 13, 1988, P.L. 100-485, Title VI, § 608(d)(2), 102 Stat. 2413; Dec. 19, 1989, P.L. 101-239, Title VI, Subtitle A, Part 1, Subpart B, §§ 6012(a)(1), 6013(a), 103 Stat. 2161, 2163; Nov. 5, 1990, P.L. 101-508, Title IV, Subtitle A, Part 1, § 4008(g)(1), (m)(3)(D), 104 Stat. 1388-45, 1388-54; Aug. 10, 1993, P.L. 103-66, Title XIII, Ch 2, Subch A, Part I, § 13508(a), 107 Stat. 579; Aug. 5, 1997, P.L. 105-33, Title IV, Subtitle E, Ch 5, § 4453(a), 111 Stat. 425; Dec. 21, 2000, P.L. 106-554, § 1(a)(6), 114 Stat. 2763; Dec. 8, 2003, P.L. 108-173, Tile I, § 101(e)(5), Title VII, Subtitle D, § 736(a)(7), 117 Stat. 2151, 2355.)

§ 1395i-2a. Hospital insurance benefits for disabled individuals who have exhausted other entitlement

(a) Eligibility. Every individual who--

(1) has not attained the age of 65;

(2) (A) has been entitled to benefits under this part [*42 USCS §§ 1395c* et seq.] under section 226(b) [*42 USCS § 426(b)*], and

(B) (i) continues to have the disabling physical or mental impairment on the basis of which the individual was found to be under a disability or to be a disabled qualified railroad retirement beneficiary, or (ii) is blind (within the meaning of section 216(i)(1) [*42 USCS § 416(i)(1)*]), but

(C) whose entitlement under section 226(b) [*42 USCS § 426(b)*] ends due solely to the individual having earnings that exceed the substantial gainful activity amount (as defined in section 223(d)(4) [*42 USCS § 423(d)(4)*]); and

(3) is not otherwise entitled to benefits under this part [*42 USCS §§ 1395c* et seq.],

shall be eligible to enroll in the insurance program established by this part [*42 USCS §§ 1395c* et seq.].

(b) Enrollment.

(1) An individual may enroll under this section only in such manner and form as may be prescribed in regulations, and only during an enrollment period prescribed in or under this section.

(2) The individual's initial enrollment period shall begin with the month in which the individual receives notice that the individual's entitlement to benefits under section 226(b) [*42 USCS § 426(b)*] will end due solely to the individual having earnings that exceed the substantial gainful activity amount (as defined in section 223(d)(4) [*42 USCS § 423(d)(4)*]) and shall end 7 months later.

(3) There shall be a general enrollment period during the period beginning on January 1 and ending on March 31 of each year (beginning with 1990).

(c) Coverage period.

(1) The period (in this subsection referred to as a "coverage period") during which an individual is entitled to benefits under the insurance program under this part [*42 USCS §§ 1395c* et seq.] shall begin on whichever of the following is the latest:

(A) In the case of an individual who enrolls under subsection (b)(2) before the month in which the individual first satisfies subsection (a), the first day of such month.

(B) In the case of an individual who enrolls under subsection (b)(2) in the month in which the individual first satisfies subsection (a), the first day of the month following the month in which the individual so enrolls.

(C) In the case of an individual who enrolls under subsection (b)(2) in the month following the month in which the individual first satisfies subsection (a), the first day of the second month following the month in which the individual so enrolls.

(D) In the case of an individual who enrolls under subsection (b)(2) more than one month following the month in which the individual first satisfies subsection (a), the first day of the third month following the month in which the individual so enrolls.

(E) In the case of an individual who enrolls under subsection (b)(3), the July 1 following the month in which the individual so enrolls.

(2) An individual's coverage period under this section shall continue until the individual's enrollment is terminated as follows:

(A) As of the month following the month in which the Secretary provides notice to the individual that the individual no longer meets the condition described in subsection (a)(2)(B).

(B) As of the month following the month in which the individual files notice that the individual no longer wishes to participate in the insurance program established by this part [*42 USCS §§ 1395c* et seq.].

(C) As of the month before the first month in which the individual becomes eligible for hospital insurance benefits under section 226(a) or 226A [*42 USCS § 426(a)* or *426-1*].

(D) As of a date, determined under regulations of the Secretary, for nonpayment of premiums.

The regulations under subparagraph (D) may provide a grace period of not longer than 90 days, which may be extended to not to exceed 180 days in any case where the Secretary determines that there was good cause for failure to pay the overdue premiums within such 90-day period. Termination of coverage under this section shall result in simultaneous termination of any coverage affected under any other part of this *title [42 USCS §§ 1395* et seq.].

(3) The provisions of subsections (h) and (i) of section 1837 [*42 USCS § 1395p(h)* and(i)] apply to enrollment and nonenrollment under this section in the same manner as they apply to enrollment and nonenrollment and special enrollment periods under section 1818 [*42 USCS § 1395i-2*].

(d) Payment of premiums.

(1) (A) Premiums for enrollment under this section shall be paid to the Secretary at such times, and in such manner, as the Secretary shall by regulations prescribe, and shall be deposited in the Treasury to the credit of the Federal Hospital Insurance Trust Fund.

(B) (i) Subject to clause (ii), such premiums shall be payable for the period commencing with the first month of an individual's coverage period and ending with the month in which the individual dies or, if earlier, in which the individual's coverage period terminates.

(ii) Such premiums shall not be payable for any month in which the individual is eligible for benefits under this part [*42 USCS §§ 1395c* et seq.] pursuant to section 226(b) [*42 USCS § 426(b)*].

(2) The provisions of subsections (d) through (f) of section 1818 [*42 USCS § 1395i-2(d)*-(f)] (relating to premiums) shall apply to individuals enrolled under this section in the same manner as they apply to individuals enrolled under that section.

HISTORY:

(Aug. 14, 1935, ch 531, Title XVIII, Part A, § 1818A, as added Dec. 19, 1989, P.L. 101-239, Title VI, Subtitle A, Part 1, Subpart B, § 6012(a)(2), 103 Stat. 2162; Nov. 5, 1990, P.L. 101-508, Title IV, Subtitle A, Part 1, § 4008(m)(3)(C), 104 Stat. 1388-54.)

§ 1395i-3. Requirements for, and assuring quality of care in, skilled nursing facilities

(a) "Skilled nursing facility" defined. In this *title [42 USCS §§ 1395* et seq.], the term "skilled nursing facility" means an institution (or a distinct part of an institution) which--

(1) is primarily engaged in providing to residents--

(A) skilled nursing care and related services for residents who require medical or nursing care, or

(B) rehabilitation services for the rehabilitation of injured, disabled, or sick persons,

and is not primarily for the care and treatment of mental diseases;

(2) has in effect a transfer agreement (meeting the requirements of section 1861(l) [*42 USCS § 1395x(l)*]) with one or more hospitals having agreements in effect under section 1866 [*42 USCS § 1395cc*]; and

(3) meets the requirements for a skilled nursing facility described in subsections (b), (c), and (d) of this section.

(b) Requirements relating to provision of services.

(1) Quality of life.

(A) In general. A skilled nursing facility must care for its residents in such a manner and in such an environment as will promote maintenance or enhancement of the quality of life of each resident.

(B) Quality assessment and assurance. A skilled nursing facility must maintain a quality assessment and assurance committee, consisting of the director of nursing services, a physician designated by the facility, and at least 3 other members of the facility's staff, which (i) meets at least quarterly to identify issues with respect to which quality assessment and assurance activities are necessary and (ii) develops and implements appropriate plans of action to correct identified quality deficiencies. A State or the Secretary may not require disclosure of the records of such committee except insofar as such disclosure is related to the compliance of such committee with the requirements of this subparagraph.

(2) Scope of services and activities under plan of care. A skilled nursing facility must provide services to attain or maintain the highest practicable physical, mental, and psychosocial well-being of each resident, in accordance with a written plan of care which--

(A) describes the medical, nursing, and psychosocial needs of the resident and how such needs will be met;

(B) is initially prepared, with the participation to the extent practicable of the resident or the resident's family or legal representative, by a team which includes the resident's attending physician and a registered professional nurse with responsibility for the resident; and

(C) is periodically reviewed and revised by such team after each assessment under paragraph (3).

(3) Residents' assessment.

(A) Requirement. A skilled nursing facility must conduct a comprehensive, accurate, standardized, reproducible assessment of each resident's functional capacity, which assessment--

(i) describes the resident's capability to perform daily life functions and significant impairments in functional capacity;

(ii) is based on a uniform minimum data set specified by the Secretary under subsection (f)(6)(A);

(iii) uses an instrument which is specified by the State under subsection (e)(5); and

(iv) includes the identification of medical problems.

(B) Certification.

(i) In general. Each such assessment must be conducted or coordinated (with the appropriate participation of health professionals) by a registered professional nurse who signs and certifies the completion of the assessment. Each individual who completes a portion of such an assessment shall sign and certify as to the accuracy of that portion of the assessment.

(ii) Penalty for falsification.

(I) An individual who willfully and knowingly certifies under clause (i) a material and false statement in a resident assessment is subject to a civil money penalty of not more than $ 1,000 with respect to each assessment.

(II) An individual who willfully and knowingly causes another individual to certify under clause (i) a material and false statement in a resident assessment is subject to a civil money penalty of not more than $ 5,000 with respect to each assessment.

(III) The provisions of section 1128A [*42 USCS § 1320a-7a*] (other than subsections (a) and (b)) shall apply to a civil money penalty under this clause in the same manner as such provisions apply to a penalty or proceeding under section 1128A(a) [*42 USCS § 1320a-7a(a)*].

(iii) Use of independent assessors. If a State determines, under a survey under subsection (g) or otherwise, that there has been a knowing and willful certification of false assessments under this paragraph, the State may require (for a period specified by the State) that resident assessments under this paragraph be conducted and certified by individuals who are independent of the facility and who are approved by the State.

(C) Frequency.

(i) In general. Subject to timeframes prescribed by the Secretary under section 1888(e)(6) [*42 USCS § 1395yy(e)(6)*], such an assessment must be conducted--

(I) promptly upon (but no later than 14 days after the date of) admission for each individual admitted on or after October 1, 1990, and by not later than January 1, 1991, for each resident of the facility on that date;

(II) promptly after a significant change in the resident's physical or mental condition; and

(III) in no case less often than once every 12 months.

(ii) Resident review. The skilled nursing facility must examine each resident no less frequently than once every 3 months and, as appropriate, revise the resident's assessment to assure the continuing accuracy of the assessment.

(D) Use. The results of such an assessment shall be used in developing, reviewing, and revising the resident's plan of care under paragraph (2).

(E) Coordination. Such assessments shall be coordinated with any State-required preadmission screening program to the maximum extent practicable in order to avoid duplicative testing and effort.

(4) Provision of services and activities.

(A) In general. To the extent needed to fulfill all plans of care described in paragraph (2), a skilled nursing facility must provide, directly or under arrangements (or, with respect to dental services, under agreements) with others for the provision of--

(i) nursing services and specialized rehabilitative services to attain or maintain the highest practicable physical, mental, and psychosocial well-being of each resident;

(ii) medically-related social services to attain or maintain the highest practicable physical, mental, and psychosocial well-being of each resident;

(iii) pharmaceutical services (including procedures that assure the accurate acquiring, receiving, dispensing, and administering of all drugs and biologicals) to meet the needs of each resident;

(iv) dietary services that assure that the meals meet the daily nutritional and special dietary needs of each resident;

(v) an on-going program, directed by a qualified professional, of activities designed to meet the interests and the physical, mental, and psychosocial well-being of each resident;

(vi) routine and emergency dental services to meet the needs of each resident; and

(vii) treatment and services required by mentally ill and mentally retarded residents not otherwise provided or arranged for (or required to be provided or arranged for) by the State.

The services provided or arranged by the facility must meet professional standards of quality. Nothing in clause (vi) shall be construed as requiring a facility to provide or arrange for dental services described in that clause without additional charge.

(B) Qualified persons providing services. Services described in clauses (i), (ii), (iii), (iv), and (vi) of subparagraph (A) must be provided by qualified persons in accordance with each resident's written plan of care.

(C) Required nursing care.

(i) In general. Except as provided in clause (ii), a skilled nursing facility must provide 24-hour licensed nursing service which is sufficient to meet nursing needs of its residents and must use the services of a registered professional nurse at least 8 consecutive hours a day, 7 days a week.

(ii) Exception. To the extent that clause (i) may be deemed to require that a skilled nursing facility engage the services of a registered professional nurse for more than 40 hours a week, the Secretary is authorized to waive such requirement if the Secretary finds that--

(I) the facility is located in a rural area and the supply of skilled nursing facility services in such area is not sufficient to meet the needs of individuals residing therein,

(II) the facility has one full-time registered professional nurse who is regularly on duty at such facility 40 hours a week,

(III) the facility either has only patients whose physicians have indicated (through physicians' orders or admission notes) that each such patient does not require the services of a registered nurse or a physician for a 48-hour period, or has made arrangements for a registered professional nurse or a physician to spend such time at such facility as may be indicated as necessary by the physician to provide necessary skilled nursing services on days when the regular full-time registered professional nurse is not on duty,

(IV) the Secretary provides notice of the waiver to the State long-term care ombudsman (established under section 307(a)(12) of the Older Americans Act of 1965 [*42 USCS § 3027(a)(12)*]) and the protection and advocacy system in the State for the mentally ill and the mentally retarded, and

(V) the facility that is granted such a waiver notifies residents of the facility (or, where appropriate, the guardians or legal representatives of such residents) and members of their immediate families of the waiver.

A waiver under this subparagraph shall be subject to annual renewal.

(5) Required training of nurse aides.

(A) In general.

(i) Except as provided in clause (ii), a skilled nursing facility must not use on a full-time basis any individual as a nurse aide in the facility on or after October 1, 1990 for more than 4 months unless the individual--

(I) has completed a training and competency evaluation program, or a competency evaluation program, approved by the State under subsection (e)(1)(A), and

(II) is competent to provide nursing or nursing-related services.

(ii) A skilled nursing facility must not use on a temporary, per diem, leased, or on any basis other than as a permanent employee any individual as a nurse aide in the facility on or after January 1, 1991, unless the individual meets the requirements described in clause (i).

(B) Offering competency evaluation programs for current employees. A skilled nursing facility must provide, for individuals used as a nurse aide [nurse aides] by the facility as of January 1, 1990, for a competency evaluation program approved by the State under subsection (e)(1) and such preparation as may be necessary for the individual to complete such a program by October 1, 1990.

(C) Competency. The skilled nursing facility must not permit an individual, other than in a training and competency evaluation program approved by the State, to serve as a nurse aide or provide services of a type for which the individual has not demonstrated competency and must not use such an individual as a nurse aide unless the facility has inquired of any State registry established under subsection (e)(2)(A) that the facility believes will include information concerning the individual.

(D) Re-training required. For purposes of subparagraph (A), if, since an individual's most recent completion of a training and competency evaluation program, there has been a continuous period of 24 consecutive months during none of which the individual performed nursing or nursing-related services for monetary compensation, such individual shall complete a new training and competency evaluation program or a new competency evaluation program.

(E) Regular in-service education. The skilled nursing facility must provide such regular performance review and regular in-service education as assures that individuals used as nurse aides are competent to perform services as nurse aides, including training for individuals providing nursing and nursing-related services to residents with cognitive impairments.

(F) Nurse aide defined. In this paragraph, the term "nurse aide" means any individual providing nursing or nursing-related services to residents in a skilled nursing facility, but does not include an individual--

(i) who is a licensed health professional (as defined in subparagraph (G)) or a registered dietician, or

(ii) who volunteers to provide such services without monetary compensation.

(G) Licensed health professional defined. In this paragraph, the term "licensed health professional" means a physician, physician assistant, nurse practitioner, physical, speech, or occupational therapist, physical or occupational therapy assistant, registered professional nurse, licensed practical nurse, licensed or certified social worker, registered respiratory therapist, or certified respiratory therapy technician.

(6) Physician supervision and clinical records. A skilled nursing facility must--

(A) require that the medical care of every resident be provided under the supervision of a physician;

(B) provide for having a physician available to furnish necessary medical care in case of emergency; and

(C) maintain clinical records on all residents, which records include the plans of care (described in paragraph (2)) and the residents' assessments (described in paragraph (3)).

(7) Required social services. In the case of a skilled nursing facility with more than 120 beds, the facility must have at least one social worker (with at least a bachelor's degree in social work or similar professional qualifications) employed full-time to provide or assure the provision of social services.

(8) Information on nurse staffing.

(A) In general. A skilled nursing facility shall post daily for each shift the current number of licensed and unlicensed nursing staff directly responsible for resident care in the facility. The information shall be displayed in a uniform manner (as specified by the Secretary) and in a clearly visible place.

(B) Publication of data. A skilled nursing facility shall, upon request, make available to the public the nursing staff data described in subparagraph (A).

(c) Requirements relating to residents' rights.

(1) General rights.

(A) Specified rights. A skilled nursing facility must protect and promote the rights of each resident, including each of the following rights:

(i) Free choice. The right to choose a personal attending physician, to be fully informed in advance about care and treatment, to be fully informed in advance of any changes in care or treatment that may affect the resident's well-being, and (except with respect to a resident adjudged incompetent) to participate in planning care and treatment or changes in care and treatment.

(ii) Free from restraints. The right to be free from physical or mental abuse, corporal punishment, involuntary seclusion, and any physical or chemical restraints imposed for purposes of discipline or convenience and not required to treat the resident's medical symptoms. Restraints may only be imposed--

(I) to ensure the physical safety of the resident or other residents, and

(II) only upon the written order of a physician that specifies the duration and circumstances under which the restraints are to be used (except in emergency circumstances specified by the Secretary until such an order could reasonably be obtained).

(iii) Privacy. The right to privacy with regard to accommodations, medical treatment, written and telephonic communications, visits, and meetings of family and of resident groups.

(iv) Confidentiality. The right to confidentiality of personal and clinical records and to access to current clinical records of the resident upon request by the resident or the resident's legal representative, within 24 hours (excluding hours occurring during a weekend or holiday) after making such a request.

(v) Accommodation of needs. The right--

(I) to reside and receive services with reasonable accommodation of individual needs and preferences, except where the health or safety of the individual or other residents would be endangered, and

(II) to receive notice before the room or roommate of the resident in the facility is changed.

(vi) Grievances. The right to voice grievances with respect to treatment or care that is (or fails to be) furnished, without discrimination or reprisal for voicing the grievances and the right to prompt efforts by the facility to resolve grievances the resident may have, including those with respect to the behavior of other residents.

(vii) Participation in resident and family groups. The right of the resident to organize and participate in resident groups in the facility and the right of the resident's family to meet in the facility with the families of other residents in the facility.

(viii) Participation in other activities. The right of the resident to participate in social, religious, and community activities that do not interfere with the rights of other residents in the facility.

(ix) Examination of survey results. The right to examine, upon reasonable request, the results of the most recent survey of the facility conducted by the Secretary or a State with respect to the facility and any plan of correction in effect with respect to the facility.

(x) Refusal of certain transfers. The right to refuse a transfer to another room within the facility, if a purpose of the transfer is to relocate the resident from a portion of the facility that is a skilled nursing facility (for purposes of this *title [42 USCS §§ 1395* et seq.]) to a portion of the facility that is not such a skilled nursing facility.

(xi) Other rights. Any other right established by the Secretary.

Clause (iii) shall not be construed as requiring the provision of a private room. A resident's exercise of a right to refuse transfer under clause (x) shall not affect the resident's eligibility or entitlement to benefits under this *title [42 USCS §§ 1395* et seq.] or to medical assistance under title XIX of this Act [*42 USCS §§ 1396* et seq.].

(B) Notice of rights and services. A skilled nursing facility must--

(i) inform each resident, orally and in writing at the time of admission to the facility, of the resident's legal rights during the stay at the facility;

(ii) make available to each resident, upon reasonable request, a written statement of such rights (which statement is updated upon changes in such rights) including the notice (if any) of the State developed under section 1919(e)(6) [*42 USCS § 1396r(e)(6)*]; and

(iii) inform each other resident, in writing before or at the time of admission and periodically during the resident's stay, of services available in the facility and of related charges for such services, including any charges for services not covered under this *title [42 USCS §§ 1395* et seq.] or by the facility's basic per diem charge.

The written description of legal rights under this subparagraph shall include a description of the protection of personal funds under paragraph (6) and a statement that a resident may file a complaint with a State survey and certification agency respecting resident abuse and neglect and misappropriation of resident property in the facility.

(C) Rights of incompetent residents. In the case of a resident adjudged incompetent under the laws of a State, the rights of the resident under this *title [42 USCS §§ 1395* et seq.] shall devolve upon, and, to the extent judged necessary by a court of competent jurisdiction, be exercised by, the person appointed under State law to act on the resident's behalf.

(D) Use of psychopharmacologic drugs. Psychopharmacologic drugs may be administered only on the orders of a physician and only as part of a plan (included in the written plan of care described in paragraph (2)) designed to eliminate or modify the symptoms for which the drugs are prescribed and only if, at least annually, an independent, external consultant reviews the appropriateness of the drug plan of each resident receiving such drugs. In determining whether such a consultant is qualified to conduct reviews under the preceding sentence, the Secretary shall take into account the needs of nursing facilities under this title to have access to the services of such a consultant on a timely basis.

(E) Information respecting advance directives. A skilled nursing facility must comply with the requirement of section 1866(f) [*42 USCS § 1395cc(f)*] (relating to maintaining written policies and procedures respecting advance directives).

(2) Transfer and discharge rights.

(A) In general. A skilled nursing facility must permit each resident to remain in the facility and must not transfer or discharge the resident from the facility unless--

(i) the transfer or discharge is necessary to meet the resident's welfare and the resident's welfare cannot be met in the facility;

(ii) the transfer or discharge is appropriate because the resident's health has improved sufficiently so the resident no longer needs the services provided by the facility;

(iii) the safety of individuals in the facility is endangered;

(iv) the health of individuals in the facility would otherwise be endangered;

(v) the resident has failed, after reasonable and appropriate notice, to pay (or to have paid under this title or title XIX [*42 USCS §§ 1395* et seq. or *1396* et seq.] on the resident's behalf) for a stay at the facility; or

(vi) the facility ceases to operate.

In each of the cases described in clauses (i) through (v), the basis for the transfer or discharge must be documented in the resident's clinical record. In the cases described in clauses (i) and (ii), the documentation must be made by the resident's physician, and in the cases described in clauses (iii) and (iv) the documentation must be made by a physician.

(B) Pre-transfer and pre-discharge notice.

(i) In general. Before effecting a transfer or discharge of a resident, a skilled nursing facility must--

(I) notify the resident (and, if known, a family member of the resident or legal representative) of the transfer or discharge and the reasons therefor,

(II) record the reasons in the resident's clinical record (including any documentation required under subparagraph (A)), and

(III) include in the notice the items described in clause (iii).

(ii) Timing of notice. The notice under clause (i)(I) must be made at least 30 days in advance of the resident's transfer or discharge except--

(I) in a case described in clause (iii) or (iv) of subparagraph (A);

(II) in a case described in clause (ii) of subparagraph (A), where the resident's health improves sufficiently to allow a more immediate transfer or discharge;

(III) in a case described in clause (i) of subparagraph (A), where a more immediate transfer or discharge is necessitated by the resident's urgent medical needs; or

(IV) in a case where a resident has not resided in the facility for 30 days.

In the case of such exceptions, notice must be given as many days before the date of the transfer or discharge as is practicable.

(iii) Items included in notice. Each notice under clause (i) must include--

(I) for transfers or discharges effected on or after October 1, 1990, notice of the resident's right to appeal the transfer or discharge under the State process established under subsection (e)(3); and

(II) the name, mailing address, and telephone number of the State long-term care ombudsman (established under title III or VII of the Older Americans Act of 1965 [*42 USCS §§ 3021* et seq. or *3058* et seq.] in accordance with section 712 of the Act [*42 USCS § 3058g*]).

(C) Orientation. A skilled nursing facility must provide sufficient preparation and orientation to residents to ensure safe and orderly transfer or discharge from the facility.

(3) Access and visitation rights. A skilled nursing facility must--

(A) permit immediate access to any resident by any representative of the Secretary, by any representative of the State, by an ombudsman described in paragraph (2)(B)(iii)(II), or by the resident's individual physician;

(B) permit immediate access to a resident, subject to the resident's right to deny or withdraw consent at any time, by immediate family or other relatives of the resident;

(C) permit immediate access to a resident, subject to reasonable restrictions and the resident's right to deny or withdraw consent at any time, by others who are visiting with the consent of the resident;

(D) permit reasonable access to a resident by any entity or individual that provides health, social, legal, or other services to the resident, subject to the resident's right to deny or withdraw consent at any time; and

(E) permit representatives of the State ombudsman (described in paragraph (2)(B)(iii)(II)), with the permission of the resident (or the resident's legal representative) and consistent with State law, to examine a resident's clinical records.

(4) Equal access to quality care. A skilled nursing facility must establish and maintain identical policies and practices regarding transfer, discharge, and covered services under this title for all individuals regardless of source of payment.

(5) Admissions policy.

(A) Admissions. With respect to admissions practices, a skilled nursing facility must--

(i) (I) not require individuals applying to reside or residing in the facility to waive their rights to benefits under this *title [42 USCS §§ 1395* et seq.] or under a State plan under title XIX [*42 USCS §§ 1396* et seq.], (II) not require oral or written assurance that such individuals are not eligible for, or will not apply for, benefits under this *title [42 USCS §§ 1395* et seq.] or such a State plan, and (III) prominently display in the facility and provide to such individuals written information about how to apply for and use such benefits and how to receive refunds for previous payments covered by such benefits; and

(ii) not require a third party guarantee of payment to the facility as a condition of admission (or expedited admission) to, or continued stay in, the facility.

(B) Construction.

(i) No preemption of stricter standards. Subparagraph (A) shall not be construed as preventing States or political subdivisions therein from prohibiting, under State or local law, the discrimination against individuals who are entitled to medical assistance under this *title [42 USCS §§ 1395* et seq.] with respect to admissions practices of skilled nursing facilities.

(ii) Contracts with legal representatives. Subparagraph (A)(ii) shall not be construed as preventing a facility from requiring an individual, who has legal access to a resident's income or resources available to pay for care in the facility, to sign a contract (without incurring personal financial liability) to provide payment from the resident's income or resources for such care.

(6) Protection of resident funds.

(A) In general. The skilled nursing facility--

(i) may not require residents to deposit their personal funds with the facility, and

(ii) upon the written authorization of the resident, must hold, safeguard, and account for such personal funds under a system established and maintained by the facility in accordance with this paragraph.

(B) Management of personal funds. Upon written authorization of a resident under subparagraph (A)(ii), the facility must manage and account for the personal funds of the resident deposited with the facility as follows:

(i) Deposit. The facility must deposit any amount of personal funds in excess of $ 100 with respect to a resident in an interest bearing account (or accounts) that is separate from any of the facility's operating accounts and credits [credit] all interest earned on such separate account to such account. With respect to any other personal funds, the facility must maintain such funds in a non-interest bearing account or petty cash fund.

(ii) Accounting and records. The facility must assure a full and complete separate accounting of each such resident's personal funds, maintain a written record of all financial transactions involving the personal funds of a resident deposited with the facility, and afford the resident (or a legal representative of the resident) reasonable access to such record.

(iii) Conveyance upon death. Upon the death of a resident with such an account, the facility must convey promptly the resident's personal funds (and a final accounting of such funds) to the individual administering the resident's estate.

(C) Assurance of financial security. The facility must purchase a surety bond, or otherwise provide assurance satisfactory to the Secretary, to assure the security of all personal funds of residents deposited with the facility.

(D) Limitation on charges to personal funds. The facility may not impose a charge against the personal funds of a resident for any item or service for which payment is made under this title or title XIX [*42 USCS §§ 1395* et seq. or *1396* et seq.].

(d) Requirements relating to administration and other matters.

(1) Administration.

(A) In general. A skilled nursing facility must be administered in a manner that enables it to use its resources effectively and efficiently to attain or maintain the highest practicable physical, mental, and psychosocial well-being of each resident (consistent with requirements established under subsection (f)(5)).

(B) Required notices. If a change occurs in--

(i) the persons with an ownership or control interest (as defined in section 1124(a)(3) [*42 USCS § 1320a-3(a)(3)*]) in the facility,

(ii) the persons who are officers, directors, agents, or managing employees (as defined in section 1126(b) [*42 USCS § 1320a-5(b)*]) of the facility,

(iii) the corporation, association, or other company responsible for the management of the facility, or

(iv) the individual who is the administrator or director of nursing of the facility,

the skilled nursing facility must provide notice to the State agency responsible for the licensing of the facility, at the time of the change, of the change and of the identity of each new person, company, or individual described in the respective clause.

(C) Skilled nursing facility administrator. The administrator of a skilled nursing facility must meet standards established by the Secretary under subsection (f)(4).

(2) Licensing and Life Safety Code.

(A) Licensing. A skilled nursing facility must be licensed under applicable State and local law.

(B) Life Safety Code. A skilled nursing facility must meet such provisions of such edition (as specified by the Secretary in regulation) of the Life Safety Code of the National Fire Protection Association as are applicable to nursing homes; except that--

(i) the Secretary may waive, for such periods as he deems appropriate, specific provisions of such Code which if rigidly applied would result in unreasonable hardship upon a facility, but only if such waiver would not adversely affect the health and safety of residents or personnel, and

(ii) the provisions of such Code shall not apply in any State if the Secretary finds that in such State there is in effect a fire and safety code, imposed by State law, which adequately protects residents of and personnel in skilled nursing facilities.

(3) Sanitary and infection control and physical environment. A skilled nursing facility must--

(A) establish and maintain an infection control program designed to provide a safe, sanitary, and comfortable environment in which residents reside and to help prevent the development and transmission of disease and infection, and

(B) be designed, constructed, equipped, and maintained in a manner to protect the health and safety of residents, personnel, and the general public.

(4) Miscellaneous.

(A) Compliance with Federal, State, and local laws and professional standards. A skilled nursing facility must operate and provide services in compliance with all applicable Federal, State, and local laws and regulations (including the requirements of section 1124 [*42 USCS § 1320a-3*]) and with accepted professional standards and principles which apply to professionals providing services in such a facility.

(B) Other. A skilled nursing facility must meet such other requirements relating to the health, safety, and well-being of residents or relating to the physical facilities thereof as the Secretary may find necessary.

(e) State requirements relating to skilled nursing facility requirements. The requirements, referred to in section 1864(d) [*42 USCS § 1395aa(d)*], with respect to a State are as follows:

(1) Specification and review of nurse aide training and competency evaluation programs and of nurse aide competency evaluation programs. The State must--

(A) by not later than January 1, 1989, specify those training and competency evaluation programs, and those competency evaluation programs, that the State approves for purposes of subsection (b)(5) and that meet the requirements established under subsection (f)(2), and

(B) by not later than January 1, 1990, provide for the review and reapproval of such programs, at a frequency and using a methodology consistent with the requirements established under subsection (f)(2)(A)(iii).

The failure of the Secretary to establish requirements under subsection (f)(2) shall not relieve any State of its responsibility under this paragraph.

(2) Nurse aide registry.

(A) In general. By not later than January 1, 1989, the State shall establish and maintain a registry of all individuals who have satisfactorily completed a nurse aide training and competency evaluation program, or a nurse aide competency evaluation program, approved under paragraph (1) in the State, or any individual described in subsection (f)(2)(B)(ii) or in subparagraph (B), (C), or (D) of section 6901(b)(4) of the Omnibus Budget Reconciliation Act of 1989 [note to this section].

(B) Information in registry. The registry under subparagraph (A) shall provide (in accordance with regulations of the Secretary) for the inclusion of specific documented findings by a State under subsection (g)(1)(C) of resident neglect or abuse or misappropriation of resident property involving an individual listed in the registry, as well as any brief statement of the individual disputing the findings, but shall not include any allegations of resident abuse or neglect or misappropriation of resident property that are not specifically documented by the State under such subsection. The State shall make available to the public information in the registry. In the case of inquiries to the registry concerning an

individual listed in the registry, any information disclosed concerning such a finding shall also include disclosure of any such statement in the registry relating to the finding or a clear and accurate summary of such a statement.

(C) Prohibition against charges. A State may not impose any charges on a nurse aide relating to the registry established and maintained under subparagraph (A).

(3) State appeals process for transfers and discharges. The State, for transfers and discharges from skilled nursing facilities effected on or after October 1, 1989, must provide for a fair mechanism for hearing appeals on transfers of residents of such facilities. Such mechanism must meet the guidelines established by the Secretary under subsection (f)(3); but the failure of the Secretary to establish such guidelines shall not relieve any State of its responsibility to provide for such a fair mechanism.

(4) Skilled nursing facility administrator standards. By not later than January 1, 1990, the State must have implemented and enforced the skilled nursing facility administrator standards developed under subsection (f)(4) respecting the qualification of administrators of skilled nursing facilities.

(5) Specification of resident assessment instrument. Effective July 1, 1990, the State shall specify the instrument to be used by nursing facilities in the State in complying with the requirement of subsection (b)(3)(A)(iii). Such instrument shall be--

(A) one of the instruments designated under subsection (f)(6)(B), or

(B) an instrument which the Secretary has approved as being consistent with the minimum data set of core elements, common definitions, and utilization guidelines specified by the Secretary under subsection (f)(6)(A).

(f) Responsibilities of Secretary relating to skilled nursing facility requirements.

(1) General responsibility. It is the duty and responsibility of the Secretary to assure that requirements which govern the provision of care in skilled nursing facilities under this *title [42 USCS §§ 1395* et seq.], and the enforcement of such requirements, are adequate to protect the health, safety, welfare, and rights of residents and to promote the effective and efficient use of public moneys.

(2) Requirements for nurse aide training and competency evaluation programs and for nurse aide competency evaluation of programs.

(A) In general. For purposes of subsections (b)(5) and (e)(1)(A), the Secretary shall establish, by not later than September 1, 1988--

(i) requirements for the approval of nurse aide training and competency evaluation programs, including requirements relating to (I) the areas to be covered in such a program (including at least basic nursing skills, personal care skills, recognition of mental health and social service needs, care of cognitively impaired residents, basic restorative services, and residents' rights) and content of the curriculum, (II) minimum hours of initial and ongoing training and retraining (including not less than 75 hours in the case of initial training), (III) qualifications of instructors, and (IV) procedures for determination of competency;

(ii) requirements for the approval of nurse aide competency evaluation programs, including requirement relating to the areas to be covered in such a program, including at least basic nursing skills, personal care skills, recognition of mental health and social service needs, care of cognitively impaired residents, basic restorative services, residents' rights, and procedures for determination of competency;

(iii) requirements respecting the minimum frequency and methodology to be used by a State in reviewing such programs compliance with the requirements for such programs; and

(iv) requirements, under both such programs, that--

(I) provide procedures for determining competency that permit a nurse aide, at the nurse aide's option, to establish competency through procedures or methods other than the passing of a written examination and to have the competency evaluation conducted at the nursing facility at which the aide is (or will be) employed (unless the facility is described in subparagraph (B)(iii)(I)),

(II) prohibit the imposition on a nurse aide who is employed by (or who has received an offer of employment from) a facility on the date on which the aide begins either such program of any charges (including any charges for textbooks and other required course materials and any charges for the competency evaluation) for either such program, and

(III) in the case of a nurse aide not described in subclause (II) who is employed by (or who has received an offer of employment from) a facility not later than 12 months after completing either such program, the State shall provide for the reimbursement of costs incurred in completing such program on a prorata [pro rata] basis during the period in which the nurse aide is so employed.

(B) Approval of certain programs. Such requirements--

(i) may permit approval of programs offered by or in facilities (subject to clause (iii)), as well as outside facilities (including employee organizations), and of programs in effect on the date of the enactment of this section [enacted Dec. 22, 1987];

(ii) shall permit a State to find that an individual who has completed (before July 1, 1989) a nurse aide training and competency evaluation program shall be deemed to have completed such a program approved under subsection (b)(5) if the State determines that, at the time the program was offered, the program met the requirements for approval under such paragraph; and

(iii) subject to subparagraphs (C) and (D), shall prohibit approval of such a program--

(I) offered by or in a skilled nursing facility which, within the previous 2 years--

(a) has operated under a waiver under subsection (b)(4)(C)(ii)(II);

(b) has been subject to an extended (or partial extended) survey under subsection (g)(2)(B)(i) or section 1919(g)(2)(B)(i) [*42 USCS § 1396r(g)(2)(B)(i)*], unless the survey shows that the facility is in compliance with the requirements of subsections (b), (c), and (d) of this section; or

(c) has been assessed a civil money penalty described in subsection (h)(2)(B)(ii) or section 1919(h)(2)(A)(ii) [*42 USCS § 1396r(h)(2)(A)(ii)*] of not less than $ 5,000, or has been subject to a remedy described in clause (i) or (iii) of subsection (h)(2)(B), subsection (h)(4), section 1919(h)(1)(B)(i) [*42 USCS § 1396r(h)(1)(B)(i)*], or in clause (i), (iii), or (iv) of section 1919(h)(2)(A) [*42 USCS § 1396r(h)(2)(A)(i)*, (iii), or (iv)], or

(II) offered by or in a skilled nursing facility unless the State makes the determination, upon an individual's completion of the program, that the individual is competent to provide nursing and nursing-related services in skilled nursing facilities.

A State may not delegate (through subcontract or otherwise) its responsibility under clause (iii)(II) to the skilled nursing facility.

(C) Waiver authorized. Clause (iii)(I) of subparagraph (B) shall not apply to a program offered in (but not by) a nursing facility (or skilled nursing facility for purposes of title XVIII [*42 USCS §§ 1395* et seq.]) in a State if the State--

(i) determines that there is no other such program offered within a reasonable distance of the facility,

(ii) assures, through an oversight effort, that an adequate environment exists for operating the program in the facility, and

(iii) provides notice of such determination and assurances to the State long-term care ombudsman.

(D) Waiver of disapproval of nurse-aide training programs. Upon application of a nursing facility, the Secretary may waive the application of subparagraph (B)(iii)(I)(c) if the imposition of the civil monetary penalty was not related to the quality of care provided to residents of the facility. Nothing in this subparagraph shall be construed as eliminating any requirement upon a facility to pay a civil monetary penalty described in the preceding sentence.

(3) Federal guidelines for State appeals process for transfers and discharges. For purposes of subsections (c)(2)(B)(iii)(I) and (e)(3), by not later than October 1, 1988, the Secretary shall establish guidelines for minimum standards which State appeals processes under subsection (e)(3) must meet to provide a fair mechanism for hearing appeals on transfers and discharges of residents from skilled nursing facilities.

(4) Secretarial standards for qualification of administrators. For purposes of subsections (d)(1)(C) and (e)(4), the Secretary shall develop, by not later than March 1, 1989, standards to be applied in assuring the qualifications of administrators of skilled nursing facilities.

(5) Criteria for administration. The Secretary shall establish criteria for assessing a skilled nursing facility's compliance with the requirement of subsection (d)(1) with respect to--

(A) its governing body and management,

(B) agreements with hospitals regarding transfers of residents to and from the hospitals and to and from other skilled nursing facilities,

(C) disaster preparedness,

(D) direction of medical care by a physician,

(E) laboratory and radiological services,

(F) clinical records, and

(G) resident and advocate participation.

(6) Specification of resident assessment data set and instruments. The Secretary shall--

(A) not later than January 1, 1989, specify a minimum data set of core elements and common definitions for use by nursing facilities in conducting the assessments required under subsection (b)(3), and establish guidelines for utilization of the data set; and

(B) by not later than April 1, 1990, designate one or more instruments which are consistent with the specification made under subparagraph (A) and which a State may specify under subsection (e)(5)(A) for use by nursing facilities in complying with the requirements of subsection (b)(3)(A)(iii).

(7) List of items and services furnished in skilled nursing facilities not chargeable to the personal funds of a resident.

(A) Regulations required. Pursuant to the requirement of section 21(b) of the Medicare-Medicaid Anti-Fraud and Abuse Amendments of 1977 [*42 USCS § 1395x* note], the Secretary shall issue regulations, on or before the first day of the seventh month to begin after the date of enactment of this section [enacted Dec. 22, 1987], that define those costs

which may be charged to the personal funds of residents in skilled nursing facilities who are individuals receiving benefits under this part [*42 USCS §§ 1395c* et seq.] and those costs which are to be included in the reasonable cost (or other payment amount) under this *title [42 USCS §§ 1395* et seq.] for extended care services.

(B) Rule if failure to publish regulations. If the Secretary does not issue the regulations under subparagraph (A) on or before the date required in such subparagraph, in the case of a resident of a skilled nursing facility who is eligible to receive benefits under this part [*42 USCS §§ 1395c* et seq.], the costs which may not be charged to the personal funds of such resident (and for which payment is considered to be made under this *title [42 USCS §§ 1395* et seq.]) shall include, at a minimum, the costs for routine personal hygiene items and services furnished by the facility.

(g) Survey and certification process.

(1) State and Federal responsibility.

(A) In general. Pursuant to an agreement under section 1864 [*42 USCS § 1395aa*], each State shall be responsible for certifying, in accordance with surveys conducted under paragraph (2), the compliance of skilled nursing facilities (other than facilities of the State) with the requirements of subsections (b), (c), and (d). The Secretary shall be responsible for certifying, in accordance with surveys conducted under paragraph (2), the compliance of State skilled nursing facilities with the requirements of such subsections.

(B) Educational program. Each State shall conduct periodic educational programs for the staff and residents (and their representatives) of skilled nursing facilities in order to present current regulations, procedures, and policies under this section.

(C) Investigation of allegations of resident neglect and abuse and misappropriation of resident property. The State shall provide, through the agency responsible for surveys and certification of nursing facilities under this subsection, for a process for the receipt and timely review and investigation of allegations of neglect and abuse and misappropriation of resident property by a nurse aide of a resident in a nursing facility of by another individual used by the facility in providing services to such a resident. The State shall, after providing the individual involved with a written notice of the allegations (including a statement of the availability of a hearing for the individual to rebut the allegations) and the opportunity for a hearing on the record, make a written finding as to the accuracy of the allegations. If the State finds that a nurse aide has neglected or abused a resident or misappropriated resident property in a facility, the State shall notify the nurse aide and the registry of such finding. If the State finds that any other individual used by the facility has neglected or abused a resident or misappropriated resident property in a facility, the State shall notify the appropriate licensure authority. A State shall not make a finding that an individual has neglected a resident if the individual demonstrates that such neglect was caused by factors beyond the control of the individual.

(D) Removal of name from nurse aide registry.

(i) In general. In the case of a finding of neglect under subparagraph (C), the State shall establish a procedure to permit a nurse aide to petition the State to have his or her name removed from the registry upon a determination by the State that--

(I) the employment and personal history of the nurse aide does not reflect a pattern of abusive behavior or neglect; and

(II) the neglect involved in the original finding was a singular occurrence.

(ii) Timing of determination. In no case shall a determination on a petition submitted under clause (i) be made prior to the expiration of the 1-year period beginning on the date on which the name of the petitioner was added to the registry under subparagraph (C).

(E) Construction. The failure of the Secretary to issue regulations to carry out this subsection shall not relieve a State of its responsibility under this subsection.

(2) Surveys.

(A) Standard survey.

(i) In general. Each skilled nursing facility shall be subject to a standard survey, to be conducted without any prior notice to the facility. Any individual who notifies (or causes to be notified) a skilled nursing facility of the time or date on which such a survey is scheduled to be conducted is subject to a civil money penalty of not to exceed $ 2,000. The provisions of section 1128A [*42 USCS § 1320a-7a*] (other than subsections (a) and (b)) shall apply to a civil money penalty under the previous sentence in the same manner as such provisions apply to a penalty or proceeding under section 1128A(a) [*42 USCS § 1320a-7a(a)*]. The Secretary shall review each State's procedures for the scheduling and conduct of standard surveys to assure that the State has taken all reasonable steps to avoid giving notice of such a survey through the scheduling procedures and the conduct of the surveys themselves.

(ii) Contents. Each standard survey shall include, for a case-mix stratified sample of residents--

(I) a survey of the quality of care furnished, as measured by indicators of medical, nursing, and rehabilitative care, dietary and nutrition services, activities and social participation, and sanitation, infection control, and the physical environment,

(II) written plans of care provided under subsection (b)(2) and an audit of the residents' assessments under subsection (b)(3) to determine the accuracy of such assessments and the adequacy of such plans of care, and

(III) a review of compliance with residents' rights under subsection (c).

(iii) Frequency.

(I) In general. Each skilled nursing facility shall be subject to a standard survey not later than 15 months after the date of the previous standard survey conducted under this subparagraph. The Statewide average interval between standard surveys of skilled nursing facilities under this subsection shall not exceed 12 months.

(II) Special surveys. If not otherwise conducted under subclause (I), a standard survey (or an abbreviated standard survey) may be conducted within 2 months of any change of ownership, administration, management of a skilled nursing facility, or the director of nursing in order to determine whether the change has resulted in any decline in the quality of care furnished in the facility.

(B) Extended surveys.

(i) In general. Each skilled nursing facility which is found, under a standard survey, to have provided substandard quality of care shall be subject to an extended survey. Any other facility may, at the Secretary's or State's discretion, be subject to such an extended survey (or a partial extended survey).

(ii) Timing. The extended survey shall be conducted immediately after the standard survey (or, if not practicable, not later than 2 weeks after the date of completion of the standard survey).

(iii) Contents. In such an extended survey, the survey team shall review and identify the policies and procedures which produced such substandard quality of care and shall determine whether the facility has complied with all the requirements described in subsections (b), (c), and (d). Such review shall include an expansion of the size of the sample of residents' assessments reviewed and a review of the staffing, of in-service training, and, if appropriate, of contracts with consultants.

(iv) Construction. Nothing in this paragraph shall be construed as requiring an extended or partial extended survey as a prerequisite to imposing a sanction against a facility under subsection (h) on the basis of findings in a standard survey.

(C) Survey protocol. Standard and extended surveys shall be conducted--

(i) based upon a protocol which the Secretary has developed, tested, and validated by not later than January 1, 1990, and

(ii) by individuals, of a survey team, who meet such minimum qualifications as the Secretary establishes by not later than such date.

The failure of the Secretary to develop, test, or validate such protocols or to establish such minimum qualifications shall not relieve any State of its responsibility (or the Secretary of the Secretary's responsibility) to conduct surveys under this subsection.

(D) Consistency of surveys. Each State and the Secretary shall implement programs to measure and reduce inconsistency in the application of survey results among surveyors.

(E) Survey teams.

(i) In general. Surveys under this subsection shall be conducted by a multidisciplinary team of professionals (including a registered professional nurse).

(ii) Prohibition of conflicts of interest. A State may not use as a member of a survey team under this subsection an individual who is serving (or has served within the previous 2 years) as a member of the staff of, or as a consultant to, the facility surveyed respecting compliance with the requirements of subsections (b), (c), and (d), or who has a personal or familial financial interest in the facility being surveyed.

(iii) Training. The Secretary shall provide for the comprehensive training of State and Federal surveyors in the conduct of standard and extended surveys under this subsection, including the auditing of resident assessments and plans of care. No individual shall serve as a member of a survey team unless the individual has successfully completed a training and testing program in survey and certification techniques that has been approved by the Secretary.

(3) Validation surveys.

(A) In general. The Secretary shall conduct onsite surveys of a representative sample of skilled nursing facilities in each State, within 2 months of the date of surveys conducted under paragraph (2) by the State, in a sufficient number to allow inferences about the adequacies of each State's surveys conducted under paragraph (2). In conducting such surveys, the Secretary shall use the same survey protocols as the State is required to use under paragraph (2). If the State has determined that an individual skilled nursing facility meets the requirements of subsections (b), (c), and (d), but the Secretary determines that the facility does not meet such requirements, the Secretary's determination as to the facility's noncompliance with such requirements is binding and supersedes that of the State survey.

(B) Scope. With respect to each State, the Secretary shall conduct surveys under subparagraph (A) each year with respect to at least 5 percent of the number of skilled nursing facilities surveyed by the State in the year, but in no case less than 5 skilled nursing facilities in the State.

(C) Remedies for substandard performance. If the Secretary finds, on the basis of such surveys, that a State has failed to perform surveys as required under paragraph (2) or that a State's survey and certification performance otherwise is not adequate, the Secretary shall provide for an appropriate remedy, which may include the training of survey teams in the State.

(D) Special surveys of compliance. Where the Secretary has reason to question the compliance of a skilled nursing facility with any of the requirements of subsections (b), (c), and (d), the Secretary may conduct a survey of the facility and, on the basis of that survey, make independent and binding determinations concerning the extent to which the skilled nursing facility meets such requirements.

(4) Investigation of complaints and monitoring compliance. Each State shall maintain procedures and adequate staff to--

(A) investigate complaints of violations of requirements by skilled nursing facilities, and

(B) monitor, on-site, on a regular, as needed basis, a skilled nursing facility's compliance with the requirements of subsections (b), (c), and (d), if--

(i) the facility has been found not to be in compliance with such requirements and is in the process of correcting deficiencies to achieve such compliance;

(ii) the facility was previously found not to be in compliance with such requirements, has corrected deficiencies to achieve such compliance, and verification of continued compliance is indicated; or

(iii) the State has reason to question the compliance of the facility with such requirements.

A State may maintain and utilize a specialized team (including an attorney, an auditor, and appropriate health care professionals) for the purpose of identifying, surveying, gathering and preserving evidence, and carrying out appropriate enforcement actions against substandard skilled nursing facilities.

(5) Disclosure of results of inspections and activities.

(A) Public information. Each State, and the Secretary, shall make available to the public--

(i) information respecting all surveys and certifications made respecting skilled nursing facilities, including statements of deficiencies, within 14 calendar days after such information is made available to those facilities, and approved plans of correction,

(ii) copies of cost reports of such facilities filed under this *title [42 USCS §§ 1395* et seq.] or title XIX [*42 USCS §§ 1396* et seq.],

(iii) copies of statements of ownership under section 1124 [*42 USCS § 1320a-3*], and

(iv) information disclosed under section 1126 [*42 USCS § 1320a-5*].

(B) Notice to ombudsman. Each State shall notify the State long-term care ombudsman (established under title III or VII of the Older Americans Act of 1965 [*42 USCS §§ 3021* et seq. or *3058* et seq.] in accordance with section 712 of the Act [*42 USCS § 3058g*]) of the State's findings of noncompliance with any of the requirements of subsections (b), (c), and (d), or of any adverse action taken against a skilled nursing facility under paragraph (1), (2), or (4) of subsection (h), with respect to a skilled nursing facility in the State.

(C) Notice to physicians and skilled nursing facility administrator licensing board. If a State finds that a skilled nursing facility has provided substandard quality of care, the State shall notify--

(i) the attending physician of each resident with respect to which such finding is made, and

(ii) the State board responsible for the licensing of the skilled nursing facility administrator at the facility.

(D) Access to fraud control units. Each State shall provide its State medicaid fraud and abuse control unit (established under section 1903(q) [*42 USCS § 1396b(q)*]) with access to all information of the State agency responsible for surveys and certifications under this subsection.

(h) Enforcement process.

(1) In general. If a State finds, on the basis of a standard, extended, or partial extended survey under subsection (g)(2) or otherwise, that a skilled nursing facility no longer meets a requirement of subsection (b), (c), or (d), and further finds that the facility's deficiencies--

(A) immediately jeopardize the health or safety of its residents, the State shall recommend to the Secretary that the Secretary take such action as described in paragraph (2)(A)(i); or

(B) do not immediately jeopardize the health or safety of its residents, the State may recommend to the Secretary that the Secretary take such action as described in paragraph (2)(A)(ii).

If a State finds that a skilled nursing facility meets the requirements of subsections (b), (c), and (d), but, as of a previous period, did not meet such requirements, the State may recommend a civil money penalty under paragraph (2)(B)(ii) for the days in which it finds that the facility was not in compliance with such requirements.

(2) Secretarial authority.

(A) In general. With respect to any skilled nursing facility in a State, if the Secretary finds, or pursuant to a recommendation of the State under paragraph (1) finds, that a skilled nursing facility no longer meets a requirement of subsection (b), (c), (d), or (e), and further finds that the facility's deficiencies--

(i) immediately jeopardize the health or safety of its residents, the Secretary shall take immediate action to remove the jeopardy and correct the deficiencies through the remedy specified in subparagraph (B)(iii), or terminate the facility's participation under this *title [42 USCS §§ 1395* et seq.] and may provide, in addition, for one or more of the other remedies described in subparagraph (B); or

(ii) do not immediately jeopardize the health or safety of its residents, the Secretary may impose any of the remedies described in subparagraph (B).

Nothing in this subparagraph shall be construed as restricting the remedies available to the Secretary to remedy a skilled nursing facility's deficiencies. If the Secretary finds, or pursuant to the recommendation of the State under paragraph (1) finds, that a skilled nursing facility meets such requirements but, as of a previous period, did not meet such requirements, the Secretary may provide for a civil money penalty under subparagraph (B)(ii) for the days on which he finds that the facility was not in compliance with such requirements.

(B) Specified remedies. The Secretary may take the following actions with respect to a finding that a facility has not met an applicable requirement:

(i) Denial of payment. The Secretary may deny any further payments under this *title [42 USCS §§ 1395* et seq.] with respect to all individuals entitled to benefits under this *title [42 USCS §§ 1395* et seq.] in the facility or with respect to such individuals admitted to the facility after the effective date of the finding.

(ii) Authority with respect to civil money penalties. The Secretary may impose a civil money penalty in an amount not to exceed $ 10,000 for each day of noncompliance. The provisions of section 1128A [*42 USCS § 1320a-7a*] (other than subsections (a) and (b)) shall apply to a civil money penalty under the previous sentence in the same manner as such provisions apply to a penalty or proceeding under section 1128A(a) [*42 USCS § 1320a-7a(a)*].

(iii) Appointment of temporary management. In consultation with the State, the Secretary may appoint temporary management to oversee the operation of the facility and to assure the health and safety of the facility's residents, where there is a need for temporary management while--

(I) there is an orderly closure of the facility, or

(II) improvements are made in order to bring the facility into compliance with all the requirements of subsections (b), (c), and (d).

The temporary management under this clause shall not be terminated under subclause (II) until the Secretary has determined that the facility has the management capability to ensure continued compliance with all the requirements of subsections (b), (c), and (d).

The Secretary shall specify criteria, as to when and how each of such remedies is to be applied, the amounts of any fines, and the severity of each of these remedies, to be used in the imposition of such remedies. Such criteria shall be designed so as to minimize the time between the identification of violations and final imposition of the remedies and shall provide for the imposition of incrementally more severe fines for repeated or uncorrected deficiencies. In addition, the Secretary may provide for other specified remedies, such as directed plans of correction.

(C) Continuation of payments pending remediation. The Secretary may continue payments, over a period of not longer than 6 months after the effective date of the findings, under this *title [42 USCS §§ 1395* et seq.] with respect to a skilled nursing facility not in compliance with a requirement of subsection (b), (c), or (d), if--

(i) the State survey agency finds that it is more appropriate to take alternative action to assure compliance of the facility with the requirements than to terminate the certification of the facility,

(ii) the State has submitted a plan and timetable for corrective action to the Secretary for approval and the Secretary approves the plan of corrective action, and

(iii) the facility agrees to repay to the Federal Government payments received under this subparagraph if the corrective action is not taken in accordance with the approved plan and timetable.

The Secretary shall establish guidelines for approval of corrective actions requested by States under this subparagraph.

(D) Assuring prompt compliance. If a skilled nursing facility has not complied with any of the requirements of subsections (b), (c), and (d), within 3 months after the date the facility is found to be out of compliance with such requirements, the Secretary shall impose the remedy described in subparagraph (B)(i) for all individuals who are admitted to the facility after such date.

(E) Repeated noncompliance. In the case of a skilled nursing facility which, on 3 consecutive standard surveys conducted under subsection (g)(2), has been found to have provided substandard quality of care, the Secretary shall (regardless of what other remedies are provided)--

(i) impose the remedy described in subparagraph (B)(i), and

(ii) monitor the facility under subsection (g)(4)(B),

until the facility has demonstrated, to the satisfaction of the Secretary, that it is in compliance with the requirements of subsections (b), (c), and (d), and that it will remain in compliance with such requirements.

(3) Effective period of denial of payment. A finding to deny payment under this subsection shall terminate when the Secretary finds that the facility is in substantial compliance with all the requirements of subsections (b), (c), and (d).

(4) Immediate termination of participation for facility where Secretary finds noncompliance and immediate jeopardy. If the Secretary finds that a skilled nursing facility has not met a requirement of subsection (b), (c), or (d), and finds that the failure immediately jeopardizes the health or safety of its residents, the Secretary shall take immediate action to remove the jeopardy and correct the deficiencies through the remedy specified in paragraph (2)(B)(iii), or the Secretary shall terminate the facility's participation under this *title [42 USCS §§ 1395* et seq.]. If the facility's participation under this *title [42 USCS §§ 1395* et seq.] is terminated, the State shall provide for the safe and orderly transfer of the residents eligible under this *title [42 USCS §§ 1395* et seq.] consistent with the requirements of subsection (c)(2).

(5) Construction. The remedies provided under this subsection are in addition to those otherwise available under State or Federal law and shall not be construed as limiting such other remedies, including any remedy available to an individual at common law. The remedies described in clauses (i), and (iii) of paragraph (2)(B) may be imposed during the pendency of any hearing.

(6) Sharing of information. Notwithstanding any other provision of law, all information concerning skilled nursing facilities required by this section to be filed with the Secretary or a State agency shall be made available by such facilities to Federal or State employees for purposes consistent with the effective administration of programs established under this title and title XIX [*42 USCS §§ 1395* et seq. and *1396* et seq.], including investigations by State medicaid fraud control units.

(i) Construction. Where requirements or obligations under this section are identical to those provided under section 1919 of this Act [*42 USCS § 1396r*], the fulfillment of those requirements or obligations under section 1919 [*42 USCS § 1396r*] shall be considered to be the fulfillment of the corresponding requirements or obligations under this section.

HISTORY:

(Aug. 14, 1935, ch 531, Title XVIII, Part A, § 1819, as added and amended Dec. 22, 1987, P.L. 100-203, Title IV, Subtitle C, Part 1, §§ 4201(a)(3), 4202(a)(2), 4203(a)(2), 4206, 101 Stat. 1330-160, 1330-175, 1330-179, 1330-182; July 1, 1988, P.L. 100-360, Title IV, Subtitle B, § 411(l)(1)(A), (2)(A)-(D), (F)-(K), (L)(i), (4), (5), (7), 102 Stat. 800-805; Oct. 13, 1988, P.L. 100-485, Title VI, § 608(d)(27)(A), (C), (I), (L), 102 Stat. 2422, 2423; Dec. 19, 1989, P.L. 101-239, Title VI, Subtitle F, § 6901(b)(1), (3), (d)(4), 103 Stat. 2298, 2301; Nov. 5, 1990, P.L. 101-508, Title IV, Subtitle A, Part 1, § 4008(h)(1)(B)-(F)(i), (G), (2)(B)-(N), (m)(3)(F), Part 3, § 4206(d)(1), 104 Stat. 1388-46, 1388-116; Sept. 30, 1992, P.L. 102-375, Title VII, § 708(a)(1)(A), 106 Stat. 1292; Oct. 31, 1994, P.L. 103-432, Title I, Subtitle A, § 106(c)(1)(A), (2)(A), (3)(A), (4)(A), (B), (d)(1)-(5), 110(b), 108 Stat. 4405-4407, 4408; May 15, 1997, P.L. 105-15, § 1, 111 Stat. 34; Aug. 5, 1997, P.L. 105-33, Title IV, Subtitle E, Ch 3, § 4432(b)(5)(A), Subtitle H, Ch 6, § 4755(a), 111 Stat. 421, 526; Dec. 21, 2000, P.L. 106-554, § 1(a)(6), 114 Stat. 2763; Dec. 8, 2003, P.L. 108-173, Title VII, Subtitle D, § 736(a)(8), Title IX, Subtitle D, § 932(c)(2), 117 Stat. 2355, 2401.)

§ 1395i-4. Medicare rural hospital flexibility program

(a) Establishment. Any State that submits an application in accordance with subsection (b) may establish a medicare rural hospital flexibility program described in subsection (c).

(b) Application. A State may establish a medicare rural hospital flexibility program described in subsection (c) if the State submits to the Secretary at such time and in such form as the Secretary may require an application containing--

(1) assurances that the State--

(A) has developed, or is in the process of developing, a State rural health care plan that--

(i) provides for the creation of 1 or more rural health networks (as defined in subsection (d)) in the State;

(ii) promotes regionalization of rural health services in the State; and

(iii) improves access to hospital and other health services for rural residents of the State; and

(B) has developed the rural health care plan described in subparagraph (A) in consultation with the hospital association of the State, rural hospitals located in the State, and the State Office of Rural Health (or, in the case of a State in the process of developing such plan, that assures the Secretary that the State will consult with its State hospital association, rural hospitals located in the State, and the State Office of Rural Health in developing such plan);

(2) assurances that the State has designated (consistent with the rural health care plan described in paragraph (1)(A)), or is in the process of so designating, rural nonprofit or public hospitals or facilities located in the State as critical access hospitals; and

(3) such other information and assurances as the Secretary may require.

(c) Medicare rural hospital flexibility program described.

(1) In general. A State that has submitted an application in accordance with subsection (b), may establish a medicare rural hospital flexibility program that provides that--

(A) the State shall develop at least 1 rural health network (as defined in subsection (d)) in the State; and

(B) at least 1 facility in the State shall be designated as a critical access hospital in accordance with paragraph (2).

(2) State designation of facilities.

(A) In general. A State may designate 1 or more facilities as a critical access hospital in accordance with subparagraphs (B), (C), and (D).

(B) Criteria for designation as critical access hospital. A State may designate a facility as a critical access hospital if the facility--

(i) is a hospital that is located in a county (or equivalent unit of local government) in a rural area (as defined in section 1886(d)(2)(D) [*42 USCS § 1395ww(d)(2)(D)*]) or is treated as being located in a rural area pursuant to section 1886(d)(8)(E) [*42 USCS § 1395ww(d)(8)(E)*], and that--

(I) is located more than a 35-mile drive (or, in the case of mountainous terrain or in areas with only secondary roads available, a 15-mile drive) from a hospital, or another facility described in this subsection; or

(II) is certified before January 1, 2006, by the State as being a necessary provider of health care services to residents in the area;

(ii) makes available 24-hour emergency care services that a State determines are necessary for ensuring access to emergency care services in each area served by a critical access hospital;

(iii) provides not more than 25 acute care inpatient beds (meeting such standards as the Secretary may establish) for providing inpatient care for a period that does not exceed, as determined on an annual, average basis, 96 hours per patient;

(iv) meets such staffing requirements as would apply under section 1861(e) [*42 USCS § 1395x(e)*] to a hospital located in a rural area, except that--

(I) the facility need not meet hospital standards relating to the number of hours during a day, or days during a week, in which the facility must be open and fully staffed, except insofar as the facility is required to make available emergency care services as determined under clause (ii) and must have nursing services available on a 24-hour basis, but need not otherwise staff the facility except when an inpatient is present;

(II) the facility may provide any services otherwise required to be provided by a full-time, on site dietitian, pharmacist, laboratory technician, medical technologist, and radiological technologist on a part-time, off site basis under arrangements as defined in section 1861(w)(1) [*42 USCS § 1395x(w)(1)*]; and

(III) the inpatient care described in clause (iii) may be provided by a physician assistant, nurse practitioner, or clinical nurse specialist subject to the oversight of a physician who need not be present in the facility; and

(v) meets the requirements of section 1861(aa)(2)(I) [*42 USCS § 1395x(aa)(2)(I)*].

(C) Recently closed facilities. A State may designate a facility as a critical access hospital if the facility--

(i) was a hospital that ceased operations on or after the date that is 10 years before the date of the enactment of this subparagraph [enacted Nov. 29, 1999]; and

(ii) as of the effective date of such designation, meets the criteria for designation under subparagraph (B).

(D) Downsized facilities. A State may designate a health clinic or a health center (as defined by the State) as a critical access hospital if such clinic or center--

(i) is licensed by the State as a health clinic or a health center;

(ii) was a hospital that was downsized to a health clinic or health center; and

(iii) as of the effective date of such designation, meets the criteria for designation under subparagraph (B).

(E) Authority to establish psychiatric and rehabilitation distinct part units.

(i) In general. Subject to the succeeding provisions of this subparagraph, a critical access hospital may establish--

(I) a psychiatric unit of the hospital that is a distinct part of the hospital; and

(II) a rehabilitation unit of the hospital that is a distinct part of the hospital,

if the distinct part meets the requirements (including conditions of participation) that would otherwise apply to the distinct part if the distinct part were established by a subsection (d) hospital in accordance with the matter following clause (v) of section 1886(d)(1)(B) [*42 USCS § 1395ww(d)(1)(B)*], including any regulations adopted by the Secretary under such section.

(ii) Limitation on number of beds. The total number of beds that may be established under clause (i) for a distinct part unit may not exceed 10.

(iii) Exclusion of beds from bed count. In determining the number of beds of a critical access hospital for purposes of applying the bed limitations referred to in subparagraph (B)(iii) and subsection (f), the Secretary shall not take into account any bed established under clause (i).

(iv) Effect of failure to meet requirements. If a psychiatric or rehabilitation unit established under clause (i) does not meet the requirements described in such clause with respect to a cost reporting period, no payment may be made under this title to the hospital for services furnished in such unit during such period. Payment to the hospital for services furnished in the unit may resume only after the hospital has demonstrated to the Secretary that the unit meets such requirements.

(d) "Rural health network" defined.

(1) In general. In this section, the term "rural health network" means, with respect to a State, an organization consisting of--

(A) at least 1 facility that the State has designated or plans to designate as a critical access hospital; and

(B) at least 1 hospital that furnishes acute care services.

(2) Agreements.

(A) In general. Each critical access hospital that is a member of a rural health network shall have an agreement with respect to each item described in subparagraph (B) with at least 1 hospital that is a member of the network.

(B) Items described. The items described in this subparagraph are the following:

(i) Patient referral and transfer.

(ii) The development and use of communications systems including (where feasible)--

(I) telemetry systems; and

(II) systems for electronic sharing of patient data.

(iii) The provision of emergency and non-emergency transportation among the facility and the hospital.

(C) Credentialing and quality assurance. Each critical access hospital that is a member of a rural health network shall have an agreement with respect to credentialing and quality assurance with at least--

(i) 1 hospital that is a member of the network;

(ii) 1 peer review organization or equivalent entity; or

(iii) 1 other appropriate and qualified entity identified in the State rural health care plan.

(e) Certification by the Secretary. The Secretary shall certify a facility as a critical access hospital if the facility--

(1) is located in a State that has established a medicare rural hospital flexibility program in accordance with subsection (c);

(2) is designated as a critical access hospital by the State in which it is located; and

(3) meets such other criteria as the Secretary may require.

(f) Permitting maintenance of swing beds. Nothing in this section shall be construed to prohibit a State from designating or the Secretary from certifying a facility as a critical access hospital solely because, at the time the facility applies to the State for designation as a critical access hospital, there is in effect an agreement between the facility and the Secretary under section 1883 [*42 USCS § 1395tt*] under which the facility's inpatient hospital facilities are used for the provision of extended care services, so long as the total number of beds that may be used at any time for the furnishing of either such services or acute care inpatient services does not exceed 25 beds. For purposes of the previous sentence, any bed of a unit of the facility that is licensed as a distinct-part skilled nursing facility at the time the facility applies to the State for designation as a critical access hospital shall not be counted.

(g) Grants.

(1) Medicare rural hospital flexibility program. The Secretary may award grants to States that have submitted applications in accordance with subsection (b) for--

(A) engaging in activities relating to planning and implementing a rural health care plan;

(B) engaging in activities relating to planning and implementing rural health networks;

(C) designating facilities as critical access hospitals; and

(D) providing support for critical access hospitals for quality improvement, quality reporting, performance improvements, and benchmarking.

(2) Rural emergency medical services.

(A) In general. The Secretary may award grants to States that have submitted applications in accordance with subparagraph (B) for the establishment or expansion of a program for the provision of rural emergency medical services.

(B) Application. An application is in accordance with this subparagraph if the State submits to the Secretary at such time and in such form as the Secretary may require an application containing the assurances described in subparagraphs (A)(ii), (A)(iii), and (B) of subsection (b)(1) and paragraph (3) of that subsection.

(3) Upgrading data systems.

(A) Grants to hospitals. The Secretary may award grants to hospitals that have submitted applications in accordance with subparagraph (C) to assist eligible small rural hospitals in meeting the costs of implementing data systems required to meet requirements established under the medicare program pursuant to amendments made by the Balanced Budget Act of 1997.

(B) Eligible small rural hospital defined. For purposes of this paragraph, the term "eligible small rural hospital" means a non-Federal, short-term general acute care hospital that--

(i) is located in a rural area (as defined for purposes of section 1886(d) [*42 USCS § 1395ww(d)*]); and

(ii) has less than 50 beds.

(C) Application. A hospital seeking a grant under this paragraph shall submit an application to the Secretary on or before such date and in such form and manner as the Secretary specifies.

(D) Amount of grant. A grant to a hospital under this paragraph may not exceed $ 50,000.

(E) Use of funds. A hospital receiving a grant under this paragraph may use the funds for the purchase of computer software and hardware, the education and training of hospital staff on computer information systems, and to offset costs related to the implementation of prospective payment systems.

(F) Reports.

(i) Information. A hospital receiving a grant under this section shall furnish the Secretary with such information as the Secretary may require to evaluate the project for which the grant is made and to ensure that the grant is expended for the purposes for which it is made.

(ii) Timing of submission.

(I) Interim reports. The Secretary shall report to the Committee on Ways and Means of the House of Representatives and the Committee on Finance of the Senate at least annually on the grant program established under this section, including in such report information on the number of grants made, the nature of the projects involved, the geographic distribution of grant recipients, and such other matters as the Secretary deems appropriate.

(II) Final report. The Secretary shall submit a final report to such committees not later than 180 days after the completion of all of the projects for which a grant is made under this section.

(4) Additional requirements with respect to flex grants. With respect to grants awarded under paragraph (1) or (2) from funds appropriated for fiscal year 2005 and subsequent fiscal years--

(A) Consultation with the state hospital association and rural hospitals on the most appropriate ways to use grants. A State shall consult with the hospital association of such State and rural hospitals located in such State on the most appropriate ways to use the funds under such grant.

(B) Limitation on use of grant funds for administrative expenses. A State may not expend more than the lesser of--

(i) 15 percent of the amount of the grant for administrative expenses; or

(ii) the State's federally negotiated indirect rate for administering the grant.

(5) Use of funds for Federal administrative expenses. Of the total amount appropriated for grants under paragraphs (1) and (2) for a fiscal year (for each of fiscal years 2005 through 2008) and, of the total amount appropriated for grants under paragraphs (1), (2), and (6) for a fiscal year (beginning with fiscal year 2009), up to 5 percent of such amount shall be available to the Health Resources and Services Administration for purposes of administering such grants.

(6) Providing mental health services and other health services to veterans and other residents of rural areas.

(A) Grants to States. The Secretary may award grants to States that have submitted applications in accordance with subparagraph (B) for increasing the delivery of mental health services or other health care services deemed necessary to meet the needs of veterans of Operation Iraqi Freedom and Operation Enduring Freedom living in rural areas (as defined for purposes of section 1886(d) [*42 USCS § 1395ww(d)*] and including areas that are rural census tracks, as defined by the Administrator of the Health Resources and Services Administration), including for the provision of crisis intervention services and the detection of post-traumatic stress disorder, traumatic brain injury, and other signature injuries of veterans of Operation Iraqi Freedom and Operation Enduring Freedom, and for referral of such veterans to medical facilities operated by the Department of Veterans Affairs, and for the delivery of such services to other residents of such rural areas.

(B) Application.

(i) In general. An application is in accordance with this subparagraph if the State submits to the Secretary at such time and in such form as the Secretary may require an application containing the assurances described in subparagraphs (A)(ii) and (A)(iii) of subsection (b)(1).

(ii) Consideration of regional approaches, networks, or technology. The Secretary may, as appropriate in awarding grants to States under subparagraph (A), consider whether the application submitted by a State under this subparagraph

includes 1 or more proposals that utilize regional approaches, networks, health information technology, telehealth, or telemedicine to deliver services described in subparagraph (A) to individuals described in that subparagraph. For purposes of this clause, a network may, as the Secretary determines appropriate, include Federally qualified health centers (as defined in section 1861(aa)(4) [*42 USCS § 1395x(aa)(4)*]), rural health clinics (as defined in section 1861(aa)(2) [*42 USCS § 1395x(aa)(2)*]), home health agencies (as defined in section 1861(o) [*42 USCS § 1395x(o)*]), community mental health centers (as defined in section 1861(ff)(3)(B) [*42 USCS § 1395x(ff)(3)(B)*]) and other providers of mental health services, pharmacists, local government, and other providers deemed necessary to meet the needs of veterans.

(iii) Coordination at local level. The Secretary shall require, as appropriate, a State to demonstrate consultation with the hospital association of such State, rural hospitals located in such State, providers of mental health services, or other appropriate stakeholders for the provision of services under a grant awarded under this paragraph.

(iv) Special consideration of certain applications. In awarding grants to States under subparagraph (A), the Secretary shall give special consideration to applications submitted by States in which veterans make up a high percentage (as determined by the Secretary) of the total population of the State. Such consideration shall be given without regard to the number of veterans of Operation Iraqi Freedom and Operation Enduring Freedom living in the areas in which mental health services and other health care services would be delivered under the application.

(C) Coordination with VA. The Secretary shall, as appropriate, consult with the Director of the Office of Rural Health of the Department of Veterans Affairs in awarding and administering grants to States under subparagraph (A).

(D) Use of funds. A State awarded a grant under this paragraph may, as appropriate, use the funds to reimburse providers of services described in subparagraph (A) to individuals described in that subparagraph.

(E) Limitation on use of grant funds for administrative expenses. A State awarded a grant under this paragraph may not expend more than 15 percent of the amount of the grant for administrative expenses.

(F) Independent evaluation and final report. The Secretary shall provide for an independent evaluation of the grants awarded under subparagraph (A). Not later than 1 year after the date on which the last grant is awarded to a State under such subparagraph, the Secretary shall submit a report to Congress on such evaluation. Such report shall include an assessment of the impact of such grants on increasing the delivery of mental health services and other health services to veterans of the United States Armed Forces living in rural areas (as so defined and including such areas that are rural census tracks), with particular emphasis on the impact of such grants on the delivery of such services to veterans of Operation Enduring Freedom and Operation Iraqi Freedom, and to other individuals living in such rural areas.

(7) Critical access hospitals transitioning to skilled nursing facilities and assisted living facilities.

(A) Grants. The Secretary may award grants to eligible critical access hospitals that have submitted applications in accordance with subparagraph (B) for assisting such hospitals in the transition to skilled nursing facilities and assisted living facilities.

(B) Application. An applicable critical access hospital seeking a grant under this paragraph shall submit an application to the Secretary on or before such date and in such form and manner as the Secretary specifies.

(C) Additional requirements. The Secretary may not award a grant under this paragraph to an eligible critical access hospital unless--

(i) local organizations or the State in which the hospital is located provides matching funds; and

(ii) the hospital provides assurances that it will surrender critical access hospital status under this title within 180 days of receiving the grant.

(D) Amount of grant. A grant to an eligible critical access hospital under this paragraph may not exceed $ 1,000,000.

(E) Funding. There are appropriated from the Federal Hospital Insurance Trust Fund under section 1817 [*42 USCS § 1395i*] for making grants under this paragraph, $ 5,000,000 for fiscal year 2008.

(F) Eligible critical access hospital defined. For purposes of this paragraph, the term "eligible critical access hospital" means a critical access hospital that has an average daily acute census of less than 0.5 and an average daily swing bed census of greater than 10.0.

(h) Grandfathering provisions.

(1) In general. Any medical assistance facility operating in Montana and any rural primary care hospital designated by the Secretary under this section prior to the date of the enactment of the Balanced Budget Act of 1997 [enacted Aug. 5, 1997] shall be deemed to have been certified by the Secretary under subsection (e) as a critical access hospital if such facility or hospital is otherwise eligible to be designated by the State as a critical access hospital under subsection (c).

(2) Continuation of medical assistance facility and rural primary care hospital terms. Notwithstanding any other provision of this *title [42 USCS §§ 1395* et seq.], with respect to any medical assistance facility or rural primary care hospital described in paragraph (1), any reference in this *title [42 USCS §§ 1395* et seq.] to a "critical access hospital" shall be deemed to be a reference to a "medical assistance facility" or "rural primary care hospital".

(3) State authority to waive 35-mile rule. In the case of a facility that was designated as a critical access hospital before January 1, 2006, and was certified by the State as being a necessary provider of health care services to residents in the area under subsection (c)(2)(B)(i)(II), as in effect before such date, the authority under such subsection with respect to any redesignation of such facility shall continue to apply notwithstanding the amendment made by section 405(h)(1) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003.

(i) Waiver of conflicting part A provisions. The Secretary is authorized to waive such provisions of this part [*42 USCS §§ 1395c* et seq.] and part D [part E] [*42 USCS §§ 1395x* et seq.] as are necessary to conduct the program established under this section.

(j) Authorization of appropriations. There are authorized to be appropriated from the Federal Hospital Insurance Trust Fund for making grants to all States under subsection (g), $ 25,000,000 in each of the fiscal years 1998 through 2002, for making grants to all States under paragraphs (1) and (2) of subsection (g), $ 35,000,000 in each of fiscal years 2005 through 2008, for making grants to all States under paragraphs (1) and (2) of subsection (g), $ 55,000,000 in each of fiscal years 2009 and 2010, and for making grants to all States under paragraph (6) of subsection (g), $ 50,000,000 in each of fiscal years 2009 and 2010, to remain available until expended.

HISTORY:

(Aug. 14, 1935, ch 531, Title XVIII, Part A, § 1820, as added Dec. 19, 1989, P.L. 101-239, Title VI, Subtitle A, Part 1, Subpart A, § 6003(g)(1)(A), 103 Stat. 2145; Nov. 5, 1990, P.L. 101-508, Title IV, Subtitle A, Part 1, § 4008(d), (m)(2)(B), 104 Stat. 1388-44, 1388-53; Oct. 31, 1994, P.L. 103-432, Title I, Subtitle A, § 102(a)(1), (2), (b)(1)(A), (2), (c), (f), (h), 108 Stat. 4401-4404; Aug. 5, 1997, P.L. 105-33, Title IV, Subtitle C, § 4201(a), 111 Stat. 329, 369; Nov. 29, 1999, P.L. 106-113, Div B, § 1000(a)(6), 113 Stat. 1536; Dec. 8, 2003, P.L. 108-173, Title IV, Subtitle A, § 405(e)(1), (2), (f), (g)(1), (h), 117 Stat. 2267, 2269.)

(As amended July 15, 2008, P.L. 110-275, Title I, Subtitle B, § 121, 122 Stat. 2511.)

§ 1395i-5. Conditions for coverage of religious nonmedical health care institutional services

(a) In general. Subject to subsections (c) and (d), payment under this part [*42 USCS §§ 1395c* et seq.] may be made for inpatient hospital services or post-hospital extended care services furnished an individual in a religious nonmedical health care institution and for home health services furnished an individual by a religious nonmedical health care institution only if--

(1) the individual has an election in effect for such benefits under subsection (b); and

(2) the individual has a condition such that the individual would qualify for benefits under this part [*42 USCS §§ 1395c* et seq.] for inpatient hospital services, extended care services, or home health services, respectively, if the individual were an inpatient or resident in a hospital or skilled nursing facility, or receiving services from a home health agency, that was not such an institution.

(b) Election.

(1) In general. An individual may make an election under this subsection in a form and manner specified by the Secretary consistent with this subsection. Unless otherwise provided, such an election shall take effect immediately upon its execution. Such an election, once made, shall continue in effect until revoked.

(2) Form. The election form under this subsection shall include the following:

(A) A written statement, signed by the individual (or such individual's legal representative), that--

(i) the individual is conscientiously opposed to acceptance of nonexcepted medical treatment; and

(ii) the individual's acceptance of nonexcepted medical treatment would be inconsistent with the individual's sincere religious beliefs.

(B) A statement that the receipt of nonexcepted medical services shall constitute a revocation of the election and may limit further receipt of services described in subsection (a).

(3) Revocation. An election under this subsection by an individual may be revoked by voluntarily notifying the Secretary in writing of such revocation and shall be deemed to be revoked if the individual receives nonexcepted medical treatment for which reimbursement is made under this *title [42 USCS §§ 1395* et seq.].

(4) Limitation on subsequent elections. Once an individual's election under this subsection has been made and revoked twice--

(A) the next election may not become effective until the date that is 1 year after the date of most recent previous revocation, and

(B) any succeeding election may not become effective until the date that is 5 years after the date of the most recent previous revocation.

(5) Excepted medical treatment. For purposes of this subsection:

(A) Excepted medical treatment. The term "excepted medical treatment" means medical care or treatment (including medical and other health services)--

(i) received involuntarily, or

(ii) required under Federal or State law or law of a political subdivision of a State.

(B) Nonexcepted medical treatment. The term "nonexcepted medical treatment" means medical care or treatment (including medical and other health services) other than excepted medical treatment.

(c) Monitoring and safeguard against excessive expenditures.

(1) Estimate of expenditures. Before the beginning of each fiscal year (beginning with fiscal year 2000), the Secretary shall estimate the level of expenditures under this part [*42 USCS §§ 1395c* et seq.] for services described in subsection (a) for that fiscal year.

(2) Adjustment in payments.

(A) Proportional adjustment. If the Secretary determines that the level estimated under paragraph (1) for a fiscal year will exceed the trigger level (as defined in subparagraph (C)) for that fiscal year, the Secretary shall, subject to subparagraph (B), provide for such a proportional reduction in payment amounts under this part [*42 USCS §§ 1395c* et seq.] for services described in subsection (a) for the fiscal year involved as will assure that such level (taking into account any adjustment under subparagraph (B)) does not exceed the trigger level for that fiscal year.

(B) Alternative adjustments. The Secretary may, instead of making some or all of the reduction described in subparagraph (A), impose such other conditions or limitations with respect to the coverage of covered services (including limitations on new elections of coverage and new facilities) as may be appropriate to reduce the level of expenditures described in paragraph (1) to the trigger level.

(C) Trigger level. For purposes of this subsection--

(i) In general. Subject to adjustment under paragraph (3)(B), the "trigger level" for a year is the unadjusted trigger level described in clause (ii).

(ii) Unadjusted trigger level. The "unadjusted trigger level" for--

(I) fiscal year 1998, is $ 20,000,000, or

(II) a succeeding fiscal year is the amount specified under this clause for the previous fiscal year increased by the percentage increase in the consumer price index for all urban consumers (all items; United States city average) for the 12-month period ending with July preceding the beginning of the fiscal year.

(D) Prohibition of administrative and judicial review. There shall be no administrative or judicial review under section 1869, 1878 [*42 USCS §§ 1395ff* and *1395oo*], or otherwise of the estimation of expenditures under subparagraph (A) or the application of reduction amounts under subparagraph (B).

(E) Effect on billing. Notwithstanding any other provision of this *title [42 USCS §§ 1395* et seq.], in the case of a reduction in payment provided under this subsection for services of a religious nonmedical health care institution provided to an individual, the amount that the institution is otherwise permitted to charge the individual for such services is increased by the amount of such reduction.

(3) Monitoring expenditure level.

(A) In general. The Secretary shall monitor the expenditure level described in paragraph (2)(A) for each fiscal year (beginning with fiscal year 1999).

(B) Adjustment in trigger level.

(i) In general. If the Secretary determines that such level for a fiscal year exceeded, or was less than, the trigger level for that fiscal year, then, subject to clause (ii), the trigger level for the succeeding fiscal year shall be reduced, or increased, respectively, by the amount of such excess or deficit.

(ii) Limitation on carryforward. In no case may the increase effected under clause (i) for a fiscal year exceed $ 50,000,000.

(d) Sunset. If the Secretary determines that the level of expenditures described in subsection (c)(1) for 3 consecutive fiscal years (with the first such year being not earlier than fiscal year 2002) exceeds the trigger level for such expenditures for such years (as determined under subsection (c)(2)), benefits shall be paid under this part [*42 USCS §§ 1395c* et seq.] for services described in subsection (a) and furnished on or after the first January 1 that occurs after such 3 consecutive years only with respect to an individual who has an election in effect under subsection (b) as of such January 1 and only during the duration of such election.

(e) Annual report. At the beginning of each fiscal year (beginning with fiscal year 1999), the Secretary shall submit to the Committee on Ways and Means of the House of Representatives and the Committee on Finance of the Senate an annual report on coverage and expenditures for services described in subsection (a) under this part [*42 USCS §§ 1395c* et seq.] and under State plans under title XIX [*42 USCS §§ 1396* et seq.]. Such report shall include--

(1) level of expenditures described in subsection (c)(1) for the previous fiscal year and estimated for the fiscal year involved;

(2) trends in such level; and

(3) facts and circumstances of any significant change in such level from the level in previous fiscal years.

HISTORY:

(Aug. 14, 1935, ch 531, Title XVIII, Part A, § 1821, as added Aug. 5, 1997, P.L. 105-33, Title IV, Subtitle E, Ch 5, § 4454(a)(2), 111 Stat. 428; Dec. 8, 2003, P.L. 108-173, Title VII, Subtitle A, § 706(a), 117 Stat. 2339.)

§ 1395j. Establishment of supplementary medical insurance program for the aged and disabled

There is hereby established a voluntary insurance program to provide medical insurance benefits in accordance with the provisions of this part [*42 USCS §§ 1395j* et seq.] for aged and disabled individuals who elect to enroll under such program, to be financed from premium payments by enrollees together with contributions from funds appropriated by the Federal Government.

HISTORY:

(Aug. 14, 1935, ch 531, Title XVIII, Part B, § 1831, as added July 30, 1965, P.L. 89-97, Title I, Part 1, § 102(a), 79 Stat. 301; Oct. 30, 1972, P.L. 92-603, Title II, § 201(a)(3)(B), 86 Stat. 1371.)

§ 1395k. Scope of benefits; definitions

(a) Scope of benefits. The benefits provided to an individual by the insurance program established by this part [*42 USCS §§ 1395j* et seq.] shall consist of--

(1) entitlement to have payment made to him or on his behalf (subject to the provisions of this part [*42 USCS §§ 1395j* et seq.]) for medical and other health services, except those described in subparagraphs (B) and (D) of paragraph (2) and subparagraphs (E) and (F) of section 1842(b)(6) [*42 USCS § 1395u(b)(6)(E)*, (F)]; and

(2) entitlement to have payment made on his behalf (subject to the provisions of this part [*42 USCS §§ 1395j* et seq.]) for--

(A) home health services (other than items described in subparagraph (G) or subparagraph (I));

(B) medical and other health services (other than items described in subparagraph (G) or subparagraph (I)) furnished by a provider of services or by others under arrangement with them made by a provider of services, excluding--

(i) physician services except where furnished by--

(I) a resident or intern of a hospital, or

(II) a physician to a patient in a hospital which has a teaching program approved as specified in paragraph (6) of section 1861(b) [*42 USCS § 1395x(b)(6)*] (including services in conjunction with the teaching programs of such hospital whether or not such patient is an inpatient of such hospital) where the conditions specified in paragraph (7) of such section [*42 USCS § 1395x(b)(7)*] are met,

(ii) services for which payment may be made pursuant to section 1835(b)(2) [*42 USCS § 1395n(b)(2)*],

(iii) services described by section 1861(s)(2)(K)(i) [*42 USCS § 1395x(s)(2)(K)(i)*], certified nurse-midwife services, qualified psychologist services, and services of a certified registered nurse anesthetist;[,]

(iv) services of a nurse practitioner or clinical nurse specialist but only if no facility or other provider charges or is paid any amounts with respect to the furnishing of such services; [and]

(C) **[Caution: For provisions applicable to services furnished before July 1, 2009, see 2008 amendment note below.]** outpatient physical therapy services (other than services to which the second sentence of section 1861(p) [*42 USCS § 1395x(p)*] applies), outpatient occupational therapy services (other than services to which such sentence applies through the operation of section 1861(g) [*42 USCS § 1395x(g)*]), and outpatient speech-language pathology services (other than services to which the second sentence of section 1861(p) [*42 USCS § 1395x(p)*] applies through the application of section 1861(ll)(2) [*42 USCS § 1395x(ll)(2)*]);

(D) (i) rural health clinic services and (ii) Federally qualified health center services;

(E) comprehensive outpatient rehabilitation facility services;

(F) facility services furnished in connection with surgical procedures specified by the Secretary--

(i) pursuant to section 1833(i)(1)(A) [*42 USCS § 1395l(i)(1)(A)*] and performed in an ambulatory surgical center (which meets health, safety, and other standards specified by the Secretary in regulations) if the center has an agreement in effect with the Secretary by which the center agrees to accept the standard overhead amount determined under section 1833(i)(2)(A) [*42 USCS § 1395l(i)(2)(A)*] as full payment for such services (including intraocular lens in cases described in section 1833(i)(2)(A)(iii) [*42 USCS § 1395l(i)(2)(A)(iii)*]) and to accept an assignment described in section 1842(b)(3)(B)(ii) [*42 USCS § 1395u(b)(3)(B)(ii)*] with respect to payment for all such services (including intraocular lens in cases described in section 1833(i)(2)(A)(iii) [*42 USCS § 1395l(i)(2)(A)(iii)*) furnished by the center to individuals enrolled under this part [*42 USCS §§ 1395j* et seq.], or

(ii) pursuant to section 1833(i)(1)(B) [*42 USCS § 1395l(i)(1)(B)*] and performed by a physician, described in paragraph (1), (2), or (3) of section 1861(r) [*42 USCS § 1395x(r)(1)*, (2), or (3)], in his office, if the Secretary has determined that--

(I) a quality control and peer review organization (having a contract with the Secretary under part B of title XI of this Act [*42 USCS §§ 1320c* et seq.]) is willing, able, and has agreed to carry out a review (on a sample or other reasonable basis) of the physician's performing such procedures in the physician's office,

(II) the particular physician involved has agreed to make available to such organization such records as the Secretary determines to be necessary to carry out the review, and

(III) the physician is authorized to perform the procedure in a hospital located in the area in which the office is located,

and if the physician agrees to accept the standard overhead amount determined under section 1833(i)(2)(B) [*42 USCS § 1395l(i)(2)(B)*] as full payment for such services and to accept payment on an assignment-related basis with respect to payment for all services (including all pre- and post-operative services) described in paragraphs (1) and (2)(A) of section 1861(s) [*42 USCS § 1395x(s)(1)* and (2)(A)] and furnished in connection with such surgical procedure to individuals enrolled under this part [*42 USCS §§ 1395j* et seq.];

(G) covered items (described in section 1834(a)(13) [*42 USCS § 1395m(a)(13)*]) furnished by a provider of services or by others under arrangements with them made by a provider of services;

(H) outpatient critical access hospital services (as defined in section 1861(mm)(3)) [*42 USCS § 1395x(mm)(3)*];

(I) prosthetic devices and orthotics and prosthetics (described in section 1834(h)(4) [*42 USCS § 1395m(h)(4)*]) furnished by a provider of services or by others under arrangements with them made by a provider of services; and

(J) partial hospitalization services provided by a community mental health center (as described in section 1861(ff)(2)(B) [*42 USCS § 1395x(ff)(2)(B)*]).

(b) Definitions. For definitions of "spell of illness", "medical and other health services", and other terms used in this part [*42 USCS §§ 1395j* et seq.], see section 1861 [*42 USCS § 1395x*].

HISTORY:

(Aug. 14, 1935, ch 531, Title XVIII, Part B, § 1832, as added July 30, 1965, P.L. 89-97, Title I, Part 1, § 102(a), 79 Stat. 302; Jan. 2, 1968, P.L. 90-248, Title I, Part 3, §§ 129(c)(6)(B), 133(d), 81 Stat. 848, 851; Oct. 30, 1972, P.L. 92-603, Title II, §§ 227(e)(1), 251(a)(4), 86 Stat. 1406, 1445; Dec. 13, 1977, P.L. 95-210, § 1(a), 91 Stat. 1485; Dec. 5, 1980, P.L. 96-499, Title IX, Part B, Subpart I, §§ 930(g), 933(a), 934(a), Subpart II, § 948(a)(2), 94 Stat. 2631, 2635, 2637, 2643; Sept. 3, 1982, P.L. 97-248, Title I, Subtitle C, § 148(c), 96 Stat. 394; July 18, 1984, P.L. 98-369, Division B, Title III, Subtitle A, Part II, §§ 2341(b), 2354(b)(6), 98 Stat 1094, 1100; Oct. 21, 1986, P.L. 99-509, Title IX, Subtitle D, Part 2, § 9320(d), Part 3, §§ 9337(a), 9343(e)(1), 100 Stat. 2013, 2032, 2040; Dec. 22, 1987, P.L. 100-203, Title IV, Subtitle A, Part 3, Subpart B, §§ 4062(d)(2), 4063(e)(2), Subpart D, § 4085(i)(22)(A), 101 Stat. 1330-108, 1330-110, 1330-134; July 1, 1988, P.L. 100-360, Title I, Subtitle A, § 104(d)(3), Title II, Subtitle A, §§ 203(a), 205(a), Title IV, Subtitle B, § 411(g)(2)(E), (h)(4)(A), (7)(B), (i)(4)(C)(vi), 102 Stat. 689, 721, 729, 783, 786, 787, 789; Dec. 13, 1989, P.L. 101-234, Title I, §§ 101(a)(1), 201(a)(1), 103 Stat. 1979, 1981; Dec. 19, 1989, P.L. 101-239, Title VI, Subtitle A, Part 2, Subpart A, § 6116(a)(2), 103 Stat. 2219; Nov. 5, 1990, P.L. 101-508, Title IV, Subtitle A, Part 2, Subpart B, §§ 4153(a)(2)(A), 4155(b)(1), 4157(b), 4161(a)(3)(A), 4162(b)(1), 104 Stat. 1388-83, 1388-86, 1388-89, 1388-93, 1388-96; Aug. 5, 1997, P.L. 105-33, Title IV, Subtitle C, § 4201(c)(1), Subtitle E, Ch 3, § 4432(b)(5)(B), Subtitle F, Ch 1, Subch B, § 4511(c), Subtitle G, Ch 1, Subch A, § 4603(c)(2)(B)(ii), 111 Stat. 373, 421, 443, 471; Nov. 29, 1999, P.L. 106-113, Div B, § 1000(a)(6), 113 Stat. 1536; Dec. 21, 2000, P.L. 106-554, § 1(a)(6), 114 Stat. 2763.)

(As amended July 15, 2008, P.L. 110-275, Title I, Subtitle C, Part II, § 143(b)(1), 122 Stat. 2542.)

§ 1395l. Payment of benefits

(a) Amounts. Except as provided in section 1876 [*42 USCS § 1395mm*], and subject to the succeeding provisions of this section, there shall be paid from the Federal Supplementary Medical Insurance Trust Fund, in the case of each

individual who is covered under the insurance program established by this part [*42 USCS §§ 1395j* et seq.] and incurs expenses for services with respect to which benefits are payable under this part [*42 USCS §§ 1395j* et seq.], amounts equal to--

(1) in the case of services described in section 1832(a)(1) [*42 USCS § 1395k(a)(1)*]--80 percent of the reasonable charges for the services; except that (A) an organization which provides medical and other health services (or arranges for their availability) on a prepayment basis (and either is sponsored by a union or employer, or does not provide, or arrange for the provision of, any inpatient hospital services) may elect to be paid 80 percent of the reasonable cost of services for which payment may be made under this part [*42 USCS §§ 1395j* et seq.] on behalf of individuals enrolled in such organization in lieu of 80 percent of the reasonable charges for such services if the organization undertakes to charge such individuals no more than 20 percent of such reasonable cost plus any amounts payable by them as a result of subsection (b), (B) with respect to items and services described in section 1861(s)(10)(A) [*42 USCS § 1395x(s)(10)(A)*], the amounts paid shall be 100 percent of the reasonable charges for such items and services, (C) with respect to expenses incurred for those physicians' services for which payment may be made under this part [*42 USCS §§ 1395j* et seq.] that are described in section 1862(a)(4) [*42 USCS § 1395y(a)(4)*], the amounts paid shall be subject to such limitations as may be prescribed by regulations, (D) with respect to clinical diagnostic laboratory tests for which payment is made under this part [*42 USCS §§ 1395j* et seq.] (i) on the basis of a fee schedule under subsection (h)(1) or section 1834(d)(1) [*42 USCS § 1395m(d)(1)*], the amount paid shall be equal to 80 percent (or 100 percent, in the case of such tests for which payment is made on an assignment-related basis) of the lesser of the amount determined under such fee schedule, the limitation amount for that test determined under subsection (h)(4)(B), or the amount of the charges billed for the tests, or (ii) on the basis of a negotiated rate established under subsection (h)(6), the amount paid shall be equal to 100 percent of such negotiated rate,[,] (E) with respect to services furnished to individuals who have been determined to have end stage renal disease, the amounts paid shall be determined subject to the provisions of section 1881 [*42 USCS § 1395rr*], (F) with respect to clinical social worker services under section 1861(s)(2)(N) [*42 USCS § 1395x(s)(2)(N)*], the amounts paid shall be 80 percent of the lesser of (i) the actual charge for the services or (ii) 75 percent of the amount determined for payment of a psychologist under clause (L), (G) with respect to facility services furnished in connection with a surgical procedure specified pursuant to subsection (i)(1)(A) and furnished to an individual in an ambulatory surgical center described in such subsection, for services furnished beginning with the implementation date of a revised payment system for such services in such facilities specified in subsection (i)(2)(D), the amounts paid shall be 80 percent of the lesser of the actual charge for the services or the amount determined by the Secretary under such revised payment system, (H) with respect to services of a certified registered nurse anesthetist under section 1861(s)(11) [*42 USCS § 1395x(s)(11)*], the amounts paid shall be 80 percent of the least of the actual charge, the prevailing charge that would be recognized (or, for services furnished on or after January 1, 1992, the fee schedule amount provided under section 1848 [*42 USCS § 1395w-4*]) if the services had been performed by an anesthesiologist, or the fee schedule for such services established by the Secretary in accordance with subsection (1), (I) with respect to covered items (described in section 1834(a)(13) [*42 USCS § 1395m(a)(13)*]), the amounts paid shall be the amounts described in section 1834(a)(1) [*42 USCS § 1395m(a)(1)*], [and] (J) with respect to expenses incurred for radiologist services (as defined in section 1834(b)(6) [*42 USCS § 1395m(b)(6)*]), subject to section 1848 [*42 USCS § 1395w-4*], the amounts paid shall be 80 percent of the lesser of the actual charge for the services or the amount provided under the fee schedule established under section 1834(b) [*42 USCS § 1395m(b)*], (K) with respect to certified nurse-midwife services under section 1861(s)(2)(L) [*42 USCS § 1395x(s)(2)(L)*], the amounts paid shall be 80 percent of the lesser of the actual charge for the services or the amount determined by a fee schedule established by the Secretary for the purposes of this subparagraph (but in no event shall such fee schedule exceed 65 percent of the prevailing charge that would be allowed for the same service performed by a physician, or, for services furnished on or after January 1, 1992, 65 percent of the fee schedule amount provided under section 1848 [*42 USCS § 1395w-4*] for the same service performed by a physician), (L) with respect to qualified psychologist services under section 1861(s)(2)(M) [*42 USCS § 1395x(s)(2)(M)*], the amounts paid shall be 80 percent of the lesser of the actual charge for the services or the amount determined by a fee schedule established by the Secretary for the purposes of this subparagraph, (M) with respect to prosthetic devices and orthotics and prosthetics (as defined in section 1834(h)(4) [*42 USCS § 1395m(h)(4)*]), the amounts paid shall be the amounts described in section 1834(h)(1) [*42 USCS § 1395m(h)(1)*], (N) with respect to expenses incurred for physicians' services (as defined in section 1848(j)(3) [*42 USCS § 1395w-4(j)(3)*]), the amounts paid shall be 80 percent of the payment basis determined under section 1848(a)(1) [*42 USCS § 1395w-4(a)(1)*], (O) with respect to services described in 1861(s)(2)(K) [*42 USCS § 1395x(s)(2)(K)*] (relating to services furnished by physician assistants, nurse practitioners, or clinic nurse specialists), the amounts paid shall be equal to 80 percent of (i) the lesser of the actual charge or 85 percent of the fee schedule amount provided under section 1848 [*42 USCS § 1395w-4*], or (ii) in the case of services as an assistant at surgery, the lesser of the actual charge or 85 percent of the amount that would otherwise be recognized if performed by a physician who is serving as an assistant at surgery, (P) with respect to surgical dressings, the amounts paid shall be the amounts determined under section 1834(i) [*42 USCS § 1395m(i)*], (Q)

with respect to items or services for which fee schedules are established pursuant to section 1842(s) [*42 USCS § 1395u(s)*], the amounts paid shall be 80 percent of the lesser of the actual charge or the fee schedule established in such section, (R) with respect to ambulance services, (i) the amounts paid shall be 80 percent of the lesser of the actual charge for the services or the amount determined by a fee schedule established by the Secretary under section 1834(l) [*42 USCS § 1395m(l)*] and (ii) with respect to ambulance services described in section 1834(l)(8) [*42 USCS § 1395m(l)(8)*], the amounts paid shall be the amounts determined under section 1834(g) [*42 USCS § 1395m(g)*] for outpatient critical access hospital services, (S) with respect to drugs and biologicals (including intravenous immune globulin (as defined in section 1861(zz) [*42 USCS § 1395x(zz)*])) not paid on a cost or prospective payment basis as otherwise provided in this part [*42 USCS §§ 1395j* et seq.] (other than items and services described in subparagraph (B)), the amounts paid shall be 80 percent of the lesser of the actual charge or the payment amount established in section 1842(o) [*42 USCS § 1395u(o)*] (or, if applicable, under section 1847, 1847A, or 1847B [*42 USCS § 1395w-3, 1395w-3a,* or *1395w-3b*]), (T) with respect to medical nutrition therapy services (as defined in section 1861(vv) [*42 USCS § 1395x(vv)*]), the amount paid shall be 80 percent of the lesser of the actual charge for the services or 85 percent of the amount determined under the fee schedule established under section 1848(b) [*42 USCS § 1395w-4(b)*] for the same services if furnished by a physician, (U) with respect to facility fees described in section 1834(m)(2)(B) [*42 USCS § 1395m(m)(2)(B)*], the amounts paid shall be 80 percent of the lesser of the actual charge or the amounts specified in such section, (V) notwithstanding subparagraphs (I) (relating to durable medical equipment), (M) (relating to prosthetic devices and orthotics and prosthetics), and (Q) (relating to 1842(s) items), with respect to competitively priced items and services (described in section 1847(a)(2) [*42 USCS § 1395w-3(a)(2)*]) that are furnished in a competitive area, the amounts paid shall be the amounts described in section 1847(b)(5) [*42 USCS § 1395w-3(b)(5)*], and (W) with respect to additional preventive services (as defined in section 1861(ddd)(1) [*42 USCS § 1395x(ddd)(1)*]), the amount paid shall be (i) in the case of such services which are clinical diagnostic laboratory tests, the amount determined under subparagraph (D), and (ii) in the case of all other such services, 80 percent of the lesser of the actual charge for the service or the amount determined under a fee schedule established by the Secretary for purposes of this subparagraph;

(2) in the case of services described in section 1832(a)(2) [*42 USCS 2§ 1395k(a)(2)*] (except those services described in subparagraphs (C), (D), (E), (F), (G), (H), and (I) of such section and unless otherwise specified in section 1881 [*42 USCS § 1395rr*])--

(A) with respect to home health services (other than a covered osteoporosis drug) (as defined in section 1861(kk) [*42 USCS § 1395x(kk)*]), the amount determined under the prospective payment system under section 1895 [*42 USCS § 1395fff*];

(B) with respect to other items and services (except those described in subparagraph (C), (D), or (E) of this paragraph and except as may be provided in section 1886 or section 1888(e)(9) [*42 USCS § 1395ww* or *1395yy(e)(9)*])--

(i) furnished before January 1, 1999, the lessor of--

(I) the reasonable cost of such services, as determined under section 1861(v) [*42 USCS § 1395x(v)*], or

(II) the customary charges with respect to such services,

less the amount a provider may charge as described in clause (ii) of section 1866(a)(2)(A) [*42 USCS § 1395cc(a)(2)(A)(ii)*], but in no case may the payment for such other services exceed 80 percent of such reasonable cost, or

(ii) if such services are furnished before January 1, 1999, by a public provider of services, or by another provider which demonstrates to the satisfaction of the Secretary that a significant portion of its patients are low-income (and requests that payment be made under this clause), free of charge or at nominal charges to the public, 80 percent of the amount determined in accordance with section 1814(b)(2) [*42 USCS § 1395f(b)(2)*], or

(iii) if such services are furnished on or after January 1, 1999, the amount determined under subsection (t), or

(iv) if (and for so long as) the conditions described in section 1814(b)(3) [*42 USCS § 1395f(b)(3)*] are met, the amounts determined under the reimbursement system described in such section;

(C) with respect to services described in the second sentence of section 1861(p) [*42 USCS § 1395x(p)*], 80 percent of the reasonable charges for such services;

(D) with respect to clinical diagnostic laboratory tests for which payment is made under this part [*42 USCS §§ 1395j* et seq.] (i) on the basis of a fee schedule determined under subsection (h)(1) or section 1834(d)(1) [*42 USCS § 1395m(d)(1)*], the amount paid shall be equal to 80 percent (or 100 percent, in the case of such tests for which payment is made on an assignment-related basis or to a provider having an agreement under section 1866 [*42 USCS § 1395cc*]) of the lesser of the amount determined under such fee schedule or the amount of the charges billed for the tests, or (ii) on the basis of a negotiated rate established under subsection (h)(6), the amount paid shall be equal to 100 percent of such negotiated rate for such tests;

(E) with respect to--

(i) outpatient hospital radiology services (including diagnostic and therapeutic radiology, nuclear medicine and CAT scan procedures, magnetic resonance imaging, and ultrasound and other imaging services, but excluding screening mammography and, for services furnished on or after January 1, 2005, diagnostic mammography), and

(ii) effective for procedures performed on or after October 1, 1989, diagnostic procedures (as defined by the Secretary) described in section 1861(s)(3) [*42 USCS § 1395x(s)(3)*] (other than diagnostic x-ray tests and diagnostic laboratory tests),

the amount determined under subsection (n) or, for services or procedures performed on or after January 1, 1999, subsection (t);

(F) with respect to a covered osteoporosis drug (as defined in section 1861(kk) [*42 USCS § 1395x(kk)*]) furnished by a home health agency, 80 percent of the reasonable cost of such service, as determined under section 1861(v) [*42 USCS § 1395x(v)*]; and

(G) with respect to items and services described in section 1861(s)(10)(A) [*42 USCS § 1395x(s)(10)(A)*], the lesser of--

(i) the reasonable cost of such services, as determined under section 1861(v) [*42 USCS § 1395x(v)*], or

(ii) the customary charges with respect to such services,

or, if such services are furnished by a public provider of services, or by another provider which demonstrates to the satisfaction of the Secretary that a significant portion of its patients are low-income (and requests that payment be made under this provision), free of charge or at nominal charges to the public, the amount determined in accordance with section 1814(b)(2) [*42 USCS § 1395f(b)(2)*];

(3) in the case of services described in section 1832(a)(2)(D) [*42 USCS § 1395k(a)(2)(D)*]--

(A) except as provided in subparagraph (B), the costs which are reasonable and related to the cost of furnishing such services or which are based on such other tests of reasonableness as the Secretary may prescribe in regulations, including those authorized under section 1861(v)(1)(A) [*42 USCS § 1395x(v)(1)(A)*], less the amount a provider may charge as described in clause (ii) of section 1866(a)(2)(A) [*42 USCS § 1395cc(a)(2)(A)*], but in no case may the payment for such services (other than for items and services described in section 1861(s)(10)(A) [*42 USCS § 1395x(s)(10)(A)*]) exceed 80 percent of such costs; or

(B) with respect to the services described in clause (ii) of section 1832(a)(2)(D) [*42 USCS § 1395k(a)(2)(D)*] that are furnished to an individual enrolled with a MA plan under part C [*42 USCS §§ 1395w-21* et seq.] pursuant to a written agreement described in section 1853(a)(4) [*42 USCS § 1395w-23(a)(4)*], the amount (if any) by which--

(i) the amount of payment that would have otherwise been provided under subparagraph (A) (calculated as if "100 percent" were substituted for "80 percent" in such subparagraph) for such services if the individual had not been so enrolled; exceeds

(ii) the amount of the payments received under such written agreement for such services (not including any financial incentives provided for in such agreement such as risk pool payments, bonuses, or withholds),

less the amount the federally qualified health center may charge as described in section 1857(e)(3)(B) [*42 USCS § 1395w-27(e)(3)(B)*];

(4) in the case of facility services described in section 1832(a)(2)(F) [*42 USCS § 1395k(a)(2)(F)*], and outpatient hospital facility services furnished in connection with surgical procedures specified by the Secretary pursuant to section 1833(i)(1)(A) [subsec. (i)(1)(A) of this section], the applicable amount as determined under paragraph (2) or (3) of subsection (i) or subsection (t);

(5) in the case of covered items (described in section 1834(a)(13) [*42 USCS § 1395m(a)(13)*]) the amounts described in section 1834(a)(1) [*42 USCS § 1395m(a)(1)*];

(6) in the case of outpatient critical access hospital services, the amounts described in section 1834(g) [*42 USCS § 1395m(g)*];

(7) in the case of prosthetic devices and orthotics and prosthetics (as described in section 1834(h)(4) [*42 USCS § 1395m(h)(4)*]), the amounts described in section 1834(h) [*42 USCS § 1395m(h)*];

(8) in the case of--

(A) outpatient physical therapy services, outpatient speech-language pathology services, and outpatient occupational therapy services furnished--

(i) by a rehabilitation agency, public health agency, clinic, comprehensive outpatient rehabilitation facility, or skilled nursing facility,

(ii) by a home health agency to an individual who is not homebound, or

(iii) by another entity under an arrangement with an entity described in clause (i) or (ii); and

(B) outpatient physical therapy services, outpatient speech-language pathology services, and outpatient occupational therapy services furnished--

(i) by a hospital to an outpatient or to a hospital inpatient who is entitled to benefits under part A [*42 USCS §§ 1395c* et seq.] but has exhausted benefits for inpatient hospital services during a spell of illness or is not so entitled to benefits under part A [*42 USCS §§ 1395c* et seq.], or

(ii) by another entity under an arrangement with a hospital described in clause (i),

the amounts described in section 1834(k) [*42 USCS § 1395m(k)*]; and

(9) in the case of services described in section 1832(a)(2)(E) [*42 USCS § 1395k(a)(2)(E)*] that are not described in paragraph (8), the amounts described in section 1834(k) [*42 USCS § 1395m(k)*].

(b) Deductible provision. Before applying subsection (a) with respect to expenses incurred by an individual during any calendar year, the total amount of the expenses incurred by such individual during such year (which would, except for this subsection, constitute incurred expenses from which benefits payable under subsection (a) are determinable) shall be reduced by a deductible of $ 75 for calendar years before 1991, $ 100 for 1991 through 2004, $ 110 for 2005, and for a subsequent year the amount of such deductible for the previous year increased by the annual percentage increase in the monthly actuarial rate under section 1839(a)(1) [*42 USCS § 1395r(a)(1)*] ending with such subsequent year (rounded to the nearest $ 1); except that (1) such total amount shall not include expenses incurred for items and services described in section 1861(s)(10)(A) [*42 USCS § 1395x(s)(10)(A)*], (2) such deductible shall not apply with respect to home health services (other than a covered osteoporosis drug (as defined in section 1861(kk) [*42 USCS § 1395x(kk)*])), (3) such deductible shall not apply with respect to clinical diagnostic laboratory tests for which payment is made under this part [*42 USCS §§ 1395j* et seq.] (A) under subsection (a)(1)(D)(i) or (a)(2)(D)(i) on an assignment-related basis, or to a provider having an agreement under section 1866 [*42 USCS § 1395cc*], or (B) on the basis of a negotiated rate determined under subsection (h)(6), (4) such deductible shall not apply to Federally qualified health center services, (5) such deductible shall not apply with respect to screening mammography (as described in section 1861(jj) [*42 USCS § 1395x(jj)*]), (6) such deductible shall not apply with respect to screening pap smear and screening pelvic exam (as described in section 1861(nn) [*42 USCS § 1395x(nn)*]), (7) such deductible shall not apply with respect to ultrasound screening for abdominal aortic aneurysm (as defined in section 1861(bbb) [*42 USCS § 1395x(bbb)*]), (8) such deductible shall not apply with respect to colorectal cancer screening tests (as described in section 1861(pp)(1) [*42 USCS § 1395x(pp)(1)*]), and (9) such deductible shall not apply with respect to an initial preventive physical examination (as defined in section 1861(ww) [*42 USCS § 1395x(ww)*]). The total amount of the expenses incurred by an individual as determined under the preceding sentence shall, after the reduction specified in such sentence, be further reduced by an amount equal to the expenses incurred for the first three pints of whole blood (or equivalent quantities of packed red blood cells, as defined under regulations) furnished to the individual during the calendar year, except that such deductible for such blood shall in accordance with regulations be appropriately reduced to the extent that there has been a replacement of such blood (or equivalent quantities of packed red blood cells, as so defined); and for such purposes blood (or equivalent quantities of packed red blood cells, as so defined) furnished such individual shall be deemed replaced when the institution or other person furnishing such blood (or such equivalent quantities of packed red blood cells, as so defined) is given one pint of blood for each pint of blood (or equivalent quantities of packed red blood cells, as so defined) furnished such individual with respect to which a deduction is made under this sentence. The deductible under the previous sentence for blood or blood cells furnished an individual in a year shall be reduced to the extent that a deductible has been imposed under section 1813(a)(2) [*42 USCS § 1395e(a)(2)*] to blood or blood cells furnished the individual in the year.

(c) Copayment rates for Medicare outpatient psychiatric services.

(1) Notwithstanding any other provision of this part, with respect to expenses incurred in a calendar year in connection with the treatment of mental, psychoneurotic, and personality disorders of an individual who is not an inpatient of a hospital at the time such expenses are incurred, there shall be considered as incurred expenses for purposes of subsections (a) and (b)--

(A) for expenses incurred in years prior to 2010, only 62 1/2 percent of such expenses;

(B) for expenses incurred in 2010 or 2011, only 68 3/4 percent of such expenses;

(C) for expenses incurred in 2012, only 75 percent of such expenses;

(D) for expenses incurred in 2013, only 81 1/4 percent of such expenses; and

(E) for expenses incurred in 2014 or any subsequent calendar year, 100 percent of such expenses.

(2) For purposes of subparagraphs (A) through (D) of paragraph (1), the term "treatment" does not include brief office visits (as defined by the Secretary) for the sole purpose of monitoring or changing drug prescriptions used in the treatment of such disorders or partial hospitalization services that are not directly provided by a physician.

(d) Nonduplication of payments. No payment may be made under this part [*42 USCS §§ 1395j* et seq.] with respect to any services furnished an individual to the extent that such individual is entitled (or would be entitled except for section 1813 [*42 USCS § 1395e*]) to have payment made with respect to such services under part A [*42 USCS §§ 1395c* et seq.].

(e) Information for determination of amounts due. No payment shall be made to any provider of services or other person under this part [*42 USCS §§ 1395j* et seq.] unless there has been furnished such information as may be necessary in order to determine the amounts due such provider or other person under this part [*42 USCS §§ 1395j* et seq.] for the period with respect to which the amounts are being paid or for any prior period.

(f) Updating maximum rate of payment per visit for independent rural health clinics. In establishing limits under subsection (a) on payment for rural health clinic services provided by rural health clinics (other than such clinics in hospitals with less than 50 beds), the Secretary shall establish such limit, for services provided--

(1) in 1988, after March 31, at $ 46 per visit, and

(2) in a subsequent year, at the limit established under this subsection for the previous year increased by the percentage increase in the MEI (as defined in section 1842(i)(3) [*42 USCS § 1395u(i)(3)*]) applicable to primary care services (as defined in section 1842(i)(4) [*42 USCS § 1395u(i)(4)*]) furnished as of the first day of that year.

(g) Physical therapy services.

(1) **[Caution: For provisions applicable to services furnished before July 1, 2009, see 2008 amendment note below.]** Subject to paragraphs (4) and (5), in the case of physical therapy services of the type described in section 1861(p) [*42 USCS § 1395x(p)*] and speech-language pathology services of the type described in such section through the application of section 1861(ll)(2) [*42 USCS § 1395x(ll)(2)*], but not described in section 1833(a)(8)(B) [subsec. (a)(8)(B) of this section], and physical therapy services and speech-language pathology services of such type which are furnished by a physician or as incident to physicians' services, with respect to expenses incurred in any calendar year, no more than the amount specified in paragraph (2) for the year shall be considered as incurred expenses for purposes of subsections (a) and (b).

(2) The amount specified in this paragraph--

(A) for 1999, 2000, and 2001, is $ 1,500, and

(B) for a subsequent year is the amount specified in this paragraph for the preceding year increased by the percentage increase in the MEI (as defined in section 1842(i)(3) [*42 USCS § 1395u(i)(3)*]) for such subsequent year; except that if an increase under subparagraph (B) for a year is not a multiple of $ 10, it shall be rounded to the nearest multiple of $ 10.

(3) Subject to paragraphs (4) and (5), in the case of occupational therapy services (of the type that are described in section 1861(p) [*42 USCS § 1395x(p)*] (but not described in section 1833(a)(8)(B) [subsec. (a)(8)(B) of this section]) through the operation of section 1861(g) [*42 USCS § 1395x(g)*] and of such type which are furnished by a physician or as incident to physicians' services), with respect to expenses incurred in any calendar year, no more than the amount specified in paragraph (2) for the year shall be considered as incurred expenses for purposes of subsections (a) and (b).

(4) This subsection shall not apply to expenses incurred with respect to services furnished during 2000, 2001, 2002, 2004, and 2005.

(5) With respect to expenses incurred during the period beginning on January 1, 2006, and ending on December 31, 2009, for services, the Secretary shall implement a process under which an individual enrolled under this part may, upon request of the individual or a person on behalf of the individual, obtain an exception from the uniform dollar limitation specified in paragraph (2), for services described in paragraphs (1) and (3) if the provision of such services is determined to be medically necessary. Under such process, if the Secretary does not make a decision on such a request for an exception within 10 business days of the date of the Secretary's receipt of the request, the Secretary shall be deemed to have found the services to be medically necessary.

(h) Fee schedules for clinical diagnostic laboratory tests; percentage of prevailing charge level; nominal fee for samples; adjustments; recipients of payments; negotiated payment rate.

(1)

(A) Subject to section 1834(d)(1) [*42 USCS § 1395m(d)(1)*], the Secretary shall establish fee schedules for clinical diagnostic laboratory tests (including prostate cancer screening tests under section 1861(oo) [*42 USCS § 1395x(oo)*] consisting of prostate-specific antigen blood tests) for which payment is made under this part [*42 USCS §§ 1395j* et seq.], other than such tests performed by a provider of services for an inpatient of such provider.

(B) In the case of clinical diagnostic laboratory tests performed by a physician or by a laboratory (other than tests performed by a qualified hospital laboratory (as defined in subparagraph (D)) for outpatients of such hospital), the fee

schedules established under subparagraph (A) shall be established on a regional, statewide, or carrier service area basis (as the Secretary may determine to be appropriate) for tests furnished on or after July 1, 1984.

(C) In the case of clinical diagnostic laboratory tests performed by a qualified hospital laboratory (as defined in subparagraph (D)) for outpatients of such hospital, the fee schedules established under subparagraph (A) shall be established on a regional, statewide, or carrier service area basis (as the Secretary may determine to be appropriate) for tests furnished on or after July 1, 1984.

(D) In this subsection, the term "qualified hospital laboratory" means a hospital laboratory, in a sole community hospital (as defined in section 1886(d)(5)(D)(iii) [*42 USCS § 1395ww(d)(5)(D)(iii)*]) which provides some clinical diagnostic laboratory tests 24 hours a day in order to serve a hospital emergency room which is available to provide services 24 hours a day and 7 days a week.

(2) (A) (i) Except as provided in paragraph (4), the Secretary shall set the fee schedules at 60 percent (or, in the case of a test performed by a qualified hospital laboratory in a sole community hospital (as defined in paragraph (1)(D)) for outpatients of such hospital, 62 percent) of the prevailing charge level determined pursuant to the third and fourth sentences of section 1842(b)(3) [*42 USCS § 1395u(b)(3)*] for similar clinical diagnostic laboratory tests for the applicable region, State, or area for the 12-month period beginning July 1, 1984, adjusted annually (to become effective on January 1 of each year) by a percentage increase or decrease equal to the percentage increase or decrease in the Consumer Price Index for All Urban Consumers (United States city average) minus, for each of the years 2009 through 2013, 0.5 percentage points, and subject to such other adjustments as the Secretary determines are justified by technological changes.

(ii) Notwithstanding clause (i)--

(I) any change in the fee schedules which would have become effective under this subsection for tests furnished on or after January 1, 1988, shall not be effective for tests furnished during the 3-month period beginning on January 1, 1988,

(II) the Secretary shall not adjust the fee schedules under clause (i) to take into account any increase in the consumer price index for 1988,

(III) the annual adjustment in the fee schedules determined under clause (i) for each of the years 1991, 1992, and 1993 shall be 2 percent, and

(IV) the annual adjustment in the fee schedules determined under clause (i) for each of the years 1994 and 1995, 1998 through 2002, and 2004 through 2008 shall be 0 percent.

(iii) In establishing fee schedules under clause (i) with respect to automated tests and tests (other than cytopathology tests) which before July 1, 1984, the Secretary made subject to a limit based on lowest charge levels under the sixth sentence of section 1842(b)(3) [*42 USCS § 1395u(b)(3)*] performed after March 31, 1988, the Secretary shall reduce by 8.3 percent the fee schedules otherwise established for 1988, and such reduced fee schedules shall serve as the base for 1989 and subsequent years.

(B) The Secretary may make further adjustments or exceptions to the fee schedules to assure adequate reimbursement of (i) emergency laboratory tests needed for the provision of bona fide emergency services, and (ii) certain low volume high-cost tests where highly sophisticated equipment or extremely skilled personnel are necessary to assure quality.

(3) In addition to the amounts provided under the fee schedules, the Secretary shall provide for and establish (A) a nominal fee to cover the appropriate costs in collecting the sample on which a clinical diagnostic laboratory test was performed and for which payment is made under this part [*42 USCS §§ 1395j* et seq.], except that not more than one such fee may be provided under this paragraph with respect to samples collected in the same encounter, and (B) a fee to cover the transportation and personnel expenses for trained personnel to travel to the location of an individual to collect the sample, except that such a fee may be provided only with respect to an individual who is homebound or an inpatient in an inpatient facility (other than a hospital). In establishing a fee to cover the transportation and personnel expenses for trained personnel to travel to the location of an individual to collect a sample, the Secretary shall provide a method for computing the fee based on the number of miles traveled and the personnel costs associated with the collection of each individual sample, but the Secretary shall only be required to apply such method in the case of tests furnished during the period beginning on April 1, 1989, and ending on December 31, 1990, by a laboratory that establishes to the satisfaction of the Secretary (based on data for the 12-month period ending June 30, 1988) that (i) the laboratory is dependent upon payments under this *title [42 USCS §§ 1395* et seq.] for at least 80 percent of its collected revenues for clinical diagnostic laboratory tests, (ii) at least 85 percent of its gross revenues for such tests are attributable to tests performed with respect to individuals who are homebound or who are residents in a nursing facility, and (iii) the laboratory provided such tests for residents in nursing facilities representing at least 20 percent of the number of such facilities in the State in which the laboratory is located.

(4) (A) In establishing any fee schedule under this subsection, the Secretary may provide for an adjustment to take into account, with respect to the portion of the expenses of clinical diagnostic laboratory tests attributable to wages, the

relative difference between a region's or local area's wage rates and the wage rate presumed in the data on which the schedule is based.

(B) For purposes of subsections (a)(1)(D)(i) and (a)(2)(D)(i), the limitation amount for a clinical diagnostic laboratory test performed--

(i) on or after July 1, 1986, and before April 1, 1988, is equal to 115 percent of the median of all the fee schedules established for that test for that laboratory setting under paragraph (1),

(ii) after March 31, 1988, and before January 1, 1990, is equal to the median of all the fee schedules established for that test for that laboratory setting under paragraph (1),

(iii) after December 31, 1989, and before January 1, 1991, is equal to 93 percent of the median of all the fee schedules established for that test for that laboratory setting under paragraph (1),

(iv) after December 31, 1990, and before January 1, 1994, is equal to 88 percent of such median,

(v) after December 31, 1993, and before January 1, 1995, is equal to 84 percent of such median,

(vi) after December 31, 1994, and before January 1, 1996, is equal to 80 percent of such median,

(vii) after December 31, 1995, and before January 1, 1998, is equal to 76 percent of such median, and

(viii) after December 31, 1997, is equal to 74 percent of such median (or 100 percent of such median in the case of a clinical diagnostic laboratory test performed on or after January 1, 2001, that the Secretary determines is a new test for which no limitation amount has previously been established under this subparagraph).

(5) (A) In the case of a bill or request for payment for a clinical diagnostic laboratory test for which payment may otherwise be made under this part [*42 USCS §§ 1395j* et seq.] on an assignment-related basis or under a provider agreement under section 1866 [*42 USCS § 1395cc*], payment may be made only to the person or entity which performed or supervised the performance of such test; except that--

(i) if a physician performed or supervised the performance of such test, payment may be made to another physician with whom he shares his practice.

(ii) in the case of a test performed at the request of a laboratory by another laboratory, payment may be made to the referring laboratory but only if--

(I) the referring laboratory is located in, or is part of, a rural hospital,

(II) the referring laboratory is wholly owned by the entity performing such test, the referring laboratory wholly owns the entity performing such test, or both the referring laboratory and the entity performing such test are wholly-owned by a third entity, or

(III) not more than 30 percent of the clinical diagnostic laboratory tests for which such referring laboratory (but not including a laboratory described in subclause (II))[,] receives requests for testing during the year in which the test is performed[,] are performed by another laboratory, and

(iii) in the case of a clinical diagnostic laboratory test provided under an arrangement (as defined in section 1861(w)(1) [*42 USCS § 1395x(w)(1)*]) made by a hospital, critical access hospital, or skilled nursing facility, payment shall be made to the hospital or skilled nursing facility.

(B) In the case of such a bill or request for payment for a clinical diagnostic laboratory test for which payment may otherwise be made under this part [*42 USCS §§ 1395j* et seq.], and which is not described in subparagraph (A), payment may be made to the beneficiary only on the basis of the itemized bill of the person or entity which performed or supervised the performance of the test.

(C) Payment for a clinical diagnostic laboratory test, including a test performed in a physician's office but excluding a test performed by a rural health clinic may only be made on an assignment-related basis or to a provider of services with an agreement in effect under section 1866 [*42 USCS § 1395cc*].

(D) A person may not bill for a clinical diagnostic laboratory test, including a test performed in a physician's office but excluding a test performed by a rural health clinic, other than on an assignment-related basis. If a person knowingly and willfully and on a repeated basis bills for a clinical diagnostic laboratory test in violation of the previous sentence, the Secretary may apply sanctions against the person in the same manner as the Secretary may apply sanctions against a physician in accordance with paragraph (2) of section 1842(j) [*42 USCS § 1395u(j)(2)*] in the same manner such paragraphs apply with respect to a physician. Paragraph (4) of such section shall apply in this subparagraph in the same manner as such paragraph applies to such section.

(6) In the case of any diagnostic laboratory test payment for which is not made on the basis of a fee schedule under paragraph (1), the Secretary may establish a payment rate which is acceptable to the person or entity performing the test and which would be considered the full charge for such tests. Such negotiated rate shall be limited to an amount not in excess of the total payment that would have been made for the services in the absence of such rate.

(7) Notwithstanding paragraphs (1) and (4), the Secretary shall establish a national minimum payment amount under this subsection for a diagnostic or screening pap smear laboratory test (including all cervical cancer screening technologies that have been approved by the Food and Drug Administration as a primary screening method for detection

of cervical cancer) equal to $ 14.60 for tests furnished in 2000. For such tests furnished in subsequent years, such national minimum payment amount shall be adjusted annually as provided in paragraph (2).

(8) (A) The Secretary shall establish by regulation procedures for determining the basis for, and amount of, payment under this subsection for any clinical diagnostic laboratory test with respect to which a new or substantially revised HCPCS code is assigned on or after January 1, 2005 (in this paragraph referred to as "new tests").

(B) Determinations under subparagraph (A) shall be made only after the Secretary--

(i) makes available to the public (through an Internet website and other appropriate mechanisms) a list that includes any such test for which establishment of a payment amount under this subsection is being considered for a year;

(ii) on the same day such list is made available, causes to have published in the Federal Register notice of a meeting to receive comments and recommendations (and data on which recommendations are based) from the public on the appropriate basis under this subsection for establishing payment amounts for the tests on such list;

(iii) not less than 30 days after publication of such notice convenes a meeting, that includes representatives of officials of the Centers for Medicare & Medicaid Services involved in determining payment amounts, to receive such comments and recommendations (and data on which the recommendations are based);

(iv) taking into account the comments and recommendations (and accompanying data) received at such meeting, develops and makes available to the public (through an Internet website and other appropriate mechanisms) a list of proposed determinations with respect to the appropriate basis for establishing a payment amount under this subsection for each such code, together with an explanation of the reasons for each such determination, the data on which the determinations are based, and a request for public written comments on the proposed determination; and

(v) taking into account the comments received during the public comment period, develops and makes available to the public (through an Internet website and other appropriate mechanisms) a list of final determinations of the payment amounts for such tests under this subsection, together with the rationale for each such determination, the data on which the determinations are based, and responses to comments and suggestions received from the public.

(C) Under the procedures established pursuant to subparagraph (A), the Secretary shall--

(i) set forth the criteria for making determinations under subparagraph (A); and

(ii) make available to the public the data (other than proprietary data) considered in making such determinations.

(D) The Secretary may convene such further public meetings to receive public comments on payment amounts for new tests under this subsection as the Secretary deems appropriate.

(E) For purposes of this paragraph:

(i) The term "HCPCS" refers to the Health Care Procedure Coding System.

(ii) A code shall be considered to be "substantially revised" if there is a substantive change to the definition of the test or procedure to which the code applies (such as a new analyte or a new methodology for measuring an existing analyte-specific test).

(9) Notwithstanding any other provision in this part [*42 USCS §§ 1395j* et seq.], in the case of any diagnostic laboratory test for HbA1c that is labeled by the Food and Drug Administration for home use and is furnished on or after April 1, 2008, the payment rate for such test shall be the payment rate established under this part for a glycated hemoglobin test (identified as of October 1, 2007, by HCPCS code 83036 (and any succeeding codes)).

(i) Outpatient surgery.

(1) The Secretary shall, in consultation with appropriate medical organizations--

(A) specify those surgical procedures which are appropriately (when considered in terms of the proper utilization of hospital inpatient facilities) performed on an inpatient basis in a hospital but which also can be performed safely on an ambulatory basis in an ambulatory surgical center (meeting the standards specified under section 1832(a)(2)(F)(i) [*42 USCS § 1395k(a)(2)(F)(i)*]), critical access hospital, or hospital outpatient department, and

(B) specify those surgical procedures which are appropriately (when considered in terms of the proper utilization of hospital inpatient facilities) performed on an inpatient basis in a hospital but which also can be performed safely on an ambulatory basis in a physician's office.

The lists of procedures established under subparagraphs (A) and (B) shall be reviewed and updated not less often than every 2 years, in consultation with appropriate trade and professional organizations.

(2) (A) For services furnished prior to the implementation of the system described in subparagraph (D), subject to subparagraph (E), the amount of payment to be made for facility services furnished in connection with a surgical procedure specified pursuant to paragraph (1)(A) and furnished to an individual in an ambulatory surgical center described in such paragraph shall be equal to 80 percent of a standard overhead amount established by the Secretary (with respect to each such procedure) on the basis of the Secretary's estimate of a fair fee which--

(i) takes into account the costs incurred by such centers, or classes of centers, generally in providing services furnished in connection with the performance of such procedure, as determined in accordance with a survey (based upon

a representative sample of procedures and facilities) of the actual audited costs incurred by such centers in providing such services,

(ii) takes such costs into account in such a manner as will assure that the performance of the procedure in such a center will result in substantially less amounts paid under this *title [42 USCS §§ 1395* et seq.] than would have been paid if the procedure had been performed on an inpatient basis in a hospital, and

(iii) in the case of insertion of an intraocular lens during or subsequent to cataract surgery includes payment which is reasonable and related to the cost of acquiring the class of lens involved.

Each amount so established shall be reviewed and updated not later than July 1, 1987, and annually thereafter to take account of varying conditions in different areas.

(B) The amount of payment to be made under this part [*42 USCS §§ 1395j* et seq.] for facility services furnished, in connection with a surgical procedure specified pursuant to paragraph (1)(B), in a physician's office shall be equal to 80 percent of a standard overhead amount established by the Secretary (with respect to each such procedure) on the basis of the Secretary's estimate of a fair fee which--

(i) takes into account additional costs, not usually included in the professional fee, incurred by physicians in securing, maintaining, and staffing the facilities and ancillary services appropriate for the performance of such procedure in the physician's office, and

(ii) takes such items into account in such a manner which will assure that the performance of such procedure in the physician's office will result in substantially less amounts paid under this *title [42 USCS §§ 1395* et seq.] than would have been paid if the services had been furnished on an inpatient basis in a hospital.

Each amount so established shall be reviewed and updated not later than July 1, 1987, and annually thereafter and may be adjusted by the Secretary, when appropriate, to take account of varying conditions in different areas.

(C) (i) Notwithstanding the second sentence of each of subparagraphs (A) and (B), except as otherwise specified in clauses (ii), (iii), and (iv), if the Secretary has not updated amounts established under such subparagraphs or under subparagraph (D), with respect to facility services furnished during a fiscal year (beginning with fiscal year 1986 or a calendar year (beginning with 2006)), such amounts shall be increased by the percentage increase in the Consumer Price Index for all urban consumers (U.S. city average) as estimated by the Secretary for the 12-month period ending with the midpoint of the year involved.

(ii) In each of the fiscal years 1998 through 2002, the increase under this subparagraph shall be reduced (but not below zero) by 2.0 percentage points.

(iii) In fiscal year 2004, beginning with April 1, 2004, the increase under this subparagraph shall be the Consumer Price Index for all urban consumers (U.S. city average) as estimated by the Secretary for the 12-month period ending with March 31, 2003, minus 3.0 percentage points.

(iv) In fiscal year 2005, the last quarter of calendar year 2005, and each of calendar years 2006 through 2009, the increase under this subparagraph shall be 0 percent.

(D)

(i) Taking into account the recommendations in the report under section 626(d) of Medicare Prescription Drug, Improvement, and Modernization Act of 2003 [note to this section], the Secretary shall implement a revised payment system for payment of surgical services furnished in ambulatory surgical centers.

(ii) In the year the system described in clause (i) is implemented, such system shall be designed to result in the same aggregate amount of expenditures for such services as would be made if this subparagraph did not apply, as estimated by the Secretary and taking into account reduced expenditures that would apply if subparagraph (E) were to continue to apply, as estimated by the Secretary.

(iii) The Secretary shall implement the system described in clause (i) for periods in a manner so that it is first effective beginning on or after January 1, 2006, and not later than January 1, 2008.

(iv) The Secretary may implement such system in a manner so as to provide for a reduction in any annual update for failure to report on quality measures in accordance with paragraph (7).

(v) There shall be no administrative or judicial review under section 1869 [*42 USCS § 1395ff*], 1878 [*42 USCS § 1395oo*], or otherwise, of the classification system, the relative weights, payment amounts, and the geographic adjustment factor, if any, under this subparagraph.

(E) With respect to surgical procedures furnished on or after January 1, 2007, and before the effective date of the implementation of a revised payment system under subparagraph (D), if--

(i) the standard overhead amount under subparagraph (A) for a facility service for such procedure, without the application of any geographic adjustment, exceeds

(ii) the Medicare OPD fee schedule amount established under the prospective payment system for hospital outpatient department services under paragraph (3)(D) of section 1833(t) [*42 USCS § 1395l(t)*] for such service for such year, determined without regard to geographic adjustment under paragraph (2)(D) of such section,

the Secretary shall substitute under subparagraph (A) the amount described in clause (ii) for the standard overhead amount for such service referred to in clause (i).

(3)

(A) The aggregate amount of the payments to be made under this part [*42 USCS §§ 1395j* et seq.] for outpatient hospital facility services or critical access hospital services furnished before January 1, 1999, in connection with surgical procedures specified under paragraph (1)(A) shall be equal to the lesser of--

(i) the amount determined with respect to such services under subsection (a)(2)(B); or

(ii) the blend amount (described in subparagraph (B)).

(B) (i) The blend amount for a cost reporting period is the sum of--

(I) the cost proportion (as defined in clause (ii)(I)) of the amount described in subparagraph (A)(i), and

(II) the ASC proportion (as defined in clause (ii)(II)) of the standard overhead amount payable with respect to the same surgical procedure as if it were provided in an ambulatory surgical center in the same area, as determined under paragraph (2)(A), less the amount a provider may charge as described in clause (ii) of section 1866(a)(2)(A) [*42 USCS § 1395cc(a)(2)(A)*].

(ii) Subject to paragraph (4), in this paragraph:

(I) The term "cost proportion" means 75 percent for cost reporting periods beginning in fiscal year 1988, 50 percent for portions of cost reporting periods beginning on or after October 1, 1988, and ending on or before December 31, 1990, and 42 percent for portions of cost reporting periods beginning on or after January 1, 1991.

(II) The term "ASC proportion" means 25 percent for cost reporting periods beginning in fiscal year 1988, 50 percent for portions of cost reporting periods beginning on or after October 1, 1988, and ending on or before December 31, 1990, and 58 percent for portions of cost reporting periods beginning on or after January 1, 1991.

(4) (A) In the case of a hospital that--

(i) makes application to the Secretary and demonstrates that it specializes in eye services or eye and ear services (as determined by the Secretary),

(ii) receives more than 30 percent of its total revenues from outpatient services, and

(iii) on October 1, 1987--

(I) was an eye specialty hospital or an eye and ear specialty hospital, or

(II) was operated as an eye or eye and ear unit (as defined in subparagraph (B)) of a general acute care hospital which, on the date of the application described in clause (i), operates less than 20 percent of the beds that the hospital operated on October 1, 1987, and has sold or otherwise disposed of a substantial portion of the hospital's other acute care operations,the cost proportion and ASC proportion in effect under subclauses (I) and (II) of paragraph (3)(B)(ii) for cost reporting periods beginning in fiscal year 1988 shall remain in effect for cost reporting periods beginning on or after October 1, 1988, and before January 1, 1995.

(B) For purposes of [this] subparagraph (A)(iii)(II), the term "eye or eye and ear unit" means a physically separate or distinct unit containing separate surgical suites devoted solely to eye or eye and ear services.

(5) (A) The Secretary is authorized to provide by regulations that in the case of a surgical procedure, specified by the Secretary pursuant to paragraph (1)(A), performed in an ambulatory surgical center described in such paragraph, there shall be paid (in lieu of any amounts otherwise payable under this part [*42 USCS §§ 1395j* et seq.]) with respect to the facility services furnished by such center and with respect to all related services furnished by such center and with respect to all related services (including physicians' services, laboratory, X-ray, and diagnostic services) a single all-inclusive fee established pursuant to subparagraph (B), if all parties furnishing all such services agree to accept such fee (to be divided among the parties involved in such manner as they shall have previously agreed upon) as full payment for the services furnished.

(B) In implementing this paragraph, the Secretary shall establish with respect to each surgical procedure specified pursuant to paragraph (1)(A) the amount of the all-inclusive fee for such procedure, taking into account such factors as may be appropriate. The amount so established with respect to any surgical procedure shall be reviewed periodically and may be adjusted by the Secretary, when appropriate, to take account of varying conditions in different areas.

(6) Any person, including a facility having an agreement under section 1832(a)(2)(F)(i) [*42 USCS § 1395k(a)(2)(F)(i)*, who knowingly and willfully presents, or causes to be presented, a bill or request for payment, for an intraocular lens inserted during or subsequent to cataract surgery for which payment may be made under paragraph (2)(A)(iii), is subject to a civil money penalty of not to exceed $ 2,000. The provisions of section 1128A [*42 USCS § 1320a-7a*] (other than subsections (a) and (b)) shall apply to a civil money penalty under the previous sentence in the same manner as such provisions apply to a penalty or proceeding under section 1128A(a) [*42 USCS § 1320a-7a(a)*].

(7) (A) For purposes of paragraph (2)(D)(iv), the Secretary may provide, in the case of an ambulatory surgical center that does not submit, to the Secretary in accordance with this paragraph, data required to be submitted on measures selected under this paragraph with respect to a year, any annual increase provided under the system established under paragraph (2)(D) for such year shall be reduced by 2.0 percentage points. A reduction under this subparagraph shall

apply only with respect to the year involved and the Secretary shall not take into account such reduction in computing any annual increase factor for a subsequent year.

(B) Except as the Secretary may otherwise provide, the provisions of subparagraphs (B), (C), (D), and (E) of paragraph (17) of section 1833(t) [subsec. (t) of this section] shall apply with respect to services of ambulatory surgical centers under this paragraph in a similar manner to the manner in which they apply under such paragraph and, for purposes of this subparagraph, any reference to a hospital, outpatient setting, or outpatient hospital services is deemed a reference to an ambulatory surgical center, the setting of such a center, or services of such a center, respectively.

(j) Accrual of interest on balance of excess or deficit not paid. Whenever a final determination is made that the amount of payment made under this part [*42 USCS §§ 1395j* et seq.] either to a provider of services or to another person pursuant to an assignment under section 1842(b)(3)(B)(ii) [*42 USCS § 1395u(b)(3)(B)(ii)*] was in excess of or less than the amount of payment that is due, and payment of such excess or deficit is not made (or effected by offset) within 30 days of the date of the determination, interest shall accrue on the balance of such excess or deficit not paid or offset (to the extent that the balance is owed by or owing to the provider) at a rate determined in accordance with the regulations of the Secretary of the Treasury applicable to charges for late payments.

(k) Hepatitis B vaccine. With respect to services described in section 1861(s)(10)(B) [*42 USCS § 1395x(s)(10)(B)*], the Secretary may provide, instead of the amount of payment otherwise provided under this part [*42 USCS §§ 1395j* et seq.], for payment of such an amount or amounts as reasonably reflects the general cost of efficiently providing such services.

(l) Fee schedule for services of certified registered nurse anesthetists.

(1) (A) The Secretary shall establish a fee schedule for services of certified registered nurse anesthetists under section 1861(s)(11) [*42 USCS § 1395x(s)(11)*].

(B) In establishing the fee schedule under this paragraph the Secretary may utilize a system of time units, a system of base and time units, or any appropriate methodology.

(C) The provisions of this subsection shall not apply to certain services furnished in certain hospitals in rural areas under the provisions of section 9320(k) of the Omnibus Budget Reconciliation Act of 1986, as amended by section 6132 of the Omnibus Budget Reconciliation Act of 1989 [*42 USCS § 1395k* note].

(2) Except as provided in paragraph (3), the fee schedule established under paragraph (1) shall be initially based on audited data from cost reporting periods ending in fiscal year 1985 and such other data as the Secretary determines necessary.

(3) (A) In establishing the initial fee schedule for those services, the Secretary shall adjust the fee schedule to the extent necessary to ensure that the estimated total amount which will be paid under this title for those services plus applicable coinsurance in 1989 will equal the estimated total amount which would be paid under this title for those services in 1989 if the services were included as inpatient hospital services and payment for such services was made under part A [*42 USCS §§ 1395c* et seq.] in the same manner as payment was made in fiscal year 1987, adjusted to take into account changes in prices and technology relating to the administration of anesthesia.

(B) The Secretary shall also reduce the prevailing charge of physicians for medical direction of a certified registered nurse anesthetist, or the fee schedule for services of certified registered nurse anesthetists, or both, to the extent necessary to ensure that the estimated total amount which will be paid under this title plus applicable coinsurance for such medical direction and such services in 1989 and 1990 will not exceed the estimated total amount which would have been paid plus applicable coinsurance but for the enactment of the amendments made by section 9320 of the Omnibus Budget Reconciliation Act of 1986. A reduced prevailing charge under this subparagraph shall become the prevailing charge but for subsequent years for purposes of applying the economic index under the fourth sentence of section 1842(b)(3) [*42 USCS § 1395u(b)(3)*].

(4) (A) Except as provided in subparagraphs (C) and (D), in determining the amount paid under the fee schedule under this subsection for services furnished on or after January 1, 1991, by a certified registered nurse anesthetist who is not medically directed--

(i) the conversion factor shall be--

(I) for services furnished in 1991, $ 15.50,

(II) for services furnished in 1992, $ 15.75,

(III) for services furnished in 1993, $ 16.00,

(IV) for services furnished in 1994, $ 16.25,

(V) for services furnished in 1995, $ 16.50,

(VI) for services furnished in 1996, $ 16.75, and

(VII) for services furnished in calendar years after 1996, the previous year's conversion factor increased by the update determined under section 1848(d) [*42 USCS § 1395w-4(d)*] for physician anesthesia services for that year;

(ii) the payment areas to be used shall be the fee schedule areas used under section 1848 [*42 USCS § 1395w-4*] (or, in the case of services furnished during 1991, the localities used under section 1842(b) [*42 USCS § 1395u(b)*]) for purposes of computing payments for physicians' services that are anesthesia services;

(iii) the geographic adjustment factors to be applied to the conversion factor under clause (i) for services in a fee schedule area or locality is [are]--

(I) in the case of services furnished in 1991, the geographic work index value and the geographic practice cost index value specified in section 1842(q)(1)(B) [*42 USCS § 1395u(q)(1)(B)*] for physicians' services that are anesthesia services furnished in the area or locality, and

(II) in the case of services furnished after 1991, the geographic work index value, the geographic practice cost index value, and the geographic malpractice index value used for determining payments for physicians' services that are anesthesia services under section 1848 [*42 USCS § 1395w-4*],

with 70 percent of the conversion factor treated as attributable to work and 30 percent as attributable to overhead for services furnished in 1991 (and the portions attributable to work, practice expenses, and malpractice expenses in 1992 and thereafter being the same as is applied under section 1848 [*42 USCS § 1395w-4*]).

(B) (i) Except as provided in clause (ii) and subparagraph (D), in determining the amount paid under the fee schedule under this subsection for services furnished on or after January 1, 1991, and before January 1, 1994, by a certified registered nurse anesthetist who is medically directed, the Secretary shall apply the same methodology specified in subparagraph (A).

(ii) The conversion factor used under clause (i) shall be--

(I) for services furnished in 1991, $ 10.50,

(II) for services furnished in 1992, $ 10.75, and

(III) for services furnished in 1993, $ 11.00.

(iii) In the case of services of a certified registered nurse anesthetist who is medically directed or medically supervised by a physician which are furnished on or after January 1, 1994, the fee schedule amount shall be one-half of the amount described in section 1848(a)(5)[(4)](B) [*42 USCS § 1395w-4(a)(4)(B)*] with respect to the physician.

(C) Notwithstanding subclauses (I) through (V) of subparagraph (A)(i)--

(i) in the case of a 1990 conversion factor that is greater than $ 16.50, the conversion factor for a calendar year after 1990 and before 1996 shall be the 1990 conversion factor reduced by the product of the last digit of the calendar year and one-fifth of the amount by which the 1990 conversion factor exceeds $ 16.50; and

(ii) in the case of a 1990 conversion factor that is greater than $ 15.49 but less than $ 16.51, the conversion factor for a calendar year after 1990 and before 1996 shall be the greater of--

(I) the 1990 conversion factor, or

(II) the conversion factor specified in subparagraph (A)(i) for the year involved.

(D) Notwithstanding subparagraph (C), in no case may the conversion factor used to determine payment for services in a fee schedule area or locality under this subsection, as adjusted by the adjustment factors specified in subparagraphs [subparagraph] (A)(iii), exceed the conversion factor used to determine the amount paid for physicians' services that are anesthesia services in the area or locality.

(5) (A) Payment for the services of a certified registered nurse anesthetist (for which payment may otherwise be made under this part [*42 USCS §§ 1395j* et seq.]) may be made on the basis of a claim or request for payment presented by the certified registered nurse anesthetist furnishing such services, or by a hospital, critical access hospital, physician, group practice, or ambulatory surgical center with which the certified registered nurse anesthetist furnishing such services has an employment or contractual relationship that provides for payment to be made under this part [*42 USCS §§ 1395j* et seq.] for such services to such hospital, critical access hospital, physician, group practice, or ambulatory surgical center.

(B) No hospital or critical access hospital that presents a claim or request for payment for services of a certified nurse anesthetist under this part [*42 USCS §§ 1395j* et seq.] may treat any uncollected coinsurance amount imposed under this part [*42 USCS §§ 1395j* et seq.] with respect to such services as a bad debt of such hospital or critical access hospital for purposes of this *title [42 USCS §§ 1395* et seq.].

(6) If an adjustment under paragraph (3)(B) results in a reduction in the reasonable charge for a physicians' service and a nonparticipating physician furnishes the service to an individual entitled to benefits under this part [*42 USCS §§ 1395j* et seq.] after the effective date of the reduction, the physician's actual charge is subject to a limit under section 1842(j)(1)(D) [*42 USCS § 1395u(j)(1)(D)*].

(m) Incentive payments for physicians' services furnished in underserved areas.

(1) In the case of physicians' services furnished in a year to an individual, who is covered under the insurance program established by this part [*42 USCS §§ 1395j* et seq.] and who incurs expenses for such services, in an area that is designated (under section 332(a)(1)(A) of the Public Health Service Act [*42 USCS § 256(a)(1)(A)*]) as a health professional shortage area as identified by the Secretary prior to the beginning of such year, in addition to the amount

otherwise paid under this part [*42 USCS §§ 1395j* et seq.], there also shall be paid to the physician (or to an employer or facility in the cases described in clause (A) of section 1842(b)(6) [*42 USCS § 1395u(b)(6)(A)*]) (on a monthly or quarterly basis) from the Federal Supplementary Medical Insurance Trust Fund an amount equal to 10 percent of the payment amount for the service under this part [*42 USCS §§ 1395j* et seq.].

(2) For each health professional shortage area identified in paragraph (1) that consists of an entire county, the Secretary shall provide for the additional payment under paragraph (1) without any requirement on the physician to identify the health professional shortage area involved. The Secretary may implement the previous sentence using the method specified in subsection (u)(4)(C).

(3) The Secretary shall post on the Internet website of the Centers for Medicare & Medicaid Services a list of the health professional shortage areas identified in paragraph (1) that consist of a partial county to facilitate the additional payment under paragraph (1) in such areas.

(4) There shall be no administrative or judicial review under section 1869 [*42 USCS § 1395ff*], section 1878 [*42 USCS § 1395oo*], or otherwise, respecting--

(A) the identification of a county or area;

(B) the assignment of a specialty of any physician under this paragraph;

(C) the assignment of a physician to a county under this subsection; or

(D) the assignment of a postal ZIP Code to a county or other area under this subsection.

(n) Payments to hospital outpatient departments for radiology; amount; definition.

[(1)](A) The aggregate amount of the payments to be made for all or part of a cost reporting period for services described in subsection (a)(2)(E)(i) furnished under this part [*42 USCS §§ 1395j* et seq.] on or after October 1, 1988, and before January 1, 1999, and for services described in subsection (a)(2)(E)(ii) furnished under this part [*42 USCS §§ 1395j* et seq.] on or after October 1, 1989, and before January 1, 1999, shall be equal to the lesser of--

(i) the amount determined with respect to such services under subsection (a)(2)(B), or

(ii) the blend amount for radiology services and diagnostic procedures determined in accordance with subparagraph (B).

(B) (i) The blend amount for radiology services and diagnostic procedures for a cost reporting period is the sum of--

(I) the cost proportion (as defined in clause (ii)) of the amount described in subparagraph (A)(i); and

(II) the charge proportion (as defined in clause (ii)(II)) of 62 percent (for services described in subsection (a)(2)(E)(i)), or (for procedures described in subsection (a)(2)(E)(ii)), 42 percent or such other percent established by the Secretary (or carriers acting pursuant to guidelines issued by the Secretary) based on prevailing charges established with actual charge data, of the prevailing charge or (for services described in subsection (a)(2)(E)(i) furnished on or after April 1, 1989 and for services described in subsection (a)(2)(E)(ii) furnished on or after January 1, 1992) the fee schedule amount established for participating physicians for the same services as if they were furnished in a physician's office in the same locality as determined under section 1842(b) [*42 USCS § 1395u(b)*] (or, in the case of services furnished on or after January 1, 1992, under section 1848 [*42 USCS § 1395w-4*]), less the amount a provider may charge as described in clause (ii) of section 1866(a)(2)(A) [*42 USCS § 1395cc(a)(2)(A)*].

(ii) In this subparagraph:

(I) The term "cost proportion" means 50 percent, except that such term means 65 percent in the case of outpatient radiology services for portions of cost reporting periods which occur in fiscal year 1989 and in the case of diagnostic procedures described in subsection (a)(2)(E)(ii) for portions of cost reporting periods which occur in fiscal year 1990, and such term means 42 percent in the case of outpatient radiology services for portions of cost reporting periods beginning on or after January 1, 1991.

(II) The term "charge proportion" means 100 percent minus the cost proportion.

(o) Limitation on benefit for payment for therapeutic shoes for individuals with server diabetic foot disease.

(1) In the case of shoes described in section 1861(s)(12) [*42 USCS § 1395x(s)(12)*]--

(A) no payment may be made under this part [*42 USCS §§ 1395j* et seq.], with respect to any individual for any year, for the furnishing of--

(i) more than one pair of custom molded shoes (including inserts provided with such shoes) and 2 additional pairs of inserts for such shoes, or

(ii) more than one pair of extra-depth shoes (not including inserts provided with such shoes) and 3 pairs of inserts for such shoes, and

(B) with respect to expenses incurred in any calendar year, no more than the amount of payment applicable under paragraph (2) shall be considered as incurred expenses for purposes of subsections (a) and (b).

Payment for shoes (or inserts) under this part [*42 USCS §§ 1395j* et seq.] shall be considered to include payment for any expenses for the fitting of such shoes (or inserts).

(2) (A) Except as provided by the Secretary under subparagraphs (B) and (C), the amount of payment under this paragraph for custom molded shoes, extra-depth shoes, and inserts shall be the amount determined for such items by the Secretary under section 1834(h) [*42 USCS § 1395m(h)*].

(B) The Secretary may establish payment amounts for shoes and inserts that are lower than the amount established under section 1834(h) [*42 USCS § 1395m(h)*] if the Secretary finds that shoes and inserts of an appropriate quality are readily available at or below the amount established under such section.

(C) In accordance with procedures established by the Secretary, an individual entitled to benefits with respect to shoes described in section 1861(s)(12) [*42 USCS § 1395x(s)(12)*] may substitute modification of such shoes instead of obtaining one (or more, as specified by the Secretary) pair of inserts (other than the original pair of inserts with respect to such shoes). In such case, the Secretary shall substitute, for the payment amount established under section 1834(h) [*42 USCS § 1395m(h)*], a payment amount that the Secretary estimates will assure that there is no net increase in expenditures under this subsection as a result of this subparagraph.

(3) In this *title [42 USCS §§ 1395* et seq.], the term "shoes" includes, except for purposes of subparagraphs (A)(ii) and (B) of paragraph (2), inserts for extra-depth shoes.

(p) [Deleted]

(q) Requests for payment to include information on referring physician

(1) Each request for payment, or bill submitted, for an item or service furnished by an entity for which payment may be made under this part [*42 USCS §§ 1395j* et seq.] and for which the entity knows or has reason to believe there has been a referral by a referring physician (within the meaning of section 1877 [*42 USCS § 1395nn*]) shall include the name and unique physician identification number for the referring physician.

(2) (A) In the case of a request for payment for an item or service furnished by an entity under this part [*42 USCS §§ 1395j* et seq.] on an assignment-related basis and for which information is required to be provided under paragraph (1) but not included, payment may be denied under this part [*42 USCS §§ 1395j* et seq.].

(B) In the case of a request for payment for an item or service furnished by an entity under this part [*42 USCS §§ 1395j* et seq.] not submitted on an assignment-related basis and for which information is required to be provided under paragraph (1) but not included--

(i) if the entity knowingly and willfully fails to provide such information promptly upon request of the Secretary or a carrier, the entity may be subject to a civil money penalty in an amount not to exceed $ 2,000, and

(ii) if the entity knowingly, willfully, and in repeated cases fails, after being notified by the Secretary of the obligations and requirements of this subsection to provide the information required under paragraph (1), the entity may be subject to exclusion from participation in the programs under this Act for a period not to exceed 5 years, in accordance with the procedures of subsections (c), (f), and (g) of section 1128 [*42 USCS § 1320a-7(c)*, (f), and (g)].

The provisions of section 1128A [*42 USCS § 1320a-7a*] (other than subsections (a) and (b)) shall apply to civil money penalties under clause (i) in the same manner as they apply to a penalty or proceeding under section 1128A(a) [*42 USCS § 1320a-7a(a)*].

(r) Cap on prevailing charge; billing only on assignment-related basis.

(1) With respect to services described in section 1861(s)(2)(K)(ii) [*42 USCS § 1395x(s)(2)(K)(ii)*] (relating to nurse practitioner or clinical nurse specialist services), payment may be made on the basis of a claim or request for payment presented by the nurse practitioner or clinical nurse specialist furnishing such services, or by a hospital, critical access hospital, skilled nursing facility or nursing facility (as defined in section 1919(a) [*42 USCS § 1396r(a)*]), physician, group practice, or ambulatory surgical center with which the nurse practitioner or clinical nurse specialist has an employment or contractual relationship that provides for payment to be made under this part [*42 USCS §§ 1395j* et seq.] for such services to such hospital, physician, group practice, or ambulatory surgical center.

(2) No hospital or critical access hospital that presents a claim or request for payment under this part [*42 USCS §§ 1395j* et seq.] for services described in section 1861(s)(2)(K)(ii) [*42 USCS § 1395x(s)(2)(K)(ii)*] may treat any uncollected coinsurance amount imposed under this part [*42 USCS §§ 1395j* et seq.] with respect to such services as a bad debt of such hospital for purposes of this *title [42 USCS §§ 1395* et seq.].

(s) Other prepaid organizations. The Secretary may not provide for payment under subsection (a)(1)(A) with respect to an organization unless the organization provides assurances satisfactory to the Secretary that the organization meets the requirement of section 1866(f) [*42 USCS § 1395cc(f)*] (relating to maintaining written policies and procedures respecting advance directives).

(t) Prospective payment system for hospital outpatient department services.

(1) Amount of payment.

(A) In general. With respect to covered OPD services (as defined in subparagraph (B)) furnished during a year beginning with 1999, the amount of payment under this part [*42 USCS §§ 1395j* et seq.] shall be determined under a prospective payment system established by the Secretary in accordance with this subsection.

(B) Definition of covered OPD services. For purposes of this subsection, the term "covered OPD services"--

(i) means hospital outpatient services designated by the Secretary;

(ii) subject to clause (iv), includes inpatient hospital services designated by the Secretary that are covered under this part [*42 USCS §§ 1395j* et seq.] and furnished to a hospital inpatient who (I) is entitled to benefits under part A [*42 USCS §§ 1395c* et seq.] but has exhausted benefits for inpatient hospital services during a spell of illness, or (II) is not so entitled;

(iii) includes implantable items described in paragraph (3), (6), or (8) of section 1861(s); but

(iv) does not include any therapy services described in subsection (a)(8) or ambulance services, for which payment is made under a fee schedule described in section 1834(k) or section 1834(l) [*42 USCS § 1395m(k)* or (l)] and does not include screening mammography (as defined in section 1861(jj) [*42 USCS § 1395x(jj)*]) and diagnostic mammography.

(2) System requirements. Under the payment system--

(A) the Secretary shall develop a classification system for covered OPD services;

(B) the Secretary may establish groups of covered OPD services, within the classification system described in subparagraph (A), so that services classified within each group are comparable clinically and with respect to the use of resources and so that an implantable item is classified to the group that includes the service to which the item relates;

(C) the Secretary shall, using data on claims from 1996 and using data from the most recent available cost reports, establish relative payment weights for covered OPD services (and any groups of such services described in subparagraph (B)) based on median (or, at the election of the Secretary, mean) hospital costs and shall determine projections of the frequency of utilization of each such service (or group of services) in 1999;

(D) the Secretary shall determine a wage adjustment factor to adjust the portion of payment and coinsurance attributable to labor-related costs for relative differences in labor and labor-related costs across geographic regions in a budget neutral manner;

(E) the Secretary shall establish, in a budget neutral manner, outlier adjustments under paragraph (5) and transitional pass-through payments under paragraph (6) and other adjustments as determined to be necessary to ensure equitable payments, such as adjustments for certain classes of hospitals;

(F) the Secretary shall develop a method for controlling unnecessary increases in the volume of covered OPD services;

(G) the Secretary shall create additional groups of covered OPD services that classify separately those procedures that utilize contrast agents from those that do not; and

(H) with respect to devices of brachytherapy consisting of a seed or seeds (or radioactive source), the Secretary shall create additional groups of covered OPD services that classify such devices separately from the other services (or group of services) paid for under this subsection in a manner reflecting the number, isotope, and radioactive intensity of such devices furnished, including separate groups for palladium-103 and iodine-125 devices and for stranded and non-stranded devices furnished on or after July 1, 2007.

For purposes of subparagraph (B), items and services within a group shall not be treated as "comparable with respect to the use of resources" if the highest median cost (or mean cost, if elected by the Secretary under subparagraph (C)) for an item or service within the group is more than 2 times greater than the lowest median cost (or mean cost, if so elected) for an item or service within the group; except that the Secretary may make exceptions in unusual cases, such as low volume items and services, but may not make such an exception in the case of a drug or biological that has been designated as an orphan drug under section 526 of the Federal Food, Drug and Cosmetic Act [*21 USCS § 360bb*].

(3) Calculation of base amounts.

(A) Aggregate amounts that would be payable if deductibles were disregarded. The Secretary shall estimate the sum of--

(i) the total amounts that would be payable from the Trust Fund under this part [*42 USCS §§ 1395j* et seq.] for covered OPD services in 1999, determined without regard to this subsection, as though the deductible under section 1833(b) [subsec. (b) of this section] did not apply, and

(ii) the total amounts of copayments estimated to be paid under this subsection by beneficiaries to hospitals for covered OPD services in 1999, as though the deductible under section 1833(b) [subsec. (b) of this section] did not apply.

(B) Unadjusted copayment amount.

(i) In general. For purposes of this subsection, subject to clause (ii), the "unadjusted copayment amount" applicable to a covered OPD service (or group of such services) is 20 percent of the national median of the charges for the service (or services within the group) furnished during 1996, updated to 1999 using the Secretary's estimate of charge growth during the period.

(ii) Adjusted to be 20 percent when fully phased in. If the pre-deductible payment percentage for a covered OPD service (or group of such services) furnished in a year would be equal to or exceed 80 percent, then the unadjusted copayment amount shall be 20 percent of amount determined under subparagraph (D).

(iii) Rules for new services. The Secretary shall establish rules for establishment of an unadjusted copayment amount for a covered OPD service not furnished during 1996, based upon its classification within a group of such services.

(C) Calculation of conversion factors.

(i) For 1999.

(I) In general. The Secretary shall establish a 1999 conversion factor for determining the medicare OPD fee schedule amounts for each covered OPD service (or group of such services) furnished in 1999. Such conversion factor shall be established on the basis of the weights and frequencies described in paragraph (2)(C) and in such a manner that the sum for all services and groups of the products (described in subclause (II) for each such service or group) equals the total projected amount described in subparagraph (A).

(II) Product described. The Secretary shall determine for each service or group the product of the medicare OPD fee schedule amounts (taking into account appropriate adjustments described in paragraphs (2)(D) and (2)(E)) and the estimated frequencies for such service or group.

(ii) Subsequent years. Subject to paragraph (8)(B), the Secretary shall establish a conversion factor for covered OPD services furnished in subsequent years in an amount equal to the conversion factor established under this subparagraph and applicable to such services furnished in the previous year increased by the OPD fee schedule increase factor specified under clause (iv) for the year involved.

(iii) Adjustment for service mix changes. Insofar as the Secretary determines that the adjustments for service mix under paragraph (2) for a previous year (or estimates that such adjustments for a future year) did (or are likely to) result in a change in aggregate payments under this subsection during the year that are a result of changes in the coding or classification of covered OPD services that do not reflect real changes in service mix, the Secretary may adjust the conversion factor computed under this subparagraph for subsequent years so as to eliminate the effect of such coding or classification changes.

(iv) OPD fee schedule increase factor. For purposes of this subparagraph, subject to paragraph (17), the "OPD fee schedule increase factor" for services furnished in a year is equal to the market basket percentage increase applicable under section 1886(b)(3)(B)(iii) [*42 USCS § 1395ww(b)(3)(B)(iii)*] to hospital discharges occurring during the fiscal year ending in such year, reduced by 1 percentage point for such factor for services furnished in each of 2000 and 2002. In applying the previous sentence for years beginning with 2000, the Secretary may substitute for the market basket percentage increase an annual percentage increase that is computed and applied with respect to covered OPD services furnished in a year in the same manner as the market basket percentage increase is determined and applied to inpatient hospital services for discharges occurring in a fiscal year.

(D) Calculation of medicare OPD fee schedule amounts. The Secretary shall compute a medicare OPD fee schedule amount for each covered OPD service (or group of such services) furnished in a year, in an amount equal to the product of--

(i) the conversion factor computed under subparagraph (C) for the year, and

(ii) the relative payment weight (determined under paragraph (2)(C)) for the service or group.

(E) Pre-deductible payment percentage. The pre-deductible payment percentage for a covered OPD service (or group of such services) furnished in a year is equal to the ratio of--

(i) the medicare OPD fee schedule amount established under subparagraph (D) for the year, minus the unadjusted copayment amount determined under subparagraph (B) for the service or group, to

(ii) the medicare OPD fee schedule amount determined under subparagraph (D) for the year for such service or group.

(4) Medicare payment amount. The amount of payment made from the Trust Fund under this part [*42 USCS §§ 1395j* et seq.] for a covered OPD service (and such services classified within a group) furnished in a year is determined, subject to paragraph (7), as follows:

(A) Fee schedule adjustments. The medicare OPD fee schedule amount (computed under paragraph (3)(D)) for the service or group and year is adjusted for relative differences in the cost of labor and other factors determined by the Secretary, as computed under paragraphs (2)(D) and (2)(E).

(B) Subtract applicable deductible. Reduce the adjusted amount determined under subparagraph (A) by the amount of the deductible under section 1833(b) [subsec. (b) of this section], to the extent applicable.

(C) Apply payment proportion to remainder. The amount of payment is the amount so determined under subparagraph (B) multiplied by the pre-deductible payment percentage (as determined under paragraph (3)(E)) for the service or group and year involved, plus the amount of any reduction in the copayment amount attributable to paragraph (8)(C).

(5) Outlier adjustment.

(A) In general. Subject to subparagraph (D), the Secretary shall provide for an additional payment for each covered OPD service (or group of services) for which a hospital's charges, adjusted to cost, exceed--

(i) a fixed multiple of the sum of--

(I) the applicable medicare OPD fee schedule amount determined under paragraph (3)(D), as adjusted under paragraph (4)(A) (other than for adjustments under this paragraph or paragraph (6)); and

(II) any transitional pass-through payment under paragraph (6); and

(ii) at the option of the Secretary, such fixed dollar amount as the Secretary may establish.

(B) Amount of adjustment. The amount of the additional payment under subparagraph (A) shall be determined by the Secretary and shall approximate the marginal cost of care beyond the applicable cutoff point under such subparagraph.

(C) Limit on aggregate outlier adjustments.

(i) In general. The total of the additional payments made under this paragraph for covered OPD services furnished in a year (as estimated by the Secretary before the beginning of the year) may not exceed the applicable percentage (specified in clause (ii)) of the total program payments estimated to be made under this subsection for all covered OPD services furnished in that year. If this paragraph is first applied to less than a full year, the previous sentence shall apply only to the portion of such year.

(ii) Applicable percentage. For purposes of clause (i), the term "applicable percentage" means a percentage specified by the Secretary up to (but not to exceed)--

(I) for a year (or portion of a year) before 2004, 2.5 percent; and

(II) for 2004 and thereafter, 3.0 percent.

(D) Transitional authority. In applying subparagraph (A) for covered OPD services furnished before January 1, 2002, the Secretary may--

(i) apply such subparagraph to a bill for such services related to an outpatient encounter (rather than for a specific service or group of services) using OPD fee schedule amounts and transitional pass-through payments covered under the bill; and

(ii) use an appropriate cost-to-charge ratio for the hospital involved (as determined by the Secretary), rather than for specific departments within the hospital.

(E) Exclusion of separate drug and biological APCs from outlier payments. No additional payment shall be made under subparagraph (A) in the case of ambulatory payment classification groups established separately for drugs or biologicals.

(6) Transitional pass-through for additional costs of innovative medical devices, drugs, and biologicals.

(A) In general. The Secretary shall provide for an additional payment under this paragraph for any of the following that are provided as part of a covered OPD service (or group of services):

(i) Current orphan drugs. A drug or biological that is used for a rare disease or condition with respect to which the drug or biological has been designated as an orphan drug under section 526 of the Federal Food, Drug and Cosmetic Act [*21 USCS § 360bb*] if payment for the drug or biological as an outpatient hospital service under this part [*42 USCS §§ 1395j* et seq.] was being made on the first date that the system under this subsection is implemented.

(ii) Current cancer therapy drugs and biologicals and brachytherapy. A drug or biological that is used in cancer therapy, including (but not limited to) a chemotherapeutic agent, an antiemetic, a hematopoietic growth factor, a colony stimulating factor, a biological response modifier, a bisphosphonate, and a device of brachytherapy or temperature monitored cryoablation, if payment for such drug, biological, or device as an outpatient hospital service under this part was being made on such first date.

(iii) Current radiopharmaceutical drugs and biological products. A radiopharmaceutical drug or biological product used in diagnostic, monitoring, and therapeutic nuclear medicine procedures if payment for the drug or biological as an outpatient hospital service under this part [*42 USCS §§ 1395j* et seq.] was being made on such first date.

(iv) New medical devices, drugs, and biologicals. A medical device, drug, or biological not described in clause (i), (ii), or (iii) if--

(I) payment for the device, drug, or biological as an outpatient hospital service under this part [*42 USCS §§ 1395j* et seq.] was not being made as of December 31, 1996; and

(II) the cost of the drug or biological or the average cost of the category of devices is not insignificant in relation to the OPD fee schedule amount (as calculated under paragraph (3)(D)) payable for the service (or group of services) involved.

(B) Use of categories in determining eligibility of a device for pass-through payments. The following provisions apply for purposes of determining whether a medical device qualifies for additional payments under clause (ii) or (iv) of subparagraph (A):

(i) Establishment of initial categories.

(I) In general. The Secretary shall initially establish under this clause categories of medical devices based on type of device by April 1, 2001. Such categories shall be established in a manner such that each medical device that meets the requirements of clause (ii) or (iv) of subparagraph (A) as of January 1, 2001, is included in such a category and no such device is included in more than one category. For purposes of the preceding sentence, whether a medical device meets such requirements as of such date shall be determined on the basis of the program memoranda issued before such date.

(II) Authorization of implementation other than through regulations. The categories may be established under this clause by program memorandum or otherwise, after consultation with groups representing hospitals, manufacturers of medical devices, and other affected parties.

(ii) Establishing criteria for additional categories.

(I) In general. The Secretary shall establish criteria that will be used for creation of additional categories (other than those established under clause (i)) through rulemaking (which may include use of an interim final rule with comment period).

(II) Standard. Such categories shall be established under this clause in a manner such that no medical device is described by more than one category. Such criteria shall include a test of whether the average cost of devices that would be included in a category and are in use at the time the category is established is not insignificant, as described in subparagraph (A)(iv)(II).

(III) Deadline. Criteria shall first be established under this clause by July 1, 2001. The Secretary may establish in compelling circumstances categories under this clause before the date such criteria are established.

(IV) Adding categories. The Secretary shall promptly establish a new category of medical devices under this clause for any medical device that meets the requirements of subparagraph (A)(iv) and for which none of the categories in effect (or that were previously in effect) is appropriate.

(iii) Period for which category is in effect. A category of medical devices established under clause (i) or (ii) shall be in effect for a period of at least 2 years, but not more than 3 years, that begins--

(I) in the case of a category established under clause (i), on the first date on which payment was made under this paragraph for any device described by such category (including payments made during the period before April 1, 2001); and

(II) in the case of any other category, on the first date on which payment is made under this paragraph for any medical device that is described by such category.

(iv) Requirements treated as met. A medical device shall be treated as meeting the requirements of subparagraph (A)(iv), regardless of whether the device meets the requirement of subclause (I) of such subparagraph, if--

(I) the device is described by a category established and in effect under clause (i); or

(II) the device is described by a category established and in effect under clause (ii) and an application under section 515 of the Federal Food, Drug, and Cosmetic Act [*21 USCS § 360e*] has been approved with respect to the device, or the device has been cleared for market under section 510(k) of such Act [*21 USCS § 360(k)*], or the device is exempt from the requirements of section 510(k) of such Act [*21 USCS § 360(k)*] pursuant to subsection (l) or (m) of section 510 of such Act [*21 USCS § 360*] or section 520(g) of such Act [*21 USCS § 360j(g)*].

Nothing in this clause shall be construed as requiring an application or prior approval (other than that described in subclause (II)) in order for a covered device described by a category to qualify for payment under this paragraph.

(C) Limited period of payment.

(i) Drugs and biologicals. The payment under this paragraph with respect to a drug or biological shall only apply during a period of at least 2 years, but not more than 3 years, that begins--

(I) on the first date this subsection is implemented in the case of a drug or biological described in clause (i), (ii), or (iii) of subparagraph (A) and in the case of a drug or biological described in subparagraph (A)(iv) and for which payment under this part is made as an outpatient hospital service before such first date; or

(II) in the case of a drug or biological described in subparagraph (A)(iv) not described in subclause (I), on the first date on which payment is made under this part for the drug or biological as an outpatient hospital service.

(ii) Medical devices. Payment shall be made under this paragraph with respect to a medical device only if such device-

(I) is described by a category of medical devices established and in effect under subparagraph (B); and

(II) is provided as part of a service (or group of services) paid for under this subsection and provided during the period for which such category is in effect under such subparagraph.

(D) Amount of additional payment. Subject to subparagraph (E)(iii), the amount of the payment under this paragraph with respect to a device, drug, or biological provided as part of a covered OPD service is--

(i) in the case of a drug or biological, the amount by which the amount determined under section 1842(o) [*42 USCS § 1395u*] (or if the drug or biological is covered under a competitive acquisition contract under section 1847B [*42 USCS § 1395w-3b*], an amount determined by the Secretary equal to the average price for the drug or biological for all

competitive acquisition areas and year established under such section as calculated and adjusted by the Secretary for purposes of this paragraph) for the drug or biological exceeds the portion of the otherwise applicable medicare OPD fee schedule that the Secretary determines is associated with the drug or biological; or

(ii) in the case of a medical device, the amount by which the hospital's charges for the device, adjusted to cost, exceeds the portion of the otherwise applicable medicare OPD fee schedule that the Secretary determines is associated with the device.

(E) Limit on aggregate annual adjustment.

(i) In general. The total of the additional payments made under this paragraph for covered OPD services furnished in a year (as estimated by the Secretary before the beginning of the year) may not exceed the applicable percentage (specified in clause (ii)) of the total program payments estimated to be made under this subsection for all covered OPD services furnished in that year. If this paragraph is first applied to less than a full year, the previous sentence shall apply only to the portion of such year.

(ii) Applicable percentage. For purposes of clause (i), the term "applicable percentage" means--

(I) for a year (or portion of a year) before 2004, 2.5 percent; and

(II) for 2004 and thereafter, a percentage specified by the Secretary up to (but not to exceed) 2.0 percent.

(iii) Uniform prospective reduction if aggregate limit projected to be exceeded. If the Secretary estimates before the beginning of a year that the amount of the additional payments under this paragraph for the year (or portion thereof) as determined under clause (i) without regard to this clause will exceed the limit established under such clause, the Secretary shall reduce pro rata the amount of each of the additional payments under this paragraph for that year (or portion thereof) in order to ensure that the aggregate additional payments under this paragraph (as so estimated) do not exceed such limit.

(F) Limitation of application of functional equivalence standard.

(i) In general. The Secretary may not publish regulations that apply a functional equivalence standard to a drug or biological under this paragraph.

(ii) Application. Clause (i) shall apply to the application of a functional equivalence standard to a drug or biological on or after the date of enactment of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 [enacted Dec. 8, 2003] unless--

(I) such application was being made to such drug or biological prior to such date of enactment; and

(II) the Secretary applies such standard to such drug or biological only for the purpose of determining eligibility of such drug or biological for additional payments under this paragraph and not for the purpose of any other payments under this *title [42 USCS §§ 1395* et seq.].

(iii) Rule of construction. Nothing in this subparagraph shall be construed to effect the Secretary's authority to deem a particular drug to be identical to another drug if the 2 products are pharmaceutically equivalent and bioequivalent, as determined by the Commissioner of Food and Drugs.

(7) Transitional adjustment to limit decline in payment.

(A) Before 2002. Subject to subparagraph (D), for covered OPD services furnished before January 1, 2002, for which the PPS amount (as defined in subparagraph (E)) is--

(i) at least 90 percent, but less than 100 percent, of the pre-BBA amount (as defined in subparagraph (F)), the amount of payment under this subsection shall be increased by 80 percent of the amount of such difference;

(ii) at least 80 percent, but less than 90 percent, of the pre-BBA amount, the amount of payment under this subsection shall be increased by the amount by which (I) the product of 0.71 and the pre-BBA amount, exceeds (II) the product of 0.70 and the PPS amount;

(iii) at least 70 percent, but less than 80 percent, of the pre-BBA amount, the amount of payment under this subsection shall be increased by the amount by which (I) the product of 0.63 and the pre-BBA amount, exceeds (II) the product of 0.60 and the PPS amount; or

(iv) less than 70 percent of the pre-BBA amount, the amount of payment under this subsection shall be increased by 21 percent of the pre-BBA amount.

(B) 2002. Subject to subparagraph (D), for covered OPD services furnished during 2002, for which the PPS amount is--

(i) at least 90 percent, but less than 100 percent, of the pre-BBA amount, the amount of payment under this subsection shall be increased by 70 percent of the amount of such difference;

(ii) at least 80 percent, but less than 90 percent, of the pre-BBA amount, the amount of payment under this subsection shall be increased by the amount by which (I) the product of 0.61 and the pre-BBA amount, exceeds (II) the product of 0.60 and the PPS amount; or

(iii) less than 80 percent of the pre-BBA amount, the amount of payment under this subsection shall be increased by 13 percent of the pre-BBA amount.

(C) 2003. Subject to subparagraph (D), for covered OPD services furnished during 2003, for which the PPS amount is--

(i) at least 90 percent, but less than 100 percent, of the pre-BBA amount, the amount of payment under this subsection shall be increased by 60 percent of the amount of such difference; or

(ii) less than 90 percent of the pre-BBA amount, the amount of payment under this subsection shall be increased by 6 percent of the pre-BBA amount.

(D) Hold harmless provisions.

(i) Temporary treatment for certain rural hospitals.

(I) In the case of a hospital located in a rural area and that has not more than 100 beds or a sole community hospital (as defined in section 1886(d)(5)(D)(iii) [*42 USCS § 1395ww(d)(5)(D)(iii)*]) located in a rural area, for covered OPD services furnished before January 1, 2006, for which the PPS amount is less than the pre-BBA amount, the amount of payment under this subsection shall be increased by the amount of such difference.

(II) In the case of a hospital located in a rural area and that has not more than 100 beds and that is not a sole community hospital (as defined in section 1886(d)(5)(D)(iii) [*42 USCS § 1395ww(d)(5)(D)(iii)*]), for covered OPD services furnished on or after January 1, 2006, and before January 1, 2010, for which the PPS amount is less than the pre-BBA amount, the amount of payment under this subsection shall be increased by the applicable percentage of the amount of such difference. For purposes of the preceding sentence, the applicable percentage shall be 95 percent with respect to covered OPD services furnished in 2006, 90 percent with respect to such services furnished in 2007, and 85 percent with respect to such services furnished in 2008 or 2009.

(III) In the case of a sole community hospital (as defined in section 1886(d)(5)(D)(iii) [*42 USCS § 1395ww(d)(5)(D)(iii)*]) that has not more than 100 beds, for covered OPD services furnished on or after January 1, 2009, and before January 1, 2010, for which the PPS amount is less than the pre-BBA amount, the amount of payment under this subsection shall be increased by 85 percent of the amount of such difference.

(ii) Permanent treatment for cancer hospitals and children's hospitals. In the case of a hospital described in clause (iii) or (v) of section 1886(d)(1)(B) [*42 USCS § 1395ww(d)(1)(B)*], for covered OPD services for which the PPS amount is less than the pre-BBA amount, the amount of payment under this subsection shall be increased by the amount of such difference.

(E) PPS amount defined. In this paragraph, the term "PPS amount" means, with respect to covered OPD services, the amount payable under this title for such services (determined without regard to this paragraph), including amounts payable as copayment under paragraph (8), coinsurance under section 1866(a)(2)(A)(ii) [*42 USCS § 1395cc(a)(2)(A)(ii)*], and the deductible under section 1833(b) [subsec. (b) of this section].

(F) Pre-BBA amount defined.

(i) In general. In this paragraph, the "pre-BBA amount" means, with respect to covered OPD services furnished by a hospital in a year, an amount equal to the product of the reasonable cost of the hospital for such services for the portions of the hospital's cost reporting period (or periods) occurring in the year and the base OPD payment-to-cost ratio for the hospital (as defined in clause (ii)).

(ii) Base payment-to-cost-ratio defined. For purposes of this subparagraph, the "base payment-to-cost ratio" for a hospital means the ratio of--

(I) the hospital's reimbursement under this part for covered OPD services furnished during the cost reporting period ending in 1996 (or in the case of a hospital that did not submit a cost report for such period, during the first subsequent cost reporting period ending before 2001 for which the hospital submitted a cost report), including any reimbursement for such services through cost-sharing described in subparagraph (E), to

(II) the reasonable cost of such services for such period.

The Secretary shall determine such ratios as if the amendments made by section 4521 of the Balanced Budget Act of 1997 were in effect in 1996.

(G) Interim payments. The Secretary shall make payments under this paragraph to hospitals on an interim basis, subject to retrospective adjustments based on settled cost reports.

(H) No effect on copayments. Nothing in this paragraph shall be construed to affect the unadjusted copayment amount described in paragraph (3)(B) or the copayment amount under paragraph (8).

(I) Application without regard to budget neutrality. The additional payments made under this paragraph--

(i) shall not be considered an adjustment under paragraph (2)(E); and

(ii) shall not be implemented in a budget neutral manner.

(8) Copayment amount.

(A) In general. Except as provided in subparagraphs (B) and (C), the copayment amount under this subsection is the amount by which the amount described in paragraph (4)(B) exceeds the amount of payment determined under paragraph (4)(C).

(B) Election to offer reduced copayment amount. The Secretary shall establish a procedure under which a hospital, before the beginning of a year (beginning with 1999), may elect to reduce the copayment amount otherwise established under subparagraph (A) for some or all covered OPD services to an amount that is not less than 20 percent of the medicare OPD fee schedule amount (computed under paragraph (3)(D)) for the service involved. Under such procedures, such reduced copayment amount may not be further reduced or increased during the year involved and the hospital may disseminate information on the reduction of copayment amount effected under this subparagraph.

(C) Limitation on copayment amount.

(i) To inpatient hospital deductible amount. In no case shall the copayment amount for a procedure performed in a year exceed the amount of the inpatient hospital deductible established under section 1813(b) [*42 USCS § 1395e(b)*] for that year.

(ii) To specified percentage. The Secretary shall reduce the national unadjusted copayment amount for a covered OPD service (or group of such services) furnished in a year in a manner so that the effective copayment rate (determined on a national unadjusted basis) for that service in the year does not exceed the following percentage:

(I) For procedures performed in 2001, on or after April 1, 2001, 57 percent.

(II) For procedures performed in 2002 or 2003, 55 percent.

(III) For procedures performed in 2004, 50 percent.

(IV) For procedures performed in 2005, 45 percent.

(V) For procedures performed in 2006 and thereafter, 40 percent.

(D) No impact on deductibles. Nothing in this paragraph shall be construed as affecting a hospital's authority to waive the charging of a deductible under section 1833(b) [subsec. (b) of this section].

(E) Computation ignoring outlier and pass-through adjustments. The copayment amount shall be computed under subparagraph (A) as if the adjustments under paragraphs (5) and (6) (and any adjustment made under paragraph (2)(E) in relation to such adjustments) had not occurred.

(9) Periodic review and adjustments components of prospective payment system.

(A) Periodic review. The Secretary shall review not less often than annually and revise the groups, the relative payment weights, and the wage and other adjustments described in paragraph (2) to take into account changes in medical practice, changes in technology, the addition of new services, new cost data, and other relevant information and factors. The Secretary shall consult with an expert outside advisory panel composed of an appropriate selection of representatives of providers to review (and advise the Secretary concerning) the clinical integrity of the groups and weights. Such panel may use data collected or developed by entities and organizations (other than the Department of Health and Human Services) in conducting such review.

(B) Budget neutrality adjustment. If the Secretary makes adjustments under subparagraph (A), then the adjustments for a year may not cause the estimated amount of expenditures under this part [*42 USCS §§ 1395j* et seq.] for the year to increase or decrease from the estimated amount of expenditures under this part [*42 USCS §§ 1395j* et seq.] that would have been made if the adjustments had not been made. In determining adjustments under the preceding sentence for 2004 and 2005, the Secretary shall not take into account under this subparagraph or paragraph (2)(E) any expenditures that would not have been made but for the application of paragraph (14).

(C) Update factor. If the Secretary determines under methodologies described in paragraph (2)(F) that the volume of services paid for under this subsection increased beyond amounts established through those methodologies, the Secretary may appropriately adjust the update to the conversion factor otherwise applicable in a subsequent year.

(10) Special rule for ambulance services. The Secretary shall pay for hospital outpatient services that are ambulance services on the basis described in section 1861(v)(1)(U) [*42 USCS § 1395x(v)(1)(U)*], or, if applicable, the fee schedule established under section 1834(l) [*42 USCS § 1395m(l)*].

(11) Special rules for certain hospitals. In the case of hospitals described in clause (iii) or (v) of section 1886(d)(1)(B) [*42 USCS § 1395ww(d)(1)(B)*]--

(A) the system under this subsection shall not apply to covered OPD services furnished before January 1, 2000; and

(B) the Secretary may establish a separate conversion factor for such services in a manner that specifically takes into account the unique costs incurred by such hospitals by virtue of their patient population and service intensity.

(12) Limitation on review. There shall be no administrative or judicial review under section 1869 [*42 USCS § 1395ff*], 1878 [*42 USCS § 1395oo*], or otherwise of--

(A) the development of the classification system under paragraph (2), including the establishment of groups and relative payment weights for covered OPD services, of wage adjustment factors, other adjustments, and methods described in paragraph (2)(F);

(B) the calculation of base amounts under paragraph (3);

(C) periodic adjustments made under paragraph (6);

(D) the establishment of a separate conversion factor under paragraph (8)(B); and

(E) the determination of the fixed multiple, or a fixed dollar cutoff amount, the marginal cost of care, or applicable percentage under paragraph (5) or the determination of insignificance of cost, the duration of the additional payments, the determination and deletion of initial and new categories (consistent with subparagraphs (B) and (C) of paragraph (6)), the portion of the medicare OPD fee schedule amount associated with particular devices, drugs, or biologicals, and the application of any pro rata reduction under paragraph (6).

(13) Authorization of adjustment for rural hospitals.

(A) Study. The Secretary shall conduct a study to determine if, under the system under this subsection, costs incurred by hospitals located in rural areas by ambulatory payment classification groups (APCs) exceed those costs incurred by hospitals located in urban areas.

(B) Authorization of adjustment. Insofar as the Secretary determines under subparagraph (A) that costs incurred by hospitals located in rural areas exceed those costs incurred by hospitals located in urban areas, the Secretary shall provide for an appropriate adjustment under paragraph (2)(E) to reflect those higher costs by January 1, 2006.

(14) Drug APC payment rates.

(A) In general. The amount of payment under this subsection for a specified covered outpatient drug (defined in subparagraph (B)) that is furnished as part of a covered OPD service (or group of services)--

(i) in 2004, in the case of--

(I) a sole source drug shall in no case be less than 88 percent, or exceed 95 percent, of the reference average wholesale price for the drug;

(II) an innovator multiple source drug shall in no case exceed 68 percent of the reference average wholesale price for the drug; or

(III) a noninnovator multiple source drug shall in no case exceed 46 percent of the reference average wholesale price for the drug;

(ii) in 2005, in the case of--

(I) a sole source drug shall in no case be less than 83 percent, or exceed 95 percent, of the reference average wholesale price for the drug;

(II) an innovator multiple source drug shall in no case exceed 68 percent of the reference average wholesale price for the drug; or

(III) a noninnovator multiple source drug shall in no case exceed 46 percent of the reference average wholesale price for the drug; or

(iii) in a subsequent year, shall be equal, subject to subparagraph (E)--

(I) to the average acquisition cost for the drug for that year (which, at the option of the Secretary, may vary by hospital group (as defined by the Secretary based on volume of covered OPD services or other relevant characteristics)), as determined by the Secretary taking into account the hospital acquisition cost survey data under subparagraph (D); or

(II) if hospital acquisition cost data are not available, the average price for the drug in the year established under section 1842(o), section 1847A, or section 1847B [*42 USCS § 1395(u), 1395w-3a*, or *1395w-3b*], as the case may be, as calculated and adjusted by the Secretary as necessary for purposes of this paragraph.

(B) Specified covered outpatient drug defined.

(i) In general. In this paragraph, the term "specified covered outpatient drug" means, subject to clause (ii), a covered outpatient drug (as defined in section 1927(k)(2) [*42 USCS § 1396r-8(k)(2)*]) for which a separate ambulatory payment classification group (APC) has been established and that is--

(I) a radiopharmaceutical; or

(II) a drug or biological for which payment was made under paragraph (6) (relating to pass-through payments) on or before December 31, 2002.

(ii) Exception. Such term does not include--

(I) a drug or biological for which payment is first made on or after January 1, 2003, under paragraph (6);

(II) a drug or biological for which a temporary HCPCS code has not been assigned; or

(III) during 2004 and 2005, an orphan drug (as designated by the Secretary).

(C) Payment for designated orphan drugs during 2004 and 2005. The amount of payment under this subsection for an orphan drug designated by the Secretary under subparagraph (B)(ii)(III) that is furnished as part of a covered OPD service (or group of services) during 2004 and 2005 shall equal such amount as the Secretary may specify.

(D) Acquisition cost survey for hospital outpatient drugs.

(i) Annual GAO surveys in 2004 and 2005.

(I) In general. The Comptroller General of the United States shall conduct a survey in each of 2004 and 2005 to determine the hospital acquisition cost for each specified covered outpatient drug. Not later than April 1, 2005, the Comptroller General shall furnish data from such surveys to the Secretary for use in setting the payment rates under subparagraph (A) for 2006.

(II) Recommendations. Upon the completion of such surveys, the Comptroller General shall recommend to the Secretary the frequency and methodology of subsequent surveys to be conducted by the Secretary under clause (ii).

(ii) Subsequent secretarial surveys. The Secretary, taking into account such recommendations, shall conduct periodic subsequent surveys to determine the hospital acquisition cost for each specified covered outpatient drug for use in setting the payment rates under subparagraph (A).

(iii) Survey requirements. The surveys conducted under clauses (i) and (ii) shall have a large sample of hospitals that is sufficient to generate a statistically significant estimate of the average hospital acquisition cost for each specified covered outpatient drug. With respect to the surveys conducted under clause (i), the Comptroller General shall report to Congress on the justification for the size of the sample used in order to assure the validity of such estimates.

(iv) Differentiation in cost. In conducting surveys under clause (i), the Comptroller General shall determine and report to Congress if there is (and the extent of any) variation in hospital acquisition costs for drugs among hospitals based on the volume of covered OPD services performed by such hospitals or other relevant characteristics of such hospitals (as defined by the Comptroller General).

(v) Comment on proposed rates. Not later than 30 days after the date the Secretary promulgated proposed rules setting forth the payment rates under subparagraph (A) for 2006, the Comptroller General shall evaluate such proposed rates and submit to Congress a report regarding the appropriateness of such rates based on the surveys the Comptroller General has conducted under clause (i).

(E) Adjustment in payment rates for overhead costs.

(i) MedPAC report on drug APC design. The Medicare Payment Advisory Commission shall submit to the Secretary, not later than July 1, 2005, a report on adjustment of payment for ambulatory payment classifications for specified covered outpatient drugs to take into account overhead and related expenses, such as pharmacy services and handling costs. Such report shall include--

(I) a description and analysis of the data available with regard to such expenses;

(II) a recommendation as to whether such a payment adjustment should be made; and

(III) if such adjustment should be made, a recommendation regarding the methodology for making such an adjustment.

(ii) Adjustment authorized. The Secretary may adjust the weights for ambulatory payment classifications for specified covered outpatient drugs to take into account the recommendations contained in the report submitted under clause (i).

(F) Classes of drugs. For purposes of this paragraph:

(i) Sole source drugs. The term "sole source drug" means--

(I) a biological product (as defined under section 1861(t)(1) [*42 USCS § 1395x(t)(1)*]); or

(II) a single source drug (as defined in section 1927(k)(7)(A)(iv) [*42 USCS § 1396r-8(k)(7)(A)(iv)*]).

(ii) Innovator multiple source drugs. The term "innovator multiple source drug" has the meaning given such term in section 1927(k)(7)(A)(ii) [*42 USCS § 1396r-8(k)(7)(A)(ii)*].

(iii) Noninnovator multiple source drugs. The term "noninnovator multiple source drug" has the meaning given such term in section 1927(k)(7)(A)(iii) [*42 USCS § 1396r-8(k)(7)(A)(iii)*].

(G) Reference average wholesale price. The term "reference average wholesale price" means, with respect to a specified covered outpatient drug, the average wholesale price for the drug as determined under section 1842(o) [*42 USCS § 1395u(o)*] as of May 1, 2003.

(H) Inapplicability of expenditures in determining conversion, weighting, and other adjustment factors. Additional expenditures resulting from this paragraph shall not be taken into account in establishing the conversion, weighting, and other adjustment factors for 2004 and 2005 under paragraph (9), but shall be taken into account for subsequent years.

(15) Payment for new drugs and biologicals until HCPCS code assigned. With respect to payment under this part [*42 USCS §§ 1395j* et seq.] for an outpatient drug or biological that is covered under this part and is furnished as part of covered OPD services for which a HCPCS code has not been assigned, the amount provided for payment for such drug or biological under this part shall be equal to 95 percent of the average wholesale price for the drug or biological.

(16) Miscellaneous provisions.

(A) Application of reclassification of certain hospitals. If a hospital is being treated as being located in a rural area under section 1886(d)(8)(E) [*42 USCS § 1395ww(d)(8)(E)*], that hospital shall be treated under this subsection as being located in that rural area.

(B) Threshold for establishment of separate APCs for drugs. The Secretary shall reduce the threshold for the establishment of separate ambulatory payment classification groups (APCs) with respect to drugs or biologicals to $ 50 per administration for drugs and biologicals furnished in 2005 and 2006.

(C) Payment for devices of brachytherapy and therapeutic radiopharmaceuticals at charges adjusted to cost. Notwithstanding the preceding provisions of this subsection, for a device of brachytherapy consisting of a seed or seeds (or radioactive source) furnished on or after January 1, 2004, and before January 1, 2010, and for therapeutic

radiopharmaceuticals furnished on or after January 1, 2008, and before January 1, 2010, the payment basis for the device or therapeutic radiopharmaceutical under this subsection shall be equal to the hospital's charges for each device or therapeutic radiopharmaceutical furnished, adjusted to cost. Charges for such devices or therapeutic radiopharmaceuticals shall not be included in determining any outlier payment under this subsection.

(17) Quality reporting.

(A) Reduction in update for failure to report.

(i) In general. For purposes of paragraph (3)(C)(iv) for 2009 and each subsequent year, in the case of a subsection (d) hospital (as defined in section 1886(d)(1)(B) [*42 USCS § 1395ww(d)(1)(B)*]) that does not submit, to the Secretary in accordance with this paragraph, data required to be submitted on measures selected under this paragraph with respect to such a year, the OPD fee schedule increase factor under paragraph (3)(C)(iv) for such year shall be reduced by 2.0 percentage points.

(ii) Non-cumulative application. A reduction under this subparagraph shall apply only with respect to the year involved and the Secretary shall not take into account such reduction in computing the OPD fee schedule increase factor for a subsequent year.

(B) Form and manner of submission. Each subsection (d) hospital shall submit data on measures selected under this paragraph to the Secretary in a form and manner, and at a time, specified by the Secretary for purposes of this paragraph.

(C) Development of outpatient measures.

(i) In general. The Secretary shall develop measures that the Secretary determines to be appropriate for the measurement of the quality of care (including medication errors) furnished by hospitals in outpatient settings and that reflect consensus among affected parties and, to the extent feasible and practicable, shall include measures set forth by one or more national consensus building entities.

(ii) Construction. Nothing in this paragraph shall be construed as preventing the Secretary from selecting measures that are the same as (or a subset of) the measures for which data are required to be submitted under section 1886(b)(3)(B)(viii) [*42 USCS § 1395ww(b)(3)(B)*(viii)].

(D) Replacement of measures. For purposes of this paragraph, the Secretary may replace any measures or indicators in appropriate cases, such as where all hospitals are effectively in compliance or the measures or indicators have been subsequently shown not to represent the best clinical practice.

(E) Availability of data. The Secretary shall establish procedures for making data submitted under this paragraph available to the public. Such procedures shall ensure that a hospital has the opportunity to review the data that are to be made public with respect to the hospital prior to such data being made public. The Secretary shall report quality measures of process, structure, outcome, patients' perspectives on care, efficiency, and costs of care that relate to services furnished in outpatient settings in hospitals on the Internet website of the Centers for Medicare & Medicaid Services.

(u) Incentive payments for physician scarcity areas.

(1) In general. In the case of physicians' services furnished on or after January 1, 2005, and before July 1, 2008--

(A) by a primary care physician in a primary care scarcity county (identified under paragraph (4)); or

(B) by a physician who is not a primary care physician in a specialist care scarcity county (as so identified),

in addition to the amount of payment that would otherwise be made for such services under this part [*42 USCS §§ 1395j* et seq.], there also shall be paid an amount equal to 5 percent of the payment amount for the service under this part [*42 USCS §§ 1395j* et seq.].

(2) Determination of ratios of physicians to medicare beneficiaries in area. Based upon available data, the Secretary shall establish for each county or equivalent area in the United States, the following:

(A) Number of physicians practicing in the area. The number of physicians who furnish physicians' services in the active practice of medicine or osteopathy in that county or area, other than physicians whose practice is exclusively for the Federal Government, physicians who are retired, or physicians who only provide administrative services. Of such number, the number of such physicians who are--

(i) primary care physicians; or

(ii) physicians who are not primary care physicians.

(B) Number of medicare beneficiaries residing in the area. The number of individuals who are residing in the county and are entitled to benefits under part A [*42 USCS §§ 1395c* et seq.] or enrolled under this part [*42 USCS §§ 1395j* et seq.], or both (in this subsection referred to as "individuals").

(C) Determination of ratios.

(i) Primary care ratio. The ratio (in this paragraph referred to as the "primary care ratio") of the number of primary care physicians (determined under subparagraph (A)(i)), to the number of individuals determined under subparagraph (B).

(ii) Specialist care ratio. The ratio (in this paragraph referred to as the "specialist care ratio") of the number of other physicians (determined under subparagraph (A)(ii)), to the number of individuals determined under subparagraph (B).

(3) Ranking of counties. The Secretary shall rank each such county or area based separately on its primary care ratio and its specialist care ratio.

(4) Identification of counties.

(A) In general. The Secretary shall identify--

(i) those counties and areas (in this paragraph referred to as "primary care scarcity counties") with the lowest primary care ratios that represent, if each such county or area were weighted by the number of individuals determined under paragraph (2)(B), an aggregate total of 20 percent of the total of the individuals determined under such paragraph; and

(ii) those counties and areas (in this subsection referred to as "specialist care scarcity counties") with the lowest specialist care ratios that represent, if each such county or area were weighted by the number of individuals determined under paragraph (2)(B), an aggregate total of 20 percent of the total of the individuals determined under such paragraph.

(B) Periodic revisions. The Secretary shall periodically revise the counties or areas identified in subparagraph (A) (but not less often than once every three years) unless the Secretary determines that there is no new data available on the number of physicians practicing in the county or area or the number of individuals residing in the county or area, as identified in paragraph (2).

(C) Identification of counties where service is furnished. For purposes of paying the additional amount specified in paragraph (1), if the Secretary uses the 5-digit postal ZIP Code where the service is furnished, the dominant county of the postal ZIP Code (as determined by the United States Postal Service, or otherwise) shall be used to determine whether the postal ZIP Code is in a scarcity county identified in subparagraph (A) or revised in subparagraph (B).

(D) Special rule. With respect to physicians' services furnished on or after January 1, 2008, and before July 1, 2008, for purposes of this subsection, the Secretary shall use the primary care scarcity counties and the specialty care scarcity counties (as identified under the preceding provisions of this paragraph) that the Secretary was using under this subsection with respect to physicians' services furnished on December 31, 2007.

(E) Judicial review. There shall be no administrative or judicial review under section 1869 [*42 USCS § 1395ff*], 1878 [*42 USCS § 1395oo*], or otherwise, respecting--

(i) the identification of a county or area;

(ii) the assignment of a specialty of any physician under this paragraph;

(iii) the assignment of a physician to a county under paragraph (2); or

(iv) the assignment of a postal ZIP Code to a county or other area under this subsection.

(5) Rural census tracts. To the extent feasible, the Secretary shall treat a rural census tract of a metropolitan statistical area (as determined under the most recent modification of the Goldsmith Modification, originally published in the Federal Register on February 27, 1992 *(57 Fed. Reg. 6725))*, as an equivalent area for purposes of qualifying as a primary care scarcity county or specialist care scarcity county under this subsection.

(6) Physician defined. For purposes of this paragraph, the term "physician" means a physician described in section 1861(r)(1) [*42 USCS § 1395x(r)(1)*] and the term "primary care physician" means a physician who is identified in the available data as a general practitioner, family practice practitioner, general internist, or obstetrician or gynecologist.

(7) Publication of list of counties; posting on website. With respect to a year for which a county or area is identified or revised under paragraph (4), the Secretary shall identify such counties or areas as part of the proposed and final rule to implement the physician fee schedule under section 1848 [*42 USCS § 1395w-4*] for the applicable year. The Secretary shall post the list of counties identified or revised under paragraph (4) on the Internet website of the Centers for Medicare & Medicaid Services.

(v) Increase of FQHC payment limits. In the case of services furnished by Federally qualified health centers (as defined in section 1861(aa)(4) [*42 USCS § 1395x(aa)(4)*]), the Secretary shall establish payment limits with respect to such services under this part for services furnished--

(1) in 2010, at the limits otherwise established under this part for such year increased by $ 5; and

(2) in a subsequent year, at the limits established under this subsection for the previous year increased by the percentage increase in the MEI (as defined in section 1842(i)(3) [*42 USCS § 1395u(i)(3)*]) for such subsequent year.

(w) Methods of payment. The Secretary may develop alternative methods of payment for items and services provided under clinical trials and comparative effectiveness studies sponsored or supported by an agency of the Department of Health and Human Services, as determined by the Secretary, to those that would otherwise apply under this section, to the extent such alternative methods are necessary to preserve the scientific validity of such trials or studies, such as in

the case where masking the identity of interventions from patients and investigators is necessary to comply with the particular trial or study design.

HISTORY:

(Aug. 14, 1935, ch 531, Title XVIII, Part B, § 1833, as added July 30, 1965, P.L. 89-97, Title I, Part 1, § 102(a), 79 Stat. 302; Jan. 2, 1968, P.L. 90-248, Title I, Part 3, §§ 129(c)(7), (8), 131(a), (b), 132(b), 135(c), 81 Stat. 848-850, 853; Oct. 30, 1972, P.L. 92-603, Title II, §§ 204(a), 211(c)(4), 226(c)(2), 233(b), 245(d), 251(a)(2), (3), 279, 299K(a), 86 Stat. 1377, 1384, 1404, 1411, 1424, 1445, 1454, 1464; Oct. 25, 1977, P.L. 95-142, § 16(a), 91 Stat. 1200; Dec. 13, 1977, P.L. 95-210, § 1(b), 91 Stat. 1485; June 13, 1978, P.L. 95-292, § 4(b), (c), 92 Stat. 315; Oct. 19, 1980, P.L. 96-473, § 6(j), 94 Stat. 2266; Dec. 5, 1980, P.L. 96-499, Title IX, Part A, Subpart III, § 918(a)(4), Part B, Subpart I, §§ 930(h), 932(a)(1), 934(b), (d)(1), (3), 935(a), Subpart II, §§ 942, 943(a), 94 Stat. 2626, 2631, 2634, 2637, 2639, 2641; Dec. 28, 1980, P.L. 96-611, § 1(b)(1), (2), 94 Stat. 3566; Aug. 13, 1981, P.L. 97-35, Title XXI, Subtitle A, Ch 2, § 2106(a) Subtitle B, Ch 2, §§ 2133(a), 2134(a), 95 Stat. 792, 797; Sept. 3, 1982, P.L. 97-248, Title I, Subtitle A, Part I, Subpart A, § 101(c)(2), Subpart B, § 112(a), (b), Subpart C, § 117(a)(2), Subtitle C, § 148(d), 96 Stat. 336, 340, 355, 394; July 18, 1984, P.L. 98-369, Division B, Title III, Subtitle A, Part I, §§ 2303(a)-(d), 2305(a)-(d), 2308(b)(2)(B), 2321(b), (d)(1)-(3), (4)(A), 2323(b)(1), (2), (4), Part II, § 2354(b)(5), (7), 98 Stat. 1064, 1069, 1074, 1084-1086, 1100; Nov. 8, 1984, P.L. 98-617, § 3(b)(3), 98 Stat. 3295; April 7, 1986, P.L. 99-272, Title IX, Subtitle A, Part 3, Subpart A, § 9303(a)(1), (b)(1)-(3), Part 4, § 9401(b)(1), (2)(A)-(E), 100 Stat. 188, 189, 198, 199; Oct. 21, 1986, P.L. 99-509, Title IX, Subtitle D, Part 2, § 9320(e)(1), (2), Part 3, §§ 9337(b), 9339(e)(1), (b)(1), (2), (c)(1), 9343(a), (b), (e)(2), 100 Stat. 2014, 2032, 2035, 2038-2040; Dec. 22, 1987, P.L. 100-203, Title IV, Subtitle A, Part 3, Subpart A, §§ 4043(a), 4045(c)(2)(A), 4049(a) 4055 [4054], Subpart B, §§ 4062(d)(3), 4063(b), (e), 4064(a)(b), (c), 4066(a)(b), 4067(a), 4068(a), Subpart C, §§ 4070(a), (b)(4), 4072(b), 4073(b)(2)(t), 4077(b)(3), (4), 4073(b), 4077(b)(2), Subpart D, §§ 4084(a), 4085(b)(1), (i)(1)-(3), (21)(D)(i), (22)(B), (23), 101 Stat. 1330-85, 1330-86, 1330-87, 1330-88, 1330-90, 1330-98, 1330-108-1330-113, 1330-117, 1330-118, 1330-129-1330-133; July 1, 1988, P.L. 100-360, Title I, Subtitle A, § 104(d)(7), Title II, Subtitle A, §§ 201(a), 202(b)(1)-(3), 203(c)(1)(A)-(E), 204(d)(1), 205(c), Subtitle B, § 212(c)(2), Title IV, Subtitle B, § 411(f)(2)(D), (8)(B)(i), (C), (12)(A), (14), (g)(1)(E), (2)(D), (E), (3)(A)-(F), (4)(C), (5), (h)(1)(A), (3)(B), (4)(B)-(C), (7)(C), (D), (i)(3), (4)(B), (C)(ii), (iv), (vi), 102 Stat. 689, 699, 704, 722, 729, 730, 741, 777, 779-789; Oct. 13, 1988, P.L. 100-485, Title VI, § 608(d)(4), (22)(B), (23)(A), 102 Stat. 2414, 2420, 2421; Nov. 10, 1988, P.L. 100-647, Title VIII, Subtitle E, Part III, §§ 8421(a), 8422(a), 102 Stat. 3802; Dec. 13, 1989, P.L. 101-234, Title II, §§ 201(a)(1), 202(a), 103 Stat. 1981; Dec. 19, 1989, P.L. 101-239, Title VI, Subtitle A, Part 1, Subpart A, § 6003(e)(2)(A), (g)(3)(D)(vii), Part 2, Subpart A, §§ 6102(c)(1), (e)(1), (5), (6)(A), (7), (f)(2), 6111(a), (b)(1), 6113(b)(3)(B), (d), 6116(b)(1), Subpart B, §§ 6131(a)(1), (b), 6133(a), Part 3, Subpart A, § 6204(b), 103 Stat. 2143, 2153, 2184, 2187, 2188, 2189, 2213, 2217, 2219, 2221, 2222, 2241; Nov. 5, 1990, P.L. 101-508, Title IV, Subtitle A, Part 1, § 4008(m)(2)(C), Part 2, Subpart A, §§ 4104(b)(1), 4118(f)(2)(D), Subpart B, §§ 4151(c)(1), (2), 4153(a)(2)(B), (C), 4154(a), (b)(1), (c)(1), (e)(1), 4155(b)(2), (3), 4160, 4161(a)(3)(B), 4163(d)(1), Part 2, § 4206(b)(2), Part 3, § 4302, 104 Stat. 1388-53, 1388-59, 1388-70, 1388-73, 1388-83, 1388-84, 1388-85, 1388-86, 1388-87, 1388-91, 1388-93, 1388-100, 1388-116, 1388-125; Nov. 16, 1990, P.L. 101-597, Title IV, § 401(c)(2), 104 Stat. 3035.; Aug. 10, 1993, P.L. 103-66, Title XIII, Ch 2, Subch A, Part II, Subpart A, § 13516(b), Subpart C, § 13532(a), Subpart D, § 13544(b)(2), Subpart E, §§ 13551, 13555(a), 107 Stat. 584, 586, 590, 592; Oct. 31, 1994, P.L. 103-432, Title I, Subtitle B, Part I, § 123(b)(2)(A), (e), Part III, § 141(a), (c)(1), 147(a), (d), (e)(2), (3), (f)(6)(C)-(E), Subtitle C, § 156(a)(2)(B), 160(d)(1), 108 Stat. 4411, 4412, 4424, 4425, 4429, 4430, 4432, 4440, 4443; Aug. 5, 1997, P.L. 105-33, Title IV, Subtitle A, Ch 1, Subch A, § 4002(j)(1)(A), Subtitle B, §§ 4101(b), 4102(b), 4103(b), 4104(c)(1), (2), Subtitle (C), §§ 4201(c)(1), 4205(a)(1)(A), (2), Subtitle D, Ch 2, § 4315(b), Subtitle E, Ch 3, § 4432(b)(5)(C), Subtitle F, Ch 1, Subch B, §§ 4511(b), 4512(b)(1), Ch 2, §§ 4521(a), (b), 4523(a), (d)(1)(A)(i), (B), (2), (3), Ch 3, § 4531(b)(1), Ch 4, § 4541(a)(1), (c), (d)(1), Ch 5, §§ 4553(a), (b), 4555, 4556(b), Subtitle G, Ch 1, Subch A, § 4603(c)(2)(A), 111 Stat. 330, 360-362, 365, 373, 376, 390, 421, 442-445, 449-451, 454, 456, 460, 462, 463, 471; Nov. 29, 1999, P.L. 106-113, Div B, § 1000(a)(6), 113 Stat. 1536; Dec. 21, 2000, P.L. 106-554, § 1(a)(6), 114 Stat. 2763; Dec. 8, 2003, P.L. 108-173, Title II, Subtitle D, § 237(a), Title III, §§ 302(b)(2), 303(i)(3)(A), Title IV, Subtitle B, §§ 411(a)(1), (b), 413(a), (b)(1), Title VI, Subtitle B, § 614(a), (b), Subtitle C, §§ 621(a)(1)-(5), (b)(1), (2), 622, 624(a)(1), 626(a)-(c), 627(a), 628, 629, Subtitle D, § 642(b), Title VII, Subtitle D, § 736(b)(1), (2), Title IX, Subtitle E, § 942(b), 117 Stat. 2212, 2229, 2254, 2274, 2275, 2306, 2307, 2310, 2311, 2318, 2320, 2321, 2322, 2355, 2421.)

(As amended Feb. 8, 2006, P.L. 109-171, Title V, Subtitle B, Ch. 1, §§ 5103, 5105, 5107(a)(1), Ch. 2, §§ 5112(e), 5113(a), 120 Stat. 40, 41, 42, 44; Dec. 20, 2006, P.L. 109-432, Div B, Title I, §§ 107(a), (b)(1), 109(a)(1), (b), Title II, § 201, 120 Stat. 2983, 2984, 2985, 2986; Dec. 29, 2007, P.L. 110-173, Title I, §§ 102, 105, 106, 113, 121 Stat. 2495, 2496, 2501; July 15, 2008, P.L. 110-275, Title I, Subtitle A, Part I, §§ 101(a)(2), (b)(2), 102, Subtitle C, Part II, §§ 141, 142, 143(b)(2), (3), 145(a)(2), (b), 147, 151(a), Subtitle F, § 184, 122 Stat. 2497, 2498, 2542, 2547, 2548, 2550, 2587.)

§ 1395m. Special payment rules for particular items and services

(a) Payment for durable medical equipment.

(1) General rule for payment.

(A) In general. With respect to a covered item (as defined in paragraph (13)) for which payment is determined under this subsection, payment shall be made in the frequency specified in paragraphs (2) through (7) and in an amount equal to 80 percent of the payment basis described in subparagraph (B).

(B) Payment basis. Subject to subparagraph (F)(i), the payment basis described in this subparagraph is the lesser of--

(i) the actual charge for the item, or

(ii) the payment amount recognized under paragraphs (2) through (7) of this subsection for the item;

except that clause (i) shall not apply if the covered item is furnished by a public home health agency (or by another home health agency which demonstrates to the satisfaction of the Secretary that a significant portion of its patients are low income) free of charge or at nominal charges to the public.

(C) Exclusive payment rule. Subject to subparagraph (F)(ii), this subsection shall constitute the exclusive provision of this *title [42 USCS §§ 1395* et seq.] for payment for covered items under this part [*42 USCS §§ 1395j* et seq.] or under part A [*42 USCS §§ 1395c* et seq.] to a home health agency.

(D) Reduction in fee schedules for certain items. With respect to a seat-lift chair or transcutaneous electrical nerve stimulator furnished on or after April 1, 1990, the Secretary shall reduce the payment amount applied under subparagraph (B)(ii) for such an item by 15 percent, and, in the case of a transcutaneous electrical nerve stimulator furnished on or after January 1, 1991, the Secretary shall further reduce such payment amount (as previously reduced) by 45 percent.

(E) Clinical conditions for coverage.

(i) In general. The Secretary shall establish standards for clinical conditions for payment for covered items under this subsection.

(ii) Requirements. The standards established under clause (i) shall include the specification of types or classes of covered items that require, as a condition of payment under this subsection, a face-to-face examination of the individual by a physician (as defined in section 1861(r) [*42 USCS § 1395x(r)*]), a physician assistant, nurse practitioner, or a clinical nurse specialist (as those terms are defined in section 1861(aa)(5) [*42 USCS § 1395x(aa)(5)*]) and a prescription for the item.

(iii) Priority of establishment of standards. In establishing the standards under this subparagraph, the Secretary shall first establish standards for those covered items for which the Secretary determines there has been a proliferation of use, consistent findings of charges for covered items that are not delivered, or consistent findings of falsification of documentation to provide for payment of such covered items under this part [*42 USCS §§ 1395j* et seq.].

(iv) Standards for power wheelchairs. Effective on the date of the enactment of this subparagraph, in the case of a covered item consisting of a motorized or power wheelchair for an individual, payment may not be made for such covered item unless a physician (as defined in section 1861(r)(1) [*42 USCS § 1395x(r)(1)*]), a physician assistant, nurse practitioner, or a clinical nurse specialist (as those terms are defined in section 1861(aa)(5) [*42 USCS § 1395x(aa)(5)*]) has conducted a face-to-face examination of the individual and written a prescription for the item.

(v) Limitation on payment for covered items. Payment may not be made for a covered item under this subsection unless the item meets any standards established under this subparagraph for clinical condition of coverage.

(F) Application of competitive acquisition; limitation of inherent reasonableness authority. In the case of covered items furnished on or after January 1, 2011, subject to subparagraph (G), that are included in a competitive acquisition program in a competitive acquisition area under section 1847(a) [*42 USCS § 1395w-3(a)*]--

(i) the payment basis under this subsection for such items and services furnished in such area shall be the payment basis determined under such competitive acquisition program; and

(ii) the Secretary may use information on the payment determined under such competitive acquisition programs to adjust the payment amount otherwise recognized under subparagraph (B)(ii) for an area that is not a competitive acquisition area under section 1847 [*42 USCS § 1395w-3*] and in the case of such adjustment, paragraph (10)(B) shall not be applied.

(G) Use of information on competitive bid rates. The Secretary shall specify by regulation the methodology to be used in applying the provisions of subparagraph (F)(ii) and subsection (h)(1)(H)(ii). In promulgating such regulation, the Secretary shall consider the costs of items and services in areas in which such provisions would be applied compared to the payment rates for such items and services in competitive acquisition areas.

(2) Payment for inexpensive and other routinely purchased durable medical equipment.

(A) In general. Payment for an item of durable medical equipment (as defined in paragraph (13))--

(i) the purchase price of which does not exceed $ 150,

(ii) which the Secretary determines is acquired at least 75 percent of the time by purchase, or

(iii) which is an accessory used in conjunction with a nebulizer, aspirator, or a ventilator excluded under paragraph (3)(A),

shall be made on a rental basis or in a lump-sum amount for the purchase of the item. The payment amount recognized for purchase or rental of such equipment is the amount specified in subparagraph (B) for purchase or rental, except that the total amount of payments with respect to an item may not exceed the payment amount specified in subparagraph (B) with respect to the purchase of the item.

(B) Payment amount. For purposes of subparagraph (A), the amount specified in this subparagraph, with respect to the purchase or rental of an item furnished in a carrier service area--

(i) in 1989 and in 1990 is the average reasonable charge in the area for the purchase or rental, respectively, of the item for the 12-month period ending on June 30, 1987, increased by the percentage increase in the consumer price index for all urban consumers (U.S. city average) for the 6-month period ending with December 1987;

(ii) in 1991 is the sum of (I) 67 percent of the local payment amount for the item or device computed under subparagraph (C)(i)(I) for 1991, and (II) 33 percent of the national limited payment amount for the item or device computed under subparagraph (C)(ii) for 1991;

(iii) in 1992 is the sum of (I) 33 percent of the local payment amount for the item or device computed under subparagraph (C)(i)(II) for 1992, and (II) 67 percent of the national limited payment amount for the item or device computed under subparagraph (C)(ii) for 1992; and

(iv) in 1993 and each subsequent year is the national limited payment amount for the item or device computed under subparagraph (C)(ii) for that year (reduced by 10 percent, in the case of a blood glucose testing strip furnished after 1997 for an individual with diabetes).

(C) Computation of local payment amount and national limited payment amount. For purposes of subparagraph (B)--

(i) the local payment amount for an item or device for a year is equal to--

(I) for 1991, the amount specified in subparagraph (B)(i) for 1990 increased by the covered item update for 1991, and

(II) for 1992, 1993, and 1994, the amount determined under this clause for the preceding year increased by the covered item update for the year; and

(ii) the national limited payment amount for an item or device for a year is equal to--

(I) for 1991, the local payment amount determined under clause (i) for such item or device for that year, except that the national limited payment amount may not exceed 100 percent of the weighted average of all local payment amounts determined under such clause for such item for that year and may not be less than 85 percent of the weighted average of all local payment amounts determined under such clause for such item,

(II) for 1992 and 1993, the amount determined under this clause for the preceding year increased by the covered item update for such subsequent year,

(III) for 1994, the local payment amount determined under clause (i) for such item or device for that year, except that the national limited payment amount may not exceed 100 percent of the median of all local payment amounts determined under such clause for such item for that year and may not be less than 85 percent of the median of all local payment amounts determined under such clause for such item or device for that year, and

(IV) for each subsequent year, the amount determined under this clause for the preceding year increased by the covered item update for such subsequent year.

(3) Payment for items requiring frequent and substantial servicing.

(A) In general. Payment for a covered item (such as IPPB machines and ventilators, excluding ventilators that are either continuous airway pressure devices or intermittent assist devices with continuous airway pressure devices) for which there must be frequent and substantial servicing in order to avoid risk to the patient's health shall be made on a monthly basis for the rental of the item and the amount recognized is the amount specified in subparagraph (B).

(B) Payment amount. For purposes of subparagraph (A), the amount specified in this subparagraph, with respect to an item or device furnished in a carrier service area--

(i) in 1989 and in 1990 is the average reasonable charge in the area for the rental of the item or device for the 12-month period ending with June 1987, increased by the percentage increase in the consumer price index for all urban consumers (U.S. city average) for the 6-month period ending with December 1987;

(ii) in 1991 is the sum of (I) 67 percent of the local payment amount for the item or device computed under subparagraph (C)(i)(I) for 1991, and (II) 33 percent of the national limited payment amount for the item or device computed under subparagraph (C)(ii) for 1991;

(iii) in 1992 is the sum of (I) 33 percent of the local payment amount for the item or device computed under subparagraph (C)(i)(II) for 1992, and (II) 67 percent of the national limited payment amount for the item or device computed under subparagraph (C)(ii) for 1992; and

(iv) in 1993 and each subsequent year is the national limited payment amount for the item or device computed under subparagraph (C)(ii) for that year.

(C) Computation of local payment amount and national limited payment amount. For purposes of subparagraph (B)--

(i) the local payment amount for an item or device for a year is equal to--

(I) for 1991, the amount specified in subparagraph (B)(i) for 1990 increased by the covered item update for 1991, and

(II) for 1992, 1993, and 1994, the amount determined under this clause for the preceding year increased by the covered item update for the year; and

(ii) the national limited payment amount for an item or device for a year is equal to--

(I) for 1991, the local payment amount determined under clause (i) for such item or device for that year, except that the national limited payment amount may not exceed 100 percent of the weighted average of all local payment amounts determined under such clause for such item for that year and may not be less than 85 percent of the weighted average of all local payment amounts determined under such clause for such item,

(II) for 1992 and 1993, the amount determined under this clause for the preceding year increased by the covered item update for such subsequent year,

(III) for 1994, the local payment amount determined under clause (i) for such item or device for that year, except that the national limited payment amount may not exceed 100 percent of the median of all local payment amounts determined under such clause for such item for that year and may not be less than 85 percent of the median of all local payment amounts determined under such clause for such item or device for that year, and

(IV) for each subsequent year, the amount determined under this clause for the preceding year increased by the covered item update for such subsequent year.

(4) Payment for certain customized items. Payment with respect to a covered item that is uniquely constructed or substantially modified to meet the specific needs of an individual patient, and for the reason cannot be grouped with similar items for purposes of payment under this *title [42 USCS §§ 1395* et seq.], shall be made in a lump-sum amount (A) for the purchase of the item in a payment amount based upon the carrier's individual consideration for that item, and (B) for the reasonable and necessary maintenance and servicing for parts and labor not covered by the supplier's or manufacturer's warranty, when necessary during the period of medical need, and the amount recognized for such maintenance and servicing shall be paid on a lump-sum, as needed basis upon the carrier's individual consideration for that item.

(5) Payment for oxygen and oxygen equipment.

(A) In general. Payment for oxygen and oxygen equipment shall be made on a monthly basis in the monthly payment amount recognized under paragraph (9) for oxygen and oxygen equipment (other than portable oxygen equipment), subject to subparagraphs (B), (C), (E), and (F).

(B) Add-on for portable oxygen equipment. When portable oxygen equipment is used, but subject to subparagraph (D), the payment amount recognized under subparagraph (A) shall be increased by the monthly payment amount recognized under paragraph (9) for portable oxygen equipment.

(C) Volume adjustment. When the attending physician prescribes an oxygen flow rate--

(i) exceeding 4 liters per minute, the payment amount recognized under subparagraph (A), subject to subparagraph (D), shall be increased by 50 percent, or

(ii) of less than 1 liter per minute, the payment amount recognized under subparagraph (A) shall be decreased by 50 percent.

(D) Limit on adjustment. When portable oxygen equipment is used and the attending physician prescribes an oxygen flow rate exceeding 4 liters per minute, there shall only be an increase under either subparagraph (B) or (C), whichever increase is larger, and not under both such subparagraphs.

(E) Recertification for patients receiving home oxygen therapy. In the case of a patient receiving home oxygen therapy services who, at the time such services are initiated, has an initial arterial blood gas value at or above a partial pressure of 56 or an arterial oxygen saturation at or above 89 percent (or such other values, pressures, or criteria as the Secretary may specify) no payment may be made under this part [*42 USCS §§ 1395j* et seq.] for such services after the expiration of the 90-day period that begins on the date the patient first receives such services unless the patient's attending physician certifies that, on the basis of a follow-up test of the patient's arterial blood gas value or arterial oxygen saturation conducted during the final 30 days of such 90-day period, there is a medical need for the patient to continue to receive such services.

(F) Rental cap.

(i) In general. Payment for oxygen equipment (including portable oxygen equipment) under this paragraph may not extend over a period of continuous use (as determined by the Secretary) of longer than 36 months.

(ii) Payments and rules after rental cap. After the 36th continuous month during which payment is made for the equipment under this paragraph--

(I) the supplier furnishing such equipment under this subsection shall continue to furnish the equipment during any period of medical need for the remainder of the reasonable useful lifetime of the equipment, as determined by the Secretary;

(II) payments for oxygen shall continue to be made in the amount recognized for oxygen under paragraph (9) for the period of medical need; and

(III) maintenance and servicing payments shall, if the Secretary determines such payments are reasonable and necessary, be made (for parts and labor not covered by the supplier's or manufacturer's warranty, as determined by the Secretary to be appropriate for the equipment), and such payments shall be in an amount determined to be appropriate by the Secretary.

(6) Payment for other covered items (other than durable medical equipment). Payment for other covered items (other than durable medical equipment and other covered items described in paragraph (3), (4), or (5)) shall be made in a lump-sum amount for the purchase of the item in the amount of the purchase price recognized under paragraph (8).

(7) Payment for other items of durable medical equipment.

(A) Payment. In the case of an item of durable medical equipment not described in paragraphs (2) through (6), the following rules shall apply:

(i) Rental.

(I) In general. Except as provided in clause (iii), payment for the item shall be made on a monthly basis for the rental of the item during the period of medical need (but payments under this clause may not extend over a period of continuous use (as determined by the Secretary) of longer than 13 months).

(II) Payment amount. Subject to subparagraph (B), the amount recognized for the item, for each of the first 3 months of such period, is 10 percent of the purchase price recognized under paragraph (8) with respect to the item, and, for each of the remaining months of such period, is 7.5 percent of such purchase price.

(ii) Ownership after rental. On the first day that begins after the 13th continuous month during which payment is made for the rental of an item under clause (i), the supplier of the item shall transfer title to the item to the individual.

(iii) Purchase agreement option for power-driven wheelchairs. In the case of a power-driven wheelchair, at the time the supplier furnishes the item, the supplier shall offer the individual the option to purchase the item, and payment for such item shall be made on a lump-sum basis if the individual exercises such option.

(iv) Maintenance and servicing. After the supplier transfers title to the item under clause (ii) or in the case of a power-driven wheelchair for which a purchase agreement has been entered into under clause (iii), maintenance and servicing payments shall, if the Secretary determines such payments are reasonable and necessary, be made (for parts and labor not covered by the supplier's or manufacturer's warranty, as determined by the Secretary to be appropriate for the particular type of durable medical equipment), and such payments shall be in an amount determined to be appropriate by the Secretary.

(B) Range for rental amounts.

(i) For 1989. For items furnished during 1989, the payment amount recognized under subparagraph (A)(i) shall not be more than 115 percent, and shall not be less than 85 percent, of the prevailing charge established for rental of the item in January 1987, increased by the percentage increase in the consumer price index for all urban consumers (U.S. city average) for the 6-month period ending with December 1987.

(ii) For 1990. For items furnished during 1990, clause (i) shall apply in the same manner as it applies to items furnished during 1989.

(C) Replacement of items.

(i) Establishment of reasonable useful lifetime. In accordance with clause (iii), the Secretary shall determine and establish a reasonable useful lifetime for items of durable medical equipment for which payment may be made under this paragraph.

(ii) Payment for replacement items. If the reasonable lifetime of such an item, as so established, has been reached during a continuous period of medical need, or the carrier determines that the item is lost or irreparably damaged, the patient may elect to have payment for an item serving as a replacement for such item made--

(I) on a monthly basis for the rental of the replacement item in accordance with subparagraph (A); or

(II) in the case of an item for which a purchase agreement has been entered into under subparagraph (A)(ii) or (A)(iii), in a lump-sum amount for the purchase of the item.

(iii) Length of reasonable useful lifetime. The reasonable useful lifetime of an item of durable medical equipment under this subparagraph shall be equal to 5 years, except that, if the Secretary determines that, on the basis of prior experience in making payments for such an item under this *title [42 USCS §§ 1395* et seq.], a reasonable useful lifetime of 5 years is not appropriate with respect to a particular item, the Secretary shall establish an alternative reasonable lifetime for such item.

(8) Purchase price recognized for miscellaneous devices and items. For purposes of paragraphs (6) and (7), the amount that is recognized under this paragraph as the purchase price for a covered item is the amount described in subparagraph (C) of this paragraph, determined as follows:

(A) Computation of local purchase price. Each carrier under section 1842 [*42 USCS § 1395u*] shall compute a base local purchase price for the item as follows:

(i) The carrier shall compute a base local purchase price, for each item described--

(I) in paragraph (6) equal to the average reasonable charge in the locality for the purchase of the item for the 12-month period ending with June 1987, or

(II) in paragraph (7) equal to the average of the purchase prices on the claims submitted on an assignment-related basis for the unused item supplied during the 6-month period ending with December 1986.

(ii) The carrier shall compute a local purchase price, with respect to the furnishing of each particular item--

(I) in 1989 and 1990, equal to the base local purchase price computed under clause (i) increased by the percentage increase in the consumer price index for all urban consumers (U.S. city average) for the 6-month period ending with December 1987,

(II) in 1991, equal to the local purchase price computed under this clause for the previous year, increased by the covered item update for 1991, and decreased by the percentage by which the average of the reasonable charges for claims paid for all items described in paragraph (7) is lower than the average of the purchase prices submitted for such items during the final 9 months of 1988;[,] or

(III) in 1992, 1993, and 1994, equal to the local purchase price computed under this clause for the previous year increased by the covered item update for the year.

(B) Computation of national limited purchase price. With respect to the furnishing of a particular item in a year, the Secretary shall compute a national limited purchase price--

(i) for 1991, equal to the local purchase price computed under subparagraph (A)(ii) for the item for the year, except that such national limited purchase price may not exceed 100 percent of the weighted average of all local purchase prices for the item computed under such subparagraph for the year, and may not be less than 85 percent of the weighted average of all local purchase prices for the item computed under such subparagraph for the year;

(ii) for 1992 and 1993, the amount determined under this subparagraph for the preceding year increased by the covered item update for such subsequent year;

(iii) for 1994, the local purchase price computed under subparagraph (A)(ii) for the item for the year, except that such national limited purchase price may not exceed 100 percent of the median of all local purchase prices computed for the item under such subparagraph for the year and may not be less than 85 percent of the median of all local purchase prices computed under such subparagraph for the item for the year; and

(iv) for each subsequent year, equal to the amount determined under this subparagraph for the preceding year increased by the covered item update for such subsequent year.

(C) Purchase price recognized. For purposes of paragraphs (6) and (7), the amount that is recognized under this paragraph as the purchase price for each item furnished--

(i) in 1989 or 1990, is 100 percent of the local purchase price computed under subparagraph (A)(ii)(I);

(ii) in 1991, is the sum of (I) 67 percent of the local purchase price computed under subparagraph (A)(ii)(II) for 1991, and (II) 33 percent of the national limited purchase price computed under subparagraph (B) for 1991;

(iii) in 1992, is the sum of (I) 33 percent of the local purchase price computed under subparagraph (A)(ii)(III) for 1992, and (II) 67 percent of the national limited purchase price computed under subparagraph (B) for 1992; and

(iv) in 1993 or a subsequent year, is the national limited purchase price computed under subparagraph (B) for that year.

(9) Monthly payment amount recognized with respect to oxygen and oxygen equipment. For purposes of paragraph (5), the amount that is recognized under this paragraph for payment for oxygen and oxygen equipment is the monthly payment amount described in subparagraph (C) of this paragraph. Such amount shall be computed separately (i) for all items of oxygen and oxygen equipment (other than portable oxygen equipment) and (ii) for portable oxygen equipment (each such group referred to in this paragraph as an "item").

(A) Computation of local monthly payment rate. Each carrier under this section shall compute a base local payment rate for each item as follows:

(i) The carrier shall compute a base local average monthly payment rate per beneficiary as an amount equal to (I) the total reasonable charges for the item during the 12-month period ending with December 1986, divided by (II) the total number of months for all beneficiaries receiving the item in the area during the 12-month period for which the carrier made payment for the item under this *title [42 USCS §§ 1395* et seq.].

(ii) The carrier shall compute a local average monthly payment rate for the item applicable--

(I) to 1989 and 1990, equal to 95 percent of the base local average monthly payment rate computed under clause (i) for the item increased by the percentage increase in the consumer price index for all urban consumers (U.S. city average) for the 6-month period ending with December 1987, or

(II) to 1991, 1992, 1993, and 1994, equal to the local average monthly payment rate computed under this clause for the item for the previous year increased by the covered item increase for the year.

(B) Computation of national limited monthly payment rate. With respect to the furnishing of an item in a year, the Secretary shall compute a national limited monthly payment rate equal to--

(i) for 1991, the local monthly payment rate computed under subparagraph (A)(ii)(II) for the item for the year, except that such national limited monthly payment rate may not exceed 100 percent of the weighted average of all local monthly payment rates computed for the item under such subparagraph for the year, and may not be less than 85 percent of the weighted average of all local monthly payment rates computed for the item under such subparagraph for the year;

(ii) for 1992 and 1993, the amount determined under this subparagraph for the preceding year increased by the covered item update for such subsequent year;

(iii) for 1994, the local monthly payment rate computed under subparagraph (A)(ii) for the item for the year, except that such national limited monthly payment rate may not exceed 100 percent of the median of all local monthly payment rates computed for the item under such subparagraph for the year and may not be less than 85 percent of the median of all local monthly payment rates computed for the item under such subparagraph for the year;

(iv) for 1995, 1996, and 1997, equal to the amount determined under this subparagraph for the preceding year increased by the covered item update for such subsequent year;

(v) for 1998, 75 percent of the amount determined under this subparagraph for 1997; and

(vi) for 1999 and each subsequent year, 70 percent of the amount determined under this subparagraph for 1997.

(C) Monthly payment amount recognized. For purposes of paragraph (5), the amount that is recognized under this paragraph as the base monthly payment amount for each item furnished--

(i) in 1989 and in 1990, is 100 percent of the local average monthly payment rate computed under subparagraph (A)(ii) for the item;

(ii) in 1991, is the sum of (I) 67 percent of the local average monthly payment rate computed under subparagraph (A)(ii)(II) for the item for 1991, and (II) 33 percent of the national limited monthly payment rate computed under subparagraph (B)(i) for the item for 1991;

(iii) in 1992, is the sum of (I) 33 percent of the local average monthly payment rate computed under subparagraph (A)(ii)(II) for the item for 1992, and (II) 67 percent of the national limited monthly payment rate computed under subparagraph (B)(ii) for the item for 1992; and

(iv) in a subsequent year, is the regional monthly payment rate computed under subparagraph (B) for the item for that year.

(D) Authority to create classes.

(i) In general. Subject to clause (ii), the Secretary may establish separate classes for any item of oxygen and oxygen equipment and separate national limited monthly payment rates for each of such classes.

(ii) Budget neutrality. The Secretary may take actions under clause (i) only to the extent such actions do not result in expenditures for any year to be more or less than the expenditures which would have been made if such actions had not been taken.

(10) Exceptions and adjustments.

(A) Areas outside continental United States. Exceptions to the amounts recognized under the previous provisions of this subsection shall be made to take into account the unique circumstances of covered items furnished in Alaska, Hawaii, or Puerto Rico.

(B) Adjustment for inherent reasonableness. The Secretary is authorized to apply the provisions of paragraphs (8) and (9) of section 1842(b) [*42 USCS § 1395u(b)*] to covered items and suppliers of such items and payments under this subsection in an area and with respect to covered items and services for which the Secretary does not make a payment amount adjustment under paragraph (1)(F).

(C) Transcutaneous electrical nerve stimulator (TENS). In order to permit an attending physician time to determine whether the purchase of a transcutaneous electrical nerve stimulator is medically appropriate for a particular patient, the Secretary may determine an appropriate payment amount for the initial rental of such item for a period of not more than 2 months. If such item is subsequently purchased, the payment amount with respect to such purchase is the payment amount determined under paragraph (2).

(11) Improper billing and requirement of physician order.

(A) Improper billing for certain rental items. Notwithstanding any other provision of this *title [42 USCS §§ 1395* et seq.], a supplier of a covered item for which payment is made under this subsection and which is furnished on a rental basis shall continue to supply the item without charge (other than a charge provided under this subsection for the maintenance and servicing of the item) after rental payments may no longer be made under this subsection. If a supplier

knowingly and willfully violates the previous sentence, the Secretary may apply sanctions against the supplier under section 1842(j)(2) [*42 USCS § 1395u(j)(2)*] in the same manner such sanctions may apply with respect to a physician.

(B) Requirement of physician order. The Secretary is authorized to require, for specified covered items, that payment may be made under this subsection with respect to the item only if a physician has communicated to the supplier, before delivery of the item, a written order for the item.

(12) Regional carriers. The Secretary may designate, by regulation under section 1842 [*42 USCS § 1395u*], one carrier for one or more entire regions to process all claims within the region for covered items under this section.

(13) "Covered item" defined. In this subsection, the term "covered item" means durable medical equipment (as defined in section 1861(n) [*42 USCS § 1395x(n)*]), including such equipment described in section 1861(m)(5) [*42 USCS § 1395x(m)(5)*], but not including implantable items for which payment may be made under section 1833(t) [*42 USCS § 1395l(t)*][]].

(14) Covered item update. In this subsection, the term "covered item update" means, with respect to a year--

(A) for 1991 and 1992, the percentage increase in the consumer price index for all urban consumers (U.S. city average) for the 12-month period ending with June of the previous year reduced by 1 percentage point;

(B) for 1993, 1994, 1995, 1996, and 1997, the percentage increase in the consumer price index for all urban consumers (U.S. city average) for the 12-month period ending with June of the previous year;

(C) for each of the years 1998 through 2000, 0 percentage points;

(D) for 2001, the percentage increase in the consumer price index for all urban consumers (U.S. city average) for the 12-month period ending with June 2000;

(E) for 2002, 0 percentage points;

(F) for 2003, the percentage increase in the consumer price index for all urban consumers (U.S. urban average) for the 12-month period ending with June of the 2002;

(G) for 2004 through 2006--

(i) subject to clause (ii), in the case of class III medical devices described in section 513(a)(1)(C) of the Federal Food, Drug, and Cosmetic Act (*21 U.S.C. 360(c)(1)(C)* [*21 USCS § 360c(c)(1)(C)*]), the percentage increase described in subparagraph (B) for the year involved; and

(ii) in the case of covered items not described in clause (i), 0 percentage points;

(H) for 2007--

(i) subject to clause (ii), in the case of class III medical devices described in section 513(a)(1)(C) of the Federal Food, Drug, and Cosmetic Act (*21 U.S.C. 360(c)(1)(C)* [*21 USCS § 360c(c)(1)(C)*]), the percentage change determined by the Secretary to be appropriate taking into account recommendations contained in the report of the Comptroller General of the United States under section 302(c)(1)(B) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 [note to this section]; and

(ii) in the case of covered items not described in clause (i), 0 percentage points;

(I) for 2008--

(i) subject to clause (ii), in the case of class III medical devices described in section 513(a)(1)(C) of the Federal Food, Drug, and Cosmetic Act (*21 U.S.C. 360(c)(1)(C)* [*21 USCS § 360c(c)(1)(C)*]), the percentage increase described in subparagraph (B) (as applied to the payment amount for 2007 determined after the application of the percentage change under subparagraph (H)(i)); and

(ii) in the case of covered items not described in clause (i), 0 percentage points;

(J) for 2009--

(i) in the case of items and services furnished in any geographic area, if such items or services were selected for competitive acquisition in any area under the competitive acquisition program under section 1847(a)(1)(B)(i)(I) [*42 USCS § 1395w-3(a)(1)(B)(i)(I)*] before July 1, 2008, including related accessories but only if furnished with such items and services selected for such competition and diabetic supplies but only if furnished through mail order, - 9.5 percent; or

(ii) in the case of other items and services, the percentage increase in the consumer price index for all urban consumers (U.S. urban average) for the 12-month period ending with June 2008;

(K) for 2010, 2011, 2012, and 2013, the percentage increase in the consumer price index for all urban consumers (U.S. urban average) for the 12-month period ending with June of the previous year;

(L) for 2014--

(i) in the case of items and services described in subparagraph (J)(i) for which a payment adjustment has not been made under subsection (a)(1)(F)(ii) in any previous year, the percentage increase in the consumer price index for all urban consumers (U.S. urban average) for the 12-month period ending with June 2013, plus 2.0 percentage points; or

(ii) in the case of other items and services, the percentage increase in the consumer price index for all urban consumers (U.S. urban average) for the 12-month period ending with June 2013; and

(M) for a subsequent year, the percentage increase in the consumer price index for all urban consumers (U.S. urban average) for the 12-month period ending with June of the previous year.

(15) Advance determinations of coverage for certain items.

(A) Development of lists of items by Secretary. The Secretary may develop and periodically update a list of items for which payment may be made under this subsection that the Secretary determines, on the basis of prior payment experience, are frequently subject to unnecessary utilization throughout a carrier's entire service area or a portion of such area.

(B) Development of lists of suppliers by Secretary. The Secretary may develop and periodically update a list of suppliers of items for which payment may be made under this subsection with respect to whom--

(i) the Secretary has found that a substantial number of claims for payment under this part for items furnished by the supplier have been denied on the basis of the application of section 1862(a)(1) [*42 USCS § 1395y(a)(1)*]; or

(ii) the Secretary has identified a pattern of overutilization resulting from the business practice of the supplier.

(C) Determinations of coverage in advance. A carrier shall determine in advance of delivery of an item whether payment for the item may not be made because the item is not covered or because of the application of section 1862(a)(1) [*42 USCS § 1395y(a)(1)*] if--

(i) the item is included on the list developed by the Secretary under subparagraph (A);

(ii) the item is furnished by a supplier included on the list developed by the Secretary under subparagraph (B); or

(iii) the item is a customized item (other than inexpensive items specified by the Secretary) and the patient to whom the item is to be furnished or the supplier requests that such advance determination be made.

(16) Disclosure of information and surety bond. The Secretary shall not provide for the issuance (or renewal) of a provider number for a supplier of durable medical equipment, for purposes of payment under this part [*42 USCS §§ 1395j* et seq.] for durable medical equipment furnished by the supplier, unless the supplier provides the Secretary on a continuing basis--

(A) with--

(i) full and complete information as to the identity of each person with an ownership or control interest (as defined in section 1124(a)(3) [*42 USCS § 1320a-3(a)(3)*]) in the supplier or in any subcontractor (as defined by the Secretary in regulations) in which the supplier directly or indirectly has a 5 percent or more ownership interest; and

(ii) to the extent determined to be feasible under regulations of the Secretary, the name of any disclosing entity (as defined in section 1124(a)(2) [*42 USCS § 1320a-3(a)(2)*]) with respect to which a person with such an ownership or control interest in the supplier is a person with such an ownership or control interest in the disclosing entity; and

(B) with a surety bond in a form specified by the Secretary and in an amount that is not less than $ 50,000.

The Secretary may waive the requirement of a bond under subparagraph (B) in the case of a supplier that provides a comparable surety bond under State law. The Secretary, at the Secretary's discretion, may impose the requirements of the first sentence with respect to some or all providers of items or services under part A [*42 USCS §§ 1395c* et seq.] or some or all suppliers or other persons (other than physicians or other practitioners, as defined in section 1842(b)(18)(C) [*42 USCS § 1395u(b)(18)(C)*]) who furnish items or services under this part [*42 USCS §§ 1395j* et seq.].

(17) Prohibition against unsolicited telephone contacts by suppliers.

(A) In general. A supplier of a covered item under this subsection may not contact an individual enrolled under this part by telephone regarding the furnishing of a covered item to the individual unless 1 of the following applies:

(i) The individual has given written permission to the supplier to make contact by telephone regarding the furnishing of a covered item.

(ii) The supplier has furnished a covered item to the individual and the supplier is contacting the individual only regarding the furnishing of such covered item.

(iii) If the contact is regarding the furnishing of a covered item other than a covered item already furnished to the individual, the supplier has furnished at least 1 covered item to the individual during the 15-month period preceding the date on which the supplier makes such contact.

(B) Prohibiting payment for items furnished subsequent to unsolicited contacts. If a supplier knowingly contacts an individual in violation of subparagraph (A), no payment may be made under this part for any item subsequently furnished to the individual by the supplier.

(C) Exclusion from program for suppliers engaging in pattern of unsolicited contacts. If a supplier knowingly contacts individuals in violation of subparagraph (A) to such an extent that the supplier's conduct establishes a pattern of contacts in violation of such subparagraph, the Secretary shall exclude the supplier from participation in the programs under this Act, in accordance with the procedures set forth in subsections (c), (f), and (g) of section 1128 [*42 USCS § 1320a-7*].

(18) Refund of amounts collected for certain disallowed items.

(A) In general. If a nonparticipating supplier furnishes to an individual enrolled under this part [*42 USCS §§ 1395j* et seq.] a covered item for which no payment may be made under this part by reason of paragraph (17)(B), the supplier

shall refund on a timely basis to the patient (and shall be liable to the patient for) any amounts collected from the patient for the item, unless--

(i) the supplier establishes that the supplier did not know and could not reasonably have been expected to know that payment may not be made for the item by reason of paragraph (17)(B), or

(ii) before the item was furnished, the patient was informed that payment under this part may not be made for that item and the patient has agreed to pay for that item.

(B) Sanctions. If a supplier knowingly and willfully fails to make refunds in violation of subparagraph (A), the Secretary may apply sanctions against the supplier in accordance with section 1842(j)(2) [*42 USCS § 1395u(j)(2)*].

(C) Notice. Each carrier with a contract in effect under this part [*42 USCS §§ 1395j* et seq.] with respect to suppliers of covered items shall send any notice of denial of payment for covered items by reason of paragraph (17)(B) and for which payment is not requested on an assignment-related basis to the supplier and the patient involved.

(D) Timely basis defined. A refund under subparagraph (A) is considered to be on a timely basis only if--

(i) in the case of a supplier who does not request reconsideration or seek appeal on a timely basis, the refund is made within 30 days after the date the supplier receives a denial notice under subparagraph (C), or

(ii) in the case in which such a reconsideration or appeal is taken, the refund is made within 15 days after the date the supplier receives notice of an adverse determination on reconsideration or appeal.

(19) Certain upgraded items.

(A) Individual's right to choose upgraded item. Notwithstanding any other provision of this *title [42 USCS §§ 1395* et seq.], the Secretary may issue regulations under which an individual may purchase or rent from a supplier an item of upgraded durable medical equipment for which payment would be made under this subsection if the item were a standard item.

(B) Payments to supplier. In the case of the purchase or rental of an upgraded item under subparagraph (A)--

(i) the supplier shall receive payment under this subsection with respect to such item as if such item were a standard item; and

(ii) the individual purchasing or renting the item shall pay the supplier an amount equal to the difference between the supplier's charge and the amount under clause (i).

In no event may the supplier's charge for an upgraded item exceed the applicable fee schedule amount (if any) for such item.

(C) Consumer protection safeguards. Any regulations under subparagraph (A) shall provide for consumer protection standards with respect to the furnishing of upgraded equipment under subparagraph (A). Such regulations shall provide for--

(i) determination of fair market prices with respect to an upgraded item;

(ii) full disclosure of the availability and price of standard items and proof of receipt of such disclosure information by the beneficiary before the furnishing of the upgraded item;

(iii) conditions of participation for suppliers in the billing arrangement;

(iv) sanctions of suppliers who are determined to engage in coercive or abusive practices, including exclusion; and

(v) such other safeguards as the Secretary determines are necessary.

(20) Identification of quality standards.

(A) In general. Subject to subparagraph (C), the Secretary shall establish and implement quality standards for suppliers of items and services described in subparagraph (D) to be applied by recognized independent accreditation organizations (as designated under subparagraph (B)) and with which such suppliers shall be required to comply in order to--

(i) furnish any such item or service for which payment is made under this part [*42 USCS §§ 1395j* et seq.]; and

(ii) receive or retain a provider or supplier number used to submit claims for reimbursement for any such item or service for which payment may be made under this *title [42 USCS §§ 1395* et seq.].

(B) Designation of independent accreditation organizations **[Caution: For provisions applicable to accreditations of hospitals granted before July 15, 2010, see 2008 amendment note below.]**. Not later than the date that is 1 year after the date on which the Secretary implements the quality standards under subparagraph (A), notwithstanding section 1865(a) [*42 USCS § 1395bb(a)*], the Secretary shall designate and approve one or more independent accreditation organizations for purposes of such subparagraph.

(C) Quality standards. The quality standards described in subparagraph (A) may not be less stringent than the quality standards that would otherwise apply if this paragraph did not apply and shall include consumer services standards.

(D) Items and services described. The items and services described in this subparagraph are the following items and services, as the Secretary determines appropriate:

(i) Covered items (as defined in paragraph (13)) for which payment may otherwise be made under this subsection.

(ii) Prosthetic devices and orthotics and prosthetics described in section 1834(h)(4) [subsec. (h)(4) of this section].

(iii) Items and services described in section 1842(s)(2) [*42 USCS § 1395u(s)(2)*].

(E) Implementation. The Secretary may establish by program instruction or otherwise the quality standards under this paragraph, including subparagraph (F), after consultation with representatives of relevant parties. Such standards shall be applied prospectively and shall be published on the Internet website of the Centers for Medicare & Medicaid Services.

(F) Application of accreditation requirement. In implementing quality standards under this paragraph--

(i) subject to clause (ii), the Secretary shall require suppliers furnishing items and services described in subparagraph (D) on or after October 1, 2009, directly or as a subcontractor for another entity, to have submitted to the Secretary evidence of accreditation by an accreditation organization designated under subparagraph (B) as meeting applicable quality standards; and

(ii) in applying such standards and the accreditation requirement of clause (i) with respect to eligible professionals (as defined in section 1848(k)(3)(B) [*42 USCS § 1395w-4(k)(3)(B)*]), and including such other persons, such as orthotists and prosthetists, as specified by the Secretary, furnishing such items and services--

(I) such standards and accreditation requirement shall not apply to such professionals and persons unless the Secretary determines that the standards being applied are designed specifically to be applied to such professionals and persons; and

(II) the Secretary may exempt such professionals and persons from such standards and requirement if the Secretary determines that licensing, accreditation, or other mandatory quality requirements apply to such professionals and persons with respect to the furnishing of such items and services.

(21) Special payment rule for specified items and supplies.

(A) In general. Notwithstanding the preceding provisions of this subsection, for specified items and supplies (described in subparagraph (B)) furnished during 2005, the payment amount otherwise determined under this subsection for such specified items and supplies shall be reduced by the percentage difference between--

(i) the amount of payment otherwise determined for the specified item or supply under this subsection for 2002, and

(ii) the amount of payment for the specified item or supply under chapter 89 of title 5, United States Code [*5 USCS §§ 8901* et seq.], as identified in the column entitled "Median FEHP Price" in the table entitled "SUMMARY OF MEDICARE PRICES COMPARED TO VA, MEDICAID, RETAIL, AND FEHP PRICES FOR 16 ITEMS" included in the Testimony of the Inspector General before the Senate Committee on Appropriations, June 12, 2002, or any subsequent report by the Inspector General.

(B) Specified item or supply described. For purposes of subparagraph (A), a specified item or supply means oxygen and oxygen equipment, standard wheelchairs (including standard power wheelchairs), nebulizers, diabetic supplies consisting of lancets and testing strips, hospital beds, and air mattresses, but only if the HCPCS code for the item or supply is identified in a table referred to in subparagraph (A)(ii).

(C) Application of update to special payment amount. The covered item update under paragraph (14) for specified items and supplies for 2006 and each subsequent year shall be applied to the payment amount under subparagraph (A) unless payment is made for such items and supplies under section 1847 [*42 USCS § 1395w-3*].

(b) Fee schedules for radiologist services.

(1) Development. The Secretary shall develop--

(A) a relative value scale to serve as the basis for the payment for radiologist services under this part [*42 USCS §§ 1395j* et seq.], and

(B) using such scale and appropriate conversion factors and subject to subsection (c)(1)(A), fee schedules (on a regional, statewide, locality, or carrier service area basis) for payment for radiologist services under this part [*42 USCS §§ 1395j* et seq.], to be implemented for such services furnished during 1989.

(2) Consultation. In carrying out paragraph (1), the Secretary shall regularly consult closely with the Physician Payment Review Commission [Medicare Payment Advisory Commission], the American College of Radiology, and other organizations representing physicians or suppliers who furnish radiologist services and shall share with them the data and data analysis being used to make the determinations under paragraph (1), including data on variations in current medicare payments by geographic area, and by service and physician specialty.

(3) Considerations. In developing the relative value scale and fee schedules under paragraph (1), the Secretary--

(A) shall take into consideration variations in the cost of furnishing such services among geographic areas and among different sites where services are furnished, and

(B) may also take into consideration such other factors respecting the manner in which physicians in different specialties furnish such services as may be appropriate to assure that payment amounts are equitable and designed to promote effective and efficient provision of radiologist services by physicians in the different specialties.

(4) Savings.

(A) Budget neutral fee schedules. The Secretary shall develop preliminary fee schedules for 1989, which are designed to result in the same amount of aggregate payments (net of any coinsurance and deductibles under sections 1833(a)(1)(J) and 1833(b) [*42 USCS § 1395l(a)(1)(J)* and (b)]) for radiologist services furnished in 1989 as would have been made if this subsection had not been enacted.

(B) Initial savings. The fee schedules established for payment purposes under this subsection for services furnished in 1989 shall be 97 percent of the amounts permitted under the preliminary fee schedules developed under subparagraph (A).

(C) 1990 Fee schedules. For radiologist services (other than portable X-ray services) furnished under this part [*42 USCS §§ 1395j* et seq.] during 1990, after March 31 of such year, the conversion factors used under this subsection shall be 96 percent of the conversion factors that applied under this subsection as of December 31, 1989.

(D) 1991 fee schedules. For radiologist services (other than portable X-ray services) furnished under this part [*42 USCS §§ 1395j* et seq.] during 1991, the conversion factors used in a locality under this subsection shall, subject to clause (vii), be reduced to the adjusted conversion factor for the locality determined as follows:

(i) National weighted average conversion factor. The Secretary shall estimate the national weighted average of the conversion factors used under this subsection for services furnished during 1990 beginning on April 1, using the best available data.

(ii) Reduced national weighted average. The national weighted average estimated under clause (i) shall be reduced by 13 percent.

(iii) Computation of 1990 locality index relative to national average. The Secretary shall establish an index which reflects, for each locality, the ratio of the conversion factor used in the locality under this subsection to the national weighted average estimated under clause (i).

(iv) Adjusted conversion factor. The adjusted conversion factor for the professional or technical component of a service in a locality is the sum of 1/2 of the locally-adjusted amount determined under clause (v) and 1/2 of the GPCI-adjusted amount determined under clause (vi).

(v) Locally-adjusted amount. For purposes of clause (iv), the locally adjusted amount determined under this clause is the product of (I) the national weighted average conversion factor computed under clause (ii), and (II) the index value established under clause (iii) for the locality.

(vi) GPCI-adjusted amount. For purposes of clause (iv), the GPCI-adjusted amount determined under this clause is the sum of--

(I) the product of (a) the portion of the reduced national weighted average conversion factor computed under clause (ii) which is attributable to physician work and (b) the geographic work index value for the locality (specified in Addendum C to the Model Fee Schedule for Physician Services (published on September 4, 1990, *55 Federal Register pp. 36238-36243));* and

(II) the product of (a) the remaining portion of the reduced national weighted average conversion factor computed under clause (ii), and (b) the geographic practice cost index value specified in section 1842(b)(14)(C)(iv) [*42 USCS § 1395u(b)(14)(C)(iv)*] for the locality.

In applying this clause with respect to the professional component of a service, 80 percent of the conversion factor shall be considered to be attributable to physician work and with respect to the technical component of the service, 0 percent shall be considered to be attributable to physician work.

(vii) Limits on conversion factor. The conversion factor to be applied to a locality to the professional or technical component of a service shall not be reduced under this subparagraph by more than 9.5 percent below the conversion factor applied in the locality under subparagraph (C) to such component, but in no case shall the conversion factor be less than 60 percent of the national weighted average of the conversion factors (computed under clause (i)).

(E) Rule for certain scanning services. In the case of the technical components of magnetic resonance imaging (MRI) services and computer assisted tomography (CAT) services furnished after December 31, 1990, the amount otherwise payable shall be reduced by 10 percent.

(F) Subsequent updating. For radiologist services furnished in subsequent years, the fee schedules shall be the schedules for the previous year updated by the percentage increase in the MEI(as defined in section 1842(i)(3) [*42 USCS § 1395u(i)(3)*]) for the year.

(G) Nonparticipating physicians and suppliers. Each fee schedule so established shall provide that the payment rate recognized for nonparticipating physicians and suppliers is equal to the appropriate percent (as defined in section 1842(b)(4)(A)(iv) [*42 USCS § 1395u(b)(4)(A)(iv)*]) of the payment rate recognized for participating physicians and suppliers.

(5) Limiting charges of nonparticipating physicians and suppliers.

(A) In general. In the case of radiologist services furnished after January 1, 1989, for which payment is made under a fee schedule under this subsection, if a nonparticipating physician or supplier furnishes the service to an individual

entitled to benefits under this part [*42 USCS §§ 1395j* et seq.], the physician or supplier may not charge the individual more than the limiting charge (as defined in subparagraph (B)).

(B) Limiting charge defined. In subparagraph (A), the term "limiting charge" means, with respect to a service furnished--

(i) in 1989, 125 percent of the amount specified for the service in the appropriate fee schedule established under paragraph (1),

(ii) in 1990, 120 percent of the amount specified for the service in the appropriate fee schedule established under paragraph (1), and

(iii) after 1990, 115 percent of the amount specified for the service in the appropriate fee schedule established under paragraph (1).

(C) Enforcement. If a physician or supplier knowingly and willfully bills in violation of subparagraph (A), the Secretary may apply sanctions against such physician or supplier in accordance with section 1842(j)(2) [*42 USCS § 1395u(j)(2)*] in the same manner as such sanctions may apply to a physician.

(6) Radiologist services defined. For the purposes of this subsection and section 1833(a)(1)(J) [*42 USCS § 1395l(a)(1)(J)*], the term "radiologist services" only includes radiology services performed by, or under the direction or supervision of, a physician--

(A) who is certified, or eligible to be certified, by the American Board of Radiology, or

(B) for whom radiology services account for at least 50 percent of the total amount of charges made under this part [*42 USCS §§ 1395j* et seq.].

(c) Payment and standards for screening mammography.

(1) In general. With respect to expenses incurred for screening mammography (as defined in section 1861(jj) [*42 USCS § 1395x(jj)*]), payment may be made only--

(A) for screening mammography conducted consistent with the frequency permitted under paragraph (2); and

(B) if the screening mammography is conducted by a facility that has a certificate (or provisional certificate) issued under section 354 of the Public Health Service Act [*42 USCS § 263b*].

(2) Frequency covered.

(A) In general. Subject to revision by the Secretary under subparagraph (B)--

(i) no payment may be made under this part for screening mammography performed on a woman under 35 years of age;

(ii) payment may be made under this part for only one screening mammography performed on a woman over 34 years of age, but under 40 years of age; and

(iii) in the case of a woman over 39 years of age, payment may not be made under this part for screening mammography performed within 11 months following the month in which a previous screening mammography was performed.

(B) Revision of frequency.

(i) Review. The Secretary, in consultation with the Director of the National Cancer Institute, shall review periodically the appropriate frequency for performing screening mammography, based on age and such other factors as the Secretary believes to be pertinent.

(ii) Revision of frequency. The Secretary, taking into consideration the review made under clause (i), may revise from time to time the frequency with which screening mammography may be paid for under this subsection.

(d) Frequency limits and payment for colorectal cancer screening tests.

(1) Screening fecal-occult blood tests.

(A) Payment amount. The payment amount for colorectal cancer screening tests consisting of screening fecal-occult blood tests is equal to the payment amount established for diagnostic fecal-occult blood tests under section 1833(h) [*42 USCS § 1395l(h)*].

(B) Frequency limit. No payment may be made under this part [*42 USCS §§ 1395j* et seq.] for a colorectal cancer screening test consisting of a screening fecal-occult blood test--

(i) if the individual is under 50 years of age; or

(ii) if the test is performed within the 11 months after a previous screening fecal-occult blood test.

(2) Screening flexible sigmoidoscopies.

(A) Fee schedule. With respect to colorectal cancer screening tests consisting of screening flexible sigmoidoscopies, payment under section 1848 [*42 USCS § 1395w-4*] shall be consistent with payment under such section for similar or related services.

(B) Payment limit. In the case of screening flexible sigmoidoscopy services, payment under this part [*42 USCS §§ 1395j* et seq.] shall not exceed such amount as the Secretary specifies, based upon the rates recognized for diagnostic flexible sigmoidoscopy services.

(C) Facility payment limit.

(i) In general. Notwithstanding subsections (i)(2)(A) and (t) of section 1833 [*42 USCS § 1395l(i)(2)(A)* and (t)], in the case of screening flexible sigmoidoscopy services furnished on or after January 1, 1999, that--

(I) in accordance with regulations, may be performed in an ambulatory surgical center and for which the Secretary permits ambulatory surgical center payments under this part [*42 USCS §§ 1395j* et seq.], and

(II) are performed in an ambulatory surgical center or hospital outpatient department,

payment under this part [*42 USCS §§ 1395j* et seq.] shall be based on the lesser of the amount under the fee schedule that would apply to such services if they were performed in a hospital outpatient department in an area or the amount under the fee schedule that would apply to such services if they were performed in an ambulatory surgical center in the same area.

(ii) Limitation on coinsurance. Notwithstanding any other provision of this *title [42 USCS §§ 1395* et seq.], in the case of a beneficiary who receives the services described in clause (i)--

(I) in computing the amount of any applicable copayment, the computation of such coinsurance shall be based upon the fee schedule under which payment is made for the services, and

(II) the amount of such coinsurance is equal to 25 percent of the payment amount under the fee schedule described in subclause (I).

(D) Special rule for detected lesions. If during the course of such screening flexible sigmoidoscopy, a lesion or growth is detected which results in a biopsy or removal of the lesion or growth, payment under this part [*42 USCS §§ 1395j* et seq.] shall not be made for the screening flexible sigmoidoscopy but shall be made for the procedure classified as a flexible sigmoidoscopy with such biopsy or removal.

(E) Frequency limit. No payment may be made under this part [*42 USCS §§ 1395j* et seq.] for a colorectal cancer screening test consisting of a screening flexible sigmoidoscopy--

(i) if the individual is under 50 years of age; or

(ii) if the procedure is performed within the 47 months after a previous screening flexible sigmoidoscopy or, in the case of an individual who is not at high risk for colorectal cancer, if the procedure is performed within the 119 months after a previous screening colonoscopy.

(3) Screening colonoscopy.

(A) Fee schedule. With respect to colorectal cancer screening test consisting of a screening colonoscopy, payment under section 1848 shall be consistent with payment amounts under such section for similar or related services.

(B) Payment limit. In the case of screening colonoscopy services, payment under this part [*42 USCS §§ 1395j* et seq.] shall not exceed such amount as the Secretary specifies, based upon the rates recognized for diagnostic colonoscopy services.

(C) Facility payment limit.

(i) In general. Notwithstanding subsections (i)(2)(A) and (t) of section 1833 [*42 USCS § 1395l(i)(2)(A)* and (t)], in the case of screening colonoscopy services furnished on or after January 1, 1999, that are performed in an ambulatory surgical center or a hospital outpatient department, payment under this part [*42 USCS §§ 1395j* et seq.] shall be based on the lesser of the amount under the fee schedule that would apply to such services if they were performed in a hospital outpatient department in an area or the amount under the fee schedule that would apply to such services if they were performed in an ambulatory surgical center in the same area.

(ii) Limitation on coinsurance. Notwithstanding any other provision of this *title [42 USCS §§ 1395* et seq.], in the case of a beneficiary who receives the services described in clause (i)--

(I) in computing the amount of any applicable coinsurance, the computation of such coinsurance shall be based upon the fee schedule under which payment is made for the services, and

(II) the amount of such coinsurance is equal to 25 percent of the payment amount under the fee schedule described in subclause (I).

(D) Special rule for detected lesions. If during the course of such screening colonoscopy, a lesion or growth is detected which results in a biopsy or removal of the lesion or growth, payment under this part [*42 USCS §§ 1395j* et seq.] shall not be made for the screening colonoscopy but shall be made for the procedure classified as a colonoscopy with such biopsy or removal.

(E) Frequency limit. No payment may be made under this part [*42 USCS §§ 1395j* et seq.] for a colorectal cancer screening test consisting of a screening colonoscopy for individuals at high risk for colorectal cancer if the procedure is performed within the 23 months after a previous screening colonoscopy or for other individuals if the procedure is performed within the 119 months after a previous screening colonoscopy or within 47 months after a previous screening flexible sigmoidoscopy.

(e) Accreditation requirement for advanced diagnostic imaging services.

(1) In general.

(A) In general. Beginning with January 1, 2012, with respect to the technical component of advanced diagnostic imaging services for which payment is made under the fee schedule established under section 1848(b) [*42 USCS § 1395w-4*] and that are furnished by a supplier, payment may only be made if such supplier is accredited by an accreditation organization designated by the Secretary under paragraph (2)(B)(i).

(B) Advanced diagnostic imaging services defined. In this subsection, the term "advanced diagnostic imaging services" includes--

(i) diagnostic magnetic resonance imaging, computed tomography, and nuclear medicine (including positron emission tomography); and

(ii) such other diagnostic imaging services, including services described in section 1848(b)(4)(B) [*42 USCS § 1395w-4(b)(4)(B)*] (excluding X-ray, ultrasound, and fluoroscopy), as specified by the Secretary in consultation with physician specialty organizations and other stakeholders.

(C) Supplier defined. In this subsection, the term "supplier" has the meaning given such term in section 1861(d) [*42 USCS § 1395x(d)*].

(2) Accreditation organizations.

(A) Factors for designation of accreditation organizations. The Secretary shall consider the following factors in designating accreditation organizations under subparagraph (B)(i) and in reviewing and modifying the list of accreditation organizations designated pursuant to subparagraph (C):

(i) The ability of the organization to conduct timely reviews of accreditation applications.

(ii) Whether the organization has established a process for the timely integration of new advanced diagnostic imaging services into the organization's accreditation program.

(iii) Whether the organization uses random site visits, site audits, or other strategies for ensuring accredited suppliers maintain adherence to the criteria described in paragraph (3).

(iv) The ability of the organization to take into account the capacities of suppliers located in a rural area (as defined in section 1886(d)(2)(D) [*42 USCS § 1395ww(d)(2)(D)*]).

(v) Whether the organization has established reasonable fees to be charged to suppliers applying for accreditation.

(vi) Such other factors as the Secretary determines appropriate.

(B) Designation. Not later than January 1, 2010, the Secretary shall designate organizations to accredit suppliers furnishing the technical component of advanced diagnostic imaging services. The list of accreditation organizations so designated may be modified pursuant to subparagraph (C).

(C) Review and modification of list of accreditation organizations.

(i) In general. The Secretary shall review the list of accreditation organizations designated under subparagraph (B) taking into account the factors under subparagraph (A). Taking into account the results of such review, the Secretary may, by regulation, modify the list of accreditation organizations designated under subparagraph (B).

(ii) Special rule for accreditations done prior to removal from list of designated accreditation organizations. In the case where the Secretary removes an organization from the list of accreditation organizations designated under subparagraph (B), any supplier that is accredited by the organization during the period beginning on the date on which the organization is designated as an accreditation organization under subparagraph (B) and ending on the date on which the organization is removed from such list shall be considered to have been accredited by an organization designated by the Secretary under subparagraph (B) for the remaining period such accreditation is in effect.

(3) Criteria for accreditation. The Secretary shall establish procedures to ensure that the criteria used by an accreditation organization designated under paragraph (2)(B) to evaluate a supplier that furnishes the technical component of advanced diagnostic imaging services for the purpose of accreditation of such supplier is specific to each imaging modality. Such criteria shall include--

(A) standards for qualifications of medical personnel who are not physicians and who furnish the technical component of advanced diagnostic imaging services;

(B) standards for qualifications and responsibilities of medical directors and supervising physicians, including standards that recognize the considerations described in paragraph (4);

(C) procedures to ensure that equipment used in furnishing the technical component of advanced diagnostic imaging services meets performance specifications;

(D) standards that require the supplier have procedures in place to ensure the safety of persons who furnish the technical component of advanced diagnostic imaging services and individuals to whom such services are furnished;

(E) standards that require the establishment and maintenance of a quality assurance and quality control program by the supplier that is adequate and appropriate to ensure the reliability, clarity, and accuracy of the technical quality of diagnostic images produced by such supplier; and

(F) any other standards or procedures the Secretary determines appropriate.

(4) Recognition in standards for the evaluation of medical directors and supervising physicians. The standards described in paragraph (3)(B) shall recognize whether a medical director or supervising physician--

(A) in a particular specialty receives training in advanced diagnostic imaging services in a residency program;

(B) has attained, through experience, the necessary expertise to be a medical director or a supervising physician;

(C) has completed any continuing medical education courses relating to such services; or

(D) has met such other standards as the Secretary determines appropriate.

(5) Rule for accreditations made prior to designation. In the case of a supplier that is accredited before January 1, 2010, by an accreditation organization designated by the Secretary under paragraph (2)(B) as of January 1, 2010, such supplier shall be considered to have been accredited by an organization designated by the Secretary under such paragraph as of January 1, 2012, for the remaining period such accreditation is in effect.

(f) Reduction in payments for physician pathology services during 1991.

(1) In general. For physician pathology services furnished under this part [*42 USCS §§ 1395j* et seq.] during 1991, the prevailing charges used in a locality under this part [*42 USCS §§ 1395j* et seq.] shall be 7 percent below the prevailing charges used in the locality under this part [*42 USCS §§ 1395j* et seq.] in 1990 after March 31.

(2) Limitation. The prevailing charge for the technical and professional components of an[a] physician pathology service furnished by a physician through an independent laboratory shall not be reduced pursuant to paragraph (1) to the extent that such reduction would reduce such prevailing charge below 115 percent of the prevailing charge for the professional component of such service when furnished by a hospital-based physician in the same locality. For purposes of the preceding sentence, an independent laboratory is a laboratory that is independent of a hospital and separate from the attending or consulting physicians' office.

(g) Payment for outpatient critical access hospital services.

(1) In general. The amount of payment for outpatient critical access hospital services of a critical access hospital is equal to 101 percent of the reasonable costs of the hospital in providing such services, unless the hospital makes the election under paragraph (2).

(2) Election of cost-based hospital outpatient service payment plus fee schedule for professional services. A critical access hospital may elect to be paid for outpatient critical access hospital services amounts equal to the sum of the following, less the amount that such hospital may charge as described in section 1866(a)(2)(A) [*42 USCS § 1395cc(a)(2)(A)*]:

(A) Facility fee. With respect to facility services, not including any services for which payment may be made under subparagraph (B), the reasonable costs of the critical access hospital in providing such services.

(B) Fee schedule for professional services. With respect to professional services otherwise included within outpatient critical access hospital services, 115 percent of such amounts as would otherwise be paid under this part if such services were not included in outpatient critical access hospital services.

The Secretary may not require, as a condition for applying subparagraph (B) with respect to a critical access hospital, that each physician or other practitioner providing professional services in the hospital must assign billing rights with respect to such services, except that such subparagraph shall not apply to those physicians and practitioners who have not assigned such billing rights.

(3) Disregarding charges. The payment amounts under this subsection shall be determined without regard to the amount of the customary or other charge.

(4) Treatment of clinical diagnostic laboratory services **[Caution: For provisions applicable to services furnished before July 1, 2009, see 2008 amendment note below.]**. No coinsurance, deductible, copayment, or other cost-sharing otherwise applicable under this part [*42 USCS §§ 1395j* et seq.] shall apply with respect to clinical diagnostic laboratory services furnished as an outpatient critical access hospital service. Nothing in this *title [42 USCS §§ 1395* et seq.] shall be construed as providing for payment for clinical diagnostic laboratory services furnished as part of outpatient critical access hospital services, other than on the basis described in this subsection. For purposes of the preceding sentence and section 1861(mm)(3) [*42 USCS § 1395x(mm)(3)*], clinical diagnostic laboratory services furnished by a critical access hospital shall be treated as being furnished as part of outpatient critical access services without regard to whether the individual with respect to whom such services are furnished is physically present in the critical access hospital, or in a skilled nursing facility or a clinic (including a rural health clinic) that is operated by a critical access hospital, at the time the specimen is collected.

(5) Coverage of costs for certain emergency room on-call providers. In determining the reasonable costs of outpatient critical access hospital services under paragraphs (1) and (2)(A), the Secretary shall recognize as allowable costs, amounts (as defined by the Secretary) for reasonable compensation and related costs for physicians, physician assistants, nurse practitioners, and clinical nurse specialists who are on-call (as defined by the Secretary) to provide emergency

services but who are not present on the premises of the critical access hospital involved, and are not otherwise furnishing services covered under this *title [42 USCS §§ 1395* et seq.] and are not on-call at any other provider or facility.

(h) Payment for prosthetic devices and orthotics and prosthetics.

(1) General rule for payment.

(A) In general. Payment under this subsection for prosthetic devices and orthotics and prosthetics shall be made in a lump-sum amount for the purchase of the item in an amount equal to 80 percent of the payment basis described in subparagraph (B).

(B) Payment basis. Except as provided in subparagraphs (C), (E), and (H)(i), the payment basis described in this subparagraph is the lesser of--

(i) the actual charge for the item; or

(ii) the amount recognized under paragraph (2) as the purchase price for the item.

(C) Exception for certain public home health agencies. Subparagraph (B)(i) shall not apply to an item furnished by a public home health agency (or by another home health agency which demonstrates to the satisfaction of the Secretary that a significant portion of its patients are low income) free of charge or at nominal charges to the public.

(D) Exclusive payment rule. Subject to subparagraph (H)(ii), this subsection shall constitute the exclusive provision of this *title [42 USCS §§ 1395* et seq.] for payment for prosthetic devices, orthotics, and prosthetics under this part [*42 USCS §§ 1395j* et seq.] or under part A [*42 USCS §§ 1395c* et seq.] to a home health agency.

(E) Exception for certain items. Payment for ostomy supplies, tracheostomy supplies, and urologicals shall be made in accordance with subparagraphs (B) and (C) of section 1834(a)(2) [subsec. (a)(2)(B), (C) of this section].

(F) Special payment rules for certain prosthetics and custom-fabricated orthotics.

(i) In general. No payment shall be made under this subsection for an item of custom-fabricated orthotics described in clause (ii) or for an item of prosthetics unless such item is--

(I) furnished by a qualified practitioner; and

(II) fabricated by a qualified practitioner or a qualified supplier at a facility that meets such criteria as the Secretary determines appropriate.

(ii) Description of custom-fabricated item.

(I) In general. An item described in this clause is an item of custom-fabricated orthotics that requires education, training, and experience to custom-fabricate and that is included in a list established by the Secretary in subclause (II). Such an item does not include shoes and shoe inserts.

(II) List of items. The Secretary, in consultation with appropriate experts in orthotics (including national organizations representing manufacturers of orthotics), shall establish and update as appropriate a list of items to which this subparagraph applies. No item may be included in such list unless the item is individually fabricated for the patient over a positive model of the patient.

(iii) Qualified practitioner defined. In this subparagraph, the term "qualified practitioner" means a physician or other individual who--

(I) is a qualified physical therapist or a qualified occupational therapist;

(II) in the case of a State that provides for the licensing of orthotics and prosthetics, is licensed in orthotics or prosthetics by the State in which the item is supplied; or

(III) in the case of a State that does not provide for the licensing of orthotics and prosthetics, is specifically trained and educated to provide or manage the provision of prosthetics and custom-designed or -fabricated orthotics, and is certified by the American Board for Certification in Orthotics and Prosthetics, Inc. or by the Board for Orthotist/Prosthetist Certification, or is credentialed and approved by a program that the Secretary determines, in consultation with appropriate experts in orthotics and prosthetics, has training and education standards that are necessary to provide such prosthetics and orthotics.

(iv) Qualified supplier defined. In this subparagraph, the term "qualified supplier" means any entity that is accredited by the American Board for Certification in Orthotics and Prosthetics, Inc. or by the Board for Orthotist/Prosthetist Certification, or accredited and approved by a program that the Secretary determines has accreditation and approval standards that are essentially equivalent to those of such Board.

(G) Replacement of prosthetic devices and parts.

(i) In general. Payment shall be made for the replacement of prosthetic devices which are artificial limbs, or for the replacement of any part of such devices, without regard to continuous use or useful lifetime restrictions if an ordering physician determines that the provision of a replacement device, or a replacement part of such a device, is necessary because of any of the following:

(I) A change in the physiological condition of the patient.

(II) An irreparable change in the condition of the device, or in a part of the device.

(III) The condition of the device, or the part of the device, requires repairs and the cost of such repairs would be more than 60 percent of the cost of a replacement device, or, as the case may be, of the part being replaced.

(ii) Confirmation may be required if device or part being replaced is less than 3 years old. If a physician determines that a replacement device, or a replacement part, is necessary pursuant to clause (i)--

(I) such determination shall be controlling; and

(II) such replacement device or part shall be deemed to be reasonable and necessary for purposes of section 1862(a)(1)(A) [*42 USCS § 1395y(a)(1)(A)*];

except that if the device, or part, being replaced is less than 3 years old (calculated from the date on which the beneficiary began to use the device or part), the Secretary may also require confirmation of necessity of the replacement device or replacement part, as the case may be.

(H) Application of competitive acquisition to orthotics; limitation of inherent reasonableness authority. In the case of orthotics described in paragraph (2)(C) of section 1847(a) [*42 USCS § 1395w-3(a)*] furnished on or after January 1, 2011, subject to subsection (a)(1)(G), that are included in a competitive acquisition program in a competitive acquisition area under such section--

(i) the payment basis under this subsection for such orthotics furnished in such area shall be the payment basis determined under such competitive acquisition program; and

(ii) the Secretary may use information on the payment determined under such competitive acquisition programs to adjust the payment amount otherwise recognized under subparagraph (B)(ii) for an area that is not a competitive acquisition area under section 1847 [*42 USCS § 1395w-3*], and in the case of such adjustment, paragraphs (8) and (9) of section 1842(b) [*42 USCS § 1395u(b)*] shall not be applied.

(2) Purchase price recognized. For purposes of paragraph (1), the amount that is recognized under this paragraph as the purchase price for prosthetic devices, orthotics, and prosthetics is the amount described in subparagraph (C) of this paragraph, determined as follows:

(A) Computation of local purchase price. Each carrier under section 1842 [*42 USCS § 1395u*] shall compute a base local purchase price for the item as follows:

(i) The carrier shall compute a base local purchase price for each item equal to the average reasonable charge in the locality for the purchase of the item for the 12-month period ending with June 1987.

(ii) The carrier shall compute a local purchase price, with respect to the furnishing of each particular item--

(I) in 1989 and 1990, equal to the base local purchase price computed under clause (i) increased by the percentage increase in the consumer price index for all urban consumers (United States city average) for the 6-month period ending with December 1987, or

(II) in 1991, 1992 or 1993, equal to the local purchase price computed under this clause for the previous year increased by the applicable percentage increase for the year.

(B) Computation of regional purchase price. With respect to the furnishing of a particular item in each region (as defined by the Secretary), the Secretary shall compute a regional purchase price--

(i) for 1992, equal to the average (weighted by relative volume of all claims among carriers) of the local purchase prices for the carriers in the region computed under subparagraph (A)(ii)(II) for the year, and

(ii) for each subsequent year, equal to the regional purchase price computed under this subparagraph for the previous year increased by the applicable percentage increase for the year.

(C) Purchase price recognized. For purposes of paragraph (1) and subject to subparagraph (D), the amount that is recognized under this paragraph as the purchase price for each item furnished--

(i) in 1989, 1990, or 1991, is 100 percent of the local purchase price computed under subparagraph (A)(ii);

(ii) in 1992, is the sum of (I) 75 percent of the local purchase price computed under subparagraph (A)(ii)(II) for 1992, and (II) 25 percent of the regional purchase price computed under subparagraph (B) for 1992;

(iii) in 1993, is the sum of (I) 50 percent of the local purchase price computed under subparagraph (A)(ii)(II) for 1993, and (II) 50 percent of the regional purchase price computed under subparagraph (B) for 1993; and

(iv) in 1994 or a subsequent year, is the regional purchase price computed under subparagraph (B) for that year.

(D) Range on amount recognized. The amount that is recognized under subparagraph (C) as the purchase price for an item furnished--

(i) in 1992, may not exceed 125 percent, and may not be lower than 85 percent, of the average of the purchase prices recognized under such subparagraph for all the carrier service areas in the United States in that year; and

(ii) in a subsequent year, may not exceed 120 percent, and may not be lower than 90 percent, of the average of the purchase prices recognized under such subparagraph for all the carrier service areas in the United States in that year.

(3) Applicability of certain provisions relating to durable medical equipment. Paragraphs (12), (15), and (17) and subparagraphs (A) and (B) of paragraph (10) and paragraph (11) of subsection (a) shall apply to prosthetic devices, orthotics, and prosthetics in the same manner as such provisions apply to covered items under such subsection.

(4) Definitions. In this subsection--

(A) the term "applicable percentage increase" means--

(i) for 1991, 0 percent;

(ii) for 1992 and 1993, the percentage increase in the consumer price index for all urban consumers (United States city average) for the 12-month period ending with June of the previous year;[,]

(iii) for 1994 and 1995, 0 percent;

(iv) for 1996 and 1997, the percentage increase in the consumer price index for all urban consumers (United States city average) for the 12-month period ending with June of the previous year;[,]

(v) for each of the years 1998 through 2000, 1 percent;

(vi) for 2001, the percentage increase in the consumer price index for all urban consumers (U.S. city average) for the 12-month period ending with June 2000;

(vii) for 2002, 1 percent;

(viii) for 2003, the percentage increase in the consumer price index for all urban consumers (United States city average) for the 12-month period ending with June of the previous year;

(ix) for 2004, 2005, and 2006, 0 percent; and

(x) for a subsequent year, the percentage increase in the consumer price index for all urban consumers (United States city average) for the 12-month period ending with June of the previous year;

(B) the term "prosthetic devices" has the meaning given such term in section 1861(s)(8) [*42 USCS § 1395x(s)(8)*], except that such term does not include parenteral and enteral nutrition nutrients, supplies, and equipment and does not include an implantable item for which payment may be made under section 1833(t) [*42 USCS § 1395l(t)*]; and

(C) the term "orthotics and prosthetics" has the meaning given such term in section 1861(s)(9) [*42 USCS § 1395x(s)(9)*] (and includes shoes described in section 1861(s)(12) [*42 USCS § 1395x(s)(12)*]), but does not include intraocular lenses or medical supplies (including catheters, catheter supplies, ostomy bags, and supplies related to ostomy care) furnished by a home health agency under section 1861(m)(5) [*42 USCS § 1395x(m)(5)*].

(i) Payment for surgical dressings.

(1) In general. Payment under this subsection for surgical dressings (described in section 1861(s)(5) [*42 USCS § 1395x(s)(5)*]) shall be made in a lump sum amount for the purchase of the item in an amount equal to 80 percent of the lesser of--

(A) the actual charge for the item; or

(B) a payment amount determined in accordance with the methodology described in subparagraphs (B) and (C) of subsection (a)(2) (except that in applying such methodology, the national limited payment amount referred to in such subparagraphs shall be initially computed based on local payment amounts using average reasonable charges for the 12-month period ending December 31, 1992, increased by the covered item updates described in such subsection for 1993 and 1994).

(2) Exceptions. Paragraph (1) shall not apply to surgical dressings that are--

(A) furnished as an incident to a physician's professional service; or

(B) furnished by a home health agency.

(j) Requirements for suppliers of medical equipment and supplies.

(1) Issuance and renewal of supplier number.

(A) Payment. Except as provided in subparagraph (C), no payment may be made under this part after the date of the enactment of the Social Security Act Amendments of 1994 [enacted Oct. 31, 1994] for items furnished by a supplier of medical equipment and supplies unless such supplier obtains (and renews at such intervals as the Secretary may require) a supplier number.

(B) Standards for possessing a supplier number. A supplier may not obtain a supplier number unless--

(i) for medical equipment and supplies furnished on or after the date of the enactment of the Social Security Act Amendments of 1994 [enacted Oct. 31, 1994] and before January 1, 1996, the supplier meets standards prescribed by the Secretary in regulations issued on June 18, 1992; and

(ii) for medical equipment and supplies furnished on or after January 1, 1996, the supplier meets revised standards prescribed by the Secretary (in consultation with representatives of suppliers of medical equipment and supplies, carriers, and consumers) that shall include requirements that the supplier--

(I) comply with all applicable State and Federal licensure and regulatory requirements;

(II) maintain a physical facility on an appropriate site;

(III) have proof of appropriate liability insurance; and

(IV) meet such other requirements as the Secretary may specify.

(C) Exception for items furnished as incident to a physician's service. Subparagraph (A) shall not apply with respect to medical equipment and supplies furnished incident to a physician's service.

(D) Prohibition against multiple supplier numbers. The Secretary may not issue more than one supplier number to any supplier of medical equipment and supplies unless the issuance of more than one number is appropriate to identify subsidiary or regional entities under the supplier's ownership or control.

(E) Prohibition against delegation of supplier determinations. The Secretary may not delegate (other than by contract under section 1842 [*42 USCS § 1395u*]) the responsibility to determine whether suppliers meet the standards necessary to obtain a supplier number.

(2) Certificates of medical necessity.

(A) Limitation on information provided by suppliers on certificates of medical necessity.

(i) In general. Effective 60 days after the date of the enactment of the Social Security Act Amendments of 1994 [enacted Oct. 31, 1994], a supplier of medical equipment and supplies may distribute to physicians, or to individuals entitled to benefits under this part [*42 USCS §§ 1395j* et seq.], a certificate of medical necessity for commercial purposes which contains no more than the following information completed by the supplier:

(I) An identification of the supplier and the beneficiary to whom such medical equipment and supplies are furnished.

(II) A description of such medical equipment and supplies.

(III) Any product code identifying such medical equipment and supplies.

(IV) Any other administrative information (other than information relating to the beneficiary's medical condition) identified by the Secretary.

(ii) Information on payment amount and charges. If a supplier distributes a certificate of medical necessity containing any of the information permitted to be supplied under clause (i), the supplier shall also list on the certificate of medical necessity the fee schedule amount and the supplier's charge for the medical equipment or supplies being furnished prior to distribution of such certificate to the physician.

(iii) Penalty. Any supplier of medical equipment and supplies who knowingly and willfully distributes a certificate of medical necessity in violation of clause (i) or fails to provide the information required under clause (ii) is subject to a civil money penalty in an amount not to exceed $ 1,000 for each such certificate of medical necessity so distributed. The provisions of section 1128A [*42 USCS § 1320a-7a*] (other than subsections (a) and (b)) shall apply to civil money penalties under this subparagraph in the same manner as they apply to a penalty or proceeding under section 1128A(a) [*42 USCS § 1320a-7a(a)*].

(B) Definition. For purposes of this paragraph, the term "certificate of medical necessity" means a form or other document containing information required by the carrier to be submitted to show that an item is reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.

(3) Coverage and review criteria. The Secretary shall annually review the coverage and utilization of items of medical equipment and supplies to determine whether such items should be made subject to coverage and utilization review criteria, and if appropriate, shall develop and apply such criteria to such items.

(4) Limitation on patient liability. If a supplier of medical equipment and supplies (as defined in paragraph (5))--

(A) furnishes an item or service to a beneficiary for which no payment may be made by reason of paragraph (1);

(B) furnishes an item or service to a beneficiary for which payment is denied in advance under subsection (a)(15); or

(C) furnishes an item or service to a beneficiary for which payment is denied under section 1862(a)(1) [*42 USCS § 1395y(a)(1)*];

any expenses incurred for items and services furnished to an individual by such a supplier not on an assigned basis shall be the responsibility of such supplier. The individual shall have no financial responsibility for such expenses and the supplier shall refund on a timely basis to the individual (and shall be liable to the individual for) any amounts collected from the individual for such items or services. The provisions of subsection (a)(18) shall apply to refunds required under the previous sentence in the same manner as such provisions apply to refunds under such subsection.

(5) Definition. The term "medical equipment and supplies" means--

(A) durable medical equipment (as defined in section 1861(n) [*42 USCS § 1395x(n)*]);

(B) prosthetic devices (as described in section 1861(s)(8) [*42 USCS § 1395x(s)(8)*]);

(C) orthotics and prosthetics (as described in section 1861(s)(9) [*42 USCS § 1395x(s)(9)*]);

(D) surgical dressings (as described in section 1861(s)(5) [*42 USCS § 1395x(s)(5)*]);

(E) such other items as the Secretary may determine; and

(F) for purposes of paragraphs (1) and (3)--

(i) home dialysis supplies and equipment (as described in section 1861(s)(2)(F) [*42 USCS § 1395x(s)(2)(F)*]),

(ii) immunosuppressive drugs (as described in section 1861(s)(2)(J) [*42 USCS § 1395x(s)(2)(J)*]),

(iii) therapeutic shoes for diabetics (as described in section 1861(s)(12) [*42 USCS § 1395x(s)(12)*]),

(iv) oral drugs prescribed for use as an anticancer therapeutic agent (as described in section 1861(s)(2)(Q) [*42 USCS § 1395x(s)(2)(Q)*]), and

(v) self-administered erythropoetin (as described in section 1861(s)(2)(P) [*42 USCS § 1395x(s)(2)(P)*]).

(k) Payment for outpatient therapy services and comprehensive outpatient rehabilitation services.

(1) In general. With respect to services described in section 1833(a)(8) or 1833(a)(9) [*42 USCS § 1395l(a)(8)* or (9)] for which payment is determined under this subsection, the payment basis shall be--

(A) for services furnished during 1998, the amount determined under paragraph (2); or

(B) for services furnished during a subsequent year, 80 percent of the lesser of--

(i) the actual charge for the services, or

(ii) the applicable fee schedule amount (as defined in paragraph (3)) for the services.

(2) Payment in 1998 based upon adjusted reasonable costs. The amount under this paragraph for services is the lesser of--

(A) the charges imposed for the services, or

(B) the adjusted reasonable costs (as defined in paragraph (4)) for the services,

less 20 percent of the amount of the charges imposed for such services.

(3) Applicable fee schedule amount. In this subsection, the term "applicable fee schedule amount" means, with respect to services furnished in a year, the amount determined under the fee schedule established under section 1848 [*42 USCS § 1395w-4*] for such services furnished during the year or, if there is no such fee schedule established for such services, the amount determined under the fee schedule established for such comparable services as the Secretary specifies.

(4) Adjusted reasonable costs. In paragraph (2), the term "adjusted reasonable costs" means, with respect to any services, reasonable costs determined for such services, reduced by 10 percent. The 10-percent reduction shall not apply to services described in section 1833(a)(8)(B) [*42 USCS § 1395l(a)(8)(B)*] (relating to services provided by hospitals).

(5) Uniform coding. For claims for services submitted on or after April 1, 1998, for which the amount of payment is determined under this subsection, the claim shall include a code (or codes) under a uniform coding system specified by the Secretary that identifies the services furnished.

(6) Restraint on billing. The provisions of subparagraphs (A) and (B) of section 1842(b)(18) [*42 USCS § 1395u(b)(18)*] shall apply to therapy services for which payment is made under this subsection in the same manner as they apply to services provided by a practitioner described in section 1842(b)(18)(C) [*42 USCS § 1395u(b)(18)(C)*].

(l) Establishment of fee schedule for ambulance services.

(1) In general. The Secretary shall establish a fee schedule for payment for ambulance services whether provided directly by a supplier or provider or under arrangement with a provider under this part [*42 USCS §§ 1395j* et seq.] through a negotiated rulemaking process described in title 5, United States Code, and in accordance with the requirements of this subsection.

(2) Considerations. In establishing such fee schedule, the Secretary shall--

(A) establish mechanisms to control increases in expenditures for ambulance services under this part [*42 USCS §§ 1395j* et seq.];

(B) establish definitions for ambulance services which link payments to the type of services provided;

(C) consider appropriate regional and operational differences;

(D) consider adjustments to payment rates to account for inflation and other relevant factors; and

(E) phase in the application of the payment rates under the fee schedule in an efficient and fair manner consistent with paragraph (11), except that such phase-in shall provide for full payment of any national mileage rate for ambulance services provided by suppliers that are paid by carriers in any of the 50 States where payment by a carrier for such services for all such suppliers in such State did not, prior to the implementation of the fee schedule, include a separate amount for all mileage within the county from which the beneficiary is transported.

(3) Savings. In establishing such fee schedule, the Secretary shall--

(A) ensure that the aggregate amount of payments made for ambulance services under this part [*42 USCS §§ 1395j* et seq.] during 2000 does not exceed the aggregate amount of payments which would have been made for such services under this part [*42 USCS §§ 1395j* et seq.] during such year if the amendments made by section 4531(a) of the Balanced Budget Act of 1997 continued in effect, except that in making such determination the Secretary shall assume an update in such payments for 2002 equal to percentage increase in the consumer price index for all urban consumers (U.S. city average) for the 12-month period ending with June of the previous year reduced in the case of 2002 by 1.0 percentage points; and

(B) set the payment amounts provided under the fee schedule for services furnished in 2001 and each subsequent year at amounts equal to the payment amounts under the fee schedule for services furnished during the previous year, increased by the percentage increase in the consumer price index for all urban consumers (U.S. city average) for the 12-month period ending with June of the previous year reduced in the case of 2002 by 1.0 percentage points.

(4) Consultation. In establishing the fee schedule for ambulance services under this subsection, the Secretary shall consult with various national organizations representing individuals and entities who furnish and regulate ambulance services and share with such organizations relevant data in establishing such schedule.

(5) Limitation on review. There shall be no administrative or judicial review under section 1869 [*42 USCS § 1395ff*] or otherwise of the amounts established under the fee schedule for ambulance services under this subsection, including matters described in paragraph (2).

(6) Restraint on billing. The provisions of subparagraphs (A) and (B) of section 1842(b)(18) [*42 USCS § 1395u(b)(18)*] shall apply to ambulance services for which payment is made under this subsection in the same manner as they apply to services provided by a practitioner described in section 1842(b)(18)(C) [*42 USCS § 1395u(b)(18)(C)*].

(7) Coding system. The Secretary may require the claim for any services for which the amount of payment is determined under this subsection to include a code (or codes) under a uniform coding system specified by the Secretary that identifies the services furnished.

(8) Services furnished by critical access hospitals. Notwithstanding any other provision of this subsection, the Secretary shall pay the reasonable costs incurred in furnishing ambulance services if such services are furnished--

(A) by a critical access hospital (as defined in section 1861(mm)(1) [*42 USCS § 1395x(mm)(1)*]), or

(B) by an entity that is owned and operated by a critical access hospital,

but only if the critical access hospital or entity is the only provider or supplier of ambulance services that is located within a 35-mile drive of such critical access hospital.

(9) Transitional assistance for rural providers. In the case of ground ambulance services furnished on or after July 1, 2001, and before January 1, 2004, for which the transportation originates in a rural area (as defined in section 1886(d)(2)(D) [*42 USCS § 1395ww(d)(2)(D)*]) or in a rural census tract of a metropolitan statistical area (as determined under the most recent modification of the Goldsmith Modification, originally published in the Federal Register on February 27, 1992 *(57 Fed. Reg. 6725))*, the fee schedule established under this subsection shall provide that, with respect to the payment rate for mileage for a trip above 17 miles, and up to 50 miles, the rate otherwise established shall be increased by not less than 1/2 of the additional payment per mile established for the first 17 miles of such a trip originating in a rural area.

(10) Phase-in providing floor using blend of fee schedule and regional fee schedules. In carrying out the phase-in under paragraph (2)(E) for each level of ground service furnished in a year, the portion of the payment amount that is based on the fee schedule shall be the greater of the amount determined under such fee schedule (without regard to this paragraph) or the following blended rate of the fee schedule under paragraph (1) and of a regional fee schedule for the region involved:

(A) For 2004 (for services furnished on or after July 1, 2004), the blended rate shall be based 20 percent on the fee schedule under paragraph (1) and 80 percent on the regional fee schedule.

(B) For 2005, the blended rate shall be based 40 percent on the fee schedule under paragraph (1) and 60 percent on the regional fee schedule.

(C) For 2006, the blended rate shall be based 60 percent on the fee schedule under paragraph (1) and 40 percent on the regional fee schedule.

(D) For 2007, 2008, and 2009, the blended rate shall be based 80 percent on the fee schedule under paragraph (1) and 20 percent on the regional fee schedule.

(E) For 2010 and each succeeding year, the blended rate shall be based 100 percent on the fee schedule under paragraph (1).

For purposes of this paragraph, the Secretary shall establish a regional fee schedule for each of the nine census divisions (referred to in section 1886(d)(2) [*42 USCS § 1395ww(d)(2)*]) using the methodology (used in establishing the fee schedule under paragraph (1)) to calculate a regional conversion factor and a regional mileage payment rate and using the same payment adjustments and the same relative value units as used in the fee schedule under such paragraph.

(11) Adjustment in payment for certain long trips. In the case of ground ambulance services furnished on or after July 1, 2004, and before January 1, 2009, regardless of where the transportation originates, the fee schedule established under this subsection shall provide that, with respect to the payment rate for mileage for a trip above 50 miles the per mile rate otherwise established shall be increased by 1/4 of the payment per mile otherwise applicable to miles in excess of 50 miles in such trip.

(12) Assistance for rural providers furnishing services in low population density areas.

(A) In general. In the case of ground ambulance services furnished on or after July 1, 2004, and before January 1, 2010, for which the transportation originates in a qualified rural area (identified under subparagraph (B)(iii)), the Secretary shall provide for a percent increase in the base rate of the fee schedule for a trip established under this subsection. In establishing such percent increase, the Secretary shall estimate the average cost per trip for such services (not taking into account mileage) in the lowest quartile as compared to the average cost per trip for such services (not taking into account mileage) in the highest quartile of all rural county populations.

(B) Identification of qualified rural areas.

(i) Determination of population density in area. Based upon data from the United States decennial census for the year 2000, the Secretary shall determine, for each rural area, the population density for that area.

(ii) Ranking of areas. The Secretary shall rank each such area based on such population density.

(iii) Identification of qualified rural areas. The Secretary shall identify those areas (in subparagraph (A) referred to as "qualified rural areas") with the lowest population densities that represent, if each such area were weighted by the population of such area (as used in computing such population densities), an aggregate total of 25 percent of the total of the population of all such areas.

(iv) Rural area. For purposes of this paragraph, the term "rural area" has the meaning given such term in section 1886(d)(2)(D) [*42 USCS § 1395ww(d)(2)(D)*]. If feasible, the Secretary shall treat a rural census tract of a metropolitan statistical area (as determined under the most recent modification of the Goldsmith Modification, originally published in the Federal Register on February 27, 1992 *(57 Fed. Reg. 6725)* as a rural area for purposes of this paragraph.

(v) Judicial review. There shall be no administrative or judicial review under section 1869 [*42 USCS § 1395ff*], 1878 [*42 USCS § 1395oo*], or otherwise, respecting the identification of an area under this subparagraph.

(13) Temporary increase for ground ambulance services.

(A) In general. After computing the rates with respect to ground ambulance services under the other applicable provisions of this subsection, in the case of such services furnished on or after July 1, 2004, and before January 1, 2007, and for such services furnished on or after July 1, 2008, and before January 1, 2010 for which the transportation originates in--

(i) a rural area described in paragraph (9) or in a rural census tract described in such paragraph, the fee schedule established under this section shall provide that the rate for the service otherwise established, after the application of any increase under paragraphs (11) and (12), shall be increased by 2 percent (or 3 percent if such service is furnished on or after July 1, 2008, and before January 1, 2010); and

(ii) an area not described in clause (i), the fee schedule established under this subsection shall provide that the rate for the service otherwise established, after the application of any increase under paragraph (11), shall be increased by 1 percent (or 2 percent if such service is furnished on or after July 1, 2008, and before January 1, 2010).

(B) Application of increased payments after applicable period. The increased payments under subparagraph (A) shall not be taken into account in calculating payments for services furnished after the applicable period specified in such subparagraph.

(14) Providing appropriate coverage of rural air ambulance services.

(A) In general. The regulations described in section 1861(s)(7) [*42 USCS § 1395x(s)(7)*] shall provide, to the extent that any ambulance services (whether ground or air) may be covered under such section, that a rural air ambulance service (as defined in subparagraph (C)) is reimbursed under this subsection at the air ambulance rate if the air ambulance service--

(i) is reasonable and necessary based on the health condition of the individual being transported at or immediately prior to the time of the transport; and

(ii) complies with equipment and crew requirements established by the Secretary.

(B) Satisfaction of requirement of medically necessary. The requirement of subparagraph (A)(i) is deemed to be met for a rural air ambulance service if--

(i) subject to subparagraph (D), such service is requested by a physician or other qualified medical personnel (as specified by the Secretary) who certifies or reasonably determines that the individual's condition is such that the time needed to transport the individual by land or the instability of transportation by land poses a threat to the individual's survival or seriously endangers the individual's health; or

(ii) such service is furnished pursuant to a protocol that is established by a State or regional emergency medical service (EMS) agency and recognized or approved by the Secretary under which the use of an air ambulance is recommended, if such agency does not have an ownership interest in the entity furnishing such service.

(C) Rural air ambulance service defined. For purposes of this paragraph, the term "rural air ambulance service" means fixed wing and rotary wing air ambulance service in which the point of pick up of the individual occurs in a rural area (as defined in section 1886(d)(2)(D) [*42 USCS § 1395ww(d)(2)(D)*]) or in a rural census tract of a metropolitan statistical area (as determined under the most recent modification of the Goldsmith Modification, originally published in the Federal Register on February 27, 1992 *(57 Fed. Reg. 6725))*.

(D) Limitation.

(i) In general. Subparagraph (B)(i) shall not apply if there is a financial or employment relationship between the person requesting the rural air ambulance service and the entity furnishing the ambulance service, or an entity under common ownership with the entity furnishing the air ambulance service, or a financial relationship between an immediate family member of such requester and such an entity.

(ii) Exception. Where a hospital and the entity furnishing rural air ambulance services are under common ownership, clause (i) shall not apply to remuneration (through employment or other relationship) by the hospital of the requester or immediate family member if the remuneration is for provider-based physician services furnished in a hospital (as described in section 1887 [*42 USCS § 1395xx*]) which are reimbursed under part A [*42 USCS §§ 1395c* et seq.] and the amount of the remuneration is unrelated directly or indirectly to the provision of rural air ambulance services.

(m) Payment for telehealth services.

(1) In general. The Secretary shall pay for telehealth services that are furnished via a telecommunications system by a physician (as defined in section 1861(r) [*42 USCS § 1395x(r)*]) or a practitioner (described in section 1842(b)(18)(C) [*42 USCS § 1395u(b)(18)(C)*]) to an eligible telehealth individual enrolled under this part notwithstanding that the individual physician or practitioner providing the telehealth service is not at the same location as the beneficiary. For purposes of the preceding sentence, in the case of any Federal telemedicine demonstration program conducted in Alaska or Hawaii, the term "telecommunications system" includes store-and-forward technologies that provide for the asynchronous transmission of health care information in single or multimedia formats.

(2) Payment amount.

(A) Distant site. The Secretary shall pay to a physician or practitioner located at a distant site that furnishes a telehealth service to an eligible telehealth individual an amount equal to the amount that such physician or practitioner would have been paid under this *title [42 USCS §§ 1395* et seq.] had such service been furnished without the use of a telecommunications system.

(B) Facility fee for originating site. With respect to a telehealth service, subject to section 1833(a)(1)(U) [*42 USCS § 1395l(a)(1)(U)*], there shall be paid to the originating site a facility fee equal to--

(i) for the period beginning on October 1, 2001, and ending on December 31, 2001, and for 2002, $ 20; and

(ii) for a subsequent year, the facility fee specified in clause (i) or this clause for the preceding year increased by the percentage increase in the MEI (as defined in section 1842(i)(3) [*42 USCS § 1395u(i)(3)*]) for such subsequent year.

(C) Telepresenter not required. Nothing in this subsection shall be construed as requiring an eligible telehealth individual to be presented by a physician or practitioner at the originating site for the furnishing of a service via a telecommunications system, unless it is medically necessary (as determined by the physician or practitioner at the distant site).

(3) Limitation on beneficiary charges.

(A) Physician and practitioner. The provisions of section 1848(g) [*42 USCS § 1395w-4(g)*] and subparagraphs (A) and (B) of section 1842(b)(18) [*42 USCS § 1395u(b)(18)*] shall apply to a physician or practitioner receiving payment under this subsection in the same manner as they apply to physicians or practitioners under such sections.

(B) Originating site. The provisions of section 1842(b)(18) [*42 USCS § 1395u(b)(18)*] shall apply to originating sites receiving a facility fee in the same manner as they apply to practitioners under such section.

(4) Definitions. For purposes of this subsection:

(A) Distant site. The term "distant site" means the site at which the physician or practitioner is located at the time the service is provided via a telecommunications system.

(B) Eligible telehealth individual. The term "eligible telehealth individual" means an individual enrolled under this part who receives a telehealth service furnished at an originating site.

(C) Originating site.

(i) In general. The term "originating site" means only those sites described in clause (ii) at which the eligible telehealth individual is located at the time the service is furnished via a telecommunications system and only if such site is located--

(I) in an area that is designated as a rural health professional shortage area under section 332(a)(1)(A) of the Public Health Service Act (*42 U.S.C. 254e(a)(1)(A)*);

(II) in a county that is not included in a Metropolitan Statistical Area; or

(III) from an entity that participates in a Federal telemedicine demonstration project that has been approved by (or receives funding from) the Secretary of Health and Human Services as of December 31, 2000.

(ii) Sites described. The sites referred to in clause (i) are the following sites:

(I) The office of a physician or practitioner.

(II) A critical access hospital (as defined in section 1861(mm)(1) [*42 USCS § 1395x(mm)(1)*]).

(III) A rural health clinic (as defined in section 1861(aa)(2) [*42 USCS § 1395x(aa)(2)*]).

(IV) A federally qualified health center (as defined in section 1861(aa)(4) [*42 USCS § 1395x(aa)(4)*]).

(V) A hospital (as defined in section 1861(e) [*42 USCS § 1395x(e)*]).

(VI) A hospital-based or critical access hospital-based renal dialysis center (including satellites).

(VII) A skilled nursing facility (as defined in section 1819(a) [*42 USCS § 1395i-3(a)*]).

(VIII) A community mental health center (as defined in section 1861(ff)(3)(B) [*42 USCS § 1395x(ff)(3)(B)*]).

(D) Physician. The term "physician" has the meaning given that term in section 1861(r) [*42 USCS § 1395x(r)*].

(E) Practitioner. The term "practitioner" has the meaning given that term in section 1842(b)(18)(C) [*42 USCS § 1395u(b)(18)(C)*].

(F) Telehealth service.

(i) In general. The term "telehealth service" means professional consultations, office visits, and office psychiatry services (identified as of July 1, 2000, by HCPCS codes 99241-99275, 99201-99215, 90804-90809, and 90862 (and as subsequently modified by the Secretary)), and any additional service specified by the Secretary.

(ii) Yearly update. The Secretary shall establish a process that provides, on an annual basis, for the addition or deletion of services (and HCPCS codes), as appropriate, to those specified in clause (i) for authorized payment under paragraph (1).

HISTORY:

(Aug. 14, 1935, ch 531, Title XVIII, Part B, § 1834 as added and amended Dec. 22, 1987, P.L. 100-203, Title IV, Subtitle A, Part 3, Subpart A, § 4049(a)(2), Subpart B, § 4062(b) 101 Stat. 1330-91, 1330-100; July 1, 1988, P.L. 100-360, Title II, Subtitle A, §§ 202(b)(4), 203(c)(1)(F), 204(b), Title IV, Subtitle B, § 411(2)(3)(C)(ii), (f)(8)(A), (B)(ii), (D)(g)(1)(A), (B), 102 Stat. 704, 722, 726, 768, 779-782; Oct. 13, 1988, P.L. 100-485, Title VI, § 608(d)(21)(C)(22)(A), 102 Stat. 2420; Dec. 13, 1989, P.L. 101-234, Title II, §§ 201(a)(1), 301(b)(1), (c)(1), 103 Stat. 1981, 1985; Dec. 19, 1989, P.L. 101-239, Title VI, Subtitle A, Part 2, Subpart A, §§ 6102(f)(1), 6105(a), 6112(a), (c), (d)(1), (e)(2), 6116(b)(2), Subpart B, § 6140, 103 Stat. 2188, 2210, 2214, 2215, 2216, 2220, 2224; Nov. 5, 1990, P.L. 101-508, Title IV, Subtitle A, Part 2, Subpart A, §§ 4102(a), (d), (f), 4104(a), Subpart B, §§ 4152(a)(1), (b), (c)(1)-(4)(B)(i), (e), (f)(1), (g)(1), 4153(a)(1), (2)(D), 4163(b), 104 Stat. 1388-58, 1388-59, 1388-74, 1388-79, 1388-81, 1388-97; Aug. 10, 1993, P.L. 103-66, Title XIII, Ch 2, Subch A, Part II, Subpart D, §§ 13542(a), 13543(a), (b), 13544(a)(1), (2), (b)(1), 13545(a), 13546, 107 Stat. 587-590; Oct. 31, 1994, P.L. 103-432, Title I, Subtitle A, § 102(e), Subtitle B, Part I, § 126(b)(1)-(5), (g)(1), (10)(B), Part II, §§ 131(a), 132(a), (b), 133(a)(1), 134(a)(1), 135(a)(1), (b)(1), (3), (d), (e)(2)-(5), Part III, § 145(a), Subtitle C, § 156(a)(2)(C), 108 Stat. 4403, 4414-4416, 4421-4424, 4427, 4440; Aug. 5, 1997, P.L. 105-33, Title IV, Subtitle B, §§ 4101(a), (c), 4104(b), 4105(b)(2), Subtitle C, § 4201(c)(5), Subtitle D, Ch 2, §§ 4312(a), (c), 4316(b), Subtitle F, Ch 3, § 4531(b)(2), Ch 4, § 4541(a)(2), Ch 5, §§ 4551(a), (c)(1), 4552(a), (b), 111 Stat. 360, 363, 367, 374, 386, 387, 392, 451, 455, 457-459; Nov. 29, 1999, P.L. 106-113, Div B, § 1000(a)(6), 113 Stat. 1536; Dec. 21, 2000, P.L. 106-554, § 1(a)(6), 114 Stat. 2763; Dec. 8, 2003, P.L. 108-173, Title III, § 302(a), (c)(1)(A), (2), (3), (d)(1), (2), Title IV, Subtitle A, § 405(a)(1), (b)(1), (d)(1), Subtitle B, §§ 414(a)-(c)(1), (d), 415(a), Title VI, Subtitle C, § 627(b)(1), Title VII, Subtitle D, § 736(b)(4), (5), 117 Stat. 2223, 2230, 2231, 2266, 2267, 2278, 2280, 2281, 2321, 2356.)

(As amended Feb. 8, 2006, P.L. 109-171, Title V, Subtitle B, Ch. 1, § 5101(a)(1), (b)(1), Ch. 2, § 5113(b), 120 Stat. 37, 38, 44; July 15, 2008, P.L. 110-275, Title I, Subtitle B, § 125(b)(5), Subtitle C, Part I, § 135(a)(1), Part II, §§ 144(b)(1), 146(a), (b)(2)(A), 148(a), 149(a), 154(a)(2)(A), (3), (4), (b)(1)(A), (d)(2), 122 Stat. 2519, 2532, 2547, 2548, 2549, 2563, 2564, 2567.)

§ 1395n. Procedure for payment of claims of providers of services

(a) Conditions for payment for services described in *42 USCS § 1395k(a)(2)*. Except as provided in subsections (b), (c), and (e), payment for services described in section 1832(a)(2) [*42 USCS § 1395k(a)(2)*] furnished an individual may be made only to providers of services which are eligible therefor under section 1866(a) [*42 USCS § 1395cc(a)*], and only if--

(1) written request, signed by such individual, except in cases in which the Secretary finds it impracticable for the individual to do so, is filed for such payment in such form, in such manner and by such person or persons as the Secretary may by regulation prescribe, no later than the close of the period of 3 calendar years following the year in which such services are furnished (deeming any services furnished in the last 3 calendar months of any calendar year to have been furnished in the succeeding calendar year) except that, where the Secretary deems that efficient administration so requires, such period may be reduced to not less than 1 calendar year; and

(2) a physician certifies (and recertifies, where such services are furnished over a period of time, in such cases, with such frequency, and accompanied by such supporting material, appropriate to the case involved, as may be provided by regulations) that--

(A) in the case of home health services (i) such services are or were required because the individual is or was confined to his home (except when receiving items and services referred to in section 1861(m)(7) [*42 USCS § 1395x(m)(7)*]) and needs or needed skilled nursing care (other than solely venipuncture for the purpose of obtaining a blood sample) on an intermittent basis or physical or speech therapy or, in the case of an individual who has been

furnished home health services based on such a need and who no longer has such a need for such care or therapy, continues or continued to need occupational therapy, (ii) a plan for furnishing such services to such individual has been established and is periodically reviewed by a physician, and (iii) such services are or were furnished while the individual is or was under the care of a physician;

(B) in the case of medical and other health services, except services described in subparagraphs (B), (C), and (D) of section 1861(s)(2) [*42 USCS § 1395x(s)(2)(B)*-(D)], such services are or were medically required;

(C) in the case of outpatient physical therapy services or outpatient occupational therapy services, (i) such services are or were required because the individual needed physical therapy services or outpatient occupational therapy services, respectively, (ii) a plan for furnishing such services has been established by a physician or by the qualified physical therapist or qualified occupational therapist, respectively, providing such services and is periodically reviewed by a physician, and (iii) such services are or were furnished while the individual is or was under the care of a physician;

(D) in the case of outpatient speech pathology services, (i) such services are or were required because the individual needed speech pathology services, (ii) a plan for furnishing such services has been established by a physician or by the speech pathologist providing such services and is periodically reviewed by a physician, and (iii) such services are or were furnished while the individual is or was under the care of a physician;

(E) in the case of comprehensive outpatient rehabilitation facility services, (i) such services are or were required because the individual needed skilled rehabilitation services, (ii) a plan for furnishing such services has been established and is periodically reviewed by a physician, and (iii) such services are or were furnished while the individual is or was under the care of a physician; and

(F) in the case of partial hospitalization services, (i) the individual would require inpatient psychiatric care in the absence of such services, (ii) an individualized, written plan for furnishing such services has been established by a physician and is reviewed periodically by a physician, and (iii) such services are or were furnished while the individual is or was under the care of a physician.

[Caution: For provisions applicable to services furnished before July 1, 2009, see 2008 amendment note below.] For purposes of this section, the term "provider of services" shall include a clinic, rehabilitation agency, or public health agency if, in the case of a clinic or rehabilitation agency, such clinic or agency meets the requirements of section 1861(p)(4)(A) [*42 USCS § 1395x(p)(4)(A)*] (or meets the requirements of such section through the operation of subsection (g) or (ll)(2) of section 1861 [*42 USCS § 1395x*]), or if, in the case of a public health agency, such agency meets the requirements of section 1861(p)(4)(B) [*42 USCS § 1395x(p)(4)(B)*], (or meets the requirements of such section through the operation of subsection (g) or (ll)(2) of section 1861 [*42 USCS § 1395x*]), but only with respect to the furnishing of outpatient physical therapy services (as therein defined) or (through the operation of subsection (g) or (ll)(2) of section 1861 [*42 USCS § 1395x*]) with respect to the furnishing of outpatient occupational therapy services or outpatient speech-language pathology services, respectively.

To the extent provided by regulations, the certification and recertification requirements of paragraph (2) shall be deemed satisfied where, at a later date, a physician makes a certification of the kind provided in subparagraph (A) or (B) of paragraph (2) (whichever would have applied), but only where such certification is accompanied by such medical and other evidence as may be required by such regulations. With respect to the physician certification required by paragraph (2) for home health services furnished to any individual by a home health agency (other than an agency which is a governmental entity) and with respect to the establishment and review of a plan for such services, the Secretary shall prescribe regulations which shall become effective no later than July 1, 1981, and which prohibit a physician who has a significant ownership interest in, or a significant financial or contractual relationship with, such home health agency from performing such certification and from establishing or reviewing such plan, except that such prohibition shall not apply with respect to a home health agency which is a sole community home health agency (as determined by the Secretary). For purposes of the preceding sentence, service by a physician as an uncompensated officer or director of a home health agency shall not constitute having a significant ownership interest in, or a significant financial or contractual relationship with, such agency. For purposes of paragraph (2)(A), an individual shall be considered to be "confined to his home" if the individual has a condition, due to an illness or injury, that restricts the ability of the individual to leave his or her home except with the assistance of another individual or the aid of a supportive device (such as crutches, a cane, a wheelchair, or a walker), or if the individual has a condition such that leaving his or her home is medically contraindicated. While an individual does not have to be bedridden to be considered "confined to his home", the condition of the individual should be such that there exists a normal inability to leave home and that leaving home requires a considerable and taxing effort by the individual. Any absence of an individual from the home attributable to the need to receive health care treatment, including regular absences for the purpose of participating in therapeutic, psychosocial, or medical treatment in an adult day-care program that is licensed or certified by a State, or accredited, to furnish adult day-care services in the State shall not disqualify an individual from being considered to be "confined to his home". Any other absence of an individual from the home shall not so disqualify an individual if the

absence is of infrequent or of relatively short duration. For purposes of the preceding sentence, any absence for the purpose of attending a religious service shall be deemed to be an absence of infrequent or short duration.

(b) Conditions for payment for services described in *42 USCS § 1395x(s)*.

(1) Payment may also be made to any hospital for services described in section 1861(s) [*42 USCS § 1395x(s)*] furnished as an outpatient service by a hospital or by others under arrangements made by it to an individual entitled to benefits under this part [*42 USCS §§ 1395j* et seq.] even though such hospital does not have an agreement in effect under this *title [42 USCS §§ 1395* et seq.] if (A) such services were emergency services, (B) the Secretary would be required to make such payment if the hospital had such an agreement in effect and otherwise met the conditions of payment hereunder, and (C) such hospital has made an election pursuant to section 1814(d)(1)(C) [*42 USCS § 1395f(d)(1)(C)*] with respect to the calendar year in which such emergency services are provided. Such payments shall be made only in the amounts provided under section 1833(a)(2) [*42 USCS § 1395l(a)(2)*] and then only if such hospital agrees to comply, with respect to the emergency services provided, with the provisions of section 1866(a) [*42 USCS § 1395cc(a)*].

(2) Payment may also be made on the basis of an itemized bill to an individual for services described in paragraph (1) of this subsection if (A) payment cannot be made under such paragraph (1) solely because the hospital does not elect, in accordance with section 1814(d)(1)(C) [*42 USCS § 1395f(d)(1)(C)*], to claim such payments and (B) such individual files application (submitted within such time and in such form and manner, and containing and supported by such information as the Secretary shall by regulations prescribe) for reimbursement. The amounts payable under this paragraph shall, subject to the provisions of section 1833 [*42 USCS § 1395l*], be equal to 80 percent of the hospital's reasonable charges for such services.

(c) Collection of charges from individuals for services specified in *42 USCS § 1395x(s)*. Notwithstanding the provisions of this section and sections 1832, 1833, and 1866(a)(1)(A) [*42 USCS §§ 1395k, 1395l* and *1395cc(a)(1)(A)*], a hospital or a critical access hospital may, subject to such limitations as may be prescribed by regulations, collect from an individual the customary charges for services specified in section 1861(s) [*42 USCS § 1395x(s)*] and furnished to him by such hospital as an outpatient, but only if such charges for such services do not exceed the applicable supplementary medical insurance deductible, and such customary charges shall be regarded as expenses incurred by such individual with respect to which benefits are payable in accordance with section 1833(a)(1) [*42 USCS § 1395l(a)(1)*]. Payments under this *title [42 USCS §§ 1395* et seq.] to hospitals which have elected to make collections from individuals in accordance with the preceding sentence shall be adjusted periodically to place the hospital in the same position it would have been had it instead been reimbursed in accordance with section 1833(a)(2) [*42 USCS § 1395l(a)(2)*] (or, in the case of a critical access hospital, in accordance with section 1833(a)(6) [*42 USCS § 1395l(a)(6)*]). A critical access hospital shall be considered a hospital for purposes of this subsection.

(d) Payment to Federal provider of services or other Federal agencies prohibited. Subject to section 1880 [*42 USCS § 1395qq*], no payment may be made under this part [*42 USCS §§ 1395j* et seq.] to any Federal provider of services or other Federal agency, except a provider of services which the Secretary determines is providing services to the public generally as a community institution or agency; and no such payment may be made to any provider of services or other person for any item or service which such provider or person is obligated by a law of, or a contract with, the United States to render at public expense.

(e) Payment to fund designated by medical staff or faculty of medical school. For purposes of services (1) which are inpatient hospital services by reason of paragraph (7) of section 1861(b) [*42 USCS § 1395x(b)(7)*] or for which entitlement exists by reason of clause (II) of section 1832(a)(2)(B)(i) [*42 USCS § 1395k(a)(2)(B)(i)(II)*], and (2) for which the reasonable cost thereof is determined under section 1861(v)(1)(D) [*42 USCS § 1395x(v)(1)(D)*] (or would be if section 1886 [*42 USCS § 1395ww*] did not apply), payment under this part [*42 USCS §§ 1395j* et seq.] shall be made to such fund as may be designated by the organized medical staff of the hospital in which such services were furnished or, if such services were furnished in such hospital by the faculty of a medical school, to such fund as may be designated by such faculty, but only if--

(A) such hospital has an agreement with the Secretary under section 1866 [*42 USCS § 1395cc*], and

(B) the Secretary has received written assurances (i) that such payment will be used by such fund solely for the improvement of care to patients in such hospital or for educational or charitable purposes and (ii) the individuals who were furnished such services or any other persons will not be charged for such services (or if charged provision will be made for return of any moneys incorrectly collected).

HISTORY:

(Aug. 14, 1935, ch 531, Title XVIII, Part B, § 1835, as added July 30, 1965, P.L. 89-97, Title I, Part 1, § 102(a), 79 Stat. 303; Jan. 2, 1968, P.L. 90-248, Title I, Part 3, §§ 126(b), 129(c)(9)(A), (B), 130(a), (b), 133(e), 81 Stat. 846, 848, 849, 851; Oct. 30, 1972, P.L. 92-603, Title II, §§ 204(b), 227(e)(2), 251(b)(2), 281(f), 283(b), 86 Stat. 1377, 1406, 1445, 1456; Sept. 30, 1976, P.L. 94-437, Title IV, § 401(a) in part, 90 Stat. 1408; Dec. 5, 1980, P.L. 96-499, Title IX, Part B, Subpart I, §§ 930(e), (j), 933(b), Subpart II, § 944(a), 94 Stat. 2631, 2632, 2635, 2642; Aug. 13, 1981, P.L. 97-35, Title XXI, Subtitle A, ch 2, § 2106(b)(1), Subtitle B, ch 1, § 2122(a)(1), 95 Stat. 792, 796; April 20, 1983, P.L. 98-21, Title VI, § 602(b) in part, 97 Stat. 163; July 18, 1984, P.L. 98-369, Division B, Title III, Subtitle A, Part II, §§ 2336(a) in part, (b) in part, 2342(b), 2354(b)(1), (8), (9), 98 Stat. 1091, 1094, 1100; Nov. 8, 1984, P.L. 98-617, § 3(a)(3), 98 Stat. 3295; Oct. 21, 1986, P.L. 99-509, Title IX, Subtitle D, Part 3, § 9337(c)(1), (2) in part, 100 Stat. 2033; Dec. 22, 1987, P.L. 100-203, Title IV, Subtitle A, Part 2, Subpart B, § 4024(b), Part 3, Subpart C, § 4070(b)(3), Subpart D, § 4085(i)(4), 101 Stat. 1330-115, 1330-132; July 1, 1988, P.L. 100-360, Title II, Subtitle A, §§ 203(d)(1), 205(d), 102 Stat. 724, 731; Dec. 13, 1989, P.L. 101-234, Title II, § 201(a)(1), 103 Stat. 1981; Dec. 19, 1989, P.L. 101-239, Title VI, Subtitle A, Part 1, Subpart A, § 6003(g)(3)(D)(viii), 103 Stat. 2153; Nov. 5, 1990, P.L. 101-508, Title IV, Subtitle A, Part 1, § 4008(m)(2)(D), 104 Stat. 1388-53; Aug. 5, 1997, P.L. 105-33, Title IV, Subtitle C, § 4201(c)(1), Subtitle G, Ch 1, Subch B, § 4615(a), 111 Stat. 373, 475; Dec. 21, 2000, P.L. 106-554, § 1(a)(6), 114 Stat. 2763; Dec. 8, 2003, P.L. 108-173, Title VII, Subtitle D, § 736(c)(2)(B), 117 Stat. 2356.)

(As amended July 15, 2008, P.L. 110-275, Title I, Subtitle C, Part II, § 143(b)(4), 122 Stat. 2543.)

§ 1395o. Eligible individuals

Every individual who--

(1) is entitled to hospital insurance benefits under part A [*42 USCS §§ 1395c* et seq.], or

(2) has attained age 65 and is a resident of the United States, and is either (A) a citizen or (B) an alien lawfully admitted for permanent residence who has resided in the United States continuously during the 5 years immediately preceding the month in which he applies for enrollment under this part [*42 USCS §§ 1395j* et seq],

is eligible to enroll in the insurance program established by this part [*42 USCS §§ 1395j* et seq.].

HISTORY:

(Aug. 14, 1935, ch 531, Title XVIII, Part B, § 1836, as added July 30, 1965, P.L. 89-97, Title I, Part 1, § 102(a), 79 Stat. 304; Oct. 30, 1972, P.L. 92-603, Title II, § 201(c)(1), 86 Stat. 1372.)

§ 1395p. Enrollment periods

(a) Generally; regulations. An individual may enroll in the insurance program established by this part [*42 USCS §§ 1395j* et seq.] only in such manner and form as may be prescribed by regulations, and only during an enrollment period prescribed in or under this section.

(b) [Repealed]

(c) Initial general enrollment period; eligible individuals before March 1, 1966. In the case of individuals who first satisfy paragraph (1) or (2) of section 1836 [*42 USCS § 1395o(1)* or (2)] before March 1, 1966, the initial general enrollment period shall begin on the first day of the second month which begins after the date of enactment of this title [enacted July 30, 1965] and shall end on May 31, 1966. For purposes of this subsection and subsection (d), an individual who has attained age 65 and who satisfies paragraph (1) of section 1836 [*42 USCS § 1395o(1)*] but not paragraph (2) of such section [*42 USCS § 1395o(2)*] shall be treated as satisfying such paragraph (1) on the first day on which he is (or on filing application would have been) entitled to hospital insurance benefits under part A [*42 USCS §§ 1395c* et seq.].

(d) Eligible individuals on or after March 1, 1966. In the case of an individual who first satisfies paragraph (1) or (2) of section 1836 [*42 USCS § 1395(1)* or (2)] on or after March 1, 1966, his initial enrollment period shall begin on the first day of the third month before the month in which he first satisfies such paragraphs and shall end seven months later. Where the Secretary finds that an individual who has attained age 65 failed to enroll under this part [*42 USCS §§ 1395j* et seq.] during his initial enrollment period (based on a determination by the Secretary of the month in which such individual attained age 65), because such individual (relying on documentary evidence) was mistaken as to his correct date of birth, the Secretary shall establish for such individual an initial enrollment period based on his attaining age 65 at the time shown in such documentary evidence (with a coverage period determined under section 1838 [*42 USCS § 1395q*] as though he had attained such age at that time).

(e) General enrollment period. There shall be a general enrollment period during the period beginning on January 1 and ending on March 31 of each year.

(f) Individuals deemed enrolled in the medical insurance program. Any individual--
(1) who is eligible under section 1836 [*42 USCS § 1395o*] to enroll in the medical insurance program by reason of entitlement to hospital insurance benefits as described in paragraph (1) of such section, and
(2) whose initial enrollment period under subsection (d) begins after March 31, 1973, and
(3) who is residing in the United States, exclusive of Puerto Rico,

shall be deemed to have enrolled in the medical insurance program established by this part [*42 USCS §§ 1395j* et seq.].

(g) Commencement of enrollment period. All of the provisions of this section shall apply to individuals satisfying subsection (f), except that--
(1) in the case of an individual who satisfies subsection (f) by reason of entitlement to disability insurance benefits described in section 226(b) [*42 USCS § 426(b)*], his initial enrollment period shall begin on the first day of the later of (A) April 1973 or (B) the third month before the 25th month of such entitlement, and shall reoccur with each continuous period of eligibility (as defined in section 1839(d) [*42 USCS § 1395r(d)*]) and upon attainment of age 65;
(2) (A) in the case of an individual who is entitled to monthly benefits under section 202 or 223 [*42 USCS §§ 402* or *423*] on the first day of his initial enrollment period or becomes entitled to monthly benefits under section 202 [*42 USCS § 402*] during the first 3 months of such period, his enrollment shall be deemed to have occurred in the third month of his initial enrollment period, and
(B) in the case of an individual who is not entitled to benefits under section 202 [*42 USCS § 402*] on the first day of his initial enrollment period and does not become so entitled during the first 3 months of such period, his enrollment shall be deemed to have occurred in the month in which he files the application establishing his entitlement to hospital insurance benefits provided such filing occurs during the last 4 months of his initial enrollment period; and
(3) in the case of an individual who would otherwise satisfy subsection (f) but does not establish his entitlement to hospital insurance benefits until after the last day of his initial enrollment period (as defined in subsection (d) of this section), his enrollment shall be deemed to have occurred on the first day of the earlier of the then current or immediately succeeding general enrollment period (as defined in subsection (e) of this section).

(h) Waiver of enrollment period requirements where individual's rights were prejudiced by administrative error or inaction. In any case where the Secretary finds that an individual's enrollment or nonenrollment in the insurance program established by this part [*42 USCS §§ 1395j* et seq.] or part A [*42 USCS §§ 1395c* et seq.] pursuant to section 1818 [*42 USCS § 1395i-2*] is unintentional, inadvertent, or erroneous and is the result of the error, misrepresentation, or inaction of an officer, employee, or agent of the Federal Government, or its instrumentalities, the Secretary may take such action (including the designation for such individual of a special initial or subsequent enrollment period, with a coverage period determined on the basis thereof and with appropriate adjustments of premiums) as may be necessary to correct or eliminate the effects of such error, misrepresentation, or inaction.

(i) Special enrollment periods.
(1) In the case of an individual who--
(A) at the time the individual first satisfies paragraph (1) or (2) of section 1836 [*42 USCS § 1395o(1)* or (2)] is enrolled in a group health plan described in section 1862(b)(1)(A)(v) [*42 USCS § 1395y(b)(1)(A)(v)*] by reason of the individual's (or the individual's spouse's) current employment status, and
(B) has elected not to enroll (or to be deemed enrolled) under this section during the individual's initial enrollment period,
there shall be a special enrollment period described in paragraph (3). In the case of an individual not described in the previous sentence who has not attained the age of 65, at the time the individual first satisfies paragraph (1) of section 1836 [*42 USCS § 1395o(1)*], is enrolled in a large group health plan (as that term is defined in section 1862(b)(1)(B)(iii) [*42 USCS § 1395y(b)(1)(B)(iii)*]) by reason of the individual's current employment status (or the current employment status of a family member of the individual), and has elected not to enroll (or to be deemed enrolled) under this section during the individual's initial enrollment period, there shall be a special enrollment period described in paragraph (3)(B).
(2) In the case of an individual who--
(A) (i) has enrolled (or has been deemed to have enrolled) in the medical insurance program established under this part [*42 USCS §§ 1395j* et seq.] during the individual's initial enrollment period, or (ii) is an individual described in paragraph (1)(A);

(B) has enrolled in such program during any subsequent special enrollment period under this subsection during which the individual was not enrolled in a group health plan described in section 1862(b)(1)(A)(v) [*42 USCS § 1395y(b)(1)(A)(v)*] by reason of the individual's (or individual's spouse's) current employment status; and

(C) has not terminated enrollment under this section at any time at which the individual is not enrolled in such a group health plan by reason of the individual's (or individual's spouse's) current employment status,

there shall be a special enrollment period described in paragraph (3). In the case of an individual not described in the previous sentence who has not attained the age of 65, has enrolled (or has been deemed to have enrolled) in the medical insurance program established under this part [*42 USCS §§ 1395j* et seq.] during the individual's initial enrollment period, or is an individual described in the second sentence of paragraph (1), has enrolled in such program during any subsequent special enrollment period under this subsection during which the individual was not enrolled in a large group health plan (as that term is defined in section 1862(b)(1)(B)(iii) [*42 USCS § 1395y(b)(1)(B)(iii)*]) by reason of the individual's current employment status (or the current employment status of a family member of the individual), and has not terminated enrollment under this section at any time at which the individual is not enrolled in such a large group health plan by reason of the individual's current employment status (or the current employment status of a family member of the individual), there shall be a special enrollment period described in paragraph (3)(B).

(3) (A) The special enrollment period referred to in the first sentences of paragraphs (1) and (2) is the period including each month during any part of which the individual is enrolled in a group health plan described in section 1862(b)(1)(A)(v) [*42 USCS § 1395y(b)(1)(A)(v)*] by reason of current employment status ending with the last day of the eighth consecutive month in which the individual is at no time so enrolled.

(B) The special enrollment period referred to in the second sentences of paragraphs (1) and (2) is the period including each month during any part of which the individual is enrolled in a large group health plan (as that term is defined in section 1862(b)(1)(B)(iii) [*42 USCS § 1395y(b)(1)(B)(iii)*]) by reason of the individual's current employment status (or the current employment status of a family member of the individual) and ending with the last day of the eighth consecutive month in which the individual is at no time so enrolled.

(4) (A) In the case of an individual who is entitled to benefits under part A [*42 USCS §§ 1395c* et seq.] pursuant to section 226(b) [*42 USCS § 426(b)*] and--

(i) who at the time the individual first satisfies paragraph (1) of section 1836 [*42 USCS § 1395o(1)*]--

(I) is enrolled in a group health plan described in section 1862(b)(1)(A)(v) [*42 USCS § 1395y(b)(1)(A)(v)*] by reason of the individual's current or former employment or by reason of the current or former employment status of a member of the individual's family, and

(II) has elected not to enroll (or to be deemed enrolled) under this section during the individual's initial enrollment period; and

(ii) whose continuous enrollment under such group health plan is involuntarily terminated at a time when the enrollment under the plan is not by reason of the individual's current employment or by reason of the current employment of a member of the individual's family,

there shall be a special enrollment period described in subparagraph (B).

(B) The special enrollment period referred to in subparagraph (A) is the 6-month period beginning on the first day of the month which includes the date of the enrollment termination described in subparagraph (A)(ii).

(j) Persons who have ALS. In applying this section in the case of an individual who is entitled to benefits under part A [*42 USCS §§ 1395c* et seq.] pursuant to the operation of section 226(h) [*42 USCS § 426(h)*], the following special rules apply:

(1) The initial enrollment period under subsection (d) shall begin on the first day of the first month in which the individual satisfies the requirement of section 1836(1) [*42 USCS § 1395o(1)*].

(2) In applying subsection (g)(1), the initial enrollment period shall begin on the first day of the first month of entitlement to disability insurance benefits referred to in such subsection.

(k) Special enrollment period.

(1) In the case of an individual who--

(A) at the time the individual first satisfies paragraph (1) or (2) of section 1836 [*42 USCS § 1395o*], is described in paragraph (3), and has elected not to enroll (or to be deemed enrolled) under this section during the individual's initial enrollment period; or

(B) has terminated enrollment under this section during a month in which the individual is described in paragraph (3),

there shall be a special enrollment period described in paragraph (2).

(2) The special enrollment period described in this paragraph is the 6-month period beginning on the first day of the month which includes the date that the individual is no longer described in paragraph (3).

(3) For purposes of paragraph (1), an individual described in this paragraph is an individual who--

(A) is serving as a volunteer outside of the United States through a program--

(i) that covers at least a 12-month period; and

(ii) that is sponsored by an organization described in *section 501(c)(3) of the Internal Revenue Code of 1986* [*26 USCS § 501(c)(3)*] and exempt from taxation under section 501(a) of such Code [*26 USCS § 501(a)*]; and

(B) demonstrates health insurance coverage while serving in the program.

HISTORY:

(Aug. 14, 1935, ch 531, Title XVIII, Part B, § 1837, as added July 30, 1965, P.L. 89-97, Title I, Part 1, § 102(a), 79 Stat. 304; April 8, 1966, P.L. 89-384, § 3(a), (b), 80 Stat. 105; Jan. 2, 1968, P.L. 90-248, Title I, Part 3, §§ 136(a), 145(a), (b), 81 Stat. 853, 859; Oct. 30, 1972, P.L. 92-603, Title II, §§ 201(c)(2), 206(a), 259(a), 260, 86 Stat. 1372, 1378, 1448; June 9, 1980, P.L. 96-265, Title I, § 103(a)(3), 94 Stat. 444; Dec. 5, 1980, P.L. 96-499, Title IX, Part B, Subpart II, § 945(a), (b), 94 Stat. 2642; Aug. 13, 1981, P.L. 97-35, Title XXI, Subtitle B, Ch 4, § 2151(a)(1), (2), 95 Stat. 801; July 18, 1984, P.L. 98-369, Division B, Title III, Subtitle A, Part II, §§ 2338(b), 2354(b)(10), 98 Stat. 1092, 1101; April 7, 1986, P.L. 99-272, Title IX, Subtitle A, Part 2, Subtitle A, § 9201(c)(1), Subpart B, § 9219(a)(2), 100 Stat. 171, 182; Oct. 21, 1986, P.L. 99-509, Title IX, Subtitle D, Part 2, § 9319(c)(1)-(3), 100 Stat. 2011; Oct. 22, 1986, P.L. 99-514, Title XVIII, Subtitle C, Ch 1, § 1895(b)(12), 100 Stat. 2934; Dec. 19, 1989, P.L. 101-239, Title VI, Subtitle A, Part 3, Subpart A, § 6202(b)(4)(C), (c)(1), 103 Stat. 2233, 2234; Oct. 31, 1994, P.L. 103-432, Title I, Subtitle B, Part III, § 147(f)(1)(A), Subtitle C, § 151(c)(2), 108 Stat. 4430, 4435; Aug. 5, 1997, P.L. 105-33, Title IV, Subtitle F, Ch 6, Subch B, § 4581(b)(1), Subtitle G, Ch 3, § 4631(a)(2), 111 Stat. 465, 486; Dec. 21, 2000, P.L. 106-554, § 1(a)(6), 114 Stat. 2763.)

(As amended Feb. 8, 2006, P.L. 109-171, Title V, Subtitle B, Ch. 2, § 5115(a)(2)(A), 120 Stat. 45.)

§ 1395q. Coverage period

(a) Commencement. The period during which an individual is entitled to benefits under the insurance program established by this part [*42 USCS §§ 1395j* et seq.] (hereinafter referred to as his "coverage period") shall begin on whichever of the following is the latest:

(1) July 1, 1966, or (in the case of a disabled individual who has not attained age 65) July 1, 1973; or

(2) (A) in the case of an individual who enrolls pursuant to subsection (d) of section 1837 [*42 USCS § 1395p(d)*] before the month in which he first satisfies paragraph (1) or (2) of section 1836 [*42 USCS § 1395o(1)* or (2)], the first day of such month, or

(B) in the case of an individual who enrolls pursuant to such subsection (d) [*42 USCS § 1395p(d)*] in the month in which he first satisfies such paragraph [*42 USCS § 1395o(1)* or (2)], the first day of the month following the month in which he so enrolls, or

(C) in the case of an individual who enrolls pursuant to such subsection (d) [*42 USCS § 1395p(d)*] in the month following the month in which he first satisfies such paragraph [*42 USCS § 1395o(1)* or (2)], the first day of the second month following the month in which he so enrolls, or

(D) in the case of an individual who enrolls pursuant to such subsection (d) [*42 USCS § 1395p(d)*] more than one month following the month in which he satisfies such paragraph [*42 USCS § 1395o(1)* or (2)], the first day of the third month following the month in which he so enrolls, or

(E) in the case of an individual who enrolls pursuant to subsection (e) of section 1937 [*42 USCS § 1395p(e)*], the July 1 following the month in which he so enrolls; or

(3) (A) in the case of an individual who is deemed to have enrolled on or before the last day of the third month of his initial enrollment period, the first day of the month in which he first meets the applicable requirements of section 1836 [*42 USCS § 1395o*] or July 1, 1973, whichever is later, or

(B) in the case of an individual who is deemed to have enrolled on or after the first day of the fourth month of his initial enrollment period, as prescribed under subparagraphs (B), (C), (D), and (E) of paragraph (2) of this subsection.

(b) Continuation. An individual's coverage period shall continue until his enrollment has been terminated--

(1) by the filing of notice that the individual no longer wishes to participate in the insurance programs established by this part [*42 USCS §§ 1395j* et seq.], or

(2) for nonpayment of premiums.

The termination of a coverage period under paragraph (1) shall (except as otherwise provided in section 1843(e) [*42 USCS § 1395v(e)*]) take effect at the close of the month following the month in which the notice is filed. The termination of a coverage period under paragraph (2) shall take effect on a date determined under regulations, which

may be determined so as to provide a grace period in which overdue premiums may be paid and coverage continued. The grace period determined under the preceding sentence shall not exceed 90 days; except that it may be extended to not to exceed 180 days in any case where the Secretary determines that there was good cause for failure to pay the overdue premiums within such 90-day period.

Where an individual who is deemed to have enrolled for medical insurance pursuant to section 1837(f) [*42 USCS § 1395p(f)*] files a notice before the first day of the month in which his coverage period begins advising that he does not wish to be so enrolled, the termination of the coverage period, resulting from such deemed enrollment shall take effect with the first day of the month the coverage would have been effective. Where an individual who is deemed enrolled for medical insurance benefits pursuant to section 1837(f) [*42 USCS § 1395p(f)*] files a notice requesting termination of his deemed coverage in or after the month in which such coverage becomes effective, the termination of such coverage shall take effect at the close of the month following the month in which the notice is filed.

(c) Termination. In the case of an individual satisfying paragraph (1) of section 1836 [*42 USCS § 1395o(1)*] whose entitlement to hospital insurance benefits under part A [*42 USCS §§ 1395c* et seq.] is based on a disability rather than on his having attained the age of 65, his coverage period (and his enrollment under this part [*42 USCS §§ 1395j* et seq.]) shall be terminated as of the close of the last month for which he is entitled to hospital insurance benefits.

(d) Payment of expenses incurred during coverage period. No payments may be made under this part [*42 USCS §§ 1395j* et seq.] with respect to the expenses of an individual unless such expenses were incurred by such individual during a period which, with respect to him, is a coverage period.

(e) Commencement of coverage for special enrollment periods. Notwithstanding subsection (a), in the case of an individual who enrolls during a special enrollment period pursuant to section 1837(i)(3) or 1837(i)(4)(B) [*42 USCS § 1395p(i)(3)* or (i)(4)(B)] --

(1) in any month of the special enrollment period in which the individual is at any time enrolled in a plan (specified in subparagraph (A) or (B), as applicable, of section 1837(i)(3) [*42 USCS § 1395p(i)(3)*] or specified in section 1837(i)(4)(A)(i) [*42 USCS § 1395p(i)(4)(A)(i)*]) or in the first month following such a month, the coverage period shall begin on the first day of the month in which the individual so enrolls (or, at the option of the individual, on the first day of any of the following three months), or

(2) in any other month of the special enrollment period, the coverage period shall begin on the first day of the month following the month in which the individual so enrolls.

(f) Coverage period. Notwithstanding subsection (a), in the case of an individual who enrolls during a special enrollment period pursuant to section 1837(k) [*42 USCS § 1395p(k)*], the coverage period shall begin on the first day of the month following the month in which the individual so enrolls.

HISTORY:

(Aug. 14, 1935, ch 531, Title XVIII, Part B, § 1838, as added July 30, 1965, P.L. 89-97, Title I, Part 1, § 102(a), 79 Stat. 305; Jan. 2, 1968, P.L. 90-248, Title I, Part 3, § 145(c), 81 Stat. 859; Oct. 30, 1972, P.L. 92-603, Title II, §§ 201(c)(3), 206(b), (c), 257(a), 86 Stat. 1373, 1378, 1379, 1447; Dec. 5, 1980, P.L. 96-499, Title IX, Part B, Subpart II, §§ 945(c)(1), 947(b), 94 Stat. 2642, 2643; Aug. 13, 1981, P.L. 97-35, Title XXI, Subtitle A, Ch 2, § 2106(b)(2), Subtitle B, ch 4, 2151(a)(3), 95 Stat. 792, 802; July 18, 1984, P.L. 98-369, Division B, Title III, Subtitle A, Part II, § 2338(c), 98 Stat. 1092; April 7, 1986, P.L. 99-272, Title IX, Subtitle A, Part 2, Subpart A, § 9201(c)(2), 100 Stat. 171; Oct. 21, 1986, P.L. 99-509, Title IX, Subtitle D, Part 3, § 9344(b)(1), 100 Stat. 2041; Oct. 31, 1994, P.L. 103-432, Title I, Subtitle B, Part III, § 147(f)(1)(B), 108 Stat. 4430; Aug. 5, 1997, P.L. 105-33, Title IV, Subtitle F, Ch 6, Subch B, § 4581(b)(2), 111 Stat. 465; Dec. 8, 2003, P.L. 108-173, Title VII, Subtitle D, § 736(b)(6), 117 Stat. 2356.)

(As amended Feb. 8, 2006, P.L. 109-171, Title V, Subtitle B, Ch. 2, § 5115(a)(2)(B), 120 Stat. 46.)

§ 1395r. Amount of premiums for individuals enrolled under 42 USCS §§ 1395j et seq.

(a) Determination of monthly actuarial rates and premiums.

(1) The Secretary shall, during September of 1983 and of each year thereafter, determine the monthly actuarial rate for enrollees age 65 and over which shall be applicable for the succeeding calendar year. Such actuarial rate shall be the amount the Secretary estimates to be necessary so that the aggregate amount for such calendar year with respect to those enrollees age 65 and older will equal one-half of the total of the benefits and administrative costs which he estimates will be payable from the Federal Supplementary Medical Insurance Trust Fund for services performed and related

administrative costs incurred in such calendar year with respect to such enrollees. In calculating the monthly actuarial rate, the Secretary shall include an appropriate amount for a contingency margin.

(2) The monthly premium of each individual enrolled under this part [*42 USCS §§ 1395j* et seq.] for each month after December 1983 shall be the amount determined under paragraph (3), adjusted as required in accordance with subsections (b), (c), (f), and (i), and to reflect any credit provided under section 1854(b)(1)(C)(ii)(III) [*42 USCS § 1395w-24(b)(1)(C)(ii)(III)*].

(3) The Secretary, during September of each year, shall determine and promulgate a monthly premium rate for the succeeding calendar year that (except as provided in subsection (g)) is equal to 50 percent of the monthly actuarial rate for enrollees age 65 and over, determined according to paragraph (1), for that succeeding calendar year. Whenever the Secretary promulgates the dollar amount which shall be applicable as the monthly premium rate for any period, he shall, at the time such promulgation is announced, issue a public statement setting forth the actuarial assumptions and bases employed by him in arriving at the amount of an adequate actuarial rate for enrollees age 65 and older as provided in paragraph (1).

(4) The Secretary shall also, during September of 1983 and of each year thereafter, determine the monthly actuarial rate for disabled enrollees under age 65 which shall be applicable for the succeeding calendar year. Such actuarial rate shall be the amount the Secretary estimates to be necessary so that the aggregate amount for such calendar year with respect to disabled enrollees under age 65 will equal one-half of the total of the benefits and administrative costs which he estimates will be payable from the Federal Supplementary Medical Insurance Trust Fund for services performed and related administrative costs incurred in such calendar year with respect to such enrollees. In calculating the monthly actuarial rate under this paragraph, the Secretary shall include an appropriate amount for a contingency margin.

(b) Increase in monthly premiums. In the case of an individual whose coverage period began pursuant to an enrollment after his initial enrollment period (determined pursuant to subsection (c) or (d) of section 1837 [*42 USCS § 1395p(c)* or (d)]) and not pursuant to a special enrollment period under section 1837(i)(4) [*42 USCS § 1395p(i)(4)*], the monthly premium determined under subsection (a) (without regard to any adjustment under subsection (i)) shall be increased by 10 percent of the monthly premium so determined for each full 12 months (in the same continuous period of eligibility) in which he could have been but was not enrolled. For purposes of the preceding sentence, there shall be taken into account (1) the months which elapsed between the close of his initial enrollment period and the close of the enrollment period in which he enrolled, plus (in the case of an individual who reenrolls) (2) the months which elapsed between the date of termination of a previous coverage period and the close of the enrollment period in which he reenrolled, but there shall not be taken into account months for which the individual can demonstrate that the individual was enrolled in a group health plan described in section 1862(b)(1)(A)(v) [*42 USCS § 1395y(b)(1)(A)(v)*] by reason of the individual's (or the individual's spouse's) current employment status or months during which the individual has not attained the age of 65 and for which the individual can demonstrate that the individual was enrolled in a large group health plan (as that term is defined in section 1862(b)(1)(B)(iii) [*42 USCS § 1395y(b)(1)(B)(iii)*]) by reason of the individual's current employment status (or the current employment status of a family member of the individual) or months for which the individual can demonstrate that the individual was an individual described in section 1837(k)(3) [*42 USCS § 1395p(k)(3)*]. Any increase in an individual's monthly premium under the first sentence of this subsection with respect to a particular continuous period of eligibility shall not be applicable with respect to any other continuous period of eligibility which such individual may have. No increase in the premium shall be effected for a month in the case of an individual who enrolls under this part during 2001, 2002, 2003, or 2004 and who demonstrates to the Secretary before December 31, 2004, that the individual is a covered beneficiary (as defined in *section 1072(5) of title 10, United States Code*). The Secretary of Health and Human Services shall consult with the Secretary of Defense in identifying individuals described in the previous sentence.

(c) Premiums rounded to nearest multiple of 10 cents. If any monthly premium determined under the foregoing provisions of this section is not a multiple of 10 cents, such premium shall be rounded to the nearest multiple of 10 cents.

(d) "Continuous period of eligibility" defined. For purposes of subsection (b) (and section 1837(g)(1) [*42 USCS § 1395p(g)(1)*]), an individual's "continuous period of eligibility" is the period beginning with the first day on which he is eligible to enroll under section 1836 [*42 USCS § 1395o*] and ending with his death; except that any period during all of which an individual satisfied paragraph (1) of section 1836 [*42 USCS § 1395o(1)*] and which terminated in or before the month preceding the month in which he attained age 65 shall be a separate "continuous period of eligibility" with respect to such individual (and each such period which terminates shall be deemed not to have existed for purposes of subsequently applying this section).

(e) State payment of Part B late enrollment premium increases.

(1) Upon the request of a State (or any appropriate State or local governmental entity specified by the Secretary), the Secretary may enter into an agreement with the State (or such entity) under which the State (or such entity) agrees to pay on a quarterly or other periodic basis to the Secretary (to be deposited in the Treasury to the credit of the Federal Supplementary Medical Insurance Trust Fund) an amount equal to the amount of the part B late enrollment premium increases with respect to the premiums for eligible individuals (as defined in paragraph (3)(A)).

(2) No part B late enrollment premium increase shall apply to an eligible individual for premiums for months for which the amount of such an increase is payable under an agreement under paragraph (1).

(3) In this subsection:

(A) The term "eligible individual" means an individual who is enrolled under this part B [*42 USCS §§ 1395j* et seq.] and who is within a class of individuals specified in the agreement under paragraph (1).

(B) The term "part B late enrollment premium increase" means any increase in a premium as a result of the application of subsection (b).

(f) Limitation on increase in monthly premium. For any calendar year after 1988, if an individual is entitled to monthly benefits under section 202 or 223 [*42 USCS § 402* or *423*] or to a monthly annuity under section 3(a), 4(a), or 4(f) of the Railroad Retirement Act of 1974 [*45 USCS §§ 231b(a), 231c(a)* or (f)] for November and December of the preceding year, if the monthly premium of the individual under this section for December and for January is deducted from those benefits under section 1840(a)(1) or section 1840(b)(1) [*42 USCS § 1395s(a)(1)* or (b)(1)], and if the amount of the individual's premium is not adjusted for such January under subsection (i), the monthly premium otherwise determined under this section for an individual for that year shall not be increased, pursuant to this subsection, to the extent that such increase would reduce the amount of benefits payable to that individual for that December below the amount of benefits payable to that individual for that November (after the deduction of the premium under this section). For purposes of this subsection, retroactive adjustments or payments and deductions on account of work shall not be taken into account in determining the monthly benefits to which an individual is entitled under section 202 or 223 [*42 USCS § 402* or *423*] or under the Railroad Retirement Act of 1974.

(g) Exclusions from estimate of benefits and administrative costs. In estimating the benefits and administrative costs which will be payable from the Federal Supplementary Medical Insurance Trust Fund for a year for purposes of determining the monthly premium rate under subsection (a)(3), the Secretary shall exclude an estimate of any benefits and administrative costs attributable to--

(1) the application of section 1861(v)(1)(L)(viii) [*42 USCS § 1395x(v)(1)(L)*(viii)] or to the establishment under section 1861(v)(1)(L)(i)(V) [*42 USCS § 1395x(v)(1)(L)(i)(V)*] of a per visit limit at 106 percent of the median (instead of 105 percent of the median), but only to the extent payment for home health services under this *title [42 USCS §§ 1395* et seq.] is not being made under section 1895 [*42 USCS § 1395fff*] (relating to prospective payment for home health services); and

(2) the medicare prescription drug discount card and transitional assistance program under section 1860D-31 [*42 USCS § 1395w-141*].

(h) Potential application of comparative cost adjustment in CCA areas.

(1) In general. Certain individuals who are residing in a CCA area under section 1860C-1 [*42 USCS § 1395w-29*] who are not enrolled in an MA plan under part C [*42 USCS §§ 1395w-21* et seq.] may be subject to a premium adjustment under subsection (f) of such section for months in which the CCA program under such section is in effect in such area.

(2) No effect on late enrollment penalty or income-related adjustment in subsidies. Nothing in this subsection or section 1860C-1(f) [*42 USCS § 1395w-29(f)*] shall be construed as affecting the amount of any premium adjustment under subsection (b) or (i). Subsection (f) shall be applied without regard to any premium adjustment referred to in paragraph (1).

(3) Implementation. In order to carry out a premium adjustment under this subsection and section 1860C-1(f) [*42 USCS § 1395w-29(f)*] (insofar as it is effected through the manner of collection of premiums under section 1840(a) [*42 USCS § 1395s(a)*]), the Secretary shall transmit to the Commissioner of Social Security--

(A) at the beginning of each year, the name, social security account number, and the amount of the premium adjustment (if any) for each individual enrolled under this part for each month during the year; and

(B) periodically throughout the year, information to update the information previously transmitted under this paragraph for the year.

(i) Reduction in premium subsidy based on income.

(1) In general. In the case of an individual whose modified adjusted gross income exceeds the threshold amount under paragraph (2), the monthly amount of the premium subsidy applicable to the premium under this section for a month after December 2006 shall be reduced (and the monthly premium shall be increased) by the monthly adjustment amount specified in paragraph (3).

(2) Threshold amount. For purposes of this subsection, the threshold amount is--

(A) except as provided in subparagraph (B), $ 80,000, and

(B) in the case of a joint return, twice the amount applicable under subparagraph (A) for the calendar year.

(3) Monthly adjustment amount.

(A) In general. Subject to subparagraph (B), the monthly adjustment amount specified in this paragraph for an individual for a month in a year is equal to the product of the following:

(i) Sliding scale percentage. The applicable percentage specified in the table in subparagraph (C) for the individual minus 25 percentage points.

(ii) Unsubsidized part B premium amount. 200 percent of the monthly actuarial rate for enrollees age 65 and over (as determined under subsection (a)(1) for the year).

(B) 3-year phase in. The monthly adjustment amount specified in this paragraph for an individual for a month in a year before 2009 is equal to the following percentage of the monthly adjustment amount specified in subparagraph (A):

(i) For 2007, 33 percent.

(ii) For 2008, 67 percent.

(iii), (iv) [Deleted]

(C) Applicable percentage.

(i) In general.

If the modified adjusted gross income is:	The applicable percentage is:
More than $ 80,000 but not more than $ 100,000	35 percent
More than $ 100,000 but not more than $ 150,000	50 percent
More than $ 150,000 but not more than $ 200,000	65 percent
More than $ 200,000	80 percent.

(ii) Joint returns. In the case of a joint return, clause (i) shall be applied by substituting dollar amounts which are twice the dollar amounts otherwise applicable under clause (i) for the calendar year.

(iii) Married individuals filing separate returns. In the case of an individual who--

(I) is married as of the close of the taxable year (within the meaning of *section 7703 of the Internal Revenue Code of 1986* [*26 USCS § 7703*]) but does not file a joint return for such year, and

(II) does not live apart from such individual's spouse at all times during the taxable year,

clause (i) shall be applied by reducing each of the dollar amounts otherwise applicable under such clause for the calendar year by the threshold amount for such year applicable to an unmarried individual.

(4) Modified adjusted gross income.

(A) In general. For purposes of this subsection, the term "modified adjusted gross income" means adjusted gross income (as defined in *section 62 of the Internal Revenue Code of 1986* [*26 USCS § 62*])--

(i) determined without regard to sections 135, 911, 931, and 933 of such Code [*26 USCS §§ 135, 911, 931*, and *933*]; and

(ii) increased by the amount of interest received or accrued during the taxable year which is exempt from tax under such Code.

In the case of an individual filing a joint return, any reference in this subsection to the modified adjusted gross income of such individual shall be to such return's modified adjusted gross income.

(B) Taxable year to be used in determining modified adjusted gross income.

(i) In general. In applying this subsection for an individual's premiums in a month in a year, subject to clause (ii) and subparagraph (C), the individual's modified adjusted gross income shall be such income determined for the individual's last taxable year beginning in the second calendar year preceding the year involved.

(ii) Temporary use of other data. If, as of October 15 before a calendar year, the Secretary of the Treasury does not have adequate data for an individual in appropriate electronic form for the taxable year referred to in clause (i), the individual's modified adjusted gross income shall be determined using the data in such form from the previous taxable year. Except as provided in regulations prescribed by the Commissioner of Social Security in consultation with the Secretary, the preceding sentence shall cease to apply when adequate data in appropriate electronic form are available for the individual for the taxable year referred to in clause (i), and proper adjustments shall be made to the extent that the

premium adjustments determined under the preceding sentence were inconsistent with those determined using such taxable year.

(iii) Non-filers. In the case of individuals with respect to whom the Secretary of the Treasury does not have adequate data in appropriate electronic form for either taxable year referred to in clause (i) or clause (ii), the Commissioner of Social Security, in consultation with the Secretary, shall prescribe regulations which provide for the treatment of the premium adjustment with respect to such individual under this subsection, including regulations which provide for--

(I) the application of the highest applicable percentage under paragraph (3)(C) to such individual if the Commissioner has information which indicates that such individual's modified adjusted gross income might exceed the threshold amount for the taxable year referred to in clause (i), and

(II) proper adjustments in the case of the application of an applicable percentage under subclause (I) to such individual which is inconsistent with such individual's modified adjusted gross income for such taxable year.

(C) Use of more recent taxable year.

(i) In general. The Commissioner of Social Security in consultation with the Secretary of the Treasury shall establish a procedures under which an individual's modified adjusted gross income shall, at the request of such individual, be determined under this subsection--

(I) for a more recent taxable year than the taxable year otherwise used under subparagraph (B), or

(II) by such methodology as the Commissioner, in consultation with such Secretary, determines to be appropriate, which may include a methodology for aggregating or disaggregating information from tax returns in the case of marriage or divorce.

(ii) Standard for granting requests. A request under clause (i)(I) to use a more recent taxable year may be granted only if--

(I) the individual furnishes to such Commissioner with respect to such year such documentation, such as a copy of a filed Federal income tax return or an equivalent document, as the Commissioner specifies for purposes of determining the premium adjustment (if any) under this subsection; and

(II) the individual's modified adjusted gross income for such year is significantly less than such income for the taxable year determined under subparagraph (B) by reason of the death of such individual's spouse, the marriage or divorce of such individual, or other major life changing events specified in regulations prescribed by the Commissioner in consultation with the Secretary.

(5) Inflation adjustment.

(A) In general. In the case of any calendar year beginning after 2007, each dollar amount in paragraph (2) or (3) shall be increased by an amount equal to--

(i) such dollar amount, multiplied by

(ii) the percentage (if any) by which the average of the Consumer Price Index for all urban consumers (United States city average) for the 12-month period ending with August of the preceding calendar year exceeds such average for the 12-month period ending with August 2006.

(B) Rounding. If any dollar amount after being increased under subparagraph (A) is not a multiple of $ 1,000, such dollar amount shall be rounded to the nearest multiple of $ 1,000.

(6) Joint return defined. For purposes of this subsection, the term "joint return" has the meaning given to such term by *section 7701(a)(38) of the Internal Revenue Code of 1986* [*26 USCS § 7701(a)(38)*].

HISTORY:

(Aug. 14, 1935, ch 531, Title XVIII, Part B, § 1839, as added July 30, 1965, P.L. 89-97, Title I, Part 1, § 102(a), 79 Stat. 305; Jan. 2, 1968, P.L. 90-248, Title I, Part 3, § 145(d), 81 Stat. 859; Oct. 30, 1972, P.L. 92-603, Title II, §§ 201(c)(4), (5), 203(a)-(d), 86 Stat. 1373, 1376, 1377; Dec. 31, 1975, P.L. 94-182, Title I, § 104(a), 89 Stat. 1052; Dec. 20, 1977, P.L. 95-216, § 205(e), 91 Stat. 1529; Dec. 5, 1980, P.L. 96-499, Title IX, Part B, Subpart II, § 945(c)(2), 94 Stat. 2642; Aug. 13, 1981, P.L. 97-35, Title XXI, Subtitle B, ch 4, § 2151(a)(4), 95 Stat. 802; Sept. 3, 1982, P.L. 97-248, Title I, Subtitle A, Part II, § 124(a), (b), 96 Stat. 364; Jan. 12, 1983, P.L. 97-448, Title III, § 309(b)(8), 96 Stat. 2409; April 20, 1983, P.L. 98-21, Title VI, § 606(a)(1), (2), (3)(A)-(C), 97 Stat. 169, 170; July 18, 1984, P.L. 98-369, Division B, Title III, Subtitle A, Part II, § 2338(a), 98 Stat. 1091; July 18, 1984, P.L. 98-369, Division B, Title III, Subtitle A, Part I, § 2302(a), (b), 98 Stat. 1063; Nov. 8, 1984, P.L. 98-617, § 3(b)(4), 98 Stat. 3295; April 7, 1986, P.L. 99-272, Title IX, Subtitle A, Part 2, Subpart B, § 9219(a)(1), Part 3, Subpart B, § 9313, 100 Stat. 182, 194; Oct. 21, 1986, P.L. 99-509, Title IX, Subtitle A, § 9001(c), Subtitle D, Part 2, § 9319(c)(4), 100 Stat. 1970, 2012; Dec. 22, 1987, P.L. 100-203, Title IV, Subtitle A, Part 3, Subpart C, § 4080, 101 Stat. 1330-126; July 1, 1988, P.L. 100-360, Title II, Subtitle B, § 211(a)-(c)(1), 102 Stat. 733, 738; Oct. 13, 1988, P.L. 100-485, Title VI, § 608(d)(9), 102 Stat. 2415; Dec. 13, 1989, P.L. 101-234, Title II, § 202(a), 103 Stat. 1981; Dec. 19, 1989, P.L. 101-239, Title VI, Subtitle A, Part 3, Subpart A, § 6202(b)(4)(C), (c)(2), Part 4, § 6301, 103 Stat. 2233, 2234, 2258, Nov. 5, 1990, P.L. 101-508, Title IV, Subtitle A, Part

4, § 4301, 104 Stat. 1388-125; Aug. 10, 1993, P.L. 103-66, Title XIII, Ch 2, Subch A, Part IV, § 13571, 107 Stat. 609; Oct. 31, 1994, P.L. 103-432, Title I, Subtitle B, Part III, § 144, Subtitle C, § 151(c)(3), 108 Stat. 4427, 4435; Aug. 5, 1997, P.L. 105-33, Title IV, Subtitle F, Ch 6, Subch A, § 4571(a), (b)(1), Subch B, §§ 4581(a), 4582, Subtitle G, Ch 3, § 4631(a)(2), 111 Stat. 464, 465, 486; Oct. 21, 1998, P.L. 105-277, Div J, Title V, Subtitle A, § 5101(e), 112 Stat. 2681-915; Dec. 21, 2000, P.L. 106-554, § 1(a)(6), 114 Stat. 2763; Dec. 8, 2003, P.L. 108-173, Title I, § 105(a), Title II, Subtitle C, § 222(l)(2)(A), Subtitle E, § 241(b)(2)(A), Title VI, Subtitle C, § 625(a)(1), Title VII, Subtitle D, § 736(b)(7), Title VIII, Subtitle B, § 811(a), (b)(1), 117 Stat. 2166, 2206, 2220, 2317, 2356, 2364.)

(As amended Feb. 8, 2006, P.L. 109-171, Title V, Subtitle B, Ch. 2, §§ 5111, 5115(a)(1), 120 Stat. 43, 45.)

§ 1395s. Payment of premiums

(a) Deductions from *42 USCS §§ 402* or *423* monthly benefits.

(1) In the case of an individual who is entitled to monthly benefits under section 202 or 223 [*42 USCS §§ 402* or *423*], his monthly premiums under this part [*42 USCS §§ 1395j* et seq.] shall (except as provided in subsections (b)(1) and (c)) be collected by deducting the amount thereof from the amount of such monthly benefits. Such deduction shall be made in such manner and at such times as the Commissioner of Social Security shall by regulation prescribe. Such regulations shall be prescribed after consultation with the Secretary.

(2) The Secretary of the Treasury shall, from time to time, transfer from the Federal Old-Age and Survivors Insurance Trust Fund or the Federal Disability Insurance Trust Fund to the Federal Supplementary Medical Insurance Trust Fund the aggregate amount deducted under paragraph (1) for the period to which such transfer relates from benefits under section 202 or 223 [*42 USCS § 402* or *423*] which are payable from such Trust Fund. Such transfer shall be made on the basis of a certification by the Commissioner of Social Security and shall be appropriately adjusted to the extent that prior transfers were too great or too small.

(b) Deductions from railroad retirement annuities or pensions.

(1) In the case of an individual who is entitled to receive for a month an annuity under the Railroad Retirement Act of 1974 (whether or not such individual is also entitled for such month to a monthly insurance benefit under section 202 [*42 USCS § 402*]), his monthly premiums under this part [*42 USCS §§ 1395j* et seq.] shall (except as provided in subsection (c)) be collected by deducting the amount thereof from such annuity or pension. Such deduction shall be made in such manner and at such times as the Secretary shall by regulations prescribe. Such regulations shall be prescribed only after consultation with the Railroad Retirement Board.

(2) The Secretary of the Treasury shall, from time to time, transfer from the Railroad Retirement Account to the Federal Supplementary Medical Insurance Trust Fund the aggregate amount deducted under paragraph (1) for the period to which such transfer relates. Such transfers shall be made on the basis of a certification by the Railroad Retirement Board and shall be appropriately adjusted to the extent that prior transfers were too great or too small.

(c) Portion of monthly premium in excess of deducted amount. If an individual to whom subsection (a) or (b) applies estimates that the amount which will be available for deduction under such subsection for any premium payment period will be less than the amount of the monthly premiums for such period, he may (under regulations) pay to the Secretary such portion of the monthly premiums for such period as he desires.

(d) Deductions from civil service retirement annuities.

(1) In the case of an individual receiving an annuity under subchapter III of chapter 83 of title 5, United States Code [*5 USCS §§ 8331* et seq.], or any other law administered by the Director of the Office of Personnel Management providing retirement or survivorship protection, to whom neither subsection (a) nor subsection (b) applies, his monthly premiums under this part [*42 USCS §§ 1395j* et seq.] (and the monthly premiums of the spouse of such individual under this part [*42 USCS §§ 1395j* et seq.] if neither subsection (a) nor subsection (b) applies to such spouse and if such individual agrees) shall, upon notice from the Secretary of Health and Human Services to the Director of the Office of Personnel Management, be collected by deducting the amount thereof from each installment of such annuity. Such deduction shall be made in such manner and at such times as the Director of the Office of Personnel Management may determine. The Director of the Office of Personnel Management shall furnish such information as the Secretary of Health and Human Services may reasonably request in order to carry out his functions under this part [*42 USCS §§ 1395j* et seq.] with respect to individuals to whom this subsection applies. A plan described in section 8903 or 8903a of title 5, United States Code, may reimburse each annuitant enrolled in such plan an amount equal to the premiums paid by him under this part [*42 USCS §§ 1395j* et seq.] if such reimbursement is paid entirely from funds of such plan which are derived from sources other than the contributions described in section 8906 of such title.

(2) The Secretary of the Treasury shall, from time to time, but not less often than quarterly, transfer from the Civil Service Retirement and Disability Fund, or the account (if any) applicable in the case of such other law administered by the Director of the Office of Personnel Management, to the Federal Supplementary Medical Insurance Trust Fund the aggregate amount deducted under paragraph (1) for the period to which such transfer relates. Such transfer shall be made on the basis of a certification by the Director of the Office of Personnel Management and shall be appropriately adjusted to the extent that prior transfers were too great or too small.

(e) Manner and time of payment prescribed by Secretary. In the case of an individual who participates in the insurance program established by this part [*42 USCS §§ 1395j* et seq.] but with respect to whom none of the preceding provisions of this section applies, or with respect to whom subsection (c) applies, the premiums shall be paid to the Secretary at such times, and in such manner, as the Secretary shall by regulations prescribe.

(f) Deposit of amounts in Treasury. Amounts paid to the Secretary under subsection (c) or (e) shall be deposited in the Treasury to the credit of the Federal Supplementary Medical Insurance Trust Fund.

(g) Premium payability period. In the case of an individual who participates in the insurance program established by this part [*42 USCS §§ 1395j* et seq.], premiums shall be payable for the period commencing with the first month of his coverage period and ending with the month in which he dies or, if earlier, in which his coverage under such program terminates.

(h) Exempted monthly benefits. In the case of an individual who is enrolled under the program established by this part [*42 USCS §§ 1395j* et seq.] as a member of a coverage group to which an agreement with a State entered into pursuant to section 1843 [*42 USCS § 1395v*] is applicable, subsections (a), (b), (c), and (d) of this section shall not apply to his monthly premium for any month in this coverage period which is determined under section 1843(d) [*42 USCS § 1395v(d)*].

(i) Adjustment of monthly premium on account of payment reduction elected by Medicare + Choice organization. In the case of an individual enrolled in a Medicare + Choice plan, the Secretary shall provide for necessary adjustments of the monthly beneficiary premium to reflect 80 percent of any reduction elected under section 1854(f)(1)(E) [*42 USCS § 1395w-24(f)(1)(E)*] and to reflect any credit provided under section 1854(b)(1)(C)(iv) [*42 USCS § 1395w-24(b)(1)(C)(iv)*]. To the extent to which the Secretary determines that such an adjustment is appropriate, with the concurrence of any agency responsible for the administration of such benefits, such premium adjustment may be provided directly, as an adjustment to any social security, railroad retirement, or civil service retirement benefits, or, in the case of an individual who receives medical assistance under title XIX [*42 USCS §§ 1396* et seq.] for medicare costs described in section 1905(p)(3)(A)(ii) [*42 USCS § 1396d(p)(3)(A)(ii)*], as an adjustment to the amount otherwise owed by the State for such medical assistance.

HISTORY:

(Aug. 14, 1935, ch 531, Title XVIII, Part B, § 1840, as added July 30, 1965, P.L. 89-97, Title I, Part 1, § 102(a), 79 Stat. 306; April 8, 1966, P.L. 89-384, § 4(c), 80 Stat. 106; Jan. 2, 1968, P.L. 90-248, Title I, Part 4, § 166, Title IV, § 403(g), 81 Stat. 874, 932; Oct. 30, 1972, P.L. 92-603, Title II, §§ 201(c)(6), 263(a)-(d)(3), 86 Stat. 1373, 1448, 1449; Oct. 16, 1974, P.L. 93-445, Title III, § 306, 88 Stat. 1358; July 18, 1984, P.L. 98-369, Division B, Title III, Subtitle A, Part II, §§ 2354(b)(11), 2663(j)(2)(F)(ii), 98 Stat. 1101, 1170; June 17, 1985, P.L. 99-53, § 2(g), 99 Stat. 94; July 1, 1988, P.L. 100-360, Title II, Subtitle B, § 212(b)(1), 102 Stat. 740; Oct. 13, 1988, P.L. 100-485, Title VI, § 608(d)(10)(B), 102 Stat. 2415; Dec. 13, 1989, P.L. 101-234, Title II, § 202(a), 103 Stat. 1981; Aug. 15, 1994, P.L. 103-296, Title I, § 108(c)(2), 108 Stat. 1485; Dec. 21, 2000, P.L. 106-554, § 1(a)(6), 114 Stat. 2763; Dec. 8, 2003, P.L. 108-173, Title II, Subtitle C, § 222(l)(2)(B), 117 Stat. 2206.)

§ 1395t. Federal Supplementary Medical Insurance Fund

(a) Creation; deposits; fund transfers. There is hereby created on the books of the Treasury of the United States a trust fund to be known as the "Federal Supplementary Medical Insurance Trust Fund" (hereinafter in this section referred to as the "Trust Fund"). The Trust Fund shall consist of such gifts and bequests as may be made as provided in section 201(i)(1) [*42 USCS § 401(i)(1)*], such amounts as may be deposited in, or appropriated to, such fund as provided in this part [*42 USCS §§ 1395j* et seq.], and such amounts as may be deposited in, or appropriated to, the Medicare Prescription Drug Account established by section 1860D-16 [*42 USCS § 1395w-116*] or the Transitional Assistance Account established by section 1860D-31(k)(1) [*42 USCS § 1395w-141(k)(1)*].

(b) Board of Trustees; composition; meetings; duties. With respect to the Trust Fund, there is hereby created a body to be known as the Board of Trustees of the Trust Fund (hereinafter in this section referred to as the "Board of Trustees") composed of the Commissioner of Social Security, the Secretary of the Treasury, the Secretary of Labor, and the Secretary of Health and Human Services, all ex officio, and of two members of the public (both of whom may not be from the same political party), who shall be nominated by the President for a term of four years and subject to confirmation by the Senate. A member of the Board of Trustees serving as a member of the public and nominated and confirmed to fill a vacancy occurring during a term shall be nominated and confirmed only for the remainder of such term. An individual nominated and confirmed as a member of the public may serve in such position after the expiration of such member's term until the earlier of the time at which the member's successor takes office or the time at which a report of the Board is first issued under paragraph (2) after the expiration of the member's term. The Secretary of the Treasury shall be the Managing Trustee of the Board of Trustees (hereinafter in this section referred to as the "Managing Trustee"). The Administrator of the Centers for Medicare & Medicaid Services shall serve as the Secretary of the Board of Trustees. The Board of Trustees shall meet not less frequently than once each calendar year. It shall be the duty of the Board of Trustees to--

(1) Hold the Trust Fund;

(2) Report to the Congress not later than the first day of April of each year on the operation and status of the Trust Fund during the preceding fiscal year and on its expected operation and status during the current fiscal year and the next 2 fiscal years;

(3) Report immediately to the Congress whenever the Board is of the opinion that the amount of the Trust Fund is unduly small; and

(4) Review the general policies followed in managing the Trust Fund, and recommend changes in such policies, including necessary changes in the provisions of law which govern the way in which the Trust Fund is to be managed.

The report provided for in paragraph (2) shall include a statement of the assets of, and the disbursements made from, the Trust Fund during the preceding fiscal year, an estimate of the expected income to, and disbursements to be made from, the Trust Fund during the current fiscal year and each of the next 2 fiscal years, and a statement of the actuarial status of the Trust Fund. Such report shall also include an actuarial opinion by the Chief Actuary of the Centers for Medicare & Medicaid Services certifying that the techniques and methodologies used are generally accepted within the actuarial profession and that the assumptions and cost estimates used are reasonable. Such report shall be printed as a House document of the session of the Congress to which the report is made. A person serving on the Board of Trustees shall not be considered to be a fiduciary and shall not be personally liable for actions taken in such capacity with respect to the Trust Fund. Each report provided under paragraph (2) beginning with the report in 2005 shall include the information specified in section 801(a) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 [*42 USCS § 1395i* note].

(c) Investment of Trust Fund by Managing Trustee. It shall be the duty of the Managing Trustee to invest such portion of the Trust Fund as is not, in his judgment, required to meet current withdrawals. Such investments may be made only in interest-bearing obligations of the United States or in obligations guaranteed as to both principal and interest by the United States. For such purpose such obligations may be acquired (1) on original issue at the issue price, or (2) by purchase of outstanding obligations at the market price. The purposes for which obligations of the United States may be issued under chapter 31 of title 31, United States Code [*31 USCS §§ 3101* et seq.], are hereby extended to authorize the issuance at par of public-debt obligations for purchase by the Trust Fund. Such obligations issued for purchase by the Trust Fund shall have maturities fixed with due regard for the needs of the Trust Fund and shall bear interest at a rate equal to the average market yield (computed by the Managing Trustee on the basis of market quotations as of the end of the calendar month next preceding the date of such issue) on all marketable interest-bearing obligations of the United States then forming a part of the public debt which are not due or callable until after the expiration of 4 years from the end of such calendar month; except that where such average market yield is not a multiple of one-eighth of 1 per centum, the rate of interest on such obligations shall be the multiple of one-eighth of 1 per centum nearest such market yield. The Managing Trustee may purchase other interest-bearing obligations of the United States or obligations guaranteed as to both principal and interest by the United States, on original issue or at the market price, only where he determines that the purchase of such other obligations is in the public interest.

(d) Authority of Managing Trustee to sell obligations. Any obligations acquired by the Trust Fund (except public-debt obligations issued exclusively to the Trust Fund) may be sold by the Managing Trustee at the market price, and such public-debt obligations may be redeemed at par plus accrued interest.

(e) Interest on or proceeds from sale or redemption of obligations. The interest on, and the proceeds from the sale or redemption of, any obligations held in the Trust Fund shall be credited to and form a part of the Trust Fund.

(f) Transfers to other Funds. There shall be transferred periodically (but not less often than once each fiscal year) to the Trust Fund from the Federal Old-Age and Survivors Insurance Trust Fund and from the Federal Disability Insurance Trust Fund amounts equivalent to the amounts not previously so transferred which the Secretary of Health and Human Services shall have certified as overpayments (other than amounts so certified to the Railroad Retirement Board) pursuant to section 1870(b) of this Act [*42 USCS § 1395gg(b)*]. There shall be transferred periodically (but not less often than once each fiscal year) to the Trust Fund from the Railroad Retirement Account amounts equivalent to the amounts not previously so transferred which the Secretary of Health and Human Services shall have certified as overpayments to the Railroad Retirement Board pursuant to section 1870(b) of this Act [*42 USCS § 1395gg(b)*].

(g) Payments from Trust Fund of amounts provided for by *42 USCS §§ 1395j* et seq. or with respect to administrative expenses. The Managing Trustee shall pay from time to time from the Trust Fund such amounts as the Secretary of Health and Human Services certifies are necessary to make the payments provided for by this part [*42 USCS §§ 1395j* et seq.], and the payments with respect to administrative expenses in accordance with section 201(g)(1) [*42 USCS § 401(g)(1)*]. The payments provided for under part D [*42 USCS §§ 1395w-101* et seq.], other than under section 1860D-31(k)(2) [*42 USCS § 1395w-141(k)(2)*], shall be made from the Medicare Prescription Drug Account in the Trust Fund. The payments provided for under section 1860D-31(k)(2) [*42 USCS § 1395w-141(k)(2)*] shall be made from the Transitional Assistance Account in the Trust Fund.

(h) Payments from Trust Fund of costs incurred by Director of the Office of Personnel Management. The Managing Trustee shall pay from time to time from the Trust Fund such amounts as the Secretary of Health and Human Services certifies are necessary to pay the costs incurred by the Director of the Office of Personnel Management in making deductions pursuant to section 1840(d) [*42 USCS § 1395s(d)*] or pursuant to section 1860D-13(c)(1) or 1854(d)(2)(A) [*42 USCS § 1395w-113(c)(1)* or *1395w-24(d)(2)(A)*] (in which case payments shall be made in appropriate part from the Medicare Prescription Drug Account in the Trust Fund). During each fiscal year, or after the close of such fiscal year, the Director of the Office of Personnel Management shall certify to the Secretary the amount of the costs the Director incurred in making such deductions, and such certified amount shall be the basis for the amount of such costs certified by the Secretary to the Managing Trustee.

(i) Payments from Trust Fund of costs incurred by Railroad Retirement Board. The Managing Trustee shall pay from time to time from the Trust Fund such amounts as the Secretary of Health and Human Services certifies are necessary to pay the costs incurred by the Railroad Retirement Board for services performed pursuant to section 1840(b)(1) and section 1842(g) [*42 USCS §§ 1395s(b)(1)* and *1395u(g)*] and pursuant to sections 1860D-13(c)(1) and 1854(d)(2)(A) [*42 USCS §§ 1395w-113(c)(1)* and *1395w-24(d)(2)(A)*] (in which case payments shall be made in appropriate part from the Medicare Prescription Drug Account in the Trust Fund). During each fiscal year or after the close of such fiscal year, the Railroad Retirement Board shall certify to the Secretary the amount of the costs it incurred in performing such services and such certified amount shall be the basis for the amount of such costs certified by the Secretary to the Managing Trustee.

HISTORY:

(Aug. 14, 1935, ch 531, Title XVIII, Part B, § 1841, as added July 30, 1965, P.L. 89-97, Title I, Part 1, § 102(a), 79 Stat. 308; Jan. 2, 1968, P.L. 90-248, Title I, Part 4, § 169(a), 81 Stat. 875; Oct. 30, 1972, P.L. 92-603, Title I, § 132(e), Title II, § 263(d)(4), (e), 86 Stat. 1361, 1449; June 13, 1978, P.L. 95-292, § 5, 92 Stat. 315; April 20, 1983, P.L. 98-21, Title I, Part F, § 154(c), Title III, Part C, § 341(c), 97 Stat. 107, 135; July 18, 1984, P.L. 98-369, Division B, Title III, Subtitle A, Part II, §§ 2354(b)(2), (11), (12), 2663(j)(2)(F)(iii), 98 Stat. 1100, 1101, 1170; April 7, 1986, P.L. 99-272, Title IX, Subtitle A, Part 2, Subpart B, § 9213(b) in part, 100 Stat. 180; July 1, 1988, P.L. 100-360, Title II, Subtitle B, § 212(b)(2), (c)(4), 102 Stat. 740, 741; Nov. 10, 1988, P.L. 100-647, Title VIII, Subtitle A, § 8005(a), 102 Stat. 3781; Dec. 13, 1989, P.L. 101-234, Title II, § 202(a), 103 Stat. 1981; Aug. 15, 1994, P.L. 103-296, Title I, § 108(c)(3), 108 Stat. 1485; Dec. 8, 2003, P.L. 108-173, Title I, §§ 101(e)(3)(C), 105(d), Title VIII, Subtitle A, § 801(d)(2), Title IX, § 900(e)(1)(E), 117 Stat. 2151, 2166, 2359, 2371.)

§ 1395t-1, 1395t-2. [Repealed]

§ 1395u. Provisions relating to the administration of part B

(a) The administration of this part [*42 USCS §§ 1395j* et seq.] shall be conducted through contracts with medicare administrative contractors under section 1874A [*42 USCS § 1395kk-1*].

(b) Applicability of competitive bidding provisions; findings as to financial responsibility, etc., of carrier; contractual duties imposed by contract.

(1) [Deleted]

(2) (A), (B) [Deleted]

(C) In the case of residents of nursing facilities who receive services described in clause (i) or (ii) of section 1861(s)(2)(K) [*42 USCS § 1395x(s)(2)(K)*] performed by a member of a team, the Secretary shall instruct medicare administrative contractors to develop mechanisms which permit routine payment under this part for up to 1.5 visits per month per resident. In the previous sentence, the term "team" refers to a physician and includes a physician assistant acting under the supervision of the physician or a nurse practitioner working in collaboration with that physician, or both.

(D), (E) [Deleted]

(3) The Secretary--

(A) shall take such action as may be necessary to assure that, where payment under this part [*42 USCS §§ 1395j* et seq.] for a service is on a cost basis, the cost is reasonable cost (as determined under section 1861(v) [*42 USCS § 1395x(v)*]);

(B) shall take such action as may be necessary to assure that, where payment under this part [*42 USCS §§ 1395j* et seq.] for a service is on a charge basis, such charge will be reasonable and not higher than the charge applicable, for a comparable service and under comparable circumstances, to the policyholders and subscribers of the medicare administrative contractor, and such payment will (except as otherwise provided in section 1870(f) [*42 USCS § 1395gg(f)*]) be made--

(i) on the basis of an itemized bill; or

(ii) on the basis of an assignment under the terms of which (I) the reasonable charge is the full charge for the service, (II) the physician or other person furnishing such service agrees not to charge (and to refund amounts already collected) for services for which payment under this *title [42 USCS §§ 1395* et seq.] is denied under section 1154(a)(2) [*42 USCS § 1320c-3(a)(2)*] by reason of a determination under section 1154(a)(1)(B) [*42 USCS § 1320c-3(a)(1)(B)*], and (III) the physician or other person furnishing such service agrees not to charge (and to refund amounts already collected) for such service if payment may not be made therefor by reason of the provisions of paragraph (1) of section 1862(a) [*42 USCS § 1395y(a)(1)*], and if the individual to whom such service was furnished was without fault in incurring the expenses of such service, and if the Secretary's determination that payment (pursuant to such assignment) was incorrect and was made subsequent to the third year following the year in which notice of such payment was sent to such individual; except that the Secretary may reduce such three-year period to not less than one year if he finds such reduction is consistent with the objectives of this *title [42 USCS §§ 1395* et seq.] (except in the case of physicians' services and ambulance service furnished as described in section 1862(a)(4) [*42 USCS § 1395y(a)(4)*], other than for purposes of section 1870(f) [*42 USCS § 1395gg(f)*]);

but (in the case of bills submitted, or requests for payment made, after March 1968) only if the bill is submitted, or a written request for payment is made in such other form as may be permitted under regulations, no later than the close of the calendar year following the year in which such service is furnished (deeming any service furnished in the last 3 months of any calendar year to have been furnished in the succeeding calendar year);

(C)--(E) [Deleted]

(F) shall take such action as may be necessary to assure that where payment under this part [*42 USCS §§ 1395j* et seq.] for a service rendered is on a charge basis, such payment shall be determined on the basis of the charge that is determined in accordance with this section on the basis of customary and prevailing charge levels in effect at the time the service was rendered or, in the case of services rendered more than 12 months before the year in which the bill is submitted or request for payment is made, on the basis of such levels in effect for the 12-month period preceding such year;

(G) shall, for a service that is furnished with respect to an individual enrolled under this part, that is not paid on an assignment-related basis, and that is subject to a limiting charge under section 1848(g) [*42 USCS § 1395w-4(g)*]--

(i) determine, prior to making payment, whether the amount billed for such service exceeds the limiting charge applicable under section 1848(g)(2) [*42 USCS § 1395w-4(g)*];

(ii) notify the physician, supplier, or other person periodically (but not less often than once every 30 days) of determinations that amounts billed exceeded such applicable limiting charges; and

(iii) provide for prompt response to inquiries of physicians, suppliers, and other persons concerning the accuracy of such limiting charges for their services;

(H) shall implement--

(i) programs to recruit and retain physicians as participating physicians in the area served by the medicare administrative contractor, including educational and outreach activities and the use of professional relations personnel to handle billing and other problems relating to payment of claims of participating physicians; and

(ii) programs to familiarize beneficiaries with the participating physician program and to assist such beneficiaries in locating participating physicians;

(I) [Deleted]

(J), (K) [Repealed]

(L) shall monitor and profile physicians' billing patterns within each area or locality and provide comparative data to physicians whose utilization patterns vary significantly from other physicians in the same payment area or locality.

In determining the reasonable charge for services for purposes of this paragraph, there shall be taken into consideration the customary charges for similar services generally made by the physician or other person furnishing such services, as well as the prevailing charges in the locality for similar services. No charge may be determined to be reasonable in the case of bills submitted or requests for payment made under this part [*42 USCS §§ 1395j* et seq.] after December 31, 1970, if it exceeds the higher of (i) the prevailing charge recognized by the carrier and found acceptable by the Secretary for similar services in the same locality in administering this part [*42 USCS §§ 1395j* et seq.] on December 31, 1970, or (ii) the prevailing charge level that, on the basis of statistical data and methodology acceptable to the Secretary, would cover 75 percent of the customary charges made for similar services in the same locality during the 12-month period ending on the March 31 last preceding the start of the twelve-month period (beginning October 1 of each year) in which the service is rendered. In the case of physicians' services the prevailing charge level determined for purposes of clause (ii) of the preceding sentence for any twelve-month period (beginning after June 30, 1973) specified in clause (ii) of such sentence may not exceed (in the aggregate) the level determined under such clause for the fiscal year ending June 30, 1973, or (with respect to physicians' services furnished in a year after 1987) the level determined under this sentence (or under any other provision of law affecting the prevailing charge level) for the previous year except to the extent that the Secretary finds, on the basis of appropriate economic index data, that such higher level is justified by year-to-year economic changes. With respect to power-operated wheelchairs for which payment may be made in accordance with section 1861(s)(6) [*42 USCS § 1395x(s)(6)*], charges determined to be reasonable may not exceed the lowest charge at which power-operated wheelchairs are available in the locality. In the case of medical services, supplies, and equipment (including equipment servicing) that, in the judgment of the Secretary, do not generally vary significantly in quality from one supplier to another, the charges incurred after December 31, 1972, determined to be reasonable may not exceed the lowest charge levels at which such services, supplies, and equipment are widely and consistently available in a locality except to the extent and under the circumstances specified by the Secretary. The requirement in subparagraph (B) that a bill be submitted or request for payment be made by the close of the following calendar year shall not apply if (I) failure to submit the bill or request the payment by the close of such year is due to the error or misrepresentation of an officer, employee, fiscal intermediary, carrier, medicare administrative contractor, or agent of the Department of Health and Human Services performing functions under this *title [42 USCS §§ 1395* et seq.] and acting within the scope of his or its authority, and (II) the bill is submitted or the payment is requested promptly after such error or misrepresentation is eliminated or corrected. The amount of any charges for outpatient services which shall be considered reasonable shall be subject to the limitations established by regulations issued by the Secretary pursuant to section 1861(v)(1)(K) [*42 USCS § 1395x(v)(1)(K)*], and in determining the reasonable charge for such services, the Secretary may limit such reasonable charge to a percentage of the amount of the prevailing charge for similar services furnished in a physician's office, taking into account the extent to which overhead costs associated with such outpatient services have been included in the reasonable cost or charge of the facility.

(4)

(A) (i) In determining the prevailing charge levels under the third and fourth sentences of paragraph (3) for physicians' services furnished during the 15-month period beginning July 1, 1984, the Secretary shall not set any level higher than the same level as was set for the 12-month period beginning July 1, 1983.

(ii) (I) In determining the prevailing charge levels under the third and fourth sentences of paragraph (3) for physicians' services furnished during the 8-month period beginning May 1, 1986, by a physician who is not a participating physician (as defined in subsection (h)(1)) at the time of furnishing the services, the Secretary shall not set any level higher than the same level as was set for the 12-month period beginning July 1, 1983.

(II) In determining the prevailing charge levels under the fourth sentence of paragraph (3) for physicians' services furnished during the 8-month period beginning May 1, 1986, by a physician who is a participating physician (as defined in subsection (h)(1)) at the time of furnishing the services, the Secretary shall permit an additional one percentage point increase in the increase otherwise permitted under that sentence.

(iii) In determining the maximum allowable prevailing charges which may be recognized consistent with the index described in the fourth sentence of paragraph (3) for physicians' services furnished on or after January 1, 1987, by participating physicians, the Secretary shall treat the maximum allowable prevailing charges recognized as of December 31, 1986, under such sentence with respect to participating physicians as having been justified by economic changes.

(iv) The reasonable charge for physicians' services furnished on or after January 1, 1987, and before January 1, 1992, by a nonparticipating physician shall be no greater than the applicable percent of the prevailing charge levels established under the third and fourth sentences of paragraph (3) (or under any other applicable provision of law affecting the prevailing charge level). In the previous sentence, the term "applicable percent" means for services furnished (I) on or after January 1, 1987, and before April 1, 1988, 96 percent, (II) on or after April 1, 1988, and before January 1, 1989, 95.5 percent, and (III) on or after January 1, 1989, 95 percent.

(v) In determining the prevailing charge levels under the third and fourth sentences of paragraph (3) for physicians' services furnished during the 3-month period beginning January 1, 1988, the Secretary shall not set any level higher than the same level as was set for the 12-month period beginning January 1, 1987.

(vi) Before each year (beginning with 1989), the Secretary shall establish a prevailing charge floor for primary care services (as defined in subsection (i)(4) equal to 60 percent of the estimated average prevailing charge levels based on the best available data (determined, for participating physicians under the third and fourth sentences of paragraph (3) and under paragraph (4), without regard to this clause and without regard to physician specialty) for such service for all localities in the United States (weighted by the relative frequency of the service in each locality) for the year.

(vii) Beginning with 1987, the percentage increase in the MEI (as defined in subsection (i)(3)) for each year shall be the same for nonparticipating physicians as for participating physicians.

(B) (i) In determining the reasonable charge under paragraph (3) for physicians' services furnished during the 15-month period beginning July 1, 1984, the customary charges shall be the same customary charges as were recognized under this section for the 12-month period beginning July 1, 1983.

(ii) In determining the reasonable charge under paragraph (3) for physicians' services furnished during the 8-month period beginning May 1, 1986, by a physician who is not a participating physician (as defined in subsection (h)(1)) at the time of furnishing the services--

(I) if the physician was not a participating physician at any time during the 12-month period beginning on October 1, 1984, the customary charges shall be the same customary charges as were recognized under this section for the 12-month period beginning July 1, 1983, and

(II) if the physician was a participating physician at any time during the 12-month period beginning on October 1, 1984, the physician's customary charges shall be determined based upon the physician's actual charges billed during the 12-month period ending on March 31, 1985.

(iii) In determining the reasonable charge under paragraph (3) for physicians' services furnished during the 3-month period beginning January 1, 1988, the customary charges shall be the same customary charges as were recognized under this section for the 12-month period beginning January 1, 1987.

(iv) In determining the reasonable charge under paragraph (3) for physicians' services (other than primary care services, as defined in subsection (i)(4)) furnished during 1991, the customary charges shall be the same customary charges as were recognized under this section for the 9-month period beginning April 1, 1990. In a case in which subparagraph (F) applies (relating to new physicians) so as to limit the customary charges of a physician during 1990 to a percent of prevailing charges, the previous sentence shall not prevent such limit on customary charges under such subparagraph from increasing in 1991 to a higher percent of such prevailing charges.

(C) In determining the prevailing charge levels under the third and fourth sentences of paragraph (3) for physicians' services furnished during periods beginning after September 30, 1985, the Secretary shall treat the level as set under subparagraph (A)(i) as having fully provided for the economic changes which would have been taken into account but for the limitations contained in subparagraph (A)(i).

(D) (i) In determining the customary charges for physicians' services furnished during the 8-month period beginning May 1, 1986, or the 12-month period beginning January 1, 1987, by a physician who was not a participating physician (as defined in subsection (h)(1)) on September 30, 1985, the Secretary shall not recognize increases in actual charges for services furnished during the 15-month period beginning on July 1, 1984, above the level of the physician's actual charges billed in the 3-month period ending on June 30, 1984.

(ii) In determining the customary charges for physicians' services furnished during the 12-month period beginning January 1, 1987, by a physician who is not a participating physician (as defined in subsection (h)(1)) on April 30, 1986, the Secretary shall not recognize increases in actual charges for services furnished during the 7-month period beginning on October 1, 1985, above the level of the physician's actual charges billed during the 3-month period ending on June 30, 1984.

(iii) In determining the customary charges for physicians' services furnished during the 12-month period beginning January 1, 1987, or January 1, 1988, by a physician who is not a participating physician (as defined in subsection (h)(1))

on December 31, 1986, the Secretary shall not recognize increases in actual charges for services furnished during the 8-month period beginning on May 1, 1986, above the level of the physician's actual charges billed during the 3-month period ending on June 30, 1984.

(iv) In determining the customary charges for a physicians' service furnished on or after January 1, 1988, if a physician was a nonparticipating physician in a previous year (beginning with 1987), the Secretary shall not recognize any amount of such actual charges (for that service furnished during such previous year) that exceeds the maximum allowable actual charge for such service established under subsection (j)(1)(C).

(E) (i) For purposes of this part [*42 USCS §§ 1395j* et seq.] for physicians' services furnished in 1987, the percentage increase in the MEI is 3.2 percent.

(ii) For purposes of this part [*42 USCS §§ 1395j* et seq.] for physicians' services furnished in 1988, on or after April 1, the percentage increase in the MEI is--

(I) 3.6 percent for primary care services (as defined in subsection (i)(4)), and

(II) 1 percent for other physicians' services.

(iii) For purposes of this part [*42 USCS §§ 1395j* et seq.] for physicians' services furnished in 1989, the percentage increase in the MEI is--

(I) 3.0 percent for primary care services, and

(II) 1 percent for other physicians' services.

(iv) For purposes of this part [*42 USCS §§ 1395j* et seq.] for items and services furnished in 1990, after March 31, 1990, the percentage increase in the MEI is--

(I) 0 percent for radiology services, for anesthesia services, and for other services specified in the list referred to in paragraph (14)(C)(i),

(II) 2 percent for other services (other than primary care services), and

(III) such percentage increase in the MEI (as defined in subsection (i)(3)) as would be otherwise determined for primary care services (as defined in subsection (i)(4)).

(v) For purposes of this part [*42 USCS §§ 1395j* et seq.] for items and services furnished in 1991, the percentage increase in the MEI is--

(I) 0 percent for services (other than primary care services), and

(II) 2 percent for primary care services (as defined in subsection (i)(4)).

(5) [Deleted]

(6) No payment under this part [*42 USCS §§ 1395j* et seq.] for a service provided to any individual shall (except as provided in section 1870 [*42 USCS § 1395gg*]) be made to anyone other than such individual or (pursuant to an assignment described in subparagraph (B)(ii) of paragraph (3)) the physician or other person who provided the service, except that (A) payment may be made (i) to the employer of such physician or other person if such physician or other person is required as a condition of his employment to turn over his fee for such service to his employer, or (ii) where the service was provided under a contractual arrangement between such physician or other person and an entity, to the entity if, under the contractual arrangement, the entity submits the bill for the service and the contractual arrangement meets such program integrity and other safeguards as the Secretary may determine to be appropriate, (B) payment may be made to an entity (i) which provides coverage of the services under a health benefits plan, but only to the extent that payment is not made under this part [*42 USCS §§ 1395j* et seq.], (ii) which has paid the person who provided the service an amount (including the amount payable under this part [*42 USCS §§ 1395j* et seq.]) which that person has accepted as payment in full for the service, and (iii) to which the individual has agreed in writing that payment may be made under this part [*42 USCS §§ 1395j* et seq.], (C) in the case of services described in clause (i) of section 1861(s)(2)(K) [*42 USCS § 1395x(s)(2)(K)*], payment shall be made to either (i) the employer of the physician assistant involved, or (ii) with respect to a physician assistant who was the owner of a rural health clinic (as described in section 1861(aa)(2) [*42 USCS § 1395x(aa)(2)*]) for a continuous period beginning prior to the date of the enactment of the Balanced Budget Act of 1997 [enacted on Aug. 5, 1997] and ending on the date that the Secretary determines such rural health clinic no longer meets the requirements of section 1861(aa)(2) [*42 USCS § 1395x(aa)(2)*], payment may be made directly to the physician assistant, (D) payment may be made to a physician for physicians' services (and services furnished incident to such services) furnished by a second physician to patients of the first physician if (i) the first physician is unavailable to provide the services; (ii) the services are furnished pursuant to an arrangement between the two physicians that (I) is informal and reciprocal, or (II) involves per diem or other fee-for-time compensation for such services; (iii) the services are not provided by the second physician over a continuous period of more than 60 days or are provided over a longer continuous period during all of which the first physician has been called or ordered to active duty as a member of a reserve component of the Armed Forces; and (iv) the claim form submitted to the medicare administrative contractor for such services includes the second physician's unique identifier (provided under the system established under subsection (r)) and indicates that the claim meets the requirements of this subparagraph for payment to the first physician, (E) in the case of an item or service (other than services described in section 1888(e)(2)(A)(ii) [*42 USCS § 1395rr(e)(2)(A)(ii)*])

furnished by, or under arrangements made by, a skilled nursing facility to an individual who (at the time the item or service is furnished) is a resident of a skilled nursing facility, payment shall be made to the facility, (F) in the case of home health services (including medical supplies described in section 1861(m)(5) [*42 USCS § 1395x(m)(5)*], but excluding durable medical equipment to the extent provided for in such section) furnished to an individual who (at the time the item or service is furnished) is under a plan of care of a home health agency, payment shall be made to the agency (without regard to whether or not the item or service was furnished by the agency, by others under arrangement with them made by the agency, or when any other contracting or consulting arrangement, or otherwise), (G) in the case of services in a hospital or clinic to which section 1880(e) [*42 USCS § 1395qq(e)*] applies, payment shall be made to such hospital or clinic, and (H) in the case of services described in section 1861(aa)(3) [*42 USCS § 1395x(aa)(3)*] that are furnished by a health care professional under contract with a Federally qualified health center, payment shall be made to the center. No payment which under the preceding sentence may be made directly to the physician or other person providing the service involved (pursuant to an assignment described in subparagraph (B)(ii) of paragraph (3)) shall be made to anyone else under a reassignment or power of attorney (except to an employer or entity as described in subparagraph (A) of such sentence); but nothing in this subsection shall be construed (i) to prevent the making of such a payment in accordance with an assignment from the individual to whom the service was provided or a reassignment from the physician or other person providing such service if such assignment or reassignment is made to a governmental agency or entity or is established by or pursuant to the order of a court of competent jurisdiction, or (ii) to preclude an agent of the physician or other person providing the service from receiving any such payment if (but only if) such agent does so pursuant to an agency agreement under which the compensation to be paid to the agent for his services for or in connection with the billing or collection of payments due such physician or other person under this *title [42 USCS §§ 1395* et seq.] is unrelated (directly or indirectly) to the amount of such payments or the billings therefor, and is not dependent upon the actual collection of any such payment. For purposes of subparagraph (C) of the first sentence of this paragraph, an employment relationship may include any independent contractor arrangement, and employer status shall be determined in accordance with the law of the State in which the services described in such clause are performed.

(7)

(A) In the case of physicians' services furnished to a patient in a hospital with a teaching program approved as specified in section 1861(b)(6) [*42 USCS § 1395x(b)(6)*] but which does not meet the conditions described in section 1861(b)(7) [*42 USCS § 1395x(b)(7)*], the Secretary shall not provide (except on the basis described in subparagraph (C)) for payment for such services under this part [*42 USCS §§ 1395j* et seq.]--

(i) unless--

(I) the physician renders sufficient personal and identifiable physicians' services to the patient to exercise full, personal control over the management of the portion of the case for which the payment is sought,

(II) the services are of the same character as the services the physician furnishes to patients not entitled to benefits under this *title [42 USCS §§ 1395* et seq.], and

(III) at least 25 percent of the hospital's patients (during a representative past period, as determined by the Secretary) who were not entitled to benefits under this *title [42 USCS §§ 1395* et seq.] and who were furnished services described in subclauses (I) and (II) paid all or a substantial part of charges (other than nominal charges) imposed for such services; and

(ii) to the extent that the payment is based upon a reasonable charge for the services in excess of the customary charge as determined in accordance with subparagraph (B).

(B) The customary charge for such services in a hospital shall be determined in accordance with regulations issued by the Secretary and taking into account the following factors:

(i) In the case of a physician who is not a teaching physician (as defined by the Secretary), the Secretary shall take into account the amounts the physician charges for similar services in the physician's practice outside the teaching setting.

(ii) In the case of a teaching physician, if the hospital, its physicians, or other appropriate billing entity has established one or more schedules of charges which are collected for medical and surgical services, the Secretary shall base payment under this *title [42 USCS §§ 1395* et seq.] on the greatest of--

(I) the charges (other than nominal charges) which are most frequently collected in full or substantial part with respect to patients who were not entitled to benefits under this *title [42 USCS §§ 1395* et seq.] and who were furnished services described in subclauses (I) and (II) of subparagraph (A)(i),

(II) the mean of the charges (other than nominal charges) which were collected in full or substantial part with respect to such patients, or

(III) 85 percent of the prevailing charges paid for similar services in the same locality.

(iii) If all the teaching physicians in a hospital agree to have payment made for all of their physicians' services under this part [*42 USCS §§ 1395j* et seq.] furnished to patients in such hospital on an assignment-related basis, the

customary charge for such services shall be equal to 90 percent of the prevailing charges paid for similar services in the same locality.

(C) In the case of physicians' services furnished to a patient in a hospital with a teaching program approved as specified in section 1861(b)(6) [*42 USCS § 1395x(b)(6)*] but which does not meet the conditions described in section 1861(b)(7) [*42 USCS § 1395x(b)(7)*], if the conditions described in subclauses (I) and (II) of subparagraph (A)(i) are met and if the physician elects payment to be determined under this subparagraph, the Secretary shall provide for payment for such services under this part [*42 USCS §§ 1395j* et seq.] on the basis of regulations of the Secretary governing reimbursement for the services of hospital-based physicians (and not on any other basis).

(D)

(i) In the case of physicians' services furnished to a patient in a hospital with a teaching program approved as specified in section 1861(b)(6) [*42 USCS § 1395x(b)(6)*] but which does not meet the conditions described in section 1861(b)(7) [*42 USCS § 1395x(b)(7)*], no payment shall be made under this part [*42 USCS §§ 1395j* et seq.] for services of assistants at surgery with respect to a surgical procedure if such hospital has a training program relating to the medical specialty required for such surgical procedure and a qualified individual on the staff of the hospital is available to provide such services; except that payment may be made under this part [*42 USCS §§ 1395j* et seq.] for such services, to the extent that such payment is otherwise allowed under this paragraph, if such services, as determined under regulations of the Secretary--

(I) are required due to exceptional medical circumstances,

(II) are performed by team physicians needed to perform complex medical procedures, or

(III) constitute concurrent medical care relating to a medical condition which requires the presence of, and active care by, a physician of another specialty during surgery,

and under such other circumstances as the Secretary determines by regulation to be appropriate.

(ii) For purposes of this subparagraph, the term "assistant at surgery" means a physician who actively assists the physician in charge of a case in performing a surgical procedure.

(iii) The Secretary shall determine appropriate methods of reimbursement of assistants at surgery where such services are reimbursable under this part [*42 USCS §§ 1395j* et seq.].

(8)

(A)

(i) The Secretary shall by regulation--

(I) describe the factors to be used in determining the cases (of particular items or services) in which the application of this *title [42 USCS §§ 1395* et seq.] to payment under this part [*42 USCS §§ 1395j* et seq.](other than to physicians' services paid under section 1848 [*42 USCS § 1395w-4*]) results in the determination of an amount that, because of its being grossly excessive or grossly deficient, is not inherently reasonable, and

(II) provide in those cases for the factors to be considered in determining an amount that is realistic and equitable.

(ii) Notwithstanding the determination made in clause (i), the Secretary may not apply factors that would increase or decrease the payment under this part [*42 USCS §§ 1395j* et seq.] during any year for any particular item or service by more than 15 percent from such payment during the preceding year except as provided in subparagraph (B).

(B) The Secretary may make a determination under this subparagraph that would result in an increase or decrease under subparagraph (A) of more than 15 percent of the payment amount for a year, but only if--

(i) the Secretary's determination takes into account the factors described in subparagraph (C) and any additional factors the Secretary determines appropriate,

(ii) the Secretary's determination takes into account the potential impacts described in subparagraph (D), and

(iii) the Secretary complies with the procedural requirements of paragraph (9).

(C) The factors described in this subparagraph are as follows:

(i) The programs established under this *title [42 USCS §§ 1395* et seq.] and title XIX [*42 USCS §§ 1396* et seq.] are the sole or primary sources of payment for an item or service.

(ii) The payment amount does not reflect changing technology, increased facility with that technology, or reductions in acquisition or production costs.

(iii) The payment amount for an item or service under this part [*42 USCS §§ 1395j* et seq.] is substantially higher or lower than the payment made for the item or service by other purchasers.

(D) The potential impacts of a determination under subparagraph (B) on quality, access, and beneficiary liability, including the likely effects on assignment rates and participation rates.

(9) (A) The Secretary shall consult with representatives of suppliers or other individuals who furnish an item or service before making a determination under paragraph (8)(B) with regard to that item or service.

(B) The Secretary shall publish notice of a proposed determination under paragraph (8)(B) in the Federal Register--

(i) specifying the payment amount proposed to be established with respect to an item or service,

(ii) explaining the factors and data that the Secretary took into account in determining the payment amount so specified, and

(iii) explaining the potential impacts described in paragraph (8)(D).

(C) After publication of the notice required by subparagraph (B), the Secretary shall allow not less than 60 days for public comment on the proposed determination.

(D) (i) Taking into consideration the comments made by the public, the Secretary shall publish in the Federal Register a final determination under paragraph (8)(B) with respect to the payment amount to be established with respect to the item or service.

(ii) A final determination published pursuant to clause (i) shall explain the factors and data that the Secretary took into consideration in making the final determination.

(10) (A) (i) In determining the reasonable charge for procedures described in subparagraph (B) and performed during the 9-month period beginning on April 1, 1988, the prevailing charge for such procedure shall be the prevailing charge otherwise recognized for such procedure for 1987--

(I) subject to clause (iii), reduced by 2.0 percent, and

(II) further reduced by the applicable percentage specified in clause (ii).

(ii) For purposes of clause (i), the applicable percentage specified in this clause is--

(I) 15 percent, in the case of a prevailing charge otherwise recognized (without regard to this paragraph and determined without regard to physician specialty) that is at least 150 percent of the weighted national average (as determined by the Secretary) of such prevailing charges for such procedure for all localities in the United States for 1987;

(II) 0 percent, in the case of a prevailing charge that does not exceed 85 percent of such weighted national average; and

(III) in the case of any other prevailing charge, a percent determined on the basis of a straight-line sliding scale, equal to 3/13 of a percentage point for each percent by which the prevailing charge exceeds 85 percent of such weighted national average.

(iii) In no case shall the reduction under clause (i) for a procedure result in a prevailing charge in a locality for 1988 which is less than 85 percent of the Secretary's estimate of the weighted national average of such prevailing charges for such procedure for all localities in the United States for 1987 (based upon the best available data and determined without regard to physician specialty) after making the reduction described in clause (i)(I).

(B) The procedures described in this subparagraph are as follows: bronchoscopy, carpal tunnel repair, cataract surgery (including subsequent inspection of an intra-ocular lens), coronary artery bypass surgery, diagnostic and/or therapeutic dilation and curettage, knee arthroscopy, knee arthroplasty, pacemaker implantation surgery, total hip replacement, suprapubic prostatectomy, transurethral resection of the prostate, and upper gastrointestinal endoscopy.

(C) In the case of a reduction in the reasonable charge for a physicians' service under subparagraph (A), if a nonparticipating physician furnishes the service to an individual entitled to benefits under this part [*42 USCS §§ 1395j* et seq.], after the effective date of such reduction, the physician's actual charge is subject to a limit under subsection (j)(1)(D).

(D) There shall be no administrative or judicial review under section 1869 [*42 USCS § 1395ff*] or otherwise of any determination under subparagraph (A) or under paragraph (11)(B)(ii).

(11) (A) In providing payment for cataract eyeglasses and cataract contact lenses, and professional services relating to them, under this part [*42 USCS §§ 1395j* et seq.], each carrier shall--

(i) provide for separate determinations of the payment amount for the eyeglasses and lenses and of the payment amount for the professional services of a physician (as defined in section 1861(r) [*42 USCS § 1395x(r)*]), and

(ii) not recognize as reasonable for such eyeglasses and lenses more than such amount as the Secretary establishes in guidelines relating to the inherent reasonableness of charges for such eyeglasses and lenses.

(B) (i) In determining the reasonable charge under paragraph (3) for a cataract surgical procedure, subject to clause (ii), the prevailing charge for such procedure otherwise recognized for participating and nonparticipating physicians shall be reduced by 10 percent with respect to procedures performed in 1987.

(ii) In no case shall the reduction under clause (i) for a surgical procedure result in a prevailing charge in a locality for a year which is less than 75 percent of the weighted national average of such prevailing charges for such procedure for all the localities in the United States for 1986.

(C) (i) The prevailing charge level determined with respect to A-mode ophthalmic ultrasound procedures may not exceed 5 percent of the prevailing charge level established with respect to extra-capsular cataract removal with lens insertion.

(ii) The reasonable charge for an intraocular lens inserted during or subsequent to cataract surgery in a physician's office may not exceed the actual acquisition cost for the lens (taking into account any discount) plus a handling fee (not to exceed 5 percent of such actual acquisition cost).

(D) In the case of a reduction in the reasonable charge for a physicians' service or item under subparagraph (B) or (C), if a nonparticipating physician furnishes the service or item to an individual entitled to benefits under this part [*42 USCS §§ 1395j* et seq.] after the effective date of such reduction, the physician's actual charge is subject to a limit under subsection (j)(1)(D).

(12) [Repealed]

(13) (A) In determining payments under section 1833(l) and section 1848 [*42 USCS §§ 1395l(l), 1395w-4*] for anesthesia services furnished on or after January 1, 1994, the methodology for determining the base and time units used shall be the same for services furnished by physicians, for medical direction by physicians of two, three, or four certified registered nurse anesthetists, or for services furnished by a certified registered nurse anesthetist (whether or not medically directed) and shall be based on the methodology in effect, for anesthesia services furnished by physicians, as of the date of the enactment of the Omnibus Budget Reconciliation Act of 1993 [enacted Aug. 10, 1993].

(B) The Secretary shall require claims for physicians' services for medical direction of nurse anesthetists during the periods in which the provisions of subparagraph (A) apply to indicate the number of such anesthetists being medically directed concurrently at any time during the procedure, the name of each nurse anesthetist being directed, and the type of procedure for which the services are provided.

(14) (A) (i) In determining the reasonable charge for a physicians' service specified in subparagraph (C)(i) and furnished during the 9-month period beginning on April 1, 1990, the prevailing charge for such service shall be the prevailing charge otherwise recognized for such service for 1989 reduced by 15 percent or, if less, 1/3 of the percent (if any) by which the prevailing charge otherwise applied in the locality in 1989 exceeds the locally-adjusted reduced prevailing amount (as determined under subparagraph (B)(i)) for the service.

(ii) In determining the reasonable charge for a physicians' service specified in subparagraph (C)(i) and furnished during 1991, the prevailing charge for such service shall be the prevailing charge otherwise recognized for such service for the period during 1990 beginning on April 1, reduced by the same amount as the amount of the reduction effected under this paragraph (as amended by the Omnibus Budget Reconciliation Act of 1990) for such service during such period.

(B) For purposes of this paragraph:

(i) The "locally-adjusted reduced prevailing amount" for a locality for a physicians' service is equal to the product of--

(I) the reduced national weighted average prevailing charge for the service (specified under clause (ii)), and

(II) the adjustment factor (specified under clause (iii)) for the locality.

(ii) The "reduced national weighted average prevailing charge" for a physicians' service is equal to the national weighted average prevailing charge for the service (specified in subparagraph (C)(ii)) reduced by the percentage change (specified in subparagraph (C)(iii)) for the service.

(iii) The "adjustment factor", for a physicians' service for a locality, is the sum of--

(I) the practice expense component (percent), divided by 100, specified in appendix A (pages 187 through 194) of the Report of the Medicare and Medicaid Health Budget Reconciliation Amendments of 1989, prepared by the Subcommittee on Health and the Environment of the Committee on Energy and Commerce, House of Representatives, (Committee Print 101-M, 101st Congress, 1st Session) for the service, multiplied by the geographic practice cost index value (specified in subparagraph (C)(iv)) for the locality, and

(II) 1 minus the practice expense component (percent), divided by 100.

(C) For purposes of this paragraph:

(i) The procedures specified (by code and description) in the Overvalued Procedures List for Finance Committee, Revised September 20, 1989, prepared by the Physician Payment Review Commission [Medicare Payment Advisory Commission] which specification is of physicians' services that have been identified as overvalued by at least 10 percent based on a comparison of payments for such services under a resource-based relative value scale and of the national average prevailing charges under this part [*42 USCS §§ 1395j* et seq.].

(ii) The "national weighted average prevailing charge" specified in this clause, for a physicians' service specified in clause (i), is the national weighted average prevailing charge for the service in 1989 as determined by the Secretary using the best data available.

(iii) The "percentage change" specified in this clause, for a physicians' service specified in clause (i), is the percent difference (but expressed as a positive number) specified for the service in the list referred to in clause (i).

(iv) The geographic practice cost index value specified in this clause for a locality is the Geographic Overhead Costs Index specified for the locality in table 1 of the September 1989 Supplement to the Geographic Medicare Economic Index: Alternative Approaches (prepared by the Urban Institute and the Center for Health Economics Research).

(D) In the case of a reduction in the prevailing charge for a physicians' service under subparagraph (A), if a nonparticipating physician furnishes the service to an individual entitled to benefits under this part [*42 USCS §§ 1395j* et

seq.], after the effective date of such reduction, the physician's actual charge is subject to a limit under subsection (j)(1)(D).

(15) (A) In determining the reasonable charge for surgery, radiology, and diagnostic physicians' services which the Secretary shall designate (based on their high volume of expenditures under this part [*42 USCS §§ 1395j* et seq.]) and for which the prevailing charge (but for this paragraph) differs by physician specialty, the prevailing charge for such a service may not exceed the prevailing charge or fee schedule amount for that specialty of physicians that furnish the service most frequently nationally.

(B) In the case of a reduction in the prevailing charge for a physician's service under subparagraph (A), if a nonparticipating physician furnishes the service to an individual entitled to benefits under this part [*42 USCS §§ 1395j* et seq.], after the effective date of the reduction, the physician's actual charge is subject to a limit under subsection (j)(1)(D).

(16) (A) In determining the reasonable charge for all physicians' services other than physicians' services specified in subparagraph (B) furnished during 1991, the prevailing charge for a locality shall be 6.5 percent below the prevailing charges used in the locality under this part [*42 USCS §§ 1395j* et seq.] in 1990 after March 31.

(B) For purposes of subparagraph (A), the physicians' services specified in this subparagraph are as follows:

(i) Radiology, anesthesia and physician pathology services, the technical components of diagnostic tests specified in paragraph (17) and physicians' services specified in paragraph (14)(C)(i).

(ii) Primary care services specified in subsection (i)(4), hospital inpatient medical services, consultations, other visits, preventive medicine visits, psychiatric services, emergency care facility services, and critical care services.

(iii) Partial mastectomy; tendon sheath injections; and small joint arthrocentesis; femoral fracture and trochanteric fracture treatments; endotracheal intubation; thoracentesis; thoracostomy; aneurysm repair; cystourethroscopy; transurethral fulguration and resection; tympanoplasty with mastoidectomy; and ophthalmoscopy.

(17) With respect to payment under this part [*42 USCS §§ 1395j* et seq.] for the technical (as distinct from professional) component of diagnostic tests (other than clinical diagnostic laboratory tests, tests specified in paragraph (14)(C)(i), and radiology services, including portable x-ray services) which the Secretary shall designate (based on their high volume of expenditures under this part [*42 USCS §§ 1395j* et seq.]), the reasonable charge for such technical component (including the applicable portion of a global service) may not exceed the national median of such charges for all localities, as estimated by the Secretary using the best available data.

(18) (A) Payment for any service furnished by a practitioner described in subparagraph (C) and for which payment may be made under this part [*42 USCS §§ 1395j* et seq.] on a reasonable charge or fee schedule basis may only be made under this part [*42 USCS §§ 1395j* et seq.] on an assignment-related basis.

(B) A practitioner described in subparagraph (C) or other person may not bill (or collect any amount from) the individual or another person for any service described in subparagraph (A), except for deductible and coinsurance amounts applicable under this part [*42 USCS §§ 1395j* et seq.]. No person is liable for payment of any amounts billed for such a service in violation of the previous sentence. If a practitioner or other person knowingly and willfully bills (or collects an amount) for such a service in violation of such sentence, the Secretary may apply sanctions against the practitioner or other person in the same manner as the Secretary may apply sanctions against a physician in accordance with subsection (j)(2) in the same manner as such section applies with respect to a physician. Paragraph (4) of subsection (j) shall apply in this subparagraph in the same manner as such paragraph applies to such section.

(C) A practitioner described in this subparagraph is any of the following:

(i) A physician assistant, nurse practitioner, or clinical nurse specialist (as defined in section 1861(aa)(5) [*42 USCS § 1395x(aa)(5)*]).

(ii) A certified registered nurse anesthetist (as defined in section 1861(bb)(2) [*42 USCS § 1395x(bb)(2)*]).

(iii) A certified nurse-midwife (as defined in section 1861(gg)(2) [*42 USCS § 1395x(gg)(2)*]).

(iv) A clinical social worker (as defined in section 1861(hh)(1) [*42 USCS § 1395x(hh)(1)*]).

(v) A clinical psychologist (as defined by the Secretary for purposes of section 1861(ii) [*42 USCS § 1395x(ii)*]).

(vi) A registered dietitian or nutrition professional.

(D) For purposes of this paragraph, a service furnished by a practitioner described in subparagraph (C) includes any services and supplies furnished as incident to the service as would otherwise be covered under this part if furnished by a physician or as incident to a physician's service.

(19) For purposes of section 1833(a)(1) [*42 USCS § 1395m(a)(1)*], the reasonable charge for ambulance services (as described in section 1861(s)(7) [*42 USCS § 1395x(s)(7)*]) provided during calendar year 1998 and calendar year 1999 may not exceed the reasonable charge for such services provided during the previous calendar year (after application of this paragraph), increased by the percentage increase in the consumer price index for all urban consumers (U.S. city average) as estimated by the Secretary for the 12-month period ending with the midpoint of the year involved reduced by 1.0 percentage point.

(c) Advances of funds to carrier; prompt payment of claim.

(1) [Deleted]

(2) (A) Each contract under section 1874A [*42 USCS § 1395kk-1*] that provides for making payments under this part [*42 USCS §§ 1395j* et seq.] shall provide that payment shall be issued, mailed, or otherwise transmitted with respect to not less than 95 percent of all claims submitted under this part [*42 USCS §§ 1395j* et seq.]--

(i) which are clean claims, and

(ii) for which payment is not made on a periodic interim payment basis,

within the applicable number of calendar days after the date on which the claim is received.

(B) In this paragraph:

(i) The term "clean claim" means a claim that has no defect or impropriety (including any lack of any required substantiating documentation) or particular circumstance requiring special treatment that prevents timely payment from being made on the claim under this part [*42 USCS §§ 1395j* et seq.].

(ii) The term "applicable number of calendar days" means--

(I) with respect to claims received in the 12-month period beginning October 1, 1986, 30 calendar days,

(II) with respect to claims received in the 12-month period beginning October 1, 1987, 26 calendar days (or 19 calendar days with respect to claims submitted by participating physicians),

(III) with respect to claims received in the 12-month period beginning October 1, 1988, 25 calendar days (or 18 calendar days with respect to claims submitted by participating physicians),

(IV) with respect to claims received in the 12-month period beginning October 1, 1989, and claims received in any succeeding 12-month period ending on or before September 30, 1993, 24 calendar days (or 17 calendar days with respect to claims submitted by participating physicians), and

(V) with respect to claims received in the 12-month period beginning October 1, 1993, and claims received in any succeeding 12-month period, 30 calendar days.

(C) If payment is not issued, mailed, or otherwise transmitted within the applicable number of calendar days (as defined in clause (ii) of subparagraph (B)) after a clean claim (as defined in clause (i) of such subparagraph) is received, interest shall be paid at the rate used for purposes of *section 3902(a) of title 31, United States Code* (relating to interest penalties for failure to make prompt payments) for the period beginning on the day after the required payment date and ending on the date on which payment is made.

(3) (A) Each contract under this section which provides for the disbursement of funds, as described in section 1874A(a)(3)(B) [*42 USCS § 1395kk-1(a)(3)(B)*], shall provide that no payment shall be issued, mailed, or otherwise transmitted with respect to any claim submitted under this *title [42 USCS §§ 1395* et seq.] within the applicable number of calendar days after the date on which the claim is received.

(B) In this paragraph, the term "applicable number of calendar days" means--

(i) with respect to claims submitted electronically as prescribed by the Secretary, 13 days, and

(ii) with respect to claims submitted otherwise, 28 days.

(4) Neither a medicare administrative contractor nor the Secretary may impose a fee under this *title [42 USCS §§ 1395* et seq.]--

(A) for the filing of claims related to physicians' services,

(B) for an error in filing a claim relating to physicians' services or for such a claim which is denied,

(C) for any appeal under this title with respect to physicians' services,

(D) for applying for (or obtaining) a unique identifier under subsection (r), or

(E) for responding to inquiries respecting physicians' services or for providing information with respect to medical review of such services.

(5), (6) [Deleted]

(d)--(f) [Repealed]

(g) Authority of Railroad Retirement Board to enter into contracts with carriers. The Railroad Retirement Board shall, in accordance with such regulations as the Secretary may prescribe, contract with a medicare administrative contractor or contractors to perform the functions set out in this section with respect to individuals entitled to benefits as qualified railroad retirement beneficiaries pursuant to section 226(a) of this Act [*42 USCS § 426(a)*] and section 7(d) of the Railroad Retirement Act of 1974 [*45 USCS § 231f(d)*].

(h) Participating physician or supplier; agreements with Secretary; publication of directories; availability; inclusion of program in explanation of benefits; payment of claims on assignment-related basis.

(1) Any physician or supplier may voluntarily enter into an agreement with the Secretary to become a participating physician or supplier. For purposes of this section, the term "participating physician or supplier" means a physician or

supplier (excluding any provider of services) who, before the beginning of any year beginning with 1984, enters into an agreement with the Secretary which provides that such physician or supplier will accept payment under this part [*42 USCS §§ 1395j* et seq.] on an assignment-related basis for all items and services furnished to individuals enrolled under this part [*42 USCS §§ 1395j* et seq.] during such year. In the case of a newly licensed physician or a physician who begins a practice in a new area, or in the case of a new supplier who begins a new business, or in such similar cases as the Secretary may specify, such physician or supplier may enter into such an agreement after the beginning of a year, for items and services furnished during the remainder of the year.

(2) The Secretary shall maintain a toll-free telephone number or numbers at which individuals enrolled under this part [*42 USCS §§ 1395j* et seq.] may obtain the names, addresses, specialty, and telephone numbers of participating physicians and suppliers, and may request a copy of an appropriate directory published under paragraph (4). The Secretary shall, without charge, mail a copy of such directory upon such a request.

(3) (A) In any case in which[a] medicare administrative contractor having a contract under section 1874A [*42 USCS § 1395kk-1*] that provides for making payments under this part [*42 USCS §§ 1395j* et seq.] is able to develop a system for the electronic transmission to such contractor of bills for services, such contractor shall establish direct lines for the electronic receipt of claims from participating physicians and suppliers.

(B) The Secretary shall establish a procedure whereby an individual enrolled under this part may assign, in an appropriate manner on the form claiming a benefit under this part [*42 USCS §§ 1395j* et seq.] for an item or service furnished by a participating physician or supplier, the individual's rights of payment under a medicare supplemental policy (described in section 1882(g)(1) [*42 USCS § 1395ss(g)(1)*]) in which the individual is enrolled. In the case such an assignment is properly executed and a payment determination is made by a medicare administrative contractor with a contract under this section, the contractor shall transmit to the private entity issuing the medicare supplemental policy notice of such fact and shall include an explanation of benefits and any additional information that the Secretary may determine to be appropriate in order to enable the entity to decide whether (and the amount of) any payment is due under the policy. The Secretary may enter into agreements for the transmittal of such information to entities electronically. The Secretary shall impose user fees for the transmittal of information under this subparagraph by a medicare administrative contractor, whether electronically or otherwise, and such user fees shall be collected and retained by the contractor.

(4) At the beginning of each year the Secretary shall publish directories (for appropriate local geographic areas) containing the name, address, and specialty of all participating physicians and suppliers (as defined in paragraph (1)) for that area for that year. Each directory shall be organized to make the most useful presentation of the information (as determined by the Secretary) for individuals enrolled under this part [*42 USCS §§ 1395j* et seq.]. Each participating physician directory for an area shall provide an alphabetical listing of all participating physicians practicing in the area and an alphabetical listing by locality and specialty of such physicians.

(5) (A) The Secretary shall promptly notify individuals enrolled under this part [*42 USCS §§ 1395j* et seq.] through an annual mailing of the participation program under this subsection and the publication and availability of the directories and shall make appropriate area directory or directories available in each district and branch office of the Social Security Administration, in the offices of medicare administrative contractors, and to senior citizen organizations.

(B) The annual notice provided under subparagraph (A) shall include--

(i) a description of the participation program,

(ii) an explanation of the advantages to beneficiaries of obtaining covered services through a participating physician or supplier,

(iii) an explanation of the assistance offered by medicare administrative contractors in obtaining the names of participating physicians and suppliers, and

(iv) the toll-free telephone number under paragraph (2)(A) for inquiries concerning the program and for requests for free copies of appropriate directories.

(6) The Secretary shall provide that the directories shall be available for purchase by the public. The Secretary shall provide that each appropriate area directory is sent to each participating physician located in that area and that an appropriate number of copies of each such directory is sent to hospitals located in the area. Such copies shall be sent free of charge.

(7) The Secretary shall provide that each explanation of benefits provided under this part [*42 USCS §§ 1395j* et seq.] for services furnished in the United States, in conjunction with the payment of claims under section 1833(a)(1) [*42 USCS § 1395l(a)(1)*] (made other than on an assignment-related basis, shall include--

(A) a prominent reminder of the participating physician and supplier program established under this subsection (including the limitation on charges that may be imposed by such physicians and suppliers) and a clear statement of any amounts charged for the particular items or services on the claim involved above the amount recognized under this part [*42 USCS §§ 1395j* et seq.]),

(B) the toll-free telephone number or numbers, maintained under paragraph (2), at which an individual enrolled under this part [*42 USCS §§ 1395j* et seq.] may obtain information on participating physicians and suppliers,

(C) (i) an offer of assistance to such an individual in obtaining the names of participating physicians of appropriate specialty and (ii) an offer to provide a free copy of the appropriate participating physician directory, and

(D) in the case of services for which the billed amount exceeds the limiting charge imposed under section 1848(g) [*42 USCS § 1395w-4(g)*], information regarding such applicable limiting charge (including information concerning the right to a refund under section 1848(g)(1)(A)(iv) [*42 USCS § 1395w-4(g)(1)(A)(iv)*]).

(8) The Secretary may refuse to enter into an agreement with a physician or supplier under this subsection, or may terminate or refuse to renew such agreement, in the event that such physician or supplier has been convicted of a felony under Federal or State law for an offense which the Secretary determines is detrimental to the best interests of the program or program beneficiaries.

(i) Definitions. For purposes of this *title [42 USCS §§ 1395* et seq.]:

(1) A claim is considered to be paid on an "assignment-related basis" if the claim is paid on the basis of an assignment described in subsection (b)(3)(B)(ii), in accordance with subsection (b)(6)(B), or under the procedure described in section 1870(f)(1) [*42 USCS § 1395gg(f)(1)*].

(2) The term "participating physician" refers, with respect to the furnishing of services, to a physician who at the time of furnishing the services is a participating physician (under subsection (h)(1)); the term "nonparticipating physician" refers, with respect to the furnishing of services, to a physician who at the time of furnishing the services is not a participating physician; and the term "nonparticipating supplier or other person" means a supplier or other person (excluding a provider of services) that is not a participating physician or supplier (as defined in subsection (h)(1)).

(3) The term "percentage increase in the MEI" means, with respect to physicians' services furnished in a year, the percentage increase in the medicare economic index (referred to in the fourth sentence of subsection (b)(3)) applicable to such services furnished as of the first day of that year.

(4) The term "primary care services" means physicians' services which constitute office medical services, emergency department services, home medical services, skilled nursing, intermediate care, and long-term care medical services, or nursing home, boarding home, domiciliary, or custodial care medical services.

(j) Monitoring of charges by nonparticipating physicians; sanctions and penalties for excess charges.

(1) (A) In the case of a physician who is not a participating physician for items and services furnished during a portion of the 30-month period beginning July 1, 1984, the Secretary shall monitor the physician's actual charges to individuals enrolled under this part for physicians' services during that portion of that period. If such physician knowingly and willfully bills individuals enrolled under this part [*42 USCS §§ 1395j* et seq.] for actual charges in excess of such physician's actual charges for the calendar quarter beginning on April 1, 1984, the Secretary may apply sanctions against such physician in accordance with paragraph (2).

(B) (i) During any period (on or after January 1, 1987, and before the date specified in clause (ii)), during which a physician is a nonparticipating physician, the Secretary shall monitor the actual charges of each such physician for physicians' services furnished to individuals enrolled under this part [*42 USCS §§ 1395j* et seq.]. If such physician knowingly and willfully bills on a repeated basis for such a service an actual charge in excess of the maximum allowable actual charge determined under subparagraph (C) for that service, the Secretary may apply sanctions against such physician in accordance with paragraph (2).

(ii) Clause (i) shall not apply to services furnished after December 31, 1990.

(C) (i) For a particular physicians' service furnished by a nonparticipating physician to individuals enrolled under this part during a year, for purposes of subparagraph (B), the maximum allowable actual charge is determined as follows: If the physician's maximum allowable actual charge for that service in the previous year was--

(I) less than 115 percent of the applicable percent (as defined in subsection (b)(4)(A)(iv)) of the prevailing charge for the year and service involved, the maximum allowable actual charge for the year involved is the greater of the maximum allowable actual charge described in subclause (II) or the charge described in clause (ii), or

(II) equal to, or greater than, 115 percent of the applicable percent (as defined in subsection (b)(4)(A)(iv)) of the prevailing charge for the year and service involved, the maximum allowable actual charge is 101 percent of the physician's maximum allowable actual charge for the service for the previous year.

(ii) For purposes of clause (i)(I), the charge described in this clause for a particular physicians' service furnished in a year is the maximum allowable actual charge for the service of the physician for the previous year plus the product of (I) the applicable fraction (as defined in clause (iii)) and (II) the amount by which 115 percent of the prevailing charge for the year involved for such service furnished by nonparticipating physicians, exceeds the physician's maximum allowable actual charge for the service for the previous year.

(iii) In clause (ii), the "applicable fraction" is--

(I) for 1987, 1/4 ,

(II) for 1988, 1/3 ,

(III) for 1989, 1/2 , and

(IV) for any subsequent year, 1.

(iv) For purposes of determining the maximum allowable actual charge under clauses (i) and (ii) for 1987, in the case of a physicians' service for which the physician has actual charges for the calendar quarter beginning on April 1, 1984, the "maximum allowable actual charge" for 1986 is the physician's actual charge for such service furnished during such quarter.

(v) For purposes of determining the maximum allowable actual charge under clauses (i) and (ii) for a year after 1986, in the case of a physicians' service for which the physician has no actual charges for the calendar quarter beginning on April 1, 1984, and for which a maximum allowable actual charge has not been previously established under this clause, the "maximum allowable actual charge" for the previous year shall be the 50th percentile of the customary charges for the service (weighted by frequency of the service) performed by nonparticipating physicians in the locality during the 12-month period ending June 30 of that previous year.

(vi) For purposes of this subparagraph, a "physician's actual charge" for a physicians' service furnished in a year or other period is the weighted average (or, at the option of the Secretary for a service furnished in the calendar quarter beginning April 1, 1984, the median) of the physician's charges for such service furnished in the year or other period.

(vii) In the case of a nonparticipating physician who was a participating physician during a previous period, for the purpose of computing the physician's maximum allowable actual charge during the physician's period of nonparticipation, the physician shall be deemed to have had a maximum allowable actual charge during the period of participation, and such deemed maximum allowable actual charge shall be determined according to clauses (i) through (vi).

(viii) Notwithstanding any other provision of this subparagraph, the maximum allowable actual charge for a particular physician's service furnished by a nonparticipating physician to individuals enrolled under this part [*42 USCS §§ 1395j* et seq.] during the 3-month period beginning on January 1, 1988, shall be the amount determined under this subparagraph for 1987. The maximum allowable actual charge for any such service otherwise determined under this subparagraph for 1988 shall take effect on April 1, 1988.

(ix) If there is a reduction under subsection (b)(13) in the reasonable charge for medical direction furnished by a nonparticipating physician, the maximum allowable actual charge otherwise permitted under this subsection for such services shall be reduced in the same manner and in the same percentage as the reduction in such reasonable charge.

(D) (i) If an action described in clause (ii) results in a reduction in a reasonable charge for a physicians' service or item and a nonparticipating physician furnishes the service or item to an individual entitled to benefits under this part [*42 USCS §§ 1395j* et seq.] after the effective date of such action, the physician may not charge the individual more than 125 percent of the reduced payment allowance (as defined in clause (iii)) plus (for services or items furnished during the 12-month period (or 9-month period in the case of an action described in clause (ii)(II)) beginning on the effective date of the action) 1/2 of the amount by which the physician's maximum allowable actual charge for the service or item for the previous 12-month period exceeds such 125 percent level.

(ii) The first sentence of clause (i) shall apply to--

(I) an adjustment under subsection (b)(8)(B) (relating to inherent reasonableness),

(II) a reduction under subsection (b)(10)(A) or (b)(14)(A) (relating to certain overpriced procedures),

(III) a reduction under subsection (b)(11)(B) (relating to certain cataract procedures),

(IV) a prevailing charge limit established under subsection (b)(11)(C)(i) or (b)(15)(A),

(V) a reasonable charge limit established under subsection (b)(11)(C)(ii), and

(VI) an adjustment under section 1833(l)(3)(B) [*42 USCS § 1395l(l)(3)(B)*] (relating to physician supervision of certified registered nurse anesthetists).

(iii) In clause (i), the term "reduced payment allowance" means, with respect to an action--

(I) under subsection (b)(8)(B), the inherently reasonable charge established under subsection (b)(8);

(II) under subsection (b)(10)(A), (b)(11)(B), (b)(11)(C)(i), (b)(14)(A), or (b)(15)(A) or under section 1833(l)(3)(B) [*42 USCS § 13951(1)(3)(B)*], the prevailing charge for the service after the action; or

(III) under subsection (b)(11)(C)(ii), the payment allowance established under such subsection.

(iv) If a physician knowingly and willfully bills in violation of clause (i) (whether or not such charge violates subparagraph (B)), the Secretary may apply sanctions against such physician in accordance with paragraph (2).

(v) Clause (i) shall not apply to items and services furnished after December 31, 1990.

(2) Subject to paragraph (3), the sanctions which the Secretary may apply under this paragraph are--

(A) excluding a physician from participation in the programs under this Act [*42 USCS §§ 301* et seq.] for a period not to exceed 5 years, in accordance with the procedures of subsections (c), (f), and (g) of section 1128 [*42 USCS § 1320a-7(c)*, (f), and (g)], or

(B) civil monetary penalties and assessments, in the same manner as such penalties and assessments are authorized under section 1128A(a) [*42 USCS § 1320a-7a(a)*],

or both. The provisions of section 1128A [*42 USCS § 1320a-7a*] (other than the first 2 sentences of subsection (a) and other than subsection (b)) shall apply to a civil money penalty and assessment under subparagraph (B) in the same manner as such provisions apply to a penalty, assessment, or proceeding under section 1128A(a) [*42 USCS § 1320a-7a(a)*], except to the extent such provisions are inconsistent with subparagraph (A) or paragraph (3).

(3) (A) The Secretary may not exclude a physician pursuant to paragraph (2)(A) if such physician is a sole community physician or sole source of essential specialized services in a community.

(B) The Secretary shall take into account access of beneficiaries to physicians' services for which payment may be made under this part [*42 USCS §§ 1395j* et seq.] in determining whether to bar a physician from participation under paragraph (2)(A).

(4) The Secretary may, out of any civil monetary penalty or assessment collected from a physician pursuant to this subsection, make a payment to a beneficiary enrolled under this part [*42 USCS §§ 1395j* et seq.] in the nature of restitution for amounts paid by such beneficiary to such physician which was determined to be an excess charge under paragraph (1).

(k) Sanctions for billing services of assistant at cataract operations.

(1) If a physician knowingly and willfully presents or causes to be presented a claim or bills an individual enrolled under this part [*42 USCS §§ 1395j* et seq.] for charges for services as an assistant at surgery for which payment may not be made by reason of section 1862(a)(15) [*42 USCS § 1395y(a)(15)*], the Secretary may apply sanctions against such physician in accordance with subsection (j)(2) in the case of surgery performed on or after March 1, 1987.

(2) If a physician knowingly and willfully presents or causes to be presented a claim or bills an individual enrolled under this part [*42 USCS §§ 1395j* et seq.] for charges that includes a charge for an assistant at surgery for which payment may not be made by reason of section 1862(a)(15) [*42 USCS § 1395y(a)(15)*], the Secretary may apply sanctions against such physician in accordance with subsection (j)(2) in the case of surgery performed on or after March 1, 1987.

(l) Prohibition of unassigned billing of services determined to be medically unnecessary by carrier.

(1) (A) Subject to subparagraph (C), if--

(i) a nonparticipating physician furnishes services to an individual enrolled for benefits under this part [*42 USCS §§ 1395j* et seq.],

(ii) payment for such services is not accepted on an assignment-related basis,

(iii) (I) a medicare administrative contractor determines under this part [*42 USCS §§ 1395j* et seq.] or a peer review organization determines under part B of title XI [*42 USCS §§ 1320c* et seq.] that payment may not be made by reason of section 1862(a)(1) [*42 USCS § 1395y(a)(1)*] because a service otherwise covered under this title is not reasonable and necessary under the standards described in that section or (II) payment under this title for such services is denied under section 1154(a)(2) [*42 USCS § 1320c-3(a)(2)*] by reason of a determination under section 1154(a)(1)(B) [*42 USCS § 1320c-3(a)(1)(B)*], and

(iv) the physician has collected any amounts for such services,

the physician shall refund on a timely basis to the individual (and shall be liable to the individual for) any amounts so collected.

(B) A refund under subparagraph (A) is considered to be on a timely basis only if--

(i) in the case of a physician who does not request reconsideration or seek appeal on a timely basis, the refund is made within 30 days after the date the physician receives a denial notice under paragraph (2), or

(ii) in the case in which such a reconsideration or appeal is taken, the refund is made within 15 days after the date the physician receives notice of an adverse determination on reconsideration or appeal.

(C) Subparagraph (A) shall not apply to the furnishing of a service by a physician to an individual in the case described in subparagraph (A)(ii)(I) if--

(i) the physician establishes that the physician did not know and could not reasonably have been expected to know that payment may not be made for the service by reason of section 1862(a)(1) [*42 USCS § 1395y(a)(1)*], or

(ii) before the service was provided, the individual was informed that payment under this part [*42 USCS §§ 1395j* et seq.] may not be made for the specific service and the individual has agreed to pay for that service.

(2) Each medicare administrative contractor with a contract in effect under this section with respect to physicians and each peer review organization with a contract under part B of title XI [*42 USCS §§ 1320c* et seq.] shall send any notice of denial of payment for physicians' services based on section 1862(a)(1) and for which payment is not requested on an assignment-related basis to the physician and the individual involved.

(3) If a physician knowingly and willfully fails to make refunds in violation of paragraph (1)(A), the Secretary may apply sanctions against such physician in accordance with subsection (j)(2).

(m) Disclosure of information of unassigned claims for certain physicians' services.

(1) In the case of a nonparticipating physician who--

(A) performs an elective surgical procedure for an individual enrolled for benefits under this part [*42 USCS §§ 1395j* et seq.] and for which the physician's actual charge is at least $ 500, and

(B) does not accept payment for such procedure on an assignment-related basis,

the physician must disclose to the individual, in writing and in a form approved by the Secretary, the physician's estimated actual charge for the procedure, the estimated approved charge under this part [*42 USCS §§ 1395j* et seq.] for the procedure, the excess of the physician's actual charge over the approved charge, and the coinsurance amount applicable to the procedure. The written estimate may not be used as the basis for, or evidence in, a civil suit.

(2) A physician who fails to make a disclosure required under paragraph (1) with respect to a procedure shall refund on a timely basis to the individual (and shall be liable to the individual for) any amounts collected for the procedure in excess of the charges recognized and approved under this part [*42 USCS §§ 1395j* et seq.].

(3) If a physician knowingly and willfully fails to comply with paragraph (2), the Secretary may apply sanctions against such physician in accordance with subsection (j)(2).

(4) The Secretary shall provide for such monitoring of requests for payment for physicians' services to which paragraph (1) applies as is necessary to assure compliance with paragraph (2).

(n) Elimination of markup for certain purchased services.

(1) If a physician's bill or a request for payment for services billed by a physician includes a charge for a diagnostic test described in section 1861(s)(3) [*42 USCS § 1395x(s)(3)*] (other than a clinical diagnostic laboratory test) for which the bill or request for payment does not indicate that the billing physician personally performed or supervised the performance of the test or that another physician with whom the physician who shares a practice personally performed or supervised the performance of the test, the amount payable with respect to the test shall be determined as follows:

(A) If the bill or request for payment indicates that the test was performed by a supplier, identifies the supplier, and indicates the amount the supplier charged the billing physician, payment for the test (less the applicable deductible and coinsurance amounts) shall be the actual acquisition costs (net of any discounts) or, if lower, the supplier's reasonable charge (or other applicable limit) for the test.

(B) If the bill or request for payment (i) does not indicate who performed the test, or (ii) indicates that the test was performed by a supplier but does not identify the supplier or include the amount charged by the supplier, no payment shall be made under this part [*42 USCS §§ 1395j* et seq.].

(2) A physician may not bill an individual enrolled under this part [*42 USCS §§ 1395j* et seq.]--

(A) any amount other than the payment amount specified in paragraph (1)(A) and any applicable deductible and coinsurance for a diagnostic test for which payment is made pursuant to paragraph (1)(A), or

(B) any amount for a diagnostic test for which payment may not be made pursuant to paragraph (1)(B).

(3) If a physician knowingly and willfully in repeated cases bills one or more individuals in violation of paragraph (2), the Secretary may apply sanctions against such physician in accordance with section 1842(j)(2) [subsec. (j)(2) of this section].

(o) Reimbursement for drugs and biologicals.

(1) If a physician's, supplier's, or any other person's bill or request for payment for services includes a charge for a drug or biological for which payment may be made under this part [*42 USCS §§ 1395j* et seq.] and the drug or biological is not paid on a cost or prospective payment basis as otherwise provided in this part [*42 USCS §§ 1395j* et seq.], the amount payable for the drug or biological is equal to the following:

(A) In the case of any of the following drugs or biologicals, 95 percent of the average wholesale price:

(i) A drug or biological furnished before January 1, 2004.

(ii) Blood clotting factors furnished during 2004.

(iii) A drug or biological furnished during 2004 that was not available for payment under this part [*42 USCS §§ 1395j* et seq.] as of April 1, 2003.

(iv) A vaccine described in subparagraph (A) or (B) of section 1861(s)(10) [*42 USCS § 1395x(s)(10)*] furnished on or after January 1, 2004.

(v) A drug or biological furnished during 2004 in connection with the furnishing of renal dialysis services if separately billed by renal dialysis facilities.

(B) In the case of a drug or biological furnished during 2004 that is not described in--

(i) clause (ii), (iii), (iv), or (v) of subparagraph (A),

(ii) subparagraph (D)(i), or

(iii) subparagraph (F),

the amount determined under paragraph (4).

(C) In the case of a drug or biological that is not described in subparagraph (A)(iv), (D)(i), or (F) furnished on or after January 1, 2005, the amount provided under section 1847, section 1847A, section 1847B, or section 1881(b)(13) [*42 USCS § 1395w-3, 1395w-3a, 1395w-3b,* or *1395rr(b)(13)*], as the case may be for the drug or biological.

(D) (i) Except as provided in clause (ii), in the case of infusion drugs furnished through an item of durable medical equipment covered under section 1861(n) [*42 USCS § 1395x(n)*] on or after January 1, 2004, 95 percent of the average wholesale price for such drug in effect on October 1, 2003.

(ii) In the case of such infusion drugs furnished in a competitive acquisition area under section 1847 [*42 USCS § 1395w-3*] on or after January 1, 2007, the amount provided under section 1847 [*42 USCS § 1395w-3*].

(E) In the case of a drug or biological, consisting of intravenous immune globulin, furnished--

(i) in 2004, the amount of payment provided under paragraph (4); and

(ii) in 2005 and subsequent years, the amount of payment provided under section 1847A [*42 USCS § 1395w-3a*].

(F) In the case of blood and blood products (other than blood clotting factors), the amount of payment shall be determined in the same manner as such amount of payment was determined on October 1, 2003.

(G) In the case of inhalation drugs or biologicals furnished through durable medical equipment covered under section 1861(n) [*42 USCS § 1395x(n)*] that are furnished--

(i) in 2004, the amount provided under paragraph (4) for the drug or biological; and

(ii) in 2005 and subsequent years, the amount provided under section 1847A [*42 USCS § 1395w-3a*] for the drug or biological.

(2) If payment for a drug or biological is made to a licensed pharmacy approved to dispense drugs or biologicals under this part [*42 USCS §§ 1395j* et seq.], the Secretary may pay a dispensing fee (less the applicable deductible and coinsurance amounts) to the pharmacy. This paragraph shall not apply in the case of payment under paragraph (1)(C).

(3) (A) Payment for a charge for any drug or biological for which payment may be made under this part may be made only on an assignment-related basis.

(B) The provisions of subsection (b)(18)(B) shall apply to charges for such drugs or biologicals in the same manner as they apply to services furnished by a practitioner described in subsection (b)(18)(C).

(4) (A) Subject to the succeeding provisions of this paragraph, the amount of payment for a drug or biological under this paragraph furnished in 2004 is equal to 85 percent of the average wholesale price (determined as of April 1, 2003) for the drug or biological.

(B) The Secretary shall substitute for the percentage under subparagraph (A) for a drug or biological the percentage that would apply to the drug or biological under the column entitled "Average of GAO and OIG data (percent)" in the table entitled "Table 3. Medicare Part B Drugs in the Most Recent GAO and OIG Studies" published on August 20, 2003, in the Federal Register *(68 Fed. Reg. 50445).*

(C) (i) The Secretary may substitute for the percentage under subparagraph (A) a percentage that is based on data and information submitted by the manufacturer of the drug or biological by October 15, 2003.

(ii) The Secretary may substitute for the percentage under subparagraph (A) with respect to drugs and biologicals furnished during 2004 on or after April 1, 2004, a percentage that is based on data and information submitted by the manufacturer of the drug or biological after October 15, 2003, and before January 1, 2004.

(D) In no case may the percentage substituted under subparagraph (B) or (C) be less than 80 percent.

(5) (A) Subject to subparagraph (B), in the case of clotting factors furnished on or after January 1, 2005, the Secretary shall, after reviewing the January 2003 report to Congress by the Comptroller General of the United States entitled "Payment for Blood Clotting Factor Exceeds Providers Acquisition Cost", provide for a separate payment, to the entity which furnishes to the patient blood clotting factors, for items and services related to the furnishing of such factors in an amount that the Secretary determines to be appropriate. Such payment amount may take into account any or all of the following:

(i) The mixing (if appropriate) and delivery of factors to an individual, including special inventory management and storage requirements.

(ii) Ancillary supplies and patient training necessary for the self-administration of such factors.

(B) In determining the separate payment amount under subparagraph (A) for blood clotting factors furnished in 2005, the Secretary shall ensure that the total amount of payments under this part [*42 USCS §§ 1395j* et seq.] (as estimated by the Secretary) for such factors under paragraph (1)(C) and such separate payments for such factors does not exceed the total amount of payments that would have been made for such factors under this part [*42 USCS §§ 1395j* et seq.] (as estimated by the Secretary) if the amendments made by section 303 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 had not been enacted.

(C) The separate payment amount under this subparagraph for blood clotting factors furnished in 2006 or a subsequent year shall be equal to the separate payment amount determined under this paragraph for the previous year increased by the percentage increase in the consumer price index for medical care for the 12-month period ending with June of the previous year.

(6) In the case of an immunosuppressive drug described in subparagraph (J) of section 1861(s)(2) [*42 USCS § 1395x(s)(2)*] and an oral drug described in subparagraph (Q) or (T) of such section, the Secretary shall pay to the pharmacy a supplying fee for such a drug determined appropriate by the Secretary (less the applicable deductible and coinsurance amounts).

(7) There shall be no administrative or judicial review under section 1869 [*42 USCS § 1395ff*], section 1878 [*42 USCS § 1395oo*], or otherwise, of determinations of payment amounts, methods, or adjustments under paragraphs (4) through (6).

(p) Requiring submission of diagnostic information.

(1) Each request for payment, or bill submitted, for an item or service furnished by a physician or practitioner specified in subsection (b)(18)(C) for which payment may be made under this part [*42 USCS §§ 1395j* et seq.] shall include the appropriate diagnosis code (or codes) as established by the Secretary for such item or service.

(2) In the case of a request for payment for an item or service furnished by a physician or practitioner specified in subsection (b)(18)(C) on an assignment-related basis which does not include the code (or codes) required under paragraph (1), payment may be denied under this part [*42 USCS §§ 1395j* et seq.].

(3) In the case of a request for payment for an item or service furnished by a physician not submitted on an assignment-related basis and which does not include the code (or codes) required under paragraph (1)--

(A) if the physician knowingly and willfully fails to provide the code (or codes) promptly upon request of the Secretary or a medicare administrative contractor, the physician may be subject to a civil money penalty in an amount not to exceed $ 2,000, and

(B) if the physician knowingly, willfully, and in repeated cases fails, after being notified by the Secretary of the obligations and requirements of this subsection, to include the code (or codes) required under paragraph (1), the physician may be subject to the sanction described in section 1842(j)(2)(A) [subsec. (j)(2)(A) of this section].

The provisions of section 1128A [*42 USCS § 1320a-7a*] (other than subsections (a) and (b)) shall apply to civil money penalties under subparagraph (A) in the same manner as they apply to a penalty or proceeding under section 1128A(a) [*42 USCS § 1320a-7a(a)*].

(4) In the case of an item or service defined in paragraph (3), (6), (8), or (9) of subsection 1861(s) [*42 USCS § 1395x(s)*] ordered by a physician or a practitioner specified in subsection (b)(18)(C), but furnished by another entity, if the Secretary (or fiscal agent of the Secretary) requires the entity furnishing the item or service to provide diagnostic or other medical information in order for payment to be made to the entity, the physician or practitioner shall provide that information to the entity at the time that the item or service is ordered by the physician or practitioner.

(q) Anesthesia services; counting actual time units.

(1) (A) The Secretary, in consultation with groups representing physicians who furnish anesthesia services, shall establish by regulation a relative value guide for use in all localities in making payment for physician anesthesia services furnished under this part [*42 USCS §§ 1395j* et seq.]. Such guide shall be designed so as to result in expenditures under this *title [42 USCS §§ 1395* et seq.] for such services in an amount that would not exceed the amount of such expenditures which would otherwise occur.

(B) For physician anesthesia services furnished under this part [*42 USCS §§ 1395j* et seq.] during 1991, the prevailing charge conversion factor used in a locality under this subsection shall, subject to clause (iv), be reduced to the adjusted prevailing charge conversion factor for the locality determined as follows:

(i) The Secretary shall estimate the national weighted average of the prevailing charge conversion factors used under this subsection for services furnished during 1990 after March 31, using the best available data.

(ii) The national weighted average estimated under clause (i) shall be reduced by 7 percent.

(iii) The adjusted prevailing charge conversion factor for a locality is the sum of--

(I) the product of (a) the portion of the reduced national weighted average prevailing charge conversion factor computed under clause (ii) which is attributable to physician work and (b) the geographic work index value for the locality (specified in Addendum C to the Model Fee Schedule for Physician Services (published on September 4, 1990, *55 Federal Register pp. 36238-36243));* and

(II) the product of (a) the remaining portion of the reduced national weighted average prevailing charge conversion factor computed under clause (ii) and (b) the geographic practice cost index value specified in section 1842(b)(14)(C)(iv) [subsec. (b)(14)(C)(iv) of this section] for the locality.

In applying this clause, 70 percent of the prevailing charge conversion factor shall be considered to be attributable to physician work.

(iv) The prevailing charge conversion factor to be applied to a locality under this subparagraph shall not be reduced by more than 15 percent below the prevailing charge conversion factor applied in the locality for the period

during 1990 after March 31, but in no case shall the prevailing charge conversion factor be less than 60 percent of the national weighted average of the prevailing charge conversion factors (computed under clause (i)).

(2) For purposes of payment for anesthesia services (whether furnished by physicians or by certified registered nurse anesthetists) under this part [*42 USCS §§ 1395j* et seq.], the time units shall be counted based on actual time rather than rounded to full time units.

(r) Establishment of physician identification system. The Secretary shall establish a system which provides for a unique identifier for each physician who furnishes services for which payment may be made under this *title [42 USCS §§ 1395* et seq.]. Under such system, the Secretary may impose appropriate fees on such physicians to cover the costs of investigation and recertification activities with respect to the issuance of the identifiers.

(s) Establishment of fee schedule.

(1) Subject to paragraph (3), the Secretary may implement a statewide or other areawide fee schedule to be used for payment of any item or service described in paragraph (2) which is paid on a reasonable charge basis. Any fee schedule established under this paragraph for such item or service shall be updated each year by the percentage increase in the consumer price index for all urban consumers (United States city average) for the 12-month period ending with June of the preceding year, except that for items and services described in paragraph (2)(D)--

(A) for 2009 section 1834(a)(14)(J)(i) [*42 USCS § 1395m(a)(14)(J)(i)*] shall apply under this paragraph instead of the percentage increase otherwise applicable; and

(B) for 2014, if subparagraph (A) is applied to the items and services and there has not been a payment adjustment under paragraph (3)(B) for the items and services for any previous year, the percentage increase computed under section 1834(a)(14)(L)(i) [*42 USCS § 1395m(a)(14)(L)(i)*] shall apply instead of the percentage increase otherwise applicable.

(2) The items and services described in this paragraph are as follows:

(A) Medical supplies.

(B) Home dialysis supplies and equipment (as defined in section 1881(b)(8) [*42 USCS § 1395rr(b)(8)*]).

(C) [Deleted]

(D) Parenteral and enteral nutrients, equipment, and supplies.

(E) Electromyogram devices.

(F) Salivation devices.

(G) Blood products.

(H) Transfusion medicine.

(3) In the case of items and services described in paragraph (2)(D) that are included in a competitive acquisition program in a competitive acquisition area under section 1847(a) [*42 USCS § 1395w-3(a)*]--

(A) the payment basis under this subsection for such items and services furnished in such area shall be the payment basis determined under such competitive acquisition program; and

(B) the Secretary may use information on the payment determined under such competitive acquisition programs to adjust the payment amount otherwise applicable under paragraph (1) for an area that is not a competitive acquisition area under section 1847 [*42 USCS § 1395w-3*], and in the case of such adjustment, paragraphs (8) and (9) of section 1842(b) [*42 USCS § 1395u(b)*] shall not be applied.

(t) Facility provider number required on claims submitted by physicians. Each request for payment, or bill submitted, for an item or service furnished to an individual who is a resident of a skilled nursing facility, for which payment may be made under this part [*42 USCS §§ 1395j* et seq.] shall include the facility's medicare provider number.

(u) Each request for payment, or bill submitted, for a drug furnished to an individual for the treatment of anemia in connection with the treatment of cancer shall include (in a form and manner specified by the Secretary) information on the hemoglobin or hematocrit levels for the individual.

HISTORY:

(Aug. 14, 1935, ch 531, Title XVIII, Part B, § 1842, as added July 30, 1965, P.L. 89-97, Title I, Part 1, § 102(a), 79 Stat. 309; Jan. 2, 1968, P.L. 90-248, Title I, Part 3, § 125(a), Part 4, § 154(d), 81 Stat. 845, 863; Oct. 30, 1972, P.L. 92-603, Title II, §§ 211(c)(3), 224(a), 227(e)(3), 236(a), 258(a), 262(a), 263(d)(5), 281(d), 86 Stat. 1384, 1395, 1407, 1414, 1447-1449, 1455; Oct. 16, 1974, P.L. 93-445, Title III, § 307, 88 Stat. 1358; Dec. 31, 1975, P.L. 94-182, Title I, § 101(a), 89 Stat. 1051; July 16, 1976, P.L. 94-368, §§ 2, 3(a), (b), 90 Stat. 997; Oct. 25, 1977, P.L. 95-142, § 2(a)(1), 91 Stat. 1175; Dec. 20, 1977, P.L. 95-216, Title V, § 501(b), 91 Stat. 1565; Dec. 5, 1980, P.L. 96-499, Title IX, Part A, Subpart II, § 918(a)(1), Part B, Subpart II, §§ 946(a), (b), 948(b), 94 Stat. 2625, 2642, 2643; Aug. 13, 1981, P.L. 97-35, Title XXI, Subtitle B, ch 3, § 2142(b), 95 Stat. 798; Sept. 3, 1982, P.L. 97-248, Title I, Subtitle A, Part I, Subpart A, §

104(a), Subpart B, § 113(a), Part III, § 128(d)(1), 96 Stat. 336, 340, 367; July 18, 1984, P.L. 98-369, Division B, Title III, Subtitle A, Part I, §§ 2303(e), 2306(a), (b)(1), (c), 2307(a)(1), (2), 2326(c)(2), (d)(2), Part II, §§ 2339, 2354(b)(13), (14), Title IV, Subtitle D, § 2663(j)(2)(F)(iv), 98 Stat. 1066, 1070, 1071, 1073, 1087, 1088, 1093, 1101, 1170; Nov. 8, 1984, P.L. 98-617, § 3(a)(1), (b)(5), (6), 98 Stat. 3295, 3296; April 7, 1986, P.L. 99-272, Title IX, Subtitle A, Part 2, Subpart B, § 9219(b)(1)(A), (2)(A), Part 3, Subpart A, §§ 9301(b)(1), (2), (c)(2)-(4), (d)(1)-(3), 9304(a), 9306(a), 9307(c), 100 Stat. 182-188, 190, 193, 194; Oct. 21, 1986, P.L. 99-509, Title IX, Subtitle D, Part 2, § 9311(c), Part 3, §§ 9331(a)(1)-(3), (b)(1)-(3), 9332(b)(1), (2), 9333(a), (b), 9334(a), 9338, 9341(a)(2), 100 Stat. 1998, 2017, 2018, 2022, 2024, 2025, 2027, 2034, 2037; Oct. 22, 1986, P.L. 99-514, Title XVIII, Subtitle C, Ch 1, § 1895(b)(14), 100 Stat. 2934, as amended Oct. 21, 1986, P.L. 99-509, Title IX, Subtitle D, Part 1, § 9307(c)(2)(A) 99 Stat. 1995; Oct. 22, 1986, P.L. 99-514, Title XVIII, Subtitle C, Ch 1, § 1895(b)(15), (16)(A), 100 Stat. 2934; Oct. 21, 1986, P.L. 99-509, Title IX, Subtitle D, Part 2, § 9320(e)(3), Part 3, §§ 9331(c)(3)(A), 9332(a)(1), (c)(1), (d)(1), 100 Stat. 2015, 2020-2023; Aug. 18, 1987, P.L. 100-93, § 8(c)(2), 101 Stat. 692; Dec. 22, 1987, P.L. 100-203, Title IV, Subtitle A, Part 2, Subpart C, §§ 4031(a)(2), 4035(a)(2), Part 3, Subpart A, §§ 4041(a)(1), (3)(A), 4042, 4044(a), 4045(a), (c)(1), (2)(B), (D), 4046(a), 4047(a), 4048(a), (e), 4051(a), 4052(a), 4053(a), Subpart B, § 4063(a), Subpart D, §§ 4081(a), 4082(c), 4085(g)(1), (i)(5)-(7), (22)(C), (24)-(27), Part 4, § 4096(a)(1), 101 Stat. 1330-76, 1330-78, 1330-83, 1330-85, 1330-86, 1330-88, 1330-89, 1330-93, 1330-95, 1330-97, 1330-109, 1330-126, 1330-128, 1330-131, 1330-132, 1330-139; July 1, 1988, P.L. 100-360, Title II, Subtitle A, §§ 201(c), 202(c), (e)(1)-(5), (g), Subtitle C, § 223(b), (c), Title IV, Subtitle B, § 411(a)(3)(C)(i), (f)(1)(A), (B), (2)-(4)(C), (5), (6)(B), (7), (9), (11)(A), (14), (g)(2)(A)-(C), (i)(1)(A), (2), (3), (4)(C)(vi), (j)(4)(A), 102 Stat. 702, 713, 716, 717 747, 768, 776-783, 787-791; Oct. 13, 1988, P.L. 100-485, Title VI, § 608(d)(5)(A)-(D), (F), (G), (17), (21)(A), (B), (D), (24)(B), 102 Stat. 2414, 2418, 2420, 2421; Dec. 13, 1989, P.L. 101-234, Title II, §§ 201(a), 301(b)(2), (6), (c)(2), (d)(3), 103 Stat. 1981, 1985, 1986; Dec. 19, 1989, P.L. 101-239, Title VI, Subtitle A, Part 1, Subpart A, § 6003(g)(3)(D)(ix), Part 2, Subpart A, §§ 6102(b), (e)(2)-(4), (9), 6104, 6106(a), 6107(b), 6108(a)(1), (b)(1), (2), 6114(b), (c), Part 3, Subpart A, § 6202(d)(2), 103 Stat. 2153, 2184, 2187, 2188, 2208, 2210, 2212, 2213, 2218, 2235; Nov. 5, 1990, P.L. 101-508, Title IV, Subtitle A, Part 2, Subpart A, § 4101(a), (b)(1), 4103, 4105(a)(1), (2), (b)(1), 4106(a)(1), (b)(2), 4108(a), 4110(a), 4118(a)(1), (2), (f)(2)(B), (C), (i)(1), (j)(2), Subpart B, § 4155(c), 104 Stat. 1388-54, 1388-58, 1388-59, 1388-61, 1388-63, 1388-66; Nov. 16, 1990, P.L. 101-597, Title IV, § 401(c)(2), 104 Stat. 3035; Aug. 10, 1993, P.L. 103-66, Title XIII, Ch 2, Subch A, Part II, Subpart A, §§ 13515(a)(2), 13516(a)(2), 13517(b), Part III, § 13568(a), (b), 107 Stat. 583-585, 608; Oct. 31, 1994, P.L. 103-432, Title I, Subtitle B, Part I, §§ 123(b)(1), (2)(B), (c), 125(a), (b)(1), 126(a)(1), (c), (e), (g)(9), (h)(2), Part II, § 135(b)(2), Subtitle C, § 151(b)(1)(B), (2)(B), 108 Stat. 4411-4416, 4423, 4434; Aug. 21, 1996, P.L. 104-191, Title II, Subtitle A, § 202(b)(2), Subtitle C, § 221(b), 110 Stat. 1998, 2011; Aug. 5, 1997, P.L. 105-33, Title IV, Subtitle C, §§ 4201(c)(1), 4205(d)(3)(B), Subtitle D, Ch 1, § 4302(b), Ch 2, §§ 4315(a), 4316(a), 4317(a), (b), Ch 3, § 4432(b)(2), (4), Subtitle F, Ch 1, Subch B, § 4512(b)(2), (c), Ch 3, § 4531(a)(2), Ch 5, 4556(a), Subtitle G, Ch 1, Subch A, § 4603(c)(2)(B)(i), Subch B, § 4611(d), 111 Stat. 373, 377, 382, 390, 392, 421, 444, 450, 462, 471, 473; Nov. 29, 1999, P.L. 106-113, Div B, § 1000(a)(6), 113 Stat. 1536; Dec. 21, 2000, P.L. 106-554, § 1(a)(6), 114 Stat. 2763; Dec. 8, 2003, P.L. 108-173, Title III, §§ 302(d)(3), 303(b), (e), (g)(1), (i)(1), 305(a), Title VI, Subtitle C, § 627(b)(2), Title VII, Subtitle D, § 736(b)(8), (9), Title IX, Subtitle B, § 911(c), Subtitle E, § 952(a), (b), 117 Stat. 2233, 2238, 2252, 2253, 2254, 2255, 2321, 2356, 2383, 2427.)

(As amended Feb. 8, 2006, P.L. 109-171, Title V, Subtitle B, Ch. 2, §§ 5114(a)(2), 5202(a)(2), 120 Stat. 45, 47; Dec. 20, 2006, P.L. 109-432, Div B, Title I, § 110(a), Title II, § 205(b)(2), Title IV, § 405(c)(2)(A)(i), 120 Stat. 2985, 2989, 2999; Aug. 3, 2007, P.L. 110-54, § 1(a), 121 Stat. 551; Dec. 29, 2007, P.L. 110-173, Title I, § 116, 121 Stat. 2507; July 15, 2008, P.L. 110-275, Title I, Subtitle C, Part I, § 137, Part II, § 154(a)(2)(B), 122 Stat. 2540, 2563.)

§ 1395v. Agreements with States

(a) Duty of Secretary; enrollment of eligible individuals. The Secretary shall, at the request of a State made before January 1, 1970, or during 1981 or after 1988, enter into an agreement with such State pursuant to which all eligible individuals in either of the coverage groups described in subsection (b) (as specified in the agreement) will be enrolled under the program established by this part [*42 USCS §§ 1395j* et seq.].

(b) Coverage of groups to which applicable. An agreement entered into with any State pursuant to subsection (a) may be applicable to either of the following coverage groups:

(1) individuals receiving money payments under the plan of such State approved under title I or title XVI [*42 USCS §§ 301* et seq. or *1381* et seq.]; or

(2) individuals receiving money payments under all of the plans of such State approved under titles I, X, XIV, and XVI, and part A of title IV [*42 USCS §§ 301* et seq., *601* et seq., *1201* et seq., and *1351* et seq. and *1381* et seq.]

Except as provided in subsection (g), there shall be excluded from any coverage group any individual who is entitled to monthly insurance benefits under title II [*42 USCS §§ 401* et seq.] or who is entitled to receive an annuity under the Railroad Retirement Act of 1974. Effective January 1, 1974, and subject to section 1902(f) [*42 USCS § 1396a(f)*], the Secretary shall, at the request of any State not eligible to participate in the State plan program established under title XVI [*42 USCS §§ 1381* et seq.], continue in effect the agreement entered into under this section with such State subject to such modifications as the Secretary may by regulations provide to take account of the termination of any plans of such State approved under titles I, X, XIV, and XVI [*42 USCS §§ 301* et seq., *1201* et seq., *1351* et seq., and *1381* et seq.] and the establishment of the supplemental security income program under title XVI [*42 USCS §§ 1381* et seq.].

(c) Eligible individuals. For purposes of this section, an individual shall be treated as an eligible individual only if he is an eligible individual (within the meaning of section 1836 [*42 USCS § 1395o*]) on the date an agreement covering him is entered into under subsection (a) or he becomes an eligible individual (within the meaning of such section) at any time after such date; and he shall be treated as receiving money payments described in subsection (b) if he receives such payments for the month in which the agreement is entered into or any month thereafter.

(d) Monthly premiums; coverage periods. In the case of any individual enrolled pursuant to this section--

(1) the monthly premium to be paid by the State shall be determined under section 1839 [*42 USCS § 1395r*] (without any increase under subsection (b) thereof);

(2) his coverage period shall begin on whichever of the following is the latest:

(A) July 1, 1966;

(B) the first day of the third month following the month in which the State agreement is entered into;

(C) the first day of the first month in which he is both an eligible individual and a member of a coverage group specified in the agreement under this section; or

(D) such date as may be specified in the agreement; and

(3) his coverage period attributable to the agreement with the State under this section shall end on the last day of whichever of the following first occurs:

(A) the month in which he is determined by the State agency to have become ineligible both for money payments of a kind specified in the agreement and (if there is in effect a modification entered into under subsection (h)) for medical assistance, or

(B) the month preceding the first month for which he becomes entitled to monthly benefits under title II [*42 USCS §§ 401* et seq.] or to an annuity or pension under the Railroad Retirement Act of 1974.

(e) Subsec. (d)(3) terminations deemed resulting in *42 USCS § 1395p* enrollment. Any individual whose coverage period attributable to the State agreement is terminated pursuant to subsection (d)(3) shall be deemed for purposes of this part [*42 USCS §§ 1395j* et seq.] (including the continuation of his coverage period under this part [*42 USCS §§ 1395j* et seq.]) to have enrolled under section 1837 [*42 USCS § 1395p*] in the initial general enrollment period provided by section 1837(c) [*42 USCS § 1395p(c)*]. The coverage period under this part [*42 USCS §§ 1395j* et seq.] of any such individual who (in the last month of his coverage period attributable to the State agreement or in any of the following six months) files notice that he no longer wishes to participate in the insurance program established by this part [*42 USCS §§ 1395j* et seq.], shall terminate at the close of the month in which the notice is filed.

(f) "Carrier" as including State agency; provisions facilitating deductions, coinsurance, etc., and leading to economy and efficiency of operation. With respect to eligible individuals receiving money payments under the plan of a State approved under title I, X, XIV, or XVI, or part A of title IV [*42 USCS §§ 301* et seq., *601* et seq., *1201* et seq., or *1351* et seq., or *1381* et seq.], or eligible to receive medical assistance under the plan of such State approved under title XIX [*42 USCS §§ 1396* et seq.], if the agreement entered into under this section so provides, the term "carrier" as defined in section 1842(f) [*42 USCS § 1395u(f)*] also includes the State agency, specified in such agreement, which administers or supervises the administration of the plan of such State approved under title I, XVI, or XIX [*42 USCS §§ 301* et seq., *1381* et seq., or *1396* et seq.]. The agreement shall also contain such provisions as will facilitate the financial transactions of the State and the carrier with respect to deductions, coinsurance, and otherwise, and as will lead to economy and efficiency of operation, with respect to individuals receiving money payments under plans of the State approved under titles I, X, XIV, and XVI, and part A of title IV [*42 USCS §§ 301* et seq., *601* et seq., *1201* et seq., and *1351* et seq., and *1381* et seq.], and individuals eligible to receive medical assistance under the plan of the State approved under title XIX [*42 USCS §§ 1396* et seq.].

(g) Subsec. (b) exclusions from coverage groups.

(1) The Secretary shall, at the request of a State made before January 1, 1970, or during 1981 or after 1988, enter into a modification of an agreement entered into with such State pursuant to subsection (a) under which the second sentence of subsection (b) shall not apply with respect to such agreement.

(2) In the case of any individual who would (but for this subsection) be excluded from the applicable coverage group described in subsection (b) by the second sentence of such subsection--

(A) subsections (c) and (d)(2) shall be applied as if such subsections referred to the modification under this subsection (in lieu of the agreement under subsection (a)), and

(B) subsection (d)(3)(B) shall not apply so long as there is in effect a modification entered into by the State under this subsection.

(h) Modifications respecting subsec. (b) coverage groups.

(1) The Secretary shall, at the request of a State made before January 1, 1970, or during 1981 or after 1988, enter into a modification of an agreement entered into with such State pursuant to subsection (a) under which the coverage group described in subsection (b) and specified in such agreement is broadened to include (A) individuals who are eligible to receive medical assistance under the plan of such State approved under title XIX [*42 USCS §§ 1396* et seq.], or (B) qualified medicare beneficiaries (as defined in section 1905(p)(1) [*42 USCS § 1396d(p)(1)*]).

(2) For purposes of this section, an individual shall be treated as eligible to receive medical assistance under the plan of the State approved under title XIX [*42 USCS §§ 1396* et seq.] if, for the month in which the modification is entered into under this subsection or for any month thereafter, he has been determined to be eligible to receive medical assistance under such plan. In the case of any individual who would (but for this subsection) be excluded from the agreement, subsections (c) and (d)(2) shall be applied as if they referred to the modification under this subsection (in lieu of the agreement under subsection (a)), and subsection (d)(2)(C) shall be applied (except in the case of qualified medicare beneficiaries, as defined in section 1905(p)(1) [*42 USCS § 1396d(p)(1)*] by substituting "second month following the first month" for "first month".

(3) In this subsection, the term "qualified medicare beneficiary" also includes an individual described in section 1902(a)(10)(E)(iii) [*42 USCS § 1396a(a)(10)(E)(iii)*].

(i) Enrollment of qualified medicare beneficiaries. For provisions relating to enrollment of qualified medicare beneficiaries under part A [*42 USCS §§ 1395c* et seq.], see section 1818(g) [*42 USCS § 1395i-2(g)*].

HISTORY:

(Aug. 14, 1935, ch 531, Title XVIII, Part B, § 1843, as added July 30, 1965, P.L. 89-97, Title I, Part 1, § 102(a), 79 Stat. 312; April 8, 1966, P.L. 89-384, § 4(a), (b), 80 Stat. 105; Jan. 2, 1968, P.L. 90-248, Title II, Part 2, § 222(a), (b), (e), Part 3, § 241(e), 81 Stat. 900, 901, 917; Dec. 31, 1973, P.L. 93-233, § 18(l), 87 Stat. 970; Oct. 16, 1974, P.L. 93-445, Title III, § 308, 88 Stat. 1358; Dec. 5, 1980, P.L. 96-499, Title IX, Part B, Subpart II, §§ 945(e), 947(a), (c), 94 Stat. 2642, 2643; April 20, 1983, P.L. 98-21, Title VI, § 606(a)(2)(E), 97 Stat. 171; July 18, 1984, P.L. 98-369, Division B, Title III, Subtitle A, Part II, § 2354(b)(15), 98 Stat. 1101; July 1, 1988, P.L. 100-360, Title III, § 301(e), 102 Stat. 749; Oct. 13, 1988, P.L. 100-485, Title VI, § 608(d)(14)(H), 102 Stat. 2416; Dec. 19, 1989, P.L. 101-239, Title VI, Subtitle A, Part 1, Subpart B, § 6013(b), 103 Stat. 2164; Nov. 5, 1990, P.L. 101-508, Title IV, Subtitle A, Part 2, § 4501(d), 104 Stat. 1388-165.)

§ 1395w. Appropriations to cover Government contributions and contingency reserve

(a) In general. There are authorized to be appropriated from time to time, out of any moneys in the Treasury not otherwise appropriated, to the Federal Supplementary Medical Insurance Trust Fund--

(1) (A) a Government contribution equal to the aggregate premiums payable for a month for enrollees age 65 and over under this part [*42 USCS §§ 1395j* et seq.] and deposited in the Trust Fund, multiplied by the ratio of--

(i) twice the dollar amount of the actuarially adequate rate per enrollee age 65 and over as determined under section 1839(a)(1) [*42 USCS § 1395r(a)(1)*] for such month minus the dollar amount of the premium per enrollee for such month, as determined under section 1839(a)(3) [*42 USCS § 1395r(a)(3)*], to

(ii) the dollar amount of the premium per enrollee for such month, plus

(B) a Government contribution equal to the aggregate premiums payable for a month for enrollees under age 65 under this part [*42 USCS §§ 1395j* et seq.] and deposited in the Trust Fund, multiplied by the ratio of--

(i) twice the dollar amount of the actuarially adequate rate per enrollee under age 65 as determined under section 1839(a)(4) [*42 USCS § 1395r(a)(4)*] for such month minus the dollar amount of the premium per enrollee for such month, as determined under section 1839(a)(3) [*42 USCS § 1395r(a)(3)*], to

(ii) the dollar amount of the premium per enrollee for such month; minus

(C) the aggregate amount of additional premium payments attributable to the application of section 1839(i) [*42 USCS § 1395r(i)*]; plus

(2) such sums as the Secretary deems necessary to place the Trust Fund, at the end of any fiscal year occurring after June 30, 1967, in the same position in which it would have been at the end of such fiscal year if (A) a Government contribution representing the excess of the premiums deposited in the Trust Fund during the fiscal year ending June 30, 1967, over the Government contribution actually appropriated to the Trust Fund during such fiscal year had been appropriated to it on June 30, 1967, and (B) the Government contribution for premiums deposited in the Trust Fund after June 30, 1967, had been appropriated to it when such premiums were deposited.

(b) Contingency reserve. In order to assure prompt payment of benefits provided under this part [*42 USCS §§ 1395j* et seq.] and the administrative expenses thereunder during the early months of the program established by this part [*42 USCS §§ 1395j* et seq.], and to provide a contingency reserve, there is also authorized to be appropriated, out of any moneys in the Treasury not otherwise appropriated, to remain available through the calendar year 1969 for repayable advances (without interest) to the Trust Fund, an amount equal to $ 18 multiplied by the number of individuals (as estimated by the Secretary) who could be covered in July 1966 by the insurance program established by this part [*42 USCS §§ 1395j* et seq.] if they had theretofore enrolled under this part [*42 USCS §§ 1395j* et seq.].

(c) Election under *42 USCS § 1395w-24*. The Secretary shall determine the Government contribution under subparagraphs (A) and (B) of subsection (a)(1) without regard to any premium reduction resulting from an election under section 1854(f)(1)(E) [*42 USCS § 1395w-24(f)(1)(E)*] or any credits provided under section 1854(b)(1)(C)(iv) [*42 USCS § 1395w-24(b)(1)(C)(iv)*] and without regard to any premium adjustment effected under sections 1839(h) and 1860C-1(f) [*42 USCS §§ 1395r(h)* and *1395w-29(f)*] and without regard to any premium adjustment under section 1839(i) [*42 USCS § 1395r(i)*].

HISTORY:

(Aug. 14, 1935, ch 531, Title XVIII, Part B, § 1844, as added July 30, 1965, P.L. 89-97, Title I, Part 1, § 102(a), 79 Stat. 313; Jan. 2, 1968, P.L. 90-248, Title I, Part 4, § 167, 81 Stat. 874; Oct. 30, 1972, P.L. 92-603, Title II, § 203(e) in part, 86 Stat. 1377; Sept. 3, 1982, P.L. 97-248, Title I, Subtitle A, Part II, § 124(c), 96 Stat. 364; April 20, 1983, P.L. 98-21, Title VI, § 606(a)(2)(F), (G), 97 Stat. 171; July 18, 1984, P.L. 98-369, Division B, Title III, Subtitle A, Part II, § 2354(b)(16), 98 Stat. 1101; July 1, 1988, P.L. 100-360, Title II, Subtitle B, § 211(c)(2), 102 Stat. 738; Dec. 13, 1989, P.L. 101-234, Title II, § 202(a), 103 Stat. 1981; Aug. 5, 1997, P.L. 105-33, Title IV, Subtitle F, Ch 6, Subch A, § 4571(b)(2), 111 Stat. 464; Dec. 21, 2000, P.L. 106-554, § 1(a)(6), 114 Stat. 2763; Dec. 8, 2003, P.L. 108-173, Title II, Subtitle C, § 222(l)(2)(C), Subtitle E, § 241(b)(2)(B), Title VIII, Subtitle B, § 811(b)(2), 117 Stat. 2206, 2221, 2368.)

§ 1395w-1. [Repealed]

§ 1395w-2. Intermediate sanctions for providers or suppliers of clinical diagnostic laboratory tests

(a) If the Secretary determines that any provider or clinical laboratory approved for participation under this *title [42 USCS §§ 1395* et seq.] no longer substantially meets the conditions of participation or for coverage specified under this *title [42 USCS §§ 1395* et seq.] with respect to the provision of clinical diagnostic laboratory tests under this part [*42 USCS §§ 1395j* et seq.], the Secretary may (for a period not to exceed one year) impose intermediate sanctions developed pursuant to subsection (b), in lieu of terminating immediately the provider agreement or cancelling immediately certification of the clinical laboratory.

(b) (1) The Secretary shall develop and implement--

(A) a range of intermediate sanctions to apply to providers or clinical laboratories under the conditions described in subsection (a), and

(B) appropriate procedures for appealing determinations relating to the imposition of such sanctions.

(2) (A) The intermediate sanctions developed under paragraph (1) shall include--

(i) directed plans of correction,

(ii) civil money penalties in an amount not to exceed $ 10,000 for each day of substantial noncompliance,

(iii) payment for the costs of onsite monitoring by an agency responsible for conducting surveys, and

(iv) suspension of all or part of the payments to which a provider or certified clinical laboratory would otherwise be entitled under this *title [42 USCS §§ 1395* et seq.] with respect to clinical diagnostic laboratory tests furnished on or after the date on which the Secretary determines that intermediate sanctions should be imposed pursuant to subsection (a).

The provisions of section 1128A [*42 USCS § 1320a-7a*] (other than subsections (a) and (b)) shall apply to a civil money penalty under clause (ii) in the same manner as such provisions apply to a penalty or proceeding under section 1128A(a) [*42 USCS § 1320a-7a(a)*].

(B) The sanctions specified in subparagraph (A) are in addition to sanctions otherwise available under State or Federal law.

(3) The Secretary shall develop and implement specific procedures with respect to when and how each of the intermediate sanctions developed under paragraph (1) is to be applied, the amounts of any penalties, and the severity of each of these penalties. Such procedures shall be designed so as to minimize the time between identification of violations and imposition of these sanctions and shall provide for the imposition of incrementally more severe penalties for repeated or uncorrected deficiencies.

HISTORY:

(Aug. 14, 1935, ch 531, Title XVIII, Part B, § 1846, as added Dec. 22, 1987, P.L. 100-203, Title IV, Subtitle A, Part 3, Subpart B, § 4064(d)(1), 101 Stat. 1330-111; July 1, 1988, P.L. 100-360, Title II, Subtitle A, § 203(e)(4), Title IV, Subtitle B, § 411(g)(3)(G), 102 Stat. 725, 784; Oct. 13, 1988, P.L. 100-485, Title VI, § 608(d)(22)(C), 102 Stat. 2421; Dec. 13, 1989, P.L. 101-234, Title II, § 201(a)(1), 103 Stat. 1981; Nov. 5, 1990, P.L. 101-508, Title IV, Subtitle A, Part 2, Subpart B, § 4154(e)(2), 104 Stat. 1388-86.)

§ 1395w-3. Competitive acquisition of certain items and services

(a) Establishment of competitive acquisition programs.

(1) Implementation of programs.

(A) In general. The Secretary shall establish and implement programs under which competitive acquisition areas are established throughout the United States for contract award purposes for the furnishing under this part [*42 USCS §§ 1395j* et seq.] of competitively priced items and services (described in paragraph (2)) for which payment is made under this part [*42 USCS §§ 1395j* et seq.]. Such areas may differ for different items and services.

(B) Phased-in implementation. The programs--

(i) shall be phased in among competitive acquisition areas in a manner consistent with subparagraph (D) so that the competition under the programs occurs in--

(I) 10 of the largest metropolitan statistical areas in 2007;

(II) an additional 70 of the largest metropolitan statistical areas in 2011; and

(III) additional areas after 2011 (or, in the case of national mail order for items and services, after 2010); and

(ii) may be phased in first among the highest cost and highest volume items and services or those items and services that the Secretary determines have the largest savings potential.

(C) Waiver of certain provisions. In carrying out the programs, the Secretary may waive such provisions of the Federal Acquisition Regulation as are necessary for the efficient implementation of this section, other than provisions relating to confidentiality of information and such other provisions as the Secretary determines appropriate.

(D) Changes in competitive acquisition programs.

(i) Round 1 of competitive acquisition program. Notwithstanding subparagraph (B)(i)(I) and in implementing the first round of the competitive acquisition programs under this section--

(I) the contracts awarded under this section before the date of the enactment of this subparagraph are terminated, no payment shall be made under this title on or after the date of the enactment of this subparagraph based on such a contract, and, to the extent that any damages may be applicable as a result of the termination of such contracts, such damages shall be payable from the Federal Supplementary Medical Insurance Trust Fund under section 1841;

(II) the Secretary shall conduct the competition for such round in a manner so that it occurs in 2009 with respect to the same items and services and the same areas, except as provided in subclauses (III) and (IV);

(III) the Secretary shall exclude Puerto Rico so that such round of competition covers 9, instead of 10, of the largest metropolitan statistical areas; and

(IV) there shall be excluded negative pressure wound therapy items and services.

Nothing in subclause (I) shall be construed to provide an independent cause of action or right to administrative or judicial review with regard to the termination provided under such subclause.

(ii) Round 2 of competitive acquisition program. In implementing the second round of the competitive acquisition programs under this section described in subparagraph (B)(i)(II)--

(I) the metropolitan statistical areas to be included shall be those metropolitan statistical areas selected by the Secretary for such round as of June 1, 2008; and

(II) the Secretary may subdivide metropolitan statistical areas with populations (based upon the most recent data from the Census Bureau) of at least 8,000,000 into separate areas for competitive acquisition purposes.

(iii) Exclusion of certain areas in subsequent rounds of competitive acquisition programs. In implementing subsequent rounds of the competitive acquisition programs under this section, including under subparagraph (B)(i)(III), for competitions occurring before 2015, the Secretary shall exempt from the competitive acquisition program (other than national mail order) the following:

(I) Rural areas.

(II) Metropolitan statistical areas not selected under round 1 or round 2 with a population of less than 250,000.

(III) Areas with a low population density within a metropolitan statistical area that is otherwise selected, as determined for purposes of paragraph (3)(A).

(E) Verification by OIG. The Inspector General of the Department of Health and Human Services shall, through post-award audit, survey, or otherwise, assess the process used by the Centers for Medicare & Medicaid Services to conduct competitive bidding and subsequent pricing determinations under this section that are the basis for pivotal bid amounts and single payment amounts for items and services in competitive bidding areas under rounds 1 and 2 of the competitive acquisition programs under this section and may continue to verify such calculations for subsequent rounds of such programs.

(F) Supplier feedback on missing financial documentation.

(i) In general. In the case of a bid where one or more covered documents in connection with such bid have been submitted not later than the covered document review date specified in clause (ii), the Secretary--

(I) shall provide, by not later than 45 days (in the case of the first round of the competitive acquisition programs as described in subparagraph (B)(i)(I)) or 90 days (in the case of a subsequent round of such programs) after the covered document review date, for notice to the bidder of all such documents that are missing as of the covered document review date; and

(II) may not reject the bid on the basis that any covered document is missing or has not been submitted on a timely basis, if all such missing documents identified in the notice provided to the bidder under subclause (I) are submitted to the Secretary not later than 10 business days after the date of such notice.

(ii) Covered document review date. The covered document review date specified in this clause with respect to a competitive acquisition program is the later of--

(I) the date that is 30 days before the final date specified by the Secretary for submission of bids under such program; or

(II) the date that is 30 days after the first date specified by the Secretary for submission of bids under such program.

(iii) Limitations of process. The process provided under this subparagraph--

(I) applies only to the timely submission of covered documents;

(II) does not apply to any determination as to the accuracy or completeness of covered documents submitted or whether such documents meet applicable requirements;

(III) shall not prevent the Secretary from rejecting a bid based on any basis not described in clause (i)(II); and

(IV) shall not be construed as permitting a bidder to change bidding amounts or to make other changes in a bid submission.

(iv) Covered document defined. In this subparagraph, the term "covered document" means a financial, tax, or other document required to be submitted by a bidder as part of an original bid submission under a competitive acquisition program in order to meet required financial standards. Such term does not include other documents, such as the bid itself or accreditation documentation.

(2) Items and services described. The items and services referred to in paragraph (1) are the following:

(A) Durable medical equipment and medical supplies. Covered items (as defined in section 1834(a)(13) [*42 USCS § 1395m(a)(13)*]) for which payment would otherwise be made under section 1834(a) [*42 USCS § 1395m(a)*], including items used in infusion and drugs (other than inhalation drugs) and supplies used in conjunction with durable medical equipment, but excluding class III devices under the Federal Food, Drug, and Cosmetic Act and excluding certain complex rehabilitative power wheelchairs recognized by the Secretary as classified within group 3 or higher (and related accessories when furnished in connection with such wheelchairs).

(B) Other equipment and supplies. Items and services described in section 1842(s)(2)(D) [*42 USCS § 1395u(s)(2)(D)*], other than parenteral nutrients, equipment, and supplies.

(C) Off-the-shelf orthotics. Orthotics described in section 1861(s)(9) [*42 USCS § 1395x(s)(9)*] for which payment would otherwise be made under section 1834(h) [*42 USCS § 1395m(h)*] which require minimal self-adjustment for appropriate use and do not require expertise in trimming, bending, molding, assembling, or customizing to fit to the individual.

(3) Exception authority. In carrying out the programs under this section, the Secretary may exempt--

(A) rural areas and areas with low population density within urban areas that are not competitive, unless there is a significant national market through mail order for a particular item or service; and

(B) items and services for which the application of competitive acquisition is not likely to result in significant savings.

(4) Special rule for certain rented items of durable medical equipment and oxygen. In the case of a covered item for which payment is made on a rental basis under section 1834(a) [*42 USCS § 1395m(a)*] and in the case of payment for oxygen under section 1834(a)(5) [*42 USCS § 1395m(a)(5)*], the Secretary shall establish a process by which rental agreements for the covered items and supply arrangements with oxygen suppliers entered into before the application of the competitive acquisition program under this section for the item may be continued notwithstanding this section. In the case of any such continuation, the supplier involved shall provide for appropriate servicing and replacement, as required under section 1834(a) [*42 USCS § 1395m(a)*].

(5) Physician authorization.

(A) In general. With respect to items or services included within a particular HCPCS code, the Secretary may establish a process for certain items and services under which a physician may prescribe a particular brand or mode of delivery of an item or service within such code if the physician determines that use of the particular item or service would avoid an adverse medical outcome on the individual, as determined by the Secretary.

(B) No effect on payment amount. A prescription under subparagraph (A) shall not affect the amount of payment otherwise applicable for the item or service under the code involved.

(6) Application. For each competitive acquisition area in which the program is implemented under this subsection with respect to items and services, the payment basis determined under the competition conducted under subsection (b) shall be substituted for the payment basis otherwise applied under section 1834(a), section 1834(h), or section 1842(s) [*42 USCS § 1395m(a), 1395m(h)*, or *1395u(s)*], as appropriate.

(7) Exemption from competitive acquisition. The programs under this section shall not apply to the following:

(A) Certain off-the-shelf orthotics. Items and services described in paragraph (2)(C) if furnished--

(i) by a physician or other practitioner (as defined by the Secretary) to the physician's or practitioner's own patients as part of the physician's or practitioner's professional service; or

(ii) by a hospital to the hospital's own patients during an admission or on the date of discharge.

(B) Certain durable medical equipment. Those items and services described in paragraph (2)(A)--

(i) that are furnished by a hospital to the hospital's own patients during an admission or on the date of discharge; and

(ii) to which such programs would not apply, as specified by the Secretary, if furnished by a physician to the physician's own patients as part of the physician's professional service.

(b) Program requirements.

(1) In general. The Secretary shall conduct a competition among entities supplying items and services described in subsection (a)(2) for each competitive acquisition area in which the program is implemented under subsection (a) with respect to such items and services.

(2) Conditions for awarding contract.

(A) In general. The Secretary may not award a contract to any entity under the competition conducted in an competitive acquisition area pursuant to paragraph (1) to furnish such items or services unless the Secretary finds all of the following:

(i) The entity meets applicable quality standards specified by the Secretary under section 1834(a)(20) [*42 USCS § 1395m(a)(20)*].

(ii) The entity meets applicable financial standards specified by the Secretary, taking into account the needs of small providers.

(iii) The total amounts to be paid to contractors in a competitive acquisition area are expected to be less than the total amounts that would otherwise be paid.

(iv) Access of individuals to a choice of multiple suppliers in the area is maintained.

(B) Timely implementation of program. Any delay in the implementation of quality standards under section 1834(a)(20) [*42 USCS § 1395m(a)(20)*] or delay in the receipt of advice from the program oversight committee established under subsection (c) shall not delay the implementation of the competitive acquisition program under this section.

(3) Contents of contract.

(A) In general. A contract entered into with an entity under the competition conducted pursuant to paragraph (1) is subject to terms and conditions that the Secretary may specify.

(B) Term of contracts. The Secretary shall recompete contracts under this section not less often than once every 3 years.

(C) Disclosure of subcontractors.

(i) Initial disclosure. Not later than 10 days after the date a supplier enters into a contract with the Secretary under this section, such supplier shall disclose to the Secretary, in a form and manner specified by the Secretary, the information on--

(I) each subcontracting relationship that such supplier has in furnishing items and services under the contract; and

(II) whether each such subcontractor meets the requirement of section 1834(a)(20)(F)(i) [*42 USCS § 1395m(a)(20)(F)(i)*], if applicable to such subcontractor.

(ii) Subsequent disclosure. Not later than 10 days after such a supplier subsequently enters into a subcontracting relationship described in clause (i)(II), such supplier shall disclose to the Secretary, in such form and manner, the information described in subclauses (I) and (II) of clause (i).

(4) Limit on number of contractors.

(A) In general. The Secretary may limit the number of contractors in a competitive acquisition area to the number needed to meet projected demand for items and services covered under the contracts. In awarding contracts, the Secretary shall take into account the ability of bidding entities to furnish items or services in sufficient quantities to meet the anticipated needs of individuals for such items or services in the geographic area covered under the contract on a timely basis.

(B) Multiple winners. The Secretary shall award contracts to multiple entities submitting bids in each area for an item or service.

(5) Payment.

(A) In general. Payment under this part [*42 USCS §§ 1395j* et seq.] for competitively priced items and services described in subsection (a)(2) shall be based on bids submitted and accepted under this section for such items and services. Based on such bids the Secretary shall determine a single payment amount for each item or service in each competitive acquisition area.

(B) Reduced beneficiary cost-sharing.

(i) Application of coinsurance. Payment under this section for items and services shall be in an amount equal to 80 percent of the payment basis described in subparagraph (A).

(ii) Application of deductible. Before applying clause (i), the individual shall be required to meet the deductible described in section 1833(b) [*42 USCS § 1395l(b)*].

(C) Payment on assignment-related basis. Payment for any item or service furnished by the entity may only be made under this section on an assignment-related basis.

(D) Construction. Nothing in this section shall be construed as precluding the use of an advanced beneficiary notice with respect to a competitively priced item and service.

(6) Participating contractors.

(A) In general. Except as provided in subsection (a)(4), payment shall not be made for items and services described in subsection (a)(2) furnished by a contractor and for which competition is conducted under this section unless--

(i) the contractor has submitted a bid for such items and services under this section; and

(ii) the Secretary has awarded a contract to the contractor for such items and services under this section.

(B) Bid defined. In this section, the term 'bid' means an offer to furnish an item or service for a particular price and time period that includes, where appropriate, any services that are attendant to the furnishing of the item or service.

(C) Rules for mergers and acquisitions. In applying subparagraph (A) to a contractor, the contractor shall include a successor entity in the case of a merger or acquisition, if the successor entity assumes such contract along with any liabilities that may have occurred thereunder.

(D) Protection of small suppliers. In developing procedures relating to bids and the awarding of contracts under this section, the Secretary shall take appropriate steps to ensure that small suppliers of items and services have an opportunity to be considered for participation in the program under this section.

(7) Consideration in determining categories for bids. The Secretary may consider the clinical efficiency and value of specific items within codes, including whether some items have a greater therapeutic advantage to individuals.

(8) Authority to contract for education, monitoring, outreach, and complaint services. The Secretary may enter into contracts with appropriate entities to address complaints from individuals who receive items and services from an entity with a contract under this section and to conduct appropriate education of and outreach to such individuals and monitoring quality of services with respect to the program.

(9) Authority to contract for implementation. The Secretary may contract with appropriate entities to implement the competitive bidding program under this section.

(10) Special rule in case of competition for diabetic testing strips.

(A) In general. With respect to the competitive acquisition program for diabetic testing strips conducted after the first round of the competitive acquisition programs, if an entity does not demonstrate to the Secretary that its bid covers types of diabetic testing strip products that, in the aggregate and taking into account volume for the different products,

cover 50 percent (or such higher percentage as the Secretary may specify) of all such types of products, the Secretary shall reject such bid. The volume for such types of products may be determined in accordance with such data (which may be market based data) as the Secretary recognizes.

(B) Study of types of testing strip products. Before 2011, the Inspector General of the Department of Health and Human Services shall conduct a study to determine the types of diabetic testing strip products by volume that could be used to make determinations pursuant to subparagraph (A) for the first competition under the competitive acquisition program described in such subparagraph and submit to the Secretary a report on the results of the study. The Inspector General shall also conduct such a study and submit such a report before the Secretary conducts a subsequent competitive acquistion [acquisition] program described in subparagraph (A).

(11) No administrative or judicial review. There shall be no administrative or judicial review under section 1869 [*42 USCS § 1395ff*], section 1878 [*42 USCS § 1395oo*], or otherwise, of--

(A) the establishment of payment amounts under paragraph (5);

(B) the awarding of contracts under this section;

(C) the designation of competitive acquisition areas under subsection (a)(1)(A) and the identification of areas under subsection (a)(1)(D)(iii);

(D) the phased-in implementation under subsection (a)(1)(B) and implementation of subsection (a)(1)(D);

(E) the selection of items and services for competitive acquisition under subsection (a)(2);

(F) the bidding structure and number of contractors selected under this section; or

(G) the implementation of the special rule described in paragraph (10).

(c) Program Advisory and Oversight Committee.

(1) Establishment. The Secretary shall establish a Program Advisory and Oversight Committee (hereinafter in this section referred to as the "Committee").

(2) Membership; terms. The Committee shall consist of such members as the Secretary may appoint who shall serve for such term as the Secretary may specify.

(3) Duties.

(A) Advice. The Committee shall provide advice to the Secretary with respect to the following functions:

(i) The implementation of the program under this section.

(ii) The establishment of financial standards for purposes of subsection (b)(2)(A)(ii).

(iii) The establishment of requirements for collection of data for the efficient management of the program.

(iv) The development of proposals for efficient interaction among manufacturers, providers of services, suppliers (as defined in section 1861(d) [*42 USCS § 1395x(d)*]), and individuals.

(v) The establishment of quality standards under section 1834(a)(20) [*42 USCS § 1395m(a)(20)*].

(B) Additional duties. The Committee shall perform such additional functions to assist the Secretary in carrying out this section as the Secretary may specify.

(4) Inapplicability of FACA. The provisions of the Federal Advisory Committee Act (5 U.S.C. App.) shall not apply.

(5) Termination. The Committee shall terminate on December 31, 2011.

(d) Report. Not later than July 1, 2011, the Secretary shall submit to Congress a report on the programs under this section. The report shall include information on savings, reductions in cost-sharing, access to and quality of items and services, and satisfaction of individuals.

(e) [Deleted]

(f) Competitive acquisition ombudsman. The Secretary shall provide for a competitive acquisition ombudsman within the Centers for Medicare & Medicaid Services in order to respond to complaints and inquiries made by suppliers and individuals relating to the application of the competitive acquisition program under this section. The ombudsman may be within the office of the Medicare Beneficiary Ombudsman appointed under section 1808(c) [*42 USCS § 1395b-9(c)*]. The ombudsman shall submit to Congress an annual report on the activities under this subsection, which report shall be coordinated with the report provided under section 1808(c)(2)(C) [*42 USCS § 1395b-9(c)(2)(C)*].

HISTORY:

(Act Aug. 14, 1935, ch 531, Title XVIII, Part B, § 1847, as added Aug. 5, 1997, P.L. 105-33, Title IV, Subtitle D, Ch 2, § 4319(a), 111 Stat. 392; Nov. 29, 1999, P.L. 106-113, Div B, § 1000(a)(6), 113 Stat. 1536; Dec. 8, 2003, P.L. 108-173, Title III, § 302(b)(1), 117 Stat. 2224.)

(As amended July 15, 2008, P.L. 110-275, Title I, Subtitle C, Part II, §§ 145(a)(1), 154(a)(1), (b)(2), (3), (c)(2)(A), (B), (d)(1), (3), (4), 122 Stat. 2547, 2560, 2565, 2566, 2567.)

§ 1395w-3a. Use of average sales price payment methodology

(a) Application.

(1) In general. Except as provided in paragraph (2), this section shall apply to payment for drugs and biologicals that are described in section 1842(o)(1)(C) [*42 USCS § 1395u(o)(1)(C)*] and that are furnished on or after January 1, 2005.

(2) Election. This section shall not apply in the case of a physician who elects under subsection (a)(1)(A)(ii) of section 1847B [*42 USCS § 1395w-3b*] for that section to apply instead of this section for the payment for drugs and biologicals.

(b) Payment amount.

(1) In general. Subject to paragraph (7) and subsections (d)(3)(C) and (e), the amount of payment determined under this section for the billing and payment code for a drug or biological (based on a minimum dosage unit) is, subject to applicable deductible and coinsurance--

(A) in the case of a multiple source drug (as defined in subsection (c)(6)(C)), 106 percent of the amount determined under paragraph (3) for a multiple source drug furnished before April 1, 2008, or 106 percent of the amount determined under paragraph (6) for a multiple source drug furnished on or after April 1, 2008; or

(B) in the case of a single source drug or biological (as defined in subsection (c)(6)(D)), 106 percent of the amount determined under paragraph (4).

(2) Specification of unit.

(A) Specification by manufacturer. The manufacturer of a drug or biological shall specify the unit associated with each National Drug Code (including package size) as part of the submission of data under section 1927(b)(3)(A)(iii) [*42 USCS § 1396r-8(b)(3)(A)(iii)*].

(B) Unit defined. In this section, the term "unit" means, with respect to each National Drug Code (including package size) associated with a drug or biological, the lowest identifiable quantity (such as a capsule or tablet, milligram of molecules, or grams) of the drug or biological that is dispensed, exclusive of any diluent without reference to volume measures pertaining to liquids. For years after 2004, the Secretary may establish the unit for a manufacturer to report and methods for counting units as the Secretary determines appropriate to implement this section.

(3) Multiple source drug. For all drug products included within the same multiple source drug billing and payment code, the amount specified in this paragraph is the volume-weighted average of the average sales prices reported under section 1927(b)(3)(A)(iii) [*42 USCS § 1396r-8(b)(3)(A)(iii)*] determined by--

(A) computing the sum of the products (for each National Drug Code assigned to such drug products) of--

(i) the manufacturer's average sales price (as defined in subsection (c)); and

(ii) the total number of units specified under paragraph (2) sold; and

(B) dividing the sum determined under subparagraph (A) by the sum of the total number of units under subparagraph (A)(ii) for all National Drug Codes assigned to such drug products.

(4) Single source drug or biological. The amount specified in this paragraph for a single source drug or biological is the lesser of the following:

(A) Average sales price. The average sales price as determined using the methodology applied under paragraph (3) for single source drugs and biologicals furnished before April 1, 2008, and using the methodology applied under paragraph (6) for single source drugs and biologicals furnished on or after April 1, 2008, for all National Drug Codes assigned to such drug or biological product.

(B) Wholesale acquisition cost (WAC). The wholesale acquisition cost (as defined in subsection (c)(6)(B)) using the methodology applied under paragraph (3) for single source drugs and biologicals furnished before April 1, 2008, and using the methodology applied under paragraph (6) for single source drugs and biologicals furnished on or after April 1, 2008, for all National Drug Codes assigned to such drug or biological product.

(5) Basis for payment amount. The payment amount shall be determined under this subsection based on information reported under subsection (f) and without regard to any special packaging, labeling, or identifiers on the dosage form or product or package.

(6) Use of volume-weighted average sales prices in calculation of average sales price.

(A) In general. For all drug products included within the same multiple source drug billing and payment code, the amount specified in this paragraph is the volume-weighted average of the average sales prices reported under section 1927(b)(3)(A)(iii) [*42 USCS § 1396r-8(b)(3)(A)(iii)*] determined by--

(i) computing the sum of the products (for each National Drug Code assigned to such drug products) of--

(I) the manufacturer's average sales price (as defined in subsection (c)), determined by the Secretary without dividing such price by the total number of billing units for the National Drug Code for the billing and payment code; and

(II) the total number of units specified under paragraph (2) sold; and

(ii) dividing the sum determined under clause (i) by the sum of the products (for each National Drug Code assigned to such drug products) of--

(I) the total number of units specified under paragraph (2) sold; and

(II) the total number of billing units for the National Drug Code for the billing and payment code.

(B) Billing unit defined. For purposes of this subsection, the term "billing unit" means the identifiable quantity associated with a billing and payment code, as established by the Secretary.

(7) Special rule. Beginning with April 1, 2008, the payment amount for--

(A) each single source drug or biological described in section 1842(o)(1)(G) [*42 USCS § 1395u(o)(1)(G)*] that is treated as a multiple source drug because of the application of subsection (c)(6)(C)(ii) is the lower of--

(i) the payment amount that would be determined for such drug or biological applying such subsection; or

(ii) the payment amount that would have been determined for such drug or biological if such subsection were not applied; and

(B) a multiple source drug described in section 1842(o)(1)(G) [*42 USCS § 1395u(o)(1)(G)*] (excluding a drug or biological that is treated as a multiple source drug because of the application of such subsection) is the lower of--

(i) the payment amount that would be determined for such drug or biological taking into account the application of such subsection; or

(ii) the payment amount that would have been determined for such drug or biological if such subsection were not applied.

(c) Manufacturer's average sales price.

(1) In general. For purposes of this section, subject to paragraphs (2) and (3), the manufacturer's "average sales price" means, of a drug or biological for a National Drug Code for a calendar quarter for a manufacturer for a unit--

(A) the manufacturer's sales to all purchasers (excluding sales exempted in paragraph (2)) in the United States for such drug or biological in the calendar quarter; divided by

(B) the total number of such units of such drug or biological sold by the manufacturer in such quarter.

(2) Certain sales exempted from computation. In calculating the manufacturer's average sales price under this subsection, the following sales shall be excluded:

(A) Sales exempt from best price. Sales exempt from the inclusion in the determination of "best price" under section 1927(c)(1)(C)(i) [*42 USCS § 1396r-8(c)(1)(C)(i)*].

(B) Sales at nominal charge. Such other sales as the Secretary identifies as sales to an entity that are merely nominal in amount (as applied for purposes of section 1927(c)(1)(C)(ii)(III) [*42 USCS § 1396r-8(c)(1)(C)(ii)(III)*], except as the Secretary may otherwise provide).

(3) Sale price net of discounts. In calculating the manufacturer's average sales price under this subsection, such price shall include volume discounts, prompt pay discounts, cash discounts, free goods that are contingent on any purchase requirement, chargebacks, and rebates (other than rebates under section 1927 [*42 USCS § 1396r-8*]). For years after 2004, the Secretary may include in such price other price concessions, which may be based on recommendations of the Inspector General, that would result in a reduction of the cost to the purchaser.

(4) Payment methodology in cases where average sales price during first quarter of sales is unavailable. In the case of a drug or biological during an initial period (not to exceed a full calendar quarter) in which data on the prices for sales for the drug or biological is not sufficiently available from the manufacturer to compute an average sales price for the drug or biological, the Secretary may determine the amount payable under this section for the drug or biological based on--

(A) the wholesale acquisition cost; or

(B) the methodologies in effect under this part [*42 USCS §§ 1395j* et seq.] on November 1, 2003, to determine payment amounts for drugs or biologicals.

(5) Frequency of determinations.

(A) In general on a quarterly basis. The manufacturer's average sales price, for a drug or biological of a manufacturer, shall be calculated by such manufacturer under this subsection on a quarterly basis. In making such calculation insofar as there is a lag in the reporting of the information on rebates and chargebacks under paragraph (3) so that adequate data are not available on a timely basis, the manufacturer shall apply a methodology based on a 12-month rolling average for the manufacturer to estimate costs attributable to rebates and chargebacks. For years after 2004, the Secretary may establish a uniform methodology under this subparagraph to estimate and apply such costs.

(B) Updates in payment amounts. The payment amounts under subsection (b) shall be updated by the Secretary on a quarterly basis and shall be applied based upon the manufacturer's average sales price calculated for the most recent calendar quarter for which data is available.

(C) Use of contractors; implementation. The Secretary may contract with appropriate entities to calculate the payment amount under subsection (b). Notwithstanding any other provision of law, the Secretary may implement, by program instruction or otherwise, any of the provisions of this section.

(6) Definitions and other rules. In this section:

(A) Manufacturer. The term "manufacturer" means, with respect to a drug or biological, the manufacturer (as defined in section 1927(k)(5) [*42 USCS § 1396r-8(k)(5)*]).

(B) Wholesale acquisition cost. The term "wholesale acquisition cost" means, with respect to a drug or biological, the manufacturer's list price for the drug or biological to wholesalers or direct purchasers in the United States, not including prompt pay or other discounts, rebates or reductions in price, for the most recent month for which the information is available, as reported in wholesale price guides or other publications of drug or biological pricing data.

(C) Multiple source drug.

(i) In general. The term "multiple source drug" means, for a calendar quarter, a drug for which there are 2 or more drug products which--

(I) are rated as therapeutically equivalent (under the Food and Drug Administration's most recent publication of "Approved Drug Products with Therapeutic Equivalence Evaluations"),

(II) except as provided in subparagraph (E), are pharmaceutically equivalent and bioequivalent, as determined under subparagraph (F) and as determined by the Food and Drug Administration, and

(III) are sold or marketed in the United States during the quarter.

(ii) Exception. With respect to single source drugs or biologicals that are within the same billing and payment code as of October 1, 2003, the Secretary shall treat such single source drugs or biologicals as if the single source drugs or biologicals were multiple source drugs.

(D) Single source drug or biological. The term "single source drug or biological" means--

(i) a biological; or

(ii) a drug which is not a multiple source drug and which is produced or distributed under a new drug application approved by the Food and Drug Administration, including a drug product marketed by any cross-licensed producers or distributors operating under the new drug application.

(E) Exception from pharmaceutical equivalence and bioequivalence requirement. Subparagraph (C)(ii) shall not apply if the Food and Drug Administration changes by regulation the requirement that, for purposes of the publication described in subparagraph (C)(i), in order for drug products to be rated as therapeutically equivalent, they must be pharmaceutically equivalent and bioequivalent, as defined in subparagraph (F).

(F) Determination of pharmaceutical equivalence and bioequivalence. For purposes of this paragraph--

(i) drug products are pharmaceutically equivalent if the products contain identical amounts of the same active drug ingredient in the same dosage form and meet compendial or other applicable standards of strength, quality, purity, and identity; and

(ii) drugs are bioequivalent if they do not present a known or potential bioequivalence problem, or, if they do present such a problem, they are shown to meet an appropriate standard of bioequivalence.

(G) Inclusion of vaccines. In applying provisions of section 1927 [*42 USCS § 1396r-8*] under this section, "other than a vaccine" is deemed deleted from section 1927(k)(2)(B) [*42 USCS § 1396r-8(k)(2)(B)*].

(d) Monitoring of market prices.

(1) In general. The Inspector General of the Department of Health and Human Services shall conduct studies, which may include surveys, to determine the widely available market prices of drugs and biologicals to which this section applies, as the Inspector General, in consultation with the Secretary, determines to be appropriate.

(2) Comparison of prices. Based upon such studies and other data for drugs and biologicals, the Inspector General shall compare the average sales price under this section for drugs and biologicals with--

(A) the widely available market price for such drugs and biologicals (if any); and

(B) the average manufacturer price (as determined under section 1927(k)(1) [*42 USCS § 1396r-8(k)(1)*]) for such drugs and biologicals.

(3) Limitation on average sales price.

(A) In general. The Secretary may disregard the average sales price for a drug or biological that exceeds the widely available market price or the average manufacturer price for such drug or biological by the applicable threshold percentage (as defined in subparagraph (B)).

(B) Applicable threshold percentage defined. In this paragraph, the term "applicable threshold percentage" means--

(i) in 2005, in the case of an average sales price for a drug or biological that exceeds widely available market price or the average manufacturer price, 5 percent; and

(ii) in 2006 and subsequent years, the percentage applied under this subparagraph subject to such adjustment as the Secretary may specify for the widely available market price or the average manufacturer price, or both.

(C) Authority to adjust average sales price. If the Inspector General finds that the average sales price for a drug or biological exceeds such widely available market price or average manufacturer price for such drug or biological by the applicable threshold percentage, the Inspector General shall inform the Secretary (at such times as the Secretary may

specify to carry out this subparagraph) and the Secretary shall, effective as of the next quarter, substitute for the amount of payment otherwise determined under this section for such drug or biological the lesser of--

(i) the widely available market price for the drug or biological (if any); or

(ii) 103 percent of the average manufacturer price (as determined under section 1927(k)(1) [*42 USCS § 1396r-8(k)(1)*]) for the drug or biological.

(4) Civil money penalty.

(A) In general. If the Secretary determines that a manufacturer has made a misrepresentation in the reporting of the manufacturer's average sales price for a drug or biological, the Secretary may apply a civil money penalty in an amount of up to $ 10,000 for each such price misrepresentation and for each day in which such price misrepresentation was applied.

(B) Procedures. The provisions of section 1128A [*42 USCS § 1320a-7a*] (other than subsections (a) and (b)) shall apply to civil money penalties under subparagraph (B) in the same manner as they apply to a penalty or proceeding under section 1128A(a) [*42 USCS § 1320a-7a(a)*].

(5) Widely available market price.

(A) In general. In this subsection, the term "widely available market price" means the price that a prudent physician or supplier would pay for the drug or biological. In determining such price, the Inspector General shall take into account the discounts, rebates, and other price concessions routinely made available to such prudent physicians or suppliers for such drugs or biologicals.

(B) Considerations. In determining the price under subparagraph (A), the Inspector General shall consider information from one or more of the following sources:

(i) Manufacturers.

(ii) Wholesalers.

(iii) Distributors.

(iv) Physician supply houses.

(v) Specialty pharmacies.

(vi) Group purchasing arrangements.

(vii) Surveys of physicians.

(viii) Surveys of suppliers.

(ix) Information on such market prices from insurers.

(x) Information on such market prices from private health plans.

(e) Authority to use alternative payment in response to public health emergency. In the case of a public health emergency under section 319 of the Public Health Service Act [*42 USCS § 247d*] in which there is a documented inability to access drugs and biologicals, and a concomitant increase in the price, of a drug or biological which is not reflected in the manufacturer's average sales price for one or more quarters, the Secretary may use the wholesale acquisition cost (or other reasonable measure of drug or biological price) instead of the manufacturer's average sales price for such quarters and for subsequent quarters until the price and availability of the drug or biological has stabilized and is substantially reflected in the applicable manufacturer's average sales price.

(f) Quarterly report on average sales price. For requirements for reporting the manufacturer's average sales price (and, if required to make payment, the manufacturer's wholesale acquisition cost) for the drug or biological under this section, see section 1927(b)(3) [*42 USCS § 1396r-8(b)(3)*].

(g) Judicial review. There shall be no administrative or judicial review under section 1869 [*42 USCS § 1395ff*], section 1878 [*42 USCS § 1395oo*], or otherwise, of--

(1) determinations of payment amounts under this section, including the assignment of National Drug Codes to billing and payment codes;

(2) the identification of units (and package size) under subsection (b)(2);

(3) the method to allocate rebates, chargebacks, and other price concessions to a quarter if specified by the Secretary;

(4) the manufacturer's average sales price when it is used for the determination of a payment amount under this section; and

(5) the disclosure of the average manufacturer price by reason of an adjustment under subsection (d)(3)(C) or (e).

HISTORY:

(Aug. 14, 1935, ch 531, Title XVIII, Part B, § 1847A, as added Dec. 8, 2003, P.L. 108-173, Title III, § 303(c)(1), 117 Stat. 2239.)

(As amended Dec. 29, 2007, P.L. 110-173, Title I, § 112, 121 Stat. 2500.)

§ 1395w-3b. Competitive acquisition of outpatient drugs and biologicals

(a) Implementation of competitive acquisition.

(1) Implementation of program.

(A) In general. The Secretary shall establish and implement a competitive acquisition program under which--

(i) competitive acquisition areas are established for contract award purposes for acquisition of and payment for categories of competitively biddable drugs and biologicals (as defined in paragraph (2)) under this part [*42 USCS §§ 1395j* et seq.];

(ii) each physician is given the opportunity annually to elect to obtain drugs and biologicals under the program, rather than under section 1847A [*42 USCS § 1395w-3a*]; and

(iii) each physician who elects to obtain drugs and biologicals under the program makes an annual selection under paragraph (5) of the contractor through which drugs and biologicals within a category of drugs and biologicals will be acquired and delivered to the physician under this part [*42 USCS §§ 1395j* et seq.].

This section shall not apply in the case of a physician who elects section 1847A [*42 USCS § 1395w-3a*] to apply.

(B) Implementation. For purposes of implementing the program, the Secretary shall establish categories of competitively biddable drugs and biologicals. The Secretary shall phase in the program with respect to those categories beginning in 2006 in such manner as the Secretary determines to be appropriate.

(C) Waiver of certain provisions. In order to promote competition, in carrying out the program the Secretary may waive such provisions of the Federal Acquisition Regulation as are necessary for the efficient implementation of this section, other than provisions relating to confidentiality of information and such other provisions as the Secretary determines appropriate.

(D) Exclusion authority. The Secretary may exclude competitively biddable drugs and biologicals (including a class of such drugs and biologicals) from the competitive bidding system under this section if the application of competitive bidding to such drugs or biologicals--

(i) is not likely to result in significant savings; or

(ii) is likely to have an adverse impact on access to such drugs or biologicals.

(2) Competitively biddable drugs and biologicals and program defined. For purposes of this section--

(A) Competitively biddable drugs and biologicals defined. The term "competitively biddable drugs and biologicals" means a drug or biological described in section 1842(o)(1)(C) [*42 USCS § 1395u(o)(1)(C)*] and furnished on or after January 1, 2006.

(B) Program. The term "program" means the competitive acquisition program under this section.

(C) Competitive acquisition area; area. The terms "competitive acquisition area" and "area" mean an appropriate geographic region established by the Secretary under the program.

(D) Contractor. The term "contractor" means an entity that has entered into a contract with the Secretary under this section.

(3) Application of program payment methodology.

(A) In general. With respect to competitively biddable drugs and biologicals which are supplied under the program in an area and which are prescribed by a physician who has elected this section to apply--

(i) the claim for such drugs and biologicals shall be submitted by the contractor that supplied the drugs and biologicals;

(ii) collection of amounts of any deductible and coinsurance applicable with respect to such drugs and biologicals shall be the responsibility of such contractor and shall not be collected unless the drug or biological is administered to the individual involved; and

(iii) the payment under this section (and related amounts of any applicable deductible and coinsurance) for such drugs and biologicals shall be made only to such contractor upon receipt of a claim for a drug or biological supplied by the contractor for administration to a beneficiary.

(B) Process for adjustments. The Secretary shall provide a process for adjustments to payments in the case in which payment is made for drugs and biologicals which were billed at the time of dispensing but which were not actually administered.

(C) Information for purposes of cost-sharing. The Secretary shall provide a process by which physicians submit information to contractors for purposes of the collection of any applicable deductible or coinsurance amounts under subparagraph (A)(ii).

(D) Post-payment review process. The Secretary shall establish (by program instruction or otherwise) a post-payment review process (which may include the use of statistical sampling) to assure that payment is made for a drug or biological under this section only if the drug or biological has been administered to a beneficiary. The Secretary shall recoup, offset, or collect any overpayments determined by the Secretary under such process.

(4) Contract required. Payment may not be made under this part [*42 USCS §§ 1395j* et seq.] for competitively biddable drugs and biologicals prescribed by a physician who has elected this section to apply within a category and a competitive acquisition area with respect to which the program applies unless--

(A) the drugs or biologicals are supplied by a contractor with a contract under this section for such category of drugs and biologicals and area; and

(B) the physician has elected such contractor under paragraph (5) for such category and area.

(5) Contractor selection process.

(A) Annual selection.

(i) In general. The Secretary shall provide a process for the selection of a contractor, on an annual basis and in such exigent circumstances as the Secretary may provide and with respect to each category of competitively biddable drugs and biologicals for an area by selecting physicians.

(ii) Timing of selection. The selection of a contractor under clause (i) shall be made at the time of the election described in section 1847A(a) [*42 USCS § 1395w-3a(a)*] for this section to apply and shall be coordinated with agreements entered into under section 1842(h) [*42 USCS § 1395u(h)*].

(B) Information on contractors. The Secretary shall make available to physicians on an ongoing basis, through a directory posted on the Internet website of the Centers for Medicare & Medicaid Services or otherwise and upon request, a list of the contractors under this section in the different competitive acquisition areas.

(C) Selecting physician defined. For purposes of this section, the term "selecting physician" means, with respect to a contractor and category and competitive acquisition area, a physician who has elected this section to apply and has selected to apply under this section such contractor for such category and area.

(b) Program requirements.

(1) Contract for competitively biddable drugs and biologicals. The Secretary shall conduct a competition among entities for the acquisition of competitively biddable drugs and biologicals. Notwithstanding any other provision of this *title [42 USCS §§ 1395* et seq.], in the case of a multiple source drug, the Secretary shall conduct such competition among entities for the acquisition of at least one competitively biddable drug and biological within each billing and payment code within each category for each competitive acquisition area.

(2) Conditions for awarding contract.

(A) In general. The Secretary may not award a contract to any entity under the competition conducted in a competitive acquisition area pursuant to paragraph (1) with respect to the acquisition of competitively biddable drugs and biologicals within a category unless the Secretary finds that the entity meets all of the following with respect to the contract period involved:

(i) Capacity to supply competitively biddable drug or biological within category.

(I) In general. The entity has sufficient arrangements to acquire and to deliver competitively biddable drugs and biologicals within such category in the area specified in the contract.

(II) Shipment methodology. The entity has arrangements in effect for the shipment at least 5 days each week of competitively biddable drugs and biologicals under the contract and for the timely delivery (including for emergency situations) of such drugs and biologicals in the area under the contract.

(ii) Quality, service, financial performance and solvency standards. The entity meets quality, service, financial performance, and solvency standards specified by the Secretary, including--

(I) the establishment of procedures for the prompt response and resolution of complaints of physicians and individuals and of inquiries regarding the shipment of competitively biddable drugs and biologicals; and

(II) a grievance and appeals process for the resolution of disputes.

(B) Additional considerations. The Secretary may refuse to award a contract under this section, and may terminate such a contract, with an entity based upon--

(i) the suspension or revocation, by the Federal Government or a State government, of the entity's license for the distribution of drugs or biologicals (including controlled substances); or

(ii) the exclusion of the entity under section 1128 [*42 USCS § 1320a-7*] from participation under this *title [42 USCS §§ 1395* et seq.].

(C) Application of medicare provider ombudsman. For provision providing for a program-wide Medicare Provider Ombudsman to review complaints, see section 1868(b) [*42 USCS § 1395ee(b)*], as added by section 923 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003.

(3) Awarding multiple contracts for a category and area. The Secretary may limit (but not below 2) the number of qualified entities that are awarded such contracts for any category and area. The Secretary shall select among qualified entities based on the following:

(A) The bid prices for competitively biddable drugs and biologicals within the category and area.

(B) Bid price for distribution of such drugs and biologicals.

(C) Ability to ensure product integrity.

(D) Customer service.

(E) Past experience in the distribution of drugs and biologicals, including controlled substances.

(F) Such other factors as the Secretary may specify.

(4) Terms of contracts.

(A) In general. A contract entered into with an entity under the competition conducted pursuant to paragraph (1) is subject to terms and conditions that the Secretary may specify consistent with this section.

(B) Period of contracts. A contract under this section shall be for a term of 3 years, but may be terminated by the Secretary or the entity with appropriate, advance notice.

(C) Integrity of drug and biological distribution system. A contractor (as defined in subsection (a)(2)(D)) shall--

(i) acquire all drug and biological products it distributes directly from the manufacturer or from a distributor that has acquired the products directly from the manufacturer; and

(ii) comply with any product integrity safeguards as may be determined to be appropriate by the Secretary.

Nothing in this subparagraph shall be construed to relieve or exempt any contractor from the provisions of the Federal Food, Drug, and Cosmetic Act that relate to the wholesale distribution of prescription drugs or biologicals.

(D) Compliance with code of conduct and fraud and abuse rules. Under the contract--

(i) the contractor shall comply with a code of conduct, specified or recognized by the Secretary, that includes standards relating to conflicts of interest; and

(ii) the contractor shall comply with all applicable provisions relating to prevention of fraud and abuse, including compliance with applicable guidelines of the Department of Justice and the Inspector General of the Department of Health and Human Services.

(E) Direct delivery of drugs and biologicals to physicians. Under the contract the contractor shall only supply competitively biddable drugs and biologicals directly to the selecting physicians and not directly to individuals, except under circumstances and settings where an individual currently receives a drug or biological in the individual's home or other non-physician office setting as the Secretary may provide. The contractor shall not deliver drugs and biologicals to a selecting physician except upon receipt of a prescription for such drugs and biologicals, and such necessary data as may be required by the Secretary to carry out this section. This section does not--

(i) require a physician to submit a prescription for each individual treatment; or

(ii) change a physician's flexibility in terms of writing a prescription for drugs or biologicals for a single treatment or a course of treatment.

(5) Permitting access to drugs and biologicals. The Secretary shall establish rules under this section under which drugs and biologicals which are acquired through a contractor under this section may be used to resupply inventories of such drugs and biologicals which are administered consistent with safe drug practices and with adequate safeguards against fraud and abuse. The previous sentence shall apply if the physicians can demonstrate to the Secretary all of the following:

(A) The drugs or biologicals are required immediately.

(B) The physician could not have reasonably anticipated the immediate requirement for the drugs or biologicals.

(C) The contractor could not deliver to the physician the drugs or biologicals in a timely manner.

(D) The drugs or biologicals were administered in an emergency situation.

(6) Construction. Nothing in this section shall be construed as waiving applicable State requirements relating to licensing of pharmacies.

(c) Bidding process.

(1) In general. In awarding a contract for a category of drugs and biologicals in an area under the program, the Secretary shall consider with respect to each entity seeking to be awarded a contract the bid price and the other factors referred to in subsection (b)(3).

(2) Bid defined. In this section, the term "bid" means an offer to furnish a competitively biddable drug or biological for a particular price and time period.

(3) Bidding on a national or regional basis. Nothing in this section shall be construed as precluding a bidder from bidding for contracts in all areas of the United States or as requiring a bidder to submit a bid for all areas of the United States.

(4) Uniformity of bids within area. The amount of the bid submitted under a contract offer for any competitively biddable drug or biological for an area shall be the same for that drug or biological for all portions of that area.

(5) Confidentiality of bids. The provisions of subparagraph (D) of section 1927(b)(3) [*42 USCS § 1396r-8(b)(3)*] shall apply to periods during which a bid is submitted with respect to a competitively biddable drug or biological under this section in the same manner as it applies to information disclosed under such section, except that any reference--

(A) in that subparagraph to a "manufacturer or wholesaler" is deemed a reference to a "bidder" under this section;

(B) in that section to "prices charged for drugs" is deemed a reference to a "bid" submitted under this section; and

(C) in clause (i) of that section to "this section", is deemed a reference to "part B of title XVIII [*42 USCS §§ 1395j* et seq.]".

(6) Inclusion of costs. The bid price submitted in a contract offer for a competitively biddable drug or biological shall--

(A) include all costs related to the delivery of the drug or biological to the selecting physician (or other point of delivery); and

(B) include the costs of dispensing (including shipping) of such drug or biological and management fees, but shall not include any costs related to the administration of the drug or biological, or wastage, spillage, or spoilage.

(7) Price adjustments during contract period; disclosure of costs. Each contract awarded shall provide for--

(A) disclosure to the Secretary the contractor's reasonable, net acquisition costs for periods specified by the Secretary, not more often than quarterly, of the contract; and

(B) appropriate price adjustments over the period of the contract to reflect significant increases or decreases in a contractor's reasonable, net acquisition costs, as so disclosed.

(d) Computation of payment amounts.

(1) In general. Payment under this section for competitively biddable drugs or biologicals shall be based on bids submitted and accepted under this section for such drugs or biologicals in an area. Based on such bids the Secretary shall determine a single payment amount for each competitively biddable drug or biological in the area.

(2) Special rules. The Secretary shall establish rules regarding the use under this section of the alternative payment amount provided under section 1847A [*42 USCS § 1395w-3a*] to the use of a price for specific competitively biddable drugs and biologicals in the following cases:

(A) New drugs and biologicals. A competitively biddable drug or biological for which a payment and billing code has not been established.

(B) Other cases. Such other exceptional cases as the Secretary may specify in regulations.

(e) Cost-sharing.

(1) Application of coinsurance. Payment under this section for competitively biddable drugs and biologicals shall be in an amount equal to 80 percent of the payment basis described in subsection (d)(1).

(2) Deductible. Before applying paragraph (1), the individual shall be required to meet the deductible described in section 1833(b) [*42 USCS § 1395l(b)*].

(3) Collection. Such coinsurance and deductible shall be collected by the contractor that supplies the drug or biological involved. Subject to subsection (a)(3)(B), such coinsurance and deductible may be collected in a manner similar to the manner in which the coinsurance and deductible are collected for durable medical equipment under this part [*42 USCS §§ 1395j* et seq.].

(f) Special payment rules.

(1) Use in exclusion cases. If the Secretary excludes a drug or biological (or class of drugs or biologicals) under subsection (a)(1)(D), the Secretary may provide for payment to be made under this part [*42 USCS §§ 1395j* et seq.] for such drugs and biologicals (or class) using the payment methodology under section 1847A [*42 USCS § 1395w-3a*] .

(2) Application of requirement for assignment. For provision requiring assignment of claims for competitively biddable drugs and biologicals, see section 1842(o)(3) [*42 USCS § 1395u(o)(3)*].

(3) Protection for beneficiary in case of medical necessity denial. For protection of individuals against liability in the case of medical necessity determinations, see section 1842(b)(3)(B)(ii)(III) [*42 USCS § 1395u(b)(3)(B)(ii)(III)*].

(g) Judicial review. There shall be no administrative or judicial review under section 1869 [*42 USCS § 1395ff*], section 1878 [*42 USCS § 1395oo*], or otherwise, of--

(1) the establishment of payment amounts under subsection (d)(1);

(2) the awarding of contracts under this section;

(3) the establishment of competitive acquisition areas under subsection (a)(2)(C);

(4) the phased-in implementation under subsection (a)(1)(B);

(5) the selection of categories of competitively biddable drugs and biologicals for competitive acquisition under such subsection or the selection of a drug in the case of multiple source drugs; or

(6) the bidding structure and number of contractors selected under this section.

HISTORY:

(Aug. 14, 1935, ch 531, Title XVIII, Part B, § 1847B, as added Dec. 8, 2003, P.L. 108-173, Title III, § 303(d)(1), 117 Stat. 2245.)

(As amended Dec. 20, 2006, P.L. 109-432, Div B, Title I, § 108(a), 120 Stat. 2983.)

§ 1395w-4. Payment for physicians' services

(a) Payment based on fee schedule.

(1) In general. Effective for all physicians' services (as defined in subsection (j)(3)) furnished under this part during a year (beginning with 1992) for which payment is otherwise made on the basis of a reasonable charge or on the basis of a fee schedule under section 1834(b) [*42 USCS § 1395m(b)*], payment under this part [*42 USCS §§ 1395j* et seq.] shall instead be based on the lesser of--

(A) the actual charge for the service, or

(B) subject to the succeeding provisions of this subsection, the amount determined under the fee schedule established under subsection (b) for services furnished during that year (in this subsection referred to as the "fee schedule amount").

(2) Transition to full fee schedule.

(A) Limiting reductions and increases to 15 percent in 1992.

(i) Limit on increase. In the case of a service in a fee schedule area (as defined in subsection (j)(2)) for which the adjusted historical payment basis (as defined in subparagraph (D)) is less than 85 percent of the fee schedule amount for services furnished in 1992, there shall be substituted for the fee schedule amount an amount equal to the adjusted historical payment basis plus 15 percent of the fee schedule amount otherwise established (without regard to this paragraph).

(ii) Limit in reduction. In the case of a service in a fee schedule area for which the adjusted historical payment basis exceeds 115 percent of the fee schedule amount for services furnished in 1992, there shall be substituted for the fee schedule amount an amount equal to the adjusted historical payment basis minus 15 percent of the fee schedule amount otherwise established (without regard to this paragraph).

(B) Special rule for 1993, 1994, and 1995. If a physicians' service in a fee schedule area is subject to the provisions of subparagraph (A) in 1992, for physicians' services furnished in the area--

(i) during 1993, there shall be substituted for the fee schedule amount an amount equal to the sum of--

(I) 75 percent of the fee schedule amount determined under subparagraph (A), adjusted by the update established under subsection (d)(3) for 1993, and

(II) 25 percent of the fee schedule amount determined under paragraph (1) for 1993 without regard to this paragraph;

(ii) during 1994, there shall be substituted for the fee schedule amount an amount equal to the sum of--

(I) 67 percent of the fee schedule amount determined under clause (i), adjusted by the update established under subsection (d)(3) for 1994 and as adjusted under subsection (c)(2)(F)(ii) and under section 13515(b) of the Omnibus Budget Reconciliation Act of 1993 [*42 USCS § 1395u* note], and

(II) 33 percent of the fee schedule amount determined under paragraph (1) for 1994 without regard to this paragraph; and

(iii) during 1995, there shall be substituted for the fee schedule amount an amount equal to the sum of--

(I) 50 percent of the fee schedule amount determined under clause (ii) adjusted by the update established under subsection (d)(3) for 1995, and

(II) 50 percent of the fee schedule amount determined under paragraph (1) for 1995 without regard to this paragraph.

(C) Special rule for anesthesia and radiology services. With respect to physicians' services which are anesthesia services, the Secretary shall provide for a transition in the same manner as a transition is provided for other services under subparagraph (B). With respect to radiology services, "109 percent" and "9 percent" shall be substituted for "115 percent" and "15 percent", respectively, in subparagraph (A)(ii).

(D) "Adjusted historical payment basis" defined.

(i) In general. In this paragraph, the term "adjusted historical payment basis" means, with respect to a physicians' service furnished in a fee schedule area, the weighted average prevailing charge applied in the area for the service in 1991 (as determined by the Secretary without regard to physician specialty and as adjusted to reflect payments for services with customary charges below the prevailing charge or other payment limitations imposed by law or regulation) adjusted by the update established under subsection (d)(3) for 1992.

(ii) Application to radiology services. In applying clause (i) in the case of physicians' services which are radiology services (including radiologist services, as defined in section 1834(b)(6) [*42 USCS § 1395m(b)(6)*]), but excluding nuclear medicine services that are subject to section 6105(b) of the Omnibus Budget Reconciliation Act of 1989 [*42*

USCS § 1395m note], there shall be substituted for the weighted average prevailing charge the amount provided under the fee schedule established for the service for the fee schedule area under section 1834(b) [*42 USCS § 1395m(b)*].

(iii) Nuclear medicine services. In applying clause (i) in the case of physicians' services which are nuclear medicine services, there shall be substituted for the weighted average prevailing charge the amount provided under section 6105(b) of the Omnibus Budget Reconciliation Act of 1989 [*42 USCS § 1395m* note].

(3) Incentives for participating physicians and suppliers. In applying paragraph (1)(B) in the case of a nonparticipating physician or a nonparticipating supplier or other person, the fee schedule amount shall be 95 percent of such amount otherwise applied under this subsection (without regard to this paragraph). In the case of physicians' services (including services which the Secretary excludes pursuant to subsection (j)(3)) of a nonparticipating physician, supplier, or other person for which payment is made under this part [*42 USCS §§ 1395j* et seq.] on a basis other than the fee schedule amount, the payment shall be based on 95 percent of the payment basis for such services furnished by a participating physician, supplier, or other person.

(4) Special rule for medical direction.

(A) In general. With respect to physicians' services furnished on or after January 1, 1994, and consisting of medical direction of two, three, or four concurrent anesthesia cases, except as provided in paragraph (5), the fee schedule amount to be applied shall be equal to one-half of the amount described in subparagraph (B).

(B) Amount. The amount described in this subparagraph, for a physician's medical direction of the performance of anesthesia services, is the following percentage of the fee schedule amount otherwise applicable under this section if the anesthesia services were personally performed by the physician alone:

(i) For services furnished during 1994, 120 percent.

(ii) For services furnished during 1995, 115 percent.

(iii) For services furnished during 1996, 110 percent.

(iv) For services furnished during 1997, 105 percent.

(v) For services furnished after 1997, 100 percent.

(5) Incentives for electronic prescribing.

(A) Adjustment.

(i) In general. Subject to subparagraph (B) and subsection (m)(2)(B), with respect to covered professional services furnished by an eligible professional during 2012 or any subsequent year, if the eligible professional is not a successful electronic prescriber for the reporting period for the year (as determined under subsection (m)(3)(B)), the fee schedule amount for such services furnished by such professional during the year (including the fee schedule amount for purposes of determining a payment based on such amount) shall be equal to the applicable percent of the fee schedule amount that would otherwise apply to such services under this subsection (determined after application of paragraph (3) but without regard to this paragraph).

(ii) Applicable percent. For purposes of clause (i), the term "applicable percent" means--

(I) for 2012, 99 percent;

(II) for 2013, 98.5 percent; and

(III) for 2014 and each subsequent year, 98 percent.

(B) Significant hardship exception. The Secretary may, on a case-by-case basis, exempt an eligible professional from the application of the payment adjustment under subparagraph (A) if the Secretary determines, subject to annual renewal, that compliance with the requirement for being a successful electronic prescriber would result in a significant hardship, such as in the case of an eligible professional who practices in a rural area without sufficient Internet access.

(C) Application.

(i) Physician reporting system rules. Paragraphs (5), (6), and (8) of subsection (k) shall apply for purposes of this paragraph in the same manner as they apply for purposes of such subsection.

(ii) Incentive payment validation rules. Clauses (ii) and (iii) of subsection (m)(5)(D) shall apply for purposes of this paragraph in a similar manner as they apply for purposes of such subsection.

(D) Definitions. For purposes of this paragraph:

(i) Eligible professional; covered professional services. The terms "eligible professional" and "covered professional services" have the meanings given such terms in subsection (k)(3).

(ii) Physician reporting system. The term "physician reporting system" means the system established under subsection (k).

(iii) Reporting period. The term "reporting period" means, with respect to a year, a period specified by the Secretary.

(6) Special rule for teaching anesthesiologists. With respect to physicians' services furnished on or after January 1, 2010, in the case of teaching anesthesiologists involved in the training of physician residents in a single anesthesia case or two concurrent anesthesia cases, the fee schedule amount to be applied shall be 100 percent of the fee schedule

amount otherwise applicable under this section if the anesthesia services were personally performed by the teaching anesthesiologist alone and paragraph (4) shall not apply if--

(A) the teaching anesthesiologist is present during all critical or key portions of the anesthesia service or procedure involved; and

(B) the teaching anesthesiologist (or another anesthesiologist with whom the teaching anesthesiologist has entered into an arrangement) is immediately available to furnish anesthesia services during the entire procedure.

(b) Establishment of fee schedules.

(1) In general. Before November 1 of the preceding year, for each year beginning with 1998, the Secretary shall establish, by regulation, fee schedules that establish payment amounts for all physicians' services furnished in all fee schedule areas (as defined in subsection (j)(2)) for the year. Except as provided in paragraph (2), each such payment amount for a service shall be equal to the product of--

(A) the relative value for the service (as determined in subsection (c)(2)),

(B) the conversion factor (established under subsection (d)) for the year, and

(C) the geographic adjustment factor (established under subsection (e)(2)) for the service for the fee schedule area.

(2) Treatment of radiology services and anesthesia services.

(A) Radiology services. With respect to radiology services (including radiologist services, as defined in section 1834(b)(6) [*42 USCS § 1395m(b)(6)*]), the Secretary shall base the relative values on the relative value scale developed under section 1834(b)(1)(A) [*42 USCS § 1395m(b)(1)(A)*], with appropriate modifications of the relative values to assure that the relative values established for radiology services which are similar or related to other physicians' services are consistent with the relative values established for those similar or related services.

(B) Anesthesia services. In establishing the fee schedule for anesthesia services for which a relative value guide has been established under section 4048(b) of the Omnibus Budget Reconciliation Act of 1987 [*42 USCS § 1395u* note], the Secretary shall use, to the extent practicable, such relative value guide, with appropriate adjustment of the conversion factor, in a manner to assure that the fee schedule amounts for anesthesia services are consistent with the fee schedule amounts for other services determined by the Secretary to be of comparable value. In applying the previous sentence, the Secretary shall adjust the conversion factor by geographic adjustment factors in the same manner as such adjustment is made under paragraph (1)(C).

(C) Consultation. The Secretary shall consult with the Physician Payment Review Commission [Medicare Payment Advisory Commission] and organizations representing physicians or suppliers who furnish radiology services and anesthesia services in applying subparagraphs (A) and (B).

(3) Treatment of interpretation of electrocardiograms. The Secretary--

(A) shall make separate payment under this section for the interpretation of electrocardiograms performed or ordered to be performed as part of or in conjunction with a visit to or a consultation with a physician, and

(B) shall adjust the relative values established for visits and consultations under subsection (c) so as not to include relative value units for interpretations of electrocardiograms in the relative value for visits and consultations.

(4) Special rule for imaging services.

(A) In general. In the case of imaging services described in subparagraph (B) furnished on or after January 1, 2007, if--

(i) the technical component (including the technical component portion of a global fee) of the service established for a year under the fee schedule described in paragraph (1) without application of the geographic adjustment factor described in paragraph (1)(C), exceeds

(ii) the Medicare OPD fee schedule amount established under the prospective payment system for hospital outpatient department services under paragraph (3)(D) of section 1833(t) [*42 USCS § 1395l(t)*] for such service for such year, determined without regard to geographic adjustment under paragraph (2)(D) of such section,

the Secretary shall substitute the amount described in clause (ii), adjusted by the geographic adjustment factor described in paragraph (1)(C), for the fee schedule amount for such technical component for such year.

(B) Imaging services described. For purposes of subparagraph (A), imaging services described in this subparagraph are imaging and computer-assisted imaging services, including X-ray, ultrasound (including echocardiography), nuclear medicine (including positron emission tomography), magnetic resonance imaging, computed tomography, and fluoroscopy, but excluding diagnostic and screening mammography.

(5) Treatment of intensive cardiac rehabilitation program **[Caution: This paragraph applies to items and services furnished on or after January 1, 2010, as provided by § 144(a)(3) of Act July 15, 2008, P.L. 110-275, which appears as a note to this section.]**.

(A) In general. In the case of an intensive cardiac rehabilitation program described in section 1861(eee)(4) [*42 USCS § 1395x(eee)(4)*], the Secretary shall substitute the Medicare OPD fee schedule amount established under the prospective payment system for hospital outpatient department service under paragraph (3)(D) of section 1833(t) [*42*

USCS § 1395l(t)] for cardiac rehabilitation (under HCPCS codes 93797 and 93798 for calendar year 2007, or any succeeding HCPCS codes for cardiac rehabilitation).

(B) Definition of session. Each of the services described in subparagraphs (A) through (E) of section 1861(eee)(3) [*42 USCS § 1395x(eee)(3)*], when furnished for one hour, is a separate session of intensive cardiac rehabilitation.

(C) Multiple sessions per day. Payment may be made for up to 6 sessions per day of the series of 72 one-hour sessions of intensive cardiac rehabilitation services described in section 1861(eee)(4)(B) [*42 USCS § 1395x(eee)(4)(B)*].

(c) Determination of relative values for physicians' services.

(1) Division of physicians' services into components. In this section, with respect to a physicians' service:

(A) Work component defined. The term "work component" means the portion of the resources used in furnishing the service that reflects physician time and intensity in furnishing the service. Such portion shall--

(i) include activities before and after direct patient contact, and

(ii) be defined, with respect to surgical procedures, to reflect a global definition including pre-operative and post-operative physicians' services.

(B) Practice expense component defined. The term "practice expense component" means the portion of the resources used in furnishing the service that reflects the general categories of expenses (such as office rent and wages of personnel, but excluding malpractice expenses) comprising practice expenses.

(C) Malpractice component defined. The term "malpractice component" means the portion of the resources used in furnishing the service that reflects malpractice expenses in furnishing the service.

(2) Determination of relative values.

(A) In general.

(i) Combination of units for components. The Secretary shall develop a methodology for combining the work, practice expense, and malpractice relative value units, determined under subparagraph (C), for each service in a manner to produce a single relative value for that service. Such relative values are subject to adjustment under subparagraph (F)(i) and section 13515(b) of the Omnibus Budget Reconciliation Act of 1993 [*42 USCS § 1395u* note].

(ii) Extrapolation. The Secretary may use extrapolation and other techniques to determine the number of relative value units for physicians' services for which specific data are not available and shall take into account recommendations of the Physician Payment Review Commission [Medicare Payment Advisory Commission] and the results of consultations with organizations representing physicians who provide such services.

(B) Periodic review and adjustments in relative values.

(i) Periodic review. The Secretary, not less often than every 5 years, shall review the relative values established under this paragraph for all physicians' services.

(ii) Adjustments.

(I) In general. The Secretary shall, to the extent the Secretary determines to be necessary and subject to subclause (II), adjust the number of such units to take into account changes in medical practice, coding changes, new data on relative value components, or the addition of new procedures. The Secretary shall publish an explanation of the basis for such adjustments.

(II) Limitation on annual adjustments. Subject to clauses (iv) and (v), the adjustments under subclause (I) for a year may not cause the amount of expenditures under this part [*42 USCS §§ 1395j* et seq.] for the year to differ by more than $ 20,000,000 from the amount of expenditures under this part [*42 USCS §§ 1395j* et seq.] that would have been made if such adjustments had not been made.

(iii) Consultation. The Secretary, in making adjustments under clause (ii), shall consult with the Medicare Payment Advisory Commission and organizations representing physicians.

(iv) Exemption of certain additional expenditures from budget neutrality. The additional expenditures attributable to--

(I) subparagraph (H) shall not be taken into account in applying clause (ii)(II) for 2004;

(II) subparagraph (I) insofar as it relates to a physician fee schedule for 2005 or 2006 shall not be taken into account in applying clause (ii)(II) for drug administration services under the fee schedule for such year for a specialty described in subparagraph (I)(ii)(II); and

(III) subparagraph (J) insofar as it relates to a physician fee schedule for 2005 or 2006 shall not be taken into account in applying clause (ii)(II) for drug administration services under the fee schedule for such year.

(v) Exemption of certain reduced expenditures from budget-neutrality calculation. The following reduced expenditures, as estimated by the Secretary, shall not be taken into account in applying clause (ii)(II):

(I) Reduced payment for multiple imaging procedures. Effective for fee schedules established beginning with 2007, reduced expenditures attributable to the multiple procedure payment reduction for imaging under the final rule published by the Secretary in the Federal Register on November 21, 2005 (42 CFR 405, et al.) insofar as it relates to the physician fee schedules for 2006 and 2007.

(II) OPD payment cap for imaging services. Effective for fee schedules established beginning with 2007, reduced expenditures attributable to subsection (b)(4).

(vi) Alternative application of budget-neutrality adjustment. Notwithstanding subsection (d)(9)(A), effective for fee schedules established beginning with 2009, with respect to the 5-year review of work relative value units used in fee schedules for 2007 and 2008, in lieu of continuing to apply budget-neutrality adjustments required under clause (ii) for 2007 and 2008 to work relative value units, the Secretary shall apply such budget-neutrality adjustments to the conversion factor otherwise determined for years beginning with 2009.

(C) Computation of relative value units for components. For purposes of this section for each physicians' service--

(i) Work relative value units. The Secretary shall determine a number of work relative value units for the service based on the relative resources incorporating physician time and intensity required in furnishing the service.

(ii) Practice expense relative value units. The Secretary shall determine a number of practice expense relative value units for the service for years before 1999 equal to the product of--

(I) the base allowed charges (as defined in subparagraph (D)) for the service, and

(II) the practice expense percentage for the service (as determined under paragraph (3)(C)(ii)),

and for years beginning with 1999 based on the relative practice expense resources involved in furnishing the service. For 1999, such number of units shall be determined based 75 percent on such product and based 25 percent on the relative practice expense resources involved in furnishing the service. For 2000, such number of units shall be determined based 50 percent on such product and based 50 percent on such relative practice expense resources. For 2001, such number of units shall be determined based 25 percent on such product and based 75 percent on such relative practice expense resources. For a subsequent year, such number of units shall be determined based entirely on such relative practice expense resources.

(iii) Malpractice relative value units. The Secretary shall determine a number of malpractice relative value units for the service for years before 2000 equal to the product of--

(I) the base allowed charges (as defined in subparagraph (D)) for the service, and

(II) the malpractice percentage for the service (as determined under paragraph (3)(C)(iii)),

and for years beginning with 2000 based on the malpractice expense resources involved in furnishing the service.

(D) Base allowed charges defined. In this paragraph, the term "base allowed charges" means, with respect to a physician's service, the national average allowed charges for the service under this part [*42 USCS §§ 1395j* et seq.] for services furnished during 1991, as estimated by the Secretary using the most recent data available.

(E) Reduction in practice expense relative value units for certain services.

(i) In general. Subject to clause (ii), the Secretary shall reduce the practice expense relative value units applied to services described in clause (iii) furnished in--

(I) 1994, by 25 percent of the number by which the number of practice expense relative value units (determined for 1994 without regard to this subparagraph) exceeds the number of work relative value units determined for 1994,

(II) 1995, by an additional 25 percent of such excess, and

(III) 1996, by an additional 25 percent of such excess.

(ii) Floor on reductions. The practice expense relative value units for a physician's service shall not be reduced under this subparagraph to a number less than 128 percent of the number of work relative value units.

(iii) Services covered. For purposes of clause (i), the services described in this clause are physicians' services that are not described in clause (iv) and for which--

(I) there are work relative value units, and

(II) the number of practice expense relative value units (determined for 1994) exceeds 128 percent of the number of work relative value units (determined for such year).

(iv) Excluded services. For purposes of clause (iii), the services described in this clause are services which the Secretary determines at least 75 percent of which are provided under this title in an office setting.

(F) Budget neutrality adjustments. The Secretary--

(i) shall reduce the relative values for all services (other than anesthesia services) established under this paragraph (and, in the case of anesthesia services, the conversion factor established by the Secretary for such services) by such percentage as the Secretary determines to be necessary so that, beginning in 1996, the amendment made by section 13514(a) of the Omnibus Budget Reconciliation Act of 1993 would not result in expenditures under this section that exceed the amount of such expenditures that would have been made if such amendment had not been made, and

(ii) shall reduce the amounts determined under subsection (a)(2)(B)(ii)(I) by such percentage as the Secretary determines to be required to assure that, taking into account the reductions made under clause (i), the amendment made by section 13514(a) of the Omnibus Budget Reconciliation Act of 1993 would not result in expenditures under this section in 1994 that exceed the amount of such expenditures that would have been made if such amendment had not been made.

(G) Adjustments in relative value units for 1998.

(i) In general. The Secretary shall--

(I) subject to clauses (iv) and (v), reduce the practice expense relative value units applied to any services described in clause (ii) furnished in 1998 to a number equal to 110 percent of the number of work relative value units, and

(II) increase the practice expense relative value units for office visit procedure codes during 1998 by a uniform percentage which the Secretary estimates will result in an aggregate increase in payments for such services equal to the aggregate decrease in payments by reason of subclause (I).

(ii) Services covered. For purposes of clause (i), the services described in this clause are physicians' services that are not described in clause (iii) and for which--

(I) there are work relative value units, and

(II) the number of practice expense relative value units (determined for 1998) exceeds 110 percent of the number of work relative value units (determined for such year).

(iii) Excluded services. For purposes of clause (ii), the services described in this clause are services which the Secretary determines at least 75 percent of which are provided under this title in an office setting.

(iv) Limitation on aggregate reallocation. If the application of clause (i)(I) would result in an aggregate amount of reductions under such clause in excess of $ 390,000,000, such clause shall be applied by substituting for 110 percent such greater percentage as the Secretary estimates will result in the aggregate amount of such reductions equaling $ 390,000,000.

(v) No reduction for certain services. Practice expense relative value units for a procedure performed in an office or in a setting out of an office shall not be reduced under clause (i) if the in-office or out-of-office practice expense relative value, respectively, for the procedure would increase under the proposed rule on resource-based practice expenses issued by the Secretary on June 18, 1997 *(62 Federal Register 33158* et seq.).

(H) Adjustments in practice expense relative value units for certain drug administration services beginning in 2004.

(i) Use of survey data. In establishing the physician fee schedule under subsection (b) with respect to payments for services furnished on or after January 1, 2004, the Secretary shall, in determining practice expense relative value units under this subsection, utilize a survey submitted to the Secretary as of January 1, 2003, by a physician specialty organization pursuant to section 212 of the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999 [note to this section] if the survey--

(I) covers practice expenses for oncology drug administration services; and

(II) meets criteria established by the Secretary for acceptance of such surveys.

(ii) Pricing of clinical oncology nurses in practice expense methodology. If the survey described in clause (i) includes data on wages, salaries, and compensation of clinical oncology nurses, the Secretary shall utilize such data in the methodology for determining practice expense relative value units under subsection (c).

(iii) Work relative value units for certain drug administration services. In establishing the relative value units under this paragraph for drug administration services described in clause (iv) furnished on or after January 1, 2004, the Secretary shall establish work relative value units equal to the work relative value units for a level 1 office medical visit for an established patient.

(iv) Drug administration services described. The drug administration services described in this clause are physicians' services--

(I) which are classified as of October 1, 2003, within any of the following groups of procedures: therapeutic or diagnostic infusions (excluding chemotherapy); chemotherapy administration services; and therapeutic, prophylactic, or diagnostic injections;

(II) for which there are no work relative value units assigned under this subsection as of such date; and

(III) for which national relative value units have been assigned under this subsection as of such date.

(I) Adjustments in practice expense relative value units for certain drug administration services beginning with 2005.

(i) In general. In establishing the physician fee schedule under subsection (b) with respect to payments for services furnished on or after January 1, 2005 or 2006, the Secretary shall adjust the practice expense relative value units for such year consistent with clause (ii).

(ii) Use of supplemental survey data.

(I) In general. Subject to subclause (II), if a specialty submits to the Secretary by not later than March 1, 2004, for 2005, or March 1, 2005, for 2006, data that includes expenses for the administration of drugs and biologicals for which the payment amount is determined pursuant to section 1842(o), the Secretary shall use such supplemental survey data in carrying out this subparagraph for the years involved insofar as they are collected and provided by entities and organizations consistent with the criteria established by the Secretary pursuant to section 212(a) of the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999 [note to this section].

(II) Limitation on specialty. Subclause (I) shall apply to a specialty only insofar as not less than 40 percent of payments for the specialty under this title in 2002 are attributable to the administration of drugs and biologicals, as determined by the Secretary.

(III) Application. This clause shall not apply with respect to a survey to which subparagraph (H)(i) applies.

(J) Provisions for appropriate reporting and billing for physicians' services associated with the administration of covered outpatient drugs and biologicals.

(i) Evaluation of codes. The Secretary shall promptly evaluate existing drug administration codes for physicians' services to ensure accurate reporting and billing for such services, taking into account levels of complexity of the administration and resource consumption.

(ii) Use of existing processes. In carrying out clause (i), the Secretary shall use existing processes for the consideration of coding changes and, to the extent coding changes are made, shall use such processes in establishing relative values for such services.

(iii) Implementation. In carrying out clause (i), the Secretary shall consult with representatives of physician specialties affected by the implementation of section 1847A or section 1847B [*42 USCS § 1395w-3a* or *1395w-3b*], and shall take such steps within the Secretary's authority to expedite such considerations under clause (ii).

(iv) Subsequent, budget neutral adjustments permitted. Nothing in subparagraph (H) or (I) or this subparagraph shall be construed as preventing the Secretary from providing for adjustments in practice expense relative value units under (and consistent with) subparagraph (B) for years after 2004, 2005, or 2006, respectively.

(3) Component percentages. For purposes of paragraph (2), the Secretary shall determine a work percentage, a practice expense percentage, and a malpractice percentage for each physician's service as follows:

(A) Division of services by specialty. For each physician's service or class of physicians' services, the Secretary shall determine the average percentage of each such service or class of services that is performed, nationwide, under this part [*42 USCS §§ 1395j* et seq.] by physicians in each of the different physician specialties (as identified by the Secretary).

(B) Division of specialty by component. The Secretary shall determine the average percentage division of resources, among the work component, the practice expense component, and the malpractice component, used by physicians in each of such specialties in furnishing physicians' services. Such percentages shall be based on national data that describe the elements of physician practice costs and revenues, by physician specialty. The Secretary may use extrapolation and other techniques to determine practice costs and revenues for specialties for which adequate data are not available.

(C) Determination of component percentages.

(i) Work percentage. The work percentage for a service (or class of services) is equal to the sum (for all physician specialties) of--

(I) the average percentage division for the work component for each physician specialty (determined under subparagraph (B)), multiplied by

(II) the proportion (determined under subparagraph (A)) of such service (or services) performed by physicians in that specialty.

(ii) Practice expense percentage. For years before 2002, the practice expense percentage for a service (or class of services) is equal to the sum (for all physician specialties) of--

(I) the average percentage division for the practice expense component for each physician specialty (determined under subparagraph (B)), multiplied by

(II) the proportion (determined under subparagraph (A)) of such service (or services) performed by physicians in that specialty.

(iii) Malpractice percentage. For years before 1999, the malpractice percentage for a service (or class of services) is equal to the sum (for all physician specialties) of--

(I) the average percentage division for the malpractice component for each physician specialty (determined under subparagraph (B)), multiplied by

(II) the proportion (determined under subparagraph (A)) of such service (or services) performed by physicians in that specialty.

(D) Periodic recomputation. The Secretary may, from time to time, provide for the recomputation of work percentages, practice expense percentages, and malpractice percentages determined under this paragraph.

(4) Ancillary policies. The Secretary may establish ancillary policies (with respect to the use of modifiers, local codes, and other matters) as may be necessary to implement this section.

(5) Coding. The Secretary shall establish a uniform procedure coding system for the coding of all physicians' services. The Secretary shall provide for an appropriate coding structure for visits and consultations. The Secretary may incorporate the use of time in the coding for visits and consultations. The Secretary, in establishing such coding system, shall consult with the Physician Payment Review Commission [Medicare Payment Advisory Commission] and other organizations representing physicians.

(6) No variation for specialists. The Secretary may not vary the conversion factor or the number of relative value units for a physicians' service based on whether the physician furnishing the service is a specialist or based on the type of specialty of the physician.

(d) Conversion factors.

(1) Establishment.

(A) In general. The conversion factor for each year shall be the conversion factor established under this subsection for the previous year (or, in the case of 1992, specified in subparagraph (B)) adjusted by the update (established under paragraph (3)) for the year involved (for years before 2001) and, for years beginning with 2001, multiplied by the update (established under paragraph (4)) for the year involved.

(B) Special provision for 1992. For purposes of subparagraph (A), the conversion factor specified in this subparagraph is a conversion factor (determined by the Secretary) which, if this section were to apply during 1991 using such conversion factor, would result in the same aggregate amount of payments under this part [*42 USCS §§ 1395j* et seq.] for physicians' services as the estimated aggregate amount of the payments under this part for such services in 1991.

(C) Special rules for 1998. Except as provided in subparagraph (D), the single conversion factor for 1998 under this subsection shall be the conversion factor for primary care services for 1997, increased by the Secretary's estimate of the weighted average of the three separate updates that would otherwise occur were it not for the enactment of chapter 1 of subtitle F of title IV of the Balanced Budget Act of 1997.

(D) Special rules for anesthesia services. The separate conversion factor for anesthesia services for a year shall be equal to 46 percent of the single conversion factor established for other physicians' services, except as adjusted for changes in work, practice expense, or malpractice relative value units.

(E) Publication and dissemination of information. The Secretary shall--

(i) cause to have published in the Federal Register not later than November 1 of each year (beginning with 2000) the conversion factor which will apply to physicians' services for the succeeding year, the update determined under paragraph (4) for such succeeding year, and the allowed expenditures under such paragraph for such succeeding year; and

(ii) make available to the Medicare Payment Advisory Commission and the public by March 1 of each year (beginning with 2000) an estimate of the sustainable growth rate and of the conversion factor which will apply to physicians' services for the succeeding year and data used in making such estimate.

(2) [Deleted]

(3) Update for 1999 and 2000.

(A) In general. Unless otherwise provided by law, subject to subparagraph (D) and the budget-neutrality factor determined by the Secretary under subsection (c)(2)(B)(ii), the update to the single conversion factor established in paragraph (1)(C) for 1999 and 2000 is equal to the product of--

(i) 1 plus the Secretary's estimate of the percentage increase in the MEI (as defined in section 1842(i)(3) [*42 USCS § 1395u(i)(3)*]) for the year (divided by 100), and

(ii) 1 plus the Secretary's estimate of the update adjustment factor for the year (divided by 100),

minus 1 and multiplied by 100.

(B) Update adjustment factor. For purposes of subparagraph (A)(ii), the "update adjustment factor" for a year is equal (as estimated by the Secretary) to--

(i) the difference between (I) the sum of the allowed expenditures for physicians' services (as determined under subparagraph (C)) for the period beginning April 1, 1997, and ending on March 31 of the year involved, and (II) the amount of actual expenditures for physicians' services furnished during the period beginning April 1, 1997, and ending on March 31 of the preceding year; divided by

(ii) the actual expenditures for physicians' services for the 12-month period ending on March 31 of the preceding year, increased by the sustainable growth rate under subsection (f) for the fiscal year which begins during such 12-month period.

(C) Determination of allowed expenditures. For purposes of this paragraph and paragraph (4), the allowed expenditures for physicians' services for the 12-month period ending with March 31 of--

(i) 1997 is equal to the actual expenditures for physicians' services furnished during such 12-month period, as estimated by the Secretary; or

(ii) a subsequent year is equal to the allowed expenditures for physicians' services for the previous year, increased by the sustainable growth rate under subsection (f) for the fiscal year which begins during such 12-month period.

(D) Restriction on variation from medicare economic index. Notwithstanding the amount of the update adjustment factor determined under subparagraph (B) for a year, the update in the conversion factor under this paragraph for the year may not be--

(i) greater than 100 times the following amount: (1.03 + (MEI percentage/100)) - 1; or

(ii) less than 100 times the following amount: (0.93 + (MEI percentage/100)) - 1,

where "MEI percentage" means the Secretary's estimate of the percentage increase in the MEI (as defined in section 1842(i)(3) [*42 USCS § 1395u(i)(3)*]) for the year involved.

(4) Update for years beginning with 2001.

(A) In general. Unless otherwise provided by law, subject to the budget-neutrality factor determined by the Secretary under subsection (c)(2)(B)(ii) and subject to adjustment under subparagraph (F), the update to the single conversion factor established in paragraph (1)(C) for a year beginning with 2001 is equal to the product of--

(i) 1 plus the Secretary's estimate of the percentage increase in the MEI (as defined in section 1842(i)(3) [*42 USCS § 1395u(i)(3)*]) for the year (divided by 100); and

(ii) 1 plus the Secretary's estimate of the update adjustment factor under subparagraph (B) for the year.

(B) Update adjustment factor. For purposes of subparagraph (A)(ii), subject to subparagraph (D) and the succeeding paragraphs of this subsection, the "update adjustment factor" for a year is equal (as estimated by the Secretary) to the sum of the following:

(i) Prior year adjustment component. An amount determined by--

(I) computing the difference (which may be positive or negative) between the amount of the allowed expenditures for physicians' services for the prior year (as determined under subparagraph (C)) and the amount of the actual expenditures for such services for that year;

(II) dividing that difference by the amount of the actual expenditures for such services for that year; and

(III) multiplying that quotient by 0.75.

(ii) Cumulative adjustment component. An amount determined by--

(I) computing the difference (which may be positive or negative) between the amount of the allowed expenditures for physicians' services (as determined under subparagraph (C)) from April 1, 1996, through the end of the prior year and the amount of the actual expenditures for such services during that period;

(II) dividing that difference by actual expenditures for such services for the prior year as increased by the sustainable growth rate under subsection (f) for the year for which the update adjustment factor is to be determined; and

(III) multiplying that quotient by 0.33.

(C) Determination of allowed expenditures. For purposes of this paragraph:

(i) Period up to April 1, 1999. The allowed expenditures for physicians' services for a period before April 1, 1999, shall be the amount of the allowed expenditures for such period as determined under paragraph (3)(C).

(ii) Transition to calendar year allowed expenditures. Subject to subparagraph (E), the allowed expenditures for--

(I) the 9-month period beginning April 1, 1999, shall be the Secretary's estimate of the amount of the allowed expenditures that would be permitted under paragraph (3)(C) for such period; and

(II) the year of 1999, shall be the Secretary's estimate of the amount of the allowed expenditures that would be permitted under paragraph (3)(C) for such year.

(iii) Years beginning with 2000. The allowed expenditures for a year (beginning with 2000) is equal to the allowed expenditures for physicians' services for the previous year, increased by the sustainable growth rate under subsection (f) for the year involved.

(D) Restriction on update adjustment factor. The update adjustment factor determined under subparagraph (B) for a year may not be less than - 0.07 or greater than 0.03.

(E) Recalculation of allowed expenditures for updates beginning with 2001. For purposes of determining the update adjustment factor for a year beginning with 2001, the Secretary shall recompute the allowed expenditures for previous periods beginning on or after April 1, 1999, consistent with subsection (f)(3).

(F) Transitional adjustment designed to provide for budget neutrality. Under this subparagraph the Secretary shall provide for an adjustment to the update under subparagraph (A)--

(i) for each of 2001, 2002, 2003, and 2004, of - 0.2 percent; and

(ii) for 2005 of + 0.8 percent.

(5) Update for 2004 and 2005. The update to the single conversion factor established in paragraph (1)(C) for each of 2004 and 2005 shall be not less than 1.5 percent.

(6) Update for 2006. The update to the single conversion factor established in paragraph (1)(C) for 2006 shall be 0 percent.

(7) Conversion factor for 2007.

(A) In general. The conversion factor that would otherwise be applicable under this subsection for 2007 shall be the amount of such conversion factor divided by the product of--

(i) 1 plus the Secretary's estimate of the percentage increase in the MEI (as defined in section 1842(i)(3) [*42 USCS § 1395u(i)(3)*]) for 2007 (divided by 100); and

(ii) 1 plus the Secretary's estimate of the update adjustment factor under paragraph (4)(B) for 2007.

(B) No effect on computation of conversion factor for 2008. The conversion factor under this subsection shall be computed under paragraph (1)(A) for 2008 as if subparagraph (A) had never applied.

(8) Update for 2008.

(A) In general. Subject to paragraph (7)(B), in lieu of the update to the single conversion factor established in paragraph (1)(C) that would otherwise apply for 2008, the update to the single conversion factor shall be 0.5 percent.

(B) No effect on computation of conversion factor for 2009. The conversion factor under this subsection shall be computed under paragraph (1)(A) for 2009 and subsequent years as if subparagraph (A) had never applied.

(9) Update for 2009.

(A) In general. Subject to paragraphs (7)(B) and (8)(B), in lieu of the update to the single conversion factor established in paragraph (1)(C) that would otherwise apply for 2009, the update to the single conversion factor shall be 1.1 percent.

(B) No effect on computation of conversion factor for 2010 and subsequent years. The conversion factor under this subsection shall be computed under paragraph (1)(A) for 2010 and subsequent years as if subparagraph (A) had never applied.

(e) Geographic adjustment factors.

(1) Establishment of geographic indices.

(A) In general. Subject to subparagraphs (B), (C), (E), and (G), the Secretary shall establish--

(i) an index which reflects the relative costs of the mix of goods and services comprising practice expenses (other than malpractice expenses) in the different fee schedule areas compared to the national average of such costs,

(ii) an index which reflects the relative costs of malpractice expenses in the different fee schedule areas compared to the national average of such costs, and

(iii) an index which reflects 1/4 of the difference between the relative value of physicians' work effort in each of the different fee schedule areas and the national average of such work effort.

(B) Class-specific geographic cost-of-practice indices. The Secretary may establish more than one index under subparagraph (A)(i) in the case of classes of physicians' services, if, because of differences in the mix of goods and services comprising practice expenses for the different classes of services, the application of a single index under such clause to different classes of such services would be substantially inequitable.

(C) Periodic review and adjustments in geographic adjustment factors. The Secretary, not less often than every 3 years, shall, in consultation with appropriate representatives of physicians, review the indices established under subparagraph (A) and the geographic index values applied under this subsection for all fee schedule areas. Based on such review, the Secretary may revise such index and adjust such index values, except that, if more than 1 year has elasped [elapsed] since the date of the last previous adjustment, the adjustment to be applied in the first year of the next adjustment shall be 1/2 of the adjustment that otherwise would be made.

(D) Use of recent data. In establishing indices and index values under this paragraph, the Secretary shall use the most recent data available relating to practice expenses, malpractice expenses, and physician work effort in different fee schedule areas.

(E) Floor at 1.0 on work geographic index. After calculating the work geographic index in subparagraph (A)(iii), for purposes of payment for services furnished on or after January 1, 2004, and before January 1, 2010, the Secretary shall increase the work geographic index to 1.00 for any locality for which such work geographic index is less than 1.00.

(F) [Not enacted]

(G) Floor for practice expense, malpractice, and work geographic indices for services furnished in Alaska. For purposes of payment for services furnished in Alaska on or after January 1, 2004, and before January 1, 2006, after calculating the practice expense, malpractice, and work geographic indices in clauses (i), (ii), and (iii) of subparagraph (A) and in subparagraph (B), the Secretary shall increase any such index to 1.67 if such index would otherwise be less than 1.67. For purposes of payment for services furnished in the State described in the preceding sentence on or after January 1, 2009, after calculating the work geographic index in subparagraph (A)(iii), the Secretary shall increase the work geographic index to 1.5 if such index would otherwise be less than 1.5[.]

(2) Computation of geographic adjustment factor. For purposes of subsection (b)(1)(C), for all physicians' services for each fee schedule area the Secretary shall establish a geographic adjustment factor equal to the sum of the geographic cost-of-practice adjustment factor (specified in paragraph (3)), the geographic malpractice adjustment factor (specified in paragraph (4)), and the geographic physician work adjustment factor (specified in paragraph (5)) for the service and the area.

(3) Geographic cost-of-practice adjustment factor. For purposes of paragraph (2), the "geographic cost-of-practice adjustment factor", for a service for a fee schedule area, is the product of--

(A) the proportion of the total relative value for the service that reflects the relative value units for the practice expense component, and

(B) the geographic cost-of-practice index value for the area for the service, based on the index established under paragraph (1)(A)(i) or (1)(B) (as the case may be).

(4) Geographic malpractice adjustment factor. For purposes of paragraph (2), the "geographic malpractice adjustment factor", for a service for a fee schedule area, is the product of--

(A) the proportion of the total relative value for the service that reflects the relative value units for the malpractice component, and

(B) the geographic malpractice index value for the area, based on the index established under paragraph (1)(A)(ii).

(5) Geographic physician work adjustment factor. For purposes of paragraph (2), the "geographic physician work adjustment factor", for a service for a fee schedule area, is the product of--

(A) the proportion of the total relative value for the service that reflects the relative value units for the work component, and

(B) the geographic physician work index value for the area, based on the index established under paragraph (1)(A)(iii).

(f) Sustainable growth rate.

(1) Publication. The Secretary shall cause to have published in the Federal Register not later than--

(A) November 1, 2000, the sustainable growth rate for 2000 and 2001; and

(B) November 1 of each succeeding year the sustainable growth rate for such succeeding year and each of the preceding 2 years.

(2) Specification of growth rate. The sustainable growth rate for all physicians' services for a fiscal year (beginning with fiscal year 1998 and ending with fiscal year 2000) and a year beginning with 2000 shall be equal to the product of--

(A) 1 plus the Secretary's estimate of the weighted average percentage increase (divided by 100) in the fees for all physicians' services in the applicable period involved,

(B) 1 plus the Secretary's estimate of the percentage change (divided by 100) in the average number of individuals enrolled under this part [*42 USCS §§ 1395j* et seq.] (other than Medicare + Choice plan enrollees) from the previous applicable period to the applicable period involved,

(C) 1 plus the Secretary's estimate of the annual average percentage growth in real gross domestic product per capita (divided by 100) during the 10-year period ending with the applicable period involved, and

(D) 1 plus the Secretary's estimate of the percentage change (divided by 100) in expenditures for all physicians' services in the applicable period (compared with the previous applicable period) which will result from changes in law and regulations, determined without taking into account estimated changes in expenditures resulting from the update adjustment factor determined under subsection (d)(3)(B) or (d)(4)(B), as the case may be,

minus 1 and multiplied by 100.

(3) Data to be used. For purposes of determining the update adjustment factor under subsection (d)(4)(B) for a year beginning with 2001, the sustainable growth rates taken into consideration in the determination under paragraph (2) shall be determined as follows.

(A) For 2001. For purposes of such calculations for 2001, the sustainable growth rates for fiscal year 2000 and the years 2000 and 2001 shall be determined on the basis of the best data available to the Secretary as of September 1, 2000.

(B) For 2002. For purposes of such calculations for 2002, the sustainable growth rates for fiscal year 2000 and for years 2000, 2001, and 2002 shall be determined on the basis of the best data available to the Secretary as of September 1, 2001.

(C) For 2003 and succeeding years. For purposes of such calculations for a year after 2002--

(i) the sustainable growth rates for that year and the preceding 2 years shall be determined on the basis of the best data available to the Secretary as of September 1 of the year preceding the year for which the calculation is made; and

(ii) the sustainable growth rate for any year before a year described in clause (i) shall be the rate as most recently determined for that year under this subsection.

Nothing in this paragraph shall be construed as affecting the sustainable growth rates established for fiscal year 1998 or fiscal year 1999.

(4) Definitions. In this subsection:

(A) Services included in physicians' services. The term "physicians' services" includes other items and services (such as clinical diagnostic laboratory tests and radiology services), specified by the Secretary, that are commonly performed or furnished by a physician or in a physician's office, but does not include services furnished to a Medicare + Choice plan enrollee.

(B) Medicare + choice plan enrollee. The term "Medicare + Choice plan enrollee" means, with respect to a fiscal year, an individual enrolled under this part [*42 USCS §§ 1395j* et seq.] who has elected to receive benefits under this *title [42 USCS §§ 1395* et seq.] for the fiscal year through a Medicare + Choice plan offered under part C [*42 USCS §§*

1395w-21 et seq.], and also includes an individual who is receiving benefits under this part [*42 USCS §§ 1395j* et seq.] through enrollment with an eligible organization with a risk-sharing contract under section 1876 [*42 USCS § 1395mm*].

(C) Applicable period. The term "applicable period" means--

(i) a fiscal year, in the case of fiscal year 1998, fiscal year 1999, and fiscal year 2000; or

(ii) a calendar year with respect to a year beginning with 2000; as the case may be.

(g) Limitation on beneficiary liability.

(1) Limitation on actual charges.

(A) In general. In the case of a nonparticipating physician or nonparticipating supplier or other person (as defined in section 1842(i)(2) [*42 USCS § 1395u(i)(2)*]) who does not accept payment on an assignment-related basis for a physician's service furnished with respect to an individual enrolled under this part [*42 USCS §§ 1395j* et seq.], the following rules apply:

(i) Application of limiting charge. No person may bill or collect an actual charge for the service in excess of the limiting charge described in paragraph (2) for such service.

(ii) No liability for excess charges. No person is liable for payment of any amounts billed for the service in excess of such limiting charge.

(iii) Correction of excess charges. If such a physician, supplier, or other person bills, but does not collect, an actual charge for a service in violation of clause (i), the physician, supplier, or other person shall reduce on a timely basis the actual charge billed for the service to an amount not to exceed the limiting charge for the service.

(iv) Refund of excess collections. If such a physician, supplier, or other person collects an actual charge for a service in violation of clause (i), the physician, supplier, or other person shall provide on a timely basis a refund to the individual charged in the amount by which the amount collected exceeded the limiting charge for the service. The amount of such a refund shall be reduced to the extent the individual has an outstanding balance owed by the individual to the physician.

(B) Sanctions. If a physician, supplier, or other person--

(i) knowingly and willfully bills or collects for services in violation of subparagraph (A)(i) on a repeated basis, or

(ii) fails to comply with clause (iii) or (iv) of subparagraph (A) on a timely basis,

the Secretary may apply sanctions against the physician, supplier, or other person in accordance with paragraph (2) of section 1842(j) [*42 USCS § 1395u(j)*]. In applying this subparagraph, paragraph (4) of such section applies in the same manner as such paragraph applies to such section and any reference in such section to a physician is deemed also to include a reference to a supplier or other person under this subparagraph.

(C) Timely basis. For purposes of this paragraph, a correction of a bill for an excess charge or refund of an amount with respect to a violation of subparagraph (A)(i) in the case of a service is considered to be provided "on a timely basis", if the reduction or refund is made not later than 30 days after the date the physician, supplier, or other person is notified by the carrier under this part [*42 USCS §§ 1395j* et seq.] of such violation and of the requirements of subparagraph (A).

(2) "Limiting charge" defined.

(A) For 1991. For physicians' services of a physician furnished during 1991, other than radiologist services subject to section 1834(b) [*42 USCS § 1395m(b)*], the "limiting charge" shall be the same percentage (or, if less, 25 percent) above the recognized payment amount under this part [*42 USCS §§ 1395j* et seq.] with respect to the physician (as a nonparticipating physician) as the percentage by which--

(i) the maximum allowable actual charge (as determined under section 1842(j)(1)(C) [*42 USCS § 1395u(j)(1)(C)*] as of December 31, 1990, or, if less, the maximum actual charge otherwise permitted for the service under this part [*42 USCS §§ 1395j* et seq.] as of such date) for the service of the physician, exceeds

(ii) the recognized payment amount for the service of the physician (as a nonparticipating physician) as of such date.

In the case of evaluation and management services (as specified in section 1842(b)(16)(B)(ii) [*42 USCS § 1395u(b)(16)(B)(ii)*]), the preceding sentence shall be applied by substituting "40 percent" for "25 percent".

(B) For 1992. For physicians' services furnished during 1992, other than radiologist services subject to section 1834(b) [*42 USCS § 1395m(b)*], the "limiting charge" shall be the same percentage (or, if less, 20 percent) above the recognized payment amount under this part [*42 USCS §§ 1395j* et seq.] for nonparticipating physicians as the percentage by which--

(i) the limiting charge (as determined under subparagraph (A) as of December 31, 1991) for the service, exceeds

(ii) the recognized payment amount for the service for nonparticipating physicians as of such date.

(C) After 1992. For physicians' services furnished in a year after 1992, the "limiting charge" shall be 115 percent of the recognized payment amount under this part [*42 USCS §§ 1395j* et seq.] for nonparticipating physicians or for nonparticipating suppliers or other persons.

(D) Recognized payment amount. In this section, the term "recognized payment amount" means, for services furnished on or after January 1, 1992, the fee schedule amount determined under subsection (a) (or, if payment under this part [*42 USCS §§ 1395j* et seq.] is made on a basis other than the fee schedule under this section, 95 percent of the other payment basis), and, for services furnished during 1991, the applicable percentage (as defined in section 1842(b)(4)(A)(iv) [*42 USCS § 1395u(b)(4)(A)(iv)*]) of the prevailing charge (or fee schedule amount) for nonparticipating physicians for that year.

(3) Limitation on charges for medicare beneficiaries eligible for medicaid benefits.

(A) In general. Payment for physicians' services furnished on or after April 1, 1990, to an individual who is enrolled under this part [*42 USCS §§ 1395j* et seq.] and eligible for any medical assistance (including as a qualified medicare beneficiary, as defined in section 1905(p)(1) [*42 USCS § 1396d(p)(1)*]) with respect to such services under a State plan approved under title XIX [*42 USCS §§ 1396* et seq.] may only be made on an assignment-related basis and the provisions of section 1902(n)(3)(A) [*42 USCS § 1396a(n)(3)(A)*] apply to further limit permissible charges under this section.

(B) Penalty. A person may not bill for physicians' services subject to subparagraph (A) other than on an assignment-related basis. No person is liable for payment of any amounts billed for such a service in violation of the previous sentence. If a person knowingly and willfully bills for physicians' services in violation of the first sentence, the Secretary may apply sanctions against the person in accordance with section 1842(j)(2) [*42 USCS § 1395u(j)(2)*].

(4) Physician submission of claims.

(A) In general. For services furnished on or after September 1, 1990, within 1 year after the date of providing a service for which payment is made under this part [*42 USCS §§ 1395j* et seq.] on a reasonable charge or fee schedule basis, a physician, supplier, or other person (or an employer or facility in the cases described in section 1842(b)(6)(A) [*42 USCS § 1395u(b)(6)(A)*])--

(i) shall complete and submit a claim for such service on a standard claim form specified by the Secretary to the carrier on behalf of a beneficiary, and

(ii) may not impose any charge relating to completing and submitting such a form.

(B) Penalty.

(i) With respect to an assigned claim wherever a physician, provider, supplier or other person (or an employer or facility in the cases described in section 1842(b)(6)(A) [*42 USCS § 1395u(b)(6)(A)*]) fails to submit such a claim as required in subparagraph (A), the Secretary shall reduce by 10 percent the amount that would otherwise be paid for such claim under this part [*42 USCS §§ 1395j* et seq.].

(ii) If a physician, supplier, or other person (or an employer or facility in the cases described in section 1842(b)(6)(A) [*42 USCS § 1395u(b)(6)(A)*]) fails to submit a claim required to be submitted under subparagraph (A) or imposes a charge in violation of such subparagraph, the Secretary shall apply the sanction with respect to such a violation in the same manner as a sanction may be imposed under section 1842(p)(3) [*42 USCS § 1395u(p)(3)*] for a violation of section 1842(p)(1) [*42 USCS § 1395u(p)(1)*].

(5) Electronic billing; direct deposit. The Secretary shall encourage and develop a system providing for expedited payment for claims submitted electronically. The Secretary shall also encourage and provide incentives allowing for direct deposit as payments for services furnished by participating physicians. The Secretary shall provide physicians with such technical information as necessary to enable such physicians to submit claims electronically. The Secretary shall submit a plan to Congress on this paragraph by May 1, 1990.

(6) Monitoring of charges.

(A) In general. The Secretary shall monitor--

(i) the actual charges of nonparticipating physicians for physicians' services furnished on or after January 1, 1991, to individuals enrolled under this part [*42 USCS §§ 1395j* et seq.], and

(ii) changes (by specialty, type of service, and geographic area) in (I) the proportion of expenditures for physicians' services provided under this part [*42 USCS §§ 1395j* et seq.] by participating physicians, (II) the proportion of expenditures for such services for which payment is made under this part on an assignment-related basis, and (III) the amounts charged above the recognized payment amounts under this part [*42 USCS §§ 1395j* et seq.].

(B) Report. The Secretary shall, by not later than April 15 of each year (beginning in 1992), report to the Congress information on the extent to which actual charges exceed limiting charges, the number and types of services involved, and the average amount of excess charges and information regarding the changes described in subparagraph (A)(ii).

(C) Plan. If the Secretary finds that there has been a significant decrease in the proportions described in subclauses (I) and (II) of subparagraph (A)(ii) or an increase in the amounts described in subclause (III) of that subparagraph, the Secretary shall develop a plan to address such a problem and transmit to Congress recommendations regarding the plan. The Medicare Payment Advisory Commission shall review the Secretary's plan and recommendations and transmit to Congress its comments regarding such plan and recommendations.

(7) Monitoring of utilization and access.

(A) In general. The Secretary shall monitor--

(i) changes in the utilization of and access to services furnished under this part [*42 USCS §§ 1395j* et seq.] within geographic, population, and service related categories,

(ii) possible sources of inappropriate utilization of services furnished under this part [*42 USCS §§ 1395j* et seq.] which contribute to the overall level of expenditures under this part [*42 USCS §§ 1395j* et seq.], and

(iii) factors underlying these changes and their interrelationships.

(B) Report. The Secretary shall by not later than April 15[,] of each year (beginning with 1991) report to the Congress on the changes described in subparagraph (A)(i) and shall include in the report an examination of the factors (including factors relating to different services and specific categories and groups of services and geographic and demographic variations in utilization) which may contribute to such changes.

(C) Recommendations. The Secretary shall include in each annual report under subparagraph (B) recommendations--

(i) addressing any identified patterns of inappropriate utilization,

(ii) on utilization review,

(iii) on physician education or patient education,

(iv) addressing any problems of beneficiary access to care made evident by the monitoring process, and

(v) on such other matters as the Secretary deems appropriate.

The Medicare Payment Advisory Commission shall comment on the Secretary's recommendations and in developing its comments, the Commission shall convene and consult a panel of physician experts to evaluate the implications of medical utilization patterns for the quality of and access to patient care.

(h) Sending information to physicians. Before the beginning of each year (beginning with 1992), the Secretary shall send to each physician or nonparticipating supplier or other person furnishing physicians' services (as defined in section 1848(j)(3) [subsec. (j)(3) of this section]) furnishing physicians' services under this part [*42 USCS §§ 1395j* et seq.], for services commonly performed by the physician, supplier, or other person, information on fee schedule amounts that apply for the year in the fee schedule area for participating and non-participating physicians, and the maximum amount that may be charged consistent with subsection (g)(2). Such information shall be transmitted in conjunction with notices to physicians, suppliers, and other persons under section 1842(h) [*42 USCS § 1395u(h)*] (relating to the participating physician program) for a year.

(i) Miscellaneous provisions.

(1) Restriction on administrative and judicial review. There shall be no administrative or judicial review under section 1869 [*42 USCS § 1395ff*] or otherwise of--

(A) the determination of the adjusted historical payment basis (as defined in subsection (a)(2)(D)(i)),

(B) the determination of relative values and relative value units under subsection (c), including adjustments under subsections (c)(2)(F), (c)(2)(H), and (c)(2)(I) and section 13515(b) of the Omnibus Budget Reconciliation Act of 1993 [*42 USCS § 1395u* note],

(C) the determination of conversion factors under subsection (d), including without limitation a prospective redetermination of the sustainable growth rates for any or all previous fiscal years,

(D) the establishment of geographic adjustment factors under subsection (e), and

(E) the establishment of the system for the coding of physicians' services under this section.

(2) Assistants-at-surgery.

(A) In general. Subject to subparagraph (B), in the case of a surgical service furnished by a physician, if payment is made separately under this part [*42 USCS §§ 1395j* et seq.] for the services of a physician serving as an assistant-at-surgery, the fee schedule amount shall not exceed 16 percent of the fee schedule amount otherwise determined under this section for the global surgical service involved.

(B) Denial of payment in certain cases. If the Secretary determines, based on the most recent data available, that for a surgical procedure (or class of surgical procedures) the national average percentage of such procedure performed under this part [*42 USCS §§ 1395j* et seq.] which involve the use of a physician as an assistant at surgery is less than 5 percent, no payment may be made under this part [*42 USCS §§ 1395j* et seq.] for services of an assistant at surgery involved in the procedure.

(3) No comparability adjustment. For physicians' services for which payment under this part [*42 USCS §§ 1395j* et seq.] is determined under this section--

(A) a carrier may not make any adjustment in the payment amount under section 1842(b)(3)(B) [*42 USCS § 1395u(b)(3)(B)*] on the basis that the payment amount is higher than the charge applicable, for comparable services and under comparable circumstances, to the policyholders and subscribers of the carrier,

(B) no payment adjustment may be made under section 1842(b)(8) [*42 USCS § 1395u(b)(8)*], and

(C) section 1842(b)(9) [*42 USCS § 1395u(b)(9)*] shall not apply.

(j) Definitions. In this section:

(1) Category. For services furnished before January 1, 1998, the term "category" means, with respect to physicians' services, surgical services, and all physicians' services other than surgical services (as defined by the Secretary and including anesthesia services), primary care services (as defined in section 1842(i)(4) [*42 USCS § 1395u(i)(4)*]), and all other physicians' services. The Secretary shall define surgical services and publish such definition in the Federal Register no later than May 1, 1990, after consultation with organizations representing physicians.

(2) Fee schedule area. The term "fee schedule area" means a locality used under section 1842(b) [*42 USCS § 1395u(b)*] for purposes of computing payment amounts for physicians' services.

(3) Physicians' services. The term "physicians" services' includes items and services described in paragraphs (1), (2)(A), (2)(D), (2)(G), (2)(P) (with respect to services described in subparagraphs (A) and (C) of section 1861(oo)(2) [*42 USCS § 1395x(oo)(2)*]), (2)(R) (with respect to services described in subparagraphs (B), (C), and (D) of section 1861(pp)(1) [*42 USCS § 1395x(pp)(1)*]), (2)(S), (2)(W), (2)(AA), (2)(DD), (2)(EE), (3), (4), (13), (14) (with respect to services described in section 1861(nn)(2) [*42 USCS § 1395x(nn)(2)*]), and (15) of section 1861(s) [*42 USCS § 1395x(s)*] (other than clinical diagnostic laboratory tests and, except for purposes of subsections (a)(3), (g), and (h)[,] such other items and services as the Secretary may specify).

(4) Practice expenses. The term "practice expenses" includes all expenses for furnishing physicians' services, excluding malpractice expenses, physician compensation, and other physician fringe benefits.

(k) Quality reporting system.

(1) In general. The Secretary shall implement a system for the reporting by eligible professionals of data on quality measures specified under paragraph (2). Such data shall be submitted in a form and manner specified by the Secretary (by program instruction or otherwise), which may include submission of such data on claims under this part [*42 USCS §§ 1395j* et seq.].

(2) Use of consensus-based quality measures.

(A) For 2007.

(i) In general. For purposes of applying this subsection for the reporting of data on quality measures for covered professional services furnished during the period beginning July 1, 2007, and ending December 31, 2007, the quality measures specified under this paragraph are the measures identified as 2007 physician quality measures under the Physician Voluntary Reporting Program as published on the public website of the Centers for Medicare & Medicaid Services as of the date of the enactment of this subsection [enacted Dec. 20, 2006], except as may be changed by the Secretary based on the results of a consensus-based process in January of 2007, if such change is published on such website by not later than April 1, 2007.

(ii) Subsequent refinements in application permitted. The Secretary may, from time to time (but not later than July 1, 2007), publish on such website (without notice or opportunity for public comment) modifications or refinements (such as code additions, corrections, or revisions) for the application of quality measures previously published under clause (i), but may not, under this clause, change the quality measures under the reporting system.

(iii) Implementation. Notwithstanding any other provision of law, the Secretary may implement by program instruction or otherwise this subsection for 2007.

(B) For 2008 and 2009.

(i) In general. For purposes of reporting data on quality measures for covered professional services furnished during 2008 and 2009, the quality measures specified under this paragraph for covered professional services shall be measures that have been adopted or endorsed by a consensus organization (such as the National Quality Forum or AQA), that include measures that have been submitted by a physician specialty, and that the Secretary identifies as having used a consensus-based process for developing such measures. Such measures shall include structural measures, such as the use of electronic health records and electronic prescribing technology.

(ii) Proposed set of measures. Not later than August 15 of each of 2007 and 2008, the Secretary shall publish in the Federal Register a proposed set of quality measures that the Secretary determines are described in clause (i) and would be appropriate for eligible professionals to use to submit data to the Secretary in 2008 or 2009, as applicable. The Secretary shall provide for a period of public comment on such set of measures.

(iii) Final set of measures. Not later than November 15 of each of 2007 and 2008, the Secretary shall publish in the Federal Register a final set of quality measures that the Secretary determines are described in clause (i) and would be appropriate for eligible professionals to use to submit data to the Secretary in 2008 or 2009, as applicable.

(C) For 2010 and subsequent years.

(i) In general. Subject to clause (ii), for purposes of reporting data on quality measures for covered professional services furnished during 2010 and each subsequent year, subject to subsection (m)(3)(C), the quality measures

(including electronic prescribing quality measures) specified under this paragraph shall be such measures selected by the Secretary from measures that have been endorsed by the entity with a contract with the Secretary under section 1890(a) [*42 USCS § 1395aaa(a)*].

(ii) Exception. In the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a) [*42 USCS § 1395aaa(a)*], the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary, such as the AQA alliance.

(D) Opportunity to provide input on measures for 2009 and subsequent years. For each quality measure (including an electronic prescribing quality measure) adopted by the Secretary under subparagraph (B) (with respect to 2009) or subparagraph (C), the Secretary shall ensure that eligible professionals have the opportunity to provide input during the development, endorsement, or selection of measures applicable to services they furnish.

(3) Covered professional services and eligible professionals defined. For purposes of this subsection:

(A) Covered professional services. The term "covered professional services" means services for which payment is made under, or is based on, the fee schedule established under this section and which are furnished by an eligible professional.

(B) Eligible professional. The term "eligible professional" means any of the following:

(i) A physician.

(ii) A practitioner described in section 1842(b)(18)(C) [*42 USCS § 1395u(b)(18)(C)*].

(iii) A physical or occupational therapist or a qualified speech-language pathologist.

(iv) Beginning with 2009, a qualified audiologist (as defined in section 1861(ll)(3)(B) [*42 USCS § 1395x(ll)(3)(B)*]).

(4) Use of registry-based reporting. As part of the publication of proposed and final quality measures for 2008 under clauses (ii) and (iii) of paragraph (2)(B), the Secretary shall address a mechanism whereby an eligible professional may provide data on quality measures through an appropriate medical registry (such as the Society of Thoracic Surgeons National Database), as identified by the Secretary.

(5) Identification units. For purposes of applying this subsection, the Secretary may identify eligible professionals through billing units, which may include the use of the Provider Identification Number, the unique physician identification number (described in section 1833(q)(1) [*42 USCS § 1395l(q)(1)*]), the taxpayer identification number, or the National Provider Identifier. For purposes of applying this subsection for 2007, the Secretary shall use the taxpayer identification number as the billing unit.

(6) Education and outreach. The Secretary shall provide for education and outreach to eligible professionals on the operation of this subsection.

(7) Limitations on review. There shall be no administrative or judicial review under section 1869 [*42 USCS § 1395ff*], section 1878 [*42 USCS § 1395oo*], or otherwise, of the development and implementation of the reporting system under paragraph (1), including identification of quality measures under paragraph (2) and the application of paragraphs (4) and (5).

(8) Implementation. The Secretary shall carry out this subsection acting through the Administrator of the Centers for Medicare & Medicaid Services.

(l) Physician Assistance and Quality Initiative Fund.

(1) Establishment. The Secretary shall establish under this subsection a Physician Assistance and Quality Initiative Fund (in this subsection referred to as the "Fund") which shall be available to the Secretary for physician payment and quality improvement initiatives, which may include application of an adjustment to the update of the conversion factor under subsection (d).

(2) Funding.

(A) Amount available.

(i) In general. Subject to clause (ii), there shall be available to the Fund the following amounts:

(I) For expenditures during 2008, an amount equal to $ 150,500,000.

(II) For expenditures during 2009, an amount equal to $ 24,500,000.

(III), (IV) [Deleted]

(ii) Limitations on expenditures.

(I) 2008. The amount available for expenditures during 2008 shall be reduced as provided by subparagraph (A) of section 225(c)(1) [unclassified] and section 524 of the Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Act, 2008 (division G of the Consolidated Appropriations Act, 2008).

(II) 2009. The amount available for expenditures during 2009 shall be reduced as provided by subparagraph (B) of such section 225(c)(1) [unclassified].

(III), (IV) [Deleted]

(B) Timely obligation of all available funds for services. The Secretary shall provide for expenditures from the Fund in a manner designed to provide (to the maximum extent feasible) for the obligation of the entire amount available for expenditures, after application of subparagraph (A)(ii), during--

(i) for payment with respect to physicians' services furnished during 2008; and

(ii) 2009 for payment with respect to physicians' services furnished during 2009.

(iii), (iv) [Deleted]

(C) Payment from Trust Fund. The amount specified in subparagraph (A) shall be available to the Fund, as expenditures are made from the Fund, from the Federal Supplementary Medical Insurance Trust Fund under section 1841 [*42 USCS § 1395t*].

(D) Funding limitation. Amounts in the Fund shall be available in advance of appropriations in accordance with subparagraph (B) but only if the total amount obligated from the Fund does not exceed the amount available to the Fund under subparagraph (A). The Secretary may obligate funds from the Fund only if the Secretary determines (and the Chief Actuary of the Centers for Medicare & Medicaid Services and the appropriate budget officer certify) that there are available in the Fund sufficient amounts to cover all such obligations incurred consistent with the previous sentence.

(E) Construction. In the case that expenditures from the Fund are applied to, or otherwise affect, a conversion factor under subsection (d) for a year, the conversion factor under such subsection shall be computed for a subsequent year as if such application or effect had never occurred.

(m) Incentive payments for quality reporting.

(1) Incentive payments.

(A) In general. For 2007 through 2010, with respect to covered professional services furnished during a reporting period by an eligible professional, if--

(i) there are any quality measures that have been established under the physician reporting system that are applicable to any such services furnished by such professional for such reporting period; and

(ii) the eligible professional satisfactorily submits (as determined under this subsection) to the Secretary data on such quality measures in accordance with such reporting system for such reporting period,

in addition to the amount otherwise paid under this part, there also shall be paid to the eligible professional (or to an employer or facility in the cases described in clause (A) of section 1842(b)(6) [*42 USCS § 1395u(b)(6)*]) or, in the case of a group practice under paragraph (3)(C), to the group practice, from the Federal Supplementary Medical Insurance Trust Fund established under section 1841 [*42 USCS § 1395t*] an amount equal to the applicable quality percent of the Secretary's estimate (based on claims submitted not later than 2 months after the end of the reporting period) of the allowed charges under this part for all such covered professional services furnished by the eligible professional (or, in the case of a group practice under paragraph (3)(C), by the group practice) during the reporting period.

(B) Applicable quality percent. For purposes of subparagraph (A), the term "applicable quality percent" means--

(i) for 2007 and 2008, 1.5 percent; and

(ii) for 2009 and 2010, 2.0 percent.

(2) Incentive payments for electronic prescribing.

(A) In general. For 2009 through 2013, with respect to covered professional services furnished during a reporting period by an eligible professional, if the eligible professional is a successful electronic prescriber for such reporting period, in addition to the amount otherwise paid under this part, there also shall be paid to the eligible professional (or to an employer or facility in the cases described in clause (A) of section 1842(b)(6) [*42 USCS § 1395u(b)(6)*]) or, in the case of a group practice under paragraph (3)(C), to the group practice, from the Federal Supplementary Medical Insurance Trust Fund established under section 1841 [*42 USCS § 1395t*] an amount equal to the applicable electronic prescribing percent of the Secretary's estimate (based on claims submitted not later than 2 months after the end of the reporting period) of the allowed charges under this part for all such covered professional services furnished by the eligible professional (or, in the case of a group practice under paragraph (3)(C), by the group practice) during the reporting period.

(B) Limitation with respect to electronic prescribing quality measures. The provisions of this paragraph and subsection (a)(5) shall not apply to an eligible professional (or, in the case of a group practice under paragraph (3)(C), to the group practice) if, for the reporting period (or, for purposes of subsection (a)(5), for the reporting period for a year)--

(i) the allowed charges under this part for all covered professional services furnished by the eligible professional (or group, as applicable) for the codes to which the electronic prescribing quality measure applies (as identified by the Secretary and published on the Internet website of the Centers for Medicare & Medicaid Services as of January 1, 2008, and as subsequently modified by the Secretary) are less than 10 percent of the total of the allowed charges under this part for all such covered professional services furnished by the eligible professional (or the group, as applicable); or

(ii) if determined appropriate by the Secretary, the eligible professional does not submit (including both electronically and nonelectronically) a sufficient number (as determined by the Secretary) of prescriptions under part D [*42 USCS §§ 1395w-101* et seq.].

If the Secretary makes the determination to apply clause (ii) for a period, then clause (i) shall not apply for such period.

(C) Applicable electronic prescribing percent. For purposes of subparagraph (A), the term "applicable electronic prescribing percent" means--

(i) for 2009 and 2010, 2.0 percent;

(ii) for 2011 and 2012, 1.0 percent; and

(iii) for 2013, 0.5 percent.

(3) Satisfactory reporting and successful electronic prescriber described.

(A) In general. For purposes of paragraph (1), an eligible professional shall be treated as satisfactorily submitting data on quality measures for covered professional services for a reporting period if quality measures have been reported as follows:

(i) Three or fewer quality measures applicable. If there are no more than 3 quality measures that are provided under the physician reporting system and that are applicable to such services of such professional furnished during the period, each such quality measure has been reported under such system in at least 80 percent of the cases in which such measure is reportable under the system.

(ii) Four or more quality measures applicable. If there are 4 or more quality measures that are provided under the physician reporting system and that are applicable to such services of such professional furnished during the period, at least 3 such quality measures have been reported under such system in at least 80 percent of the cases in which the respective measure is reportable under the system.

For years after 2008, quality measures for purposes of this subparagraph shall not include electronic prescribing quality measures.

(B) Successful electronic prescriber.

(i) In general. For purposes of paragraph (2) and subsection (a)(5), an eligible professional shall be treated as a successful electronic prescriber for a reporting period (or, for purposes of subsection (a)(5), for the reporting period for a year) if the eligible professional meets the requirement described in clause (ii), or, if the Secretary determines appropriate, the requirement described in clause (iii). If the Secretary makes the determination under the preceding sentence to apply the requirement described in clause (iii) for a period, then the requirement described in clause (ii) shall not apply for such period.

(ii) Requirement for submitting data on electronic prescribing quality measures. The requirement described in this clause is that, with respect to covered professional services furnished by an eligible professional during a reporting period (or, for purposes of subsection (a)(5), for the reporting period for a year), if there are any electronic prescribing quality measures that have been established under the physician reporting system and are applicable to any such services furnished by such professional for the period, such professional reported each such measure under such system in at least 50 percent of the cases in which such measure is reportable by such professional under such system.

(iii) Requirement for electronically prescribing under part D. The requirement described in this clause is that the eligible professional electronically submitted a sufficient number (as determined by the Secretary) of prescriptions under part D [*42 USCS §§ 1395w-101* et seq.] during the reporting period (or, for purposes of subsection (a)(5), for the reporting period for a year).

(iv) Use of part D data. Notwithstanding sections 1860D-15(d)(2)(B) and 1860D-15(f)(2) [*42 USCS § 1395w-115(d)(2)(B)* and (f)(2)], the Secretary may use data regarding drug claims submitted for purposes of section 1860D-15 [*42 USCS § 1395w-115*] that are necessary for purposes of clause (iii), paragraph (2)(B)(ii), and paragraph (5)(G).

(v) Standards for electronic prescribing. To the extent practicable, in determining whether eligible professionals meet the requirements under clauses (ii) and (iii) for purposes of clause (i), the Secretary shall ensure that eligible professionals utilize electronic prescribing systems in compliance with standards established for such systems pursuant to the Part D Electronic Prescribing Program under section 1860D-4(e) [*42 USCS § 1395w-104(e)*].

(C) Satisfactory reporting measures for group practices.

(i) In general. By January 1, 2010, the Secretary shall establish and have in place a process under which eligible professionals in a group practice (as defined by the Secretary) shall be treated as satisfactorily submitting data on quality measures under subparagraph (A) and as meeting the requirement described in subparagraph (B)(ii) for covered professional services for a reporting period (or, for purposes of subsection (a)(5), for a reporting period for a year) if, in lieu of reporting measures under subsection (k)(2)(C), the group practice reports measures determined appropriate by the Secretary, such as measures that target high-cost chronic conditions and preventive care, in a form and manner, and at a time, specified by the Secretary.

(ii) Statistical sampling model. The process under clause (i) shall provide for the use of a statistical sampling model to submit data on measures, such as the model used under the Physician Group Practice demonstration project under section 1866A [*42 USCS § 1395cc-1*].

(iii) No double payments. Payments to a group practice under this subsection by reason of the process under clause (i) shall be in lieu of the payments that would otherwise be made under this subsection to eligible professionals in the group practice for satisfactorily submitting data on quality measures.

(D) Authority to revise satisfactorily reporting data. For years after 2009, the Secretary, in consultation with stakeholders and experts, may revise the criteria under this subsection for satisfactorily submitting data on quality measures under subparagraph (A) and the criteria for submitting data on electronic prescribing quality measures under subparagraph (B)(ii).

(4) Form of payment. The payment under this subsection shall be in the form of a single consolidated payment.

(5) Application.

(A) Physician reporting system rules. Paragraphs (5), (6), and (8) of subsection (k) shall apply for purposes of this subsection in the same manner as they apply for purposes of such subsection.

(B) Coordination with other bonus payments. The provisions of this subsection shall not be taken into account in applying subsections (m) and (u) of section 1833 and any payment under such subsections shall not be taken into account in computing allowable charges under this subsection.

(C) Implementation. Notwithstanding any other provision of law, for 2007, 2008, and 2009, the Secretary may implement by program instruction or otherwise this subsection.

(D) Validation.

(i) In general. Subject to the succeeding provisions of this subparagraph, for purposes of determining whether a measure is applicable to the covered professional services of an eligible professional under this subsection for 2007 and 2008, the Secretary shall presume that if an eligible professional submits data for a measure, such measure is applicable to such professional.

(ii) Method. The Secretary may establish procedures to validate (by sampling or other means as the Secretary determines to be appropriate) whether measures applicable to covered professional services of an eligible professional have been reported.

(iii) Denial of payment authority. If the Secretary determines that an eligible professional (or, in the case of a group practice under paragraph (3)(C), the group practice) has not reported measures applicable to covered professional services of such professional, the Secretary shall not pay the incentive payment under this subsection. If such payments for such period have already been made, the Secretary shall recoup such payments from the eligible professional (or the group practice).

(E) Limitations on review. There shall be no administrative or judicial review under section 1869 [*42 USCS § 1395ff*], section 1878 [*42 USCS § 1395oo*], or otherwise of--

(i) the determination of measures applicable to services furnished by eligible professionals under this subsection;

(ii) the determination of satisfactory reporting under this subsection;

(iii) the determination of a successful electronic prescriber under paragraph (3), the limitation under paragraph (2)(B), and the exception under subsection (a)(5)(B); and

(iv) the determination of any incentive payment under this subsection and the payment adjustment under subsection (a)(5)(A).

(F) Extension. For 2008 and subsequent years, the Secretary shall establish alternative criteria for satisfactorily reporting under this subsection and alternative reporting periods under paragraph (6)(C) for reporting groups of measures under subsection (k)(2)(B) and for reporting using the method specified in subsection (k)(4).

(G) Posting on website. The Secretary shall post on the Internet website of the Centers for Medicare & Medicaid Services, in an easily understandable format, a list of the names of the following:

(i) The eligible professionals (or, in the case of reporting under paragraph (3)(C), the group practices) who satisfactorily submitted data on quality measures under this subsection.

(ii) The eligible professionals (or, in the case of reporting under paragraph (3)(C), the group practices) who are successful electronic prescribers.

(6) Definitions. For purposes of this subsection:

(A) Eligible professional; covered professional services. The terms "eligible professional" and "covered professional services" have the meanings given such terms in subsection (k)(3).

(B) Physician reporting system. The term "physician reporting system" means the system established under subsection (k).

(C) Reporting period.

(i) In general. Subject to clauses (ii) and (iii), the term "reporting period" means--

(I) for 2007, the period beginning on July 1, 2007, and ending on December 31, 2007; and

(II) for 2008, 2009, 2010, and 2011, the entire year.

(ii) Authority to revise reporting period. For years after 2009, the Secretary may revise the reporting period under clause (i) if the Secretary determines such revision is appropriate, produces valid results on measures reported, and is consistent with the goals of maximizing scientific validity and reducing administrative burden. If the Secretary revises such period pursuant to the preceding sentence, the term "reporting period" shall mean such revised period.

(iii) Reference. Any reference in this subsection to a reporting period with respect to the application of subsection (a)(5) shall be deemed a reference to the reporting period under subparagraph (D)(iii) of such subsection.

(n) Physician Feedback Program.

(1) Establishment.

(A) In general. The Secretary shall establish a Physician Feedback Program (in this subsection referred to as the "Program") under which the Secretary shall use claims data under this *title [42 USCS §§ 1395* et seq.] (and may use other data) to provide confidential reports to physicians (and, as determined appropriate by the Secretary, to groups of physicians) that measure the resources involved in furnishing care to individuals under this *title [42 USCS §§ 1395* et seq.]. If determined appropriate by the Secretary, the Secretary may include information on the quality of care furnished to individuals under this title by the physician (or group of physicians) in such reports.

(B) Resource use. The resources described in subparagraph (A) may be measured--

(i) on an episode basis;

(ii) on a per capita basis; or

(iii) on both an episode and a per capita basis.

(2) Implementation. The Secretary shall implement the Program by not later than January 1, 2009.

(3) Data for reports. To the extent practicable, reports under the Program shall be based on the most recent data available.

(4) Authority to focus application. The Secretary may focus the application of the Program as appropriate, such as focusing the Program on--

(A) physician specialties that account for a certain percentage of all spending for physicians' services under this *title [42 USCS §§ 1395* et seq.];

(B) physicians who treat conditions that have a high cost or a high volume, or both, under this *title [42 USCS §§ 1395* et seq.];

(C) physicians who use a high amount of resources compared to other physicians;

(D) physicians practicing in certain geographic areas; or

(E) physicians who treat a minimum number of individuals under this *title [42 USCS §§ 1395* et seq.].

(5) Authority to exclude certain information if insufficient information. The Secretary may exclude certain information regarding a service from a report under the Program with respect to a physician (or group of physicians) if the Secretary determines that there is insufficient information relating to that service to provide a valid report on that service.

(6) Adjustment of data. To the extent practicable, the Secretary shall make appropriate adjustments to the data used in preparing reports under the Program, such as adjustments to take into account variations in health status and other patient characteristics.

(7) Education and outreach. The Secretary shall provide for education and outreach activities to physicians on the operation of, and methodologies employed under, the Program.

(8) Disclosure exemption. Reports under the Program shall be exempt from disclosure under *section 552 of title 5, United States Code.*

HISTORY:

(Aug. 14, 1935, ch 531, Title XVIII, Part B, § 1848, as added Dec. 19, 1989, P.L. 101-239, Title VI, Subtitle A, Part 2, Subpart A, § 6102(a), 103 Stat. 2169; Nov. 5, 1990, P.L. 101-508, Title IV, Subtitle A, Part 2, Subpart A, §§ 4102(b), (g)(2), 4104(b)(2), 4105(a)(3), (c), 4106(b)(1), 4107(a)(1), 4109(a), 4116, 4118(b)-(f)(1), (k), 104 Stat. 1388-56, 1388-57-1388-60, 1388-61-1388-63, 1388-65, 1388-67, 1388-68, 1388-71; Aug. 10, 1993, P.L. 103-66, Title XIII, Ch 2, Subch A, Part II, Subpart A, §§ 13511(a), 13512-13514(a), (b), 13515(a)(1), (c), 13516(a)(2), 13517(a), 13518(a), 107 Stat. 580-586; Oct. 31, 1994, P.L. 103-432, Title I, Subtitle B, Part I, §§ 121(b)(1), (2), 122(a), (b), 123(a), (d), 126(b)(6), (g)(2)(B), (5)-(7), (10)(A), 108 Stat. 4409, 4410, 4412, 4415, 4416; Aug. 5, 1997, P.L. 105-33, Title IV, Subtitle A, Ch 3, § 4022(b)(2)(B), (C), Subtitle B, §§ 4102(d), 4103(d), 4104(d), 4105(a)(2), 4106(b), Subtitle F, Ch 1, Subch A, §§ 4501, 4502(a)(1), (b), 4503, Subtitle F, Ch 1, Subch A, §§ 4504(a), 4505(a), (b), (e), (f)(1), Subtitle G, Ch 3, § 4644(d), Subtitle H, Ch 2, § 4714(b)(2), 111 Stat. 354, 361, 362, 365, 366, 368, 432-437, 488, 510; Nov. 29, 1999, P.L. 106-113, Div B, § 1000(a)(6), 113 Stat. 1536; Dec. 21, 2000, P.L. 106-554, § 1(a)(6), 114 Stat. 2763; Feb. 20, 2003, P.L. 108-7, Div N, Title IV, § 402(a), 117 Stat. 548; Dec. 8, 2003, P.L. 108-173, Title III, § 303(a)(1), (g)(2), Title

IV, Subtitle B, § 412, Title VI, Subtitle A, §§ 601(a)(1), (2), (b)(1), 602, Subtitle B, § 611(c), Title VII, Subtitle D, § 736(b)(10), 117 Stat. 2233, 2253, 2274, 2300, 2301, 2304, 2356.)

(As amended Feb. 8, 2006, P.L. 109-171, Title V, Subtitle B, Ch. 1, §§ 5102, 5104(a), Ch. 2, § 5112(c), 120 Stat. 37, 39, 40, 44; Dec. 20, 2006, P.L. 109-432, Div B, Title I, §§ 101(a), (b), (d), 102, 120 Stat. 2975, 2980, 2981; Sept. 29, 2007, P.L. 110-90, § 6, 121 Stat. 985; Dec. 26, 2007, P.L. 110-161, Div G, Title II, § 225(c)(2), Title V, § 524, 121 Stat. 2190, 2212; Dec. 29, 2007, P.L. 110-173, Title I, §§ 101(a)(1), (2)(A), (b)(1), 103, 121 Stat. 2493, 2494, 2495; June 30, 2008, P.L. 110-252, Title VII, § 7002(c), 122 Stat. 2395; July 15, 2008, P.L. 110-275, Title I, Subtitle C, Part I, §§ 131(a)-(b)(4)(A), (5), (c)(1), 132(a), (b), 133(b), 134, 139(a), Part II, §§ 144(a)(2), 152(b)(1)(C), 122 Stat. 2520, 2525, 2526, 2528, 2532, 2541, 2546, 2552.)

§ 1395w-21. Eligibility, election, and enrollment

(a) Choice of medicare benefits through Medicare + Choice plans.

(1) In general. Subject to the provisions of this section, each Medicare + Choice eligible individual (as defined in paragraph (3)) is entitled to elect to receive benefits (other than qualified prescription drug benefits) under this *title [42 USCS §§ 1395* et seq.]--

(A) through the original medicare fee-for-service program under parts A and B [*42 USCS §§ 1395c* et seq. and *1395j* et seq.], or

(B) through enrollment in a Medicare + Choice plan under this part [*42 USCS §§ 1395w-21* et seq.],

and may elect qualified prescription drug coverage in accordance with section 1860D-1 [*42 USCS § 1395w-101*].

(2) Types of Medicare + Choice plans that may be available. A Medicare + Choice plan may be any of the following types of plans of health insurance:

(A) Coordinated care plans (including regional plans).

(i) In general. Coordinated care plans which provide health care services, including but not limited to health maintenance organization plans (with or without point of service options), plans offered by provider-sponsored organizations (as defined in section 1855(d) [*42 USCS § 1395w-25(d)*]), and regional or local preferred provider organization plans (including MA regional plans).

(ii) Specialized MA plans for special needs individuals. Specialized MA plans for special needs individuals (as defined in section 1859(b)(6) [*42 USCS § 1395w-28(b)(6)*]) may be any type of coordinated care plan.

(B) Combination of MSA plan and contributions to Medicare + Choice MSA. An MSA plan, as defined in section 1859(b)(3) [*42 USCS § 1395w-28(b)(3)*], and a contribution into a Medicare + Choice medical savings account (MSA).

(C) Private fee-for-service plans. A Medicare + Choice private fee-for-service plan, as defined in section 1859(b)(2) [*42 USCS § 1395w-28(b)(2)*].

(3) Medicare + choice eligible individual.

(A) In general. In this *title [42 USCS §§ 1395* et seq.], subject to subparagraph (B), the term "Medicare + Choice eligible individual" means an individual who is entitled to benefits under part A [*42 USCS §§ 1395c* et seq.]and enrolled under part B [*42 USCS §§ 1395j* et seq.].

(B) Special rule for end-stage renal disease. Such term shall not include an individual medically determined to have end-stage renal disease, except that--

(i) an individual who develops end-stage renal disease while enrolled in a Medicare + Choice plan may continue to be enrolled in that plan; and

(ii) in the case of such an individual who is enrolled in a Medicare + Choice plan under clause (i) (or subsequently under this clause), if the enrollment is discontinued under circumstances described in subsection (e)(4)(A), then the individual will be treated as a "Medicare + Choice eligible individual" for purposes of electing to continue enrollment in another Medicare + Choice plan.

(b) Special rules.

(1) Residence requirement.

(A) In general. Except as the Secretary may otherwise provide and except as provided in subparagraph (C), an individual is eligible to elect a Medicare + Choice plan offered by a Medicare + Choice organization only if the plan serves the geographic area in which the individual resides.

(B) Continuation of enrollment permitted. Pursuant to rules specified by the Secretary, the Secretary shall provide that an MA local plan may offer to all individuals residing in a geographic area the option to continue enrollment in the plan, notwithstanding that the individual no longer resides in the service area of the plan, so long as the plan provides that individuals exercising this option have, as part of the benefits under the original medicare fee-for-service program option, reasonable access within that geographic area to the full range of basic benefits, subject to reasonable cost sharing liability in obtaining such benefits.

(C) Continuation of enrollment permitted where service changed. Notwithstanding subparagraph (A) and in addition to subparagraph (B), if a Medicare + Choice organization eliminates from its service area a Medicare + Choice payment area that was previously within its service area, the organization may elect to offer individuals residing in all or portions of the affected area who would otherwise be ineligible to continue enrollment the option to continue enrollment in an MA local plan it offers so long as--

(i) the enrollee agrees to receive the full range of basic benefits (excluding emergency and urgently needed care) exclusively at facilities designated by the organization within the plan service area; and

(ii) there is no other Medicare + Choice plan offered in the area in which the enrollee resides at the time of the organization's election.

(2) Special rule for certain individuals covered under FEHBP or eligible for veterans or military health benefits, veterans.

(A) FEHBP. An individual who is enrolled in a health benefit plan under chapter 89 of title 5 [*5 USCS §§ 8901* et seq.], United States Code, is not eligible to enroll in an MSA plan until such time as the Director of the Office of Management and Budget certifies to the Secretary that the Office of Personnel Management has adopted policies which will ensure that the enrollment of such individuals in such plans will not result in increased expenditures for the Federal Government for health benefit plans under such chapter.

(B) VA and DOD. The Secretary may apply rules similar to the rules described in subparagraph (A) in the case of individuals who are eligible for health care benefits under chapter 55 of title 10, United States Code [*10 USCS §§ 1071* et seq.], or under chapter 17 of title 38 of such Code [*38 USCS §§ 1701* et seq.].

(3) Limitation on eligibility of qualified medicare beneficiaries and other medicaid beneficiaries to enroll in an MSA plan. An individual who is a qualified medicare beneficiary (as defined in section 1905(p)(1) [*42 USCS § 1396d(p)(1)*]), a qualified disabled and working individual (described in section 1905(s) [*42 USCS § 1396d(s)*]), an individual described in section 1902(a)(10)(E)(iii) [*42 USCS § 1396a(a)(10)(E)(iii)*], or otherwise entitled to medicare cost-sharing under a State plan under title XIX [*42 USCS §§ 1396* et seq.] is not eligible to enroll in an MSA plan.

(4) Coverage under MSA plans.

(A) In general. Under rules established by the Secretary, an individual is not eligible to enroll (or continue enrollment) in an MSA plan for a year unless the individual provides assurances satisfactory to the Secretary that the individual will reside in the United States for at least 183 days during the year.

(B) Evaluation. The Secretary shall regularly evaluate the impact of permitting enrollment in MSA plans under this part [*42 USCS §§ 1395w-21* et seq.] on selection (including adverse selection), use of preventive care, access to care, and the financial status of the Trust Funds under this *title [42 USCS §§ 1395* et seq.].

(C) Reports. The Secretary shall submit to Congress periodic reports on the numbers of individuals enrolled in such plans and on the evaluation being conducted under subparagraph (B).

(c) Process for exercising choice.

(1) In general. The Secretary shall establish a process through which elections described in subsection (a) are made and changed, including the form and manner in which such elections are made and changed. Such elections shall be made or changed only during coverage election periods specified under subsection (e) and shall become effective as provided in subsection (f).

(2) Coordination through Medicare + Choice organizations.

(A) Enrollment. Such process shall permit an individual who wishes to elect a Medicare + Choice plan offered by a Medicare + Choice organization to make such election through the filing of an appropriate election form with the organization.

(B) Disenrollment. Such process shall permit an individual, who has elected a Medicare + Choice plan offered by a Medicare + Choice organization and who wishes to terminate such election, to terminate such election through the filing of an appropriate election form with the organization.

(3) Default.

(A) Initial election.

(i) In general. Subject to clause (ii), an individual who fails to make an election during an initial election period under subsection (e)(1) is deemed to have chosen the original medicare fee-for-service program option.

(ii) Seamless continuation of coverage. The Secretary may establish procedures under which an individual who is enrolled in a health plan (other than Medicare + Choice plan) offered by a Medicare + Choice organization at the time of the initial election period and who fails to elect to receive coverage other than through the organization is deemed to have elected the Medicare + Choice plan offered by the organization (or, if the organization offers more than one such plan, such plan or plans as the Secretary identifies under such procedures).

(B) Continuing periods. An individual who has made (or is deemed to have made) an election under this section is considered to have continued to make such election until such time as--

(i) the individual changes the election under this section, or

(ii) the Medicare + Choice plan with respect to which such election is in effect is discontinued or, subject to subsection (b)(1)(B), no longer serves the area in which the individual resides.

(d) Providing information to promote informed choice.

(1) In general. The Secretary shall provide for activities under this subsection to broadly disseminate information to medicare beneficiaries (and prospective medicare beneficiaries) on the coverage options provided under this section in order to promote an active, informed selection among such options.

(2) Provision of notice.

(A) Open season notification. At least 15 days before the beginning of each annual, coordinated election period (as defined in subsection (e)(3)(B)), the Secretary shall mail to each Medicare + Choice eligible individual residing in an area the following:

(i) General information. The general information described in paragraph (3).

(ii) List of plans and comparison of plan options. A list identifying the Medicare + Choice plans that are (or will be) available to residents of the area and information described in paragraph (4) concerning such plans. Such information shall be presented in a comparative form.

(iii) Additional information. Any other information that the Secretary determines will assist the individual in making the election under this section.

The mailing of such information shall be coordinated, to the extent practicable, with the mailing of any annual notice under section 1804 [*42 USCS § 1395b-2*].

(B) Notification to newly eligible Medicare + Choice eligible individuals. To the extent practicable, the Secretary shall, not later than 30 days before the beginning of the initial Medicare + Choice enrollment period for an individual described in subsection (e)(1), mail to the individual the information described in subparagraph (A).

(C) Form. The information disseminated under this paragraph shall be written and formatted using language that is easily understandable by medicare beneficiaries.

(D) Periodic updating. The information described in subparagraph (A) shall be updated on at least an annual basis to reflect changes in the availability of Medicare + Choice plans and the benefits and Medicare + Choice monthly basic and supplemental beneficiary premiums for such plans.

(3) General information. General information under this paragraph, with respect to coverage under this part [*42 USCS §§ 1395w-21* et seq.] during a year, shall include the following:

(A) Benefits under original medicare fee-for-service program option. A general description of the benefits covered under the original medicare fee-for-service program under parts A and B [*42 USCS §§ 1395c* et seq. and *1395j* et seq.], including--

(i) covered items and services,

(ii) beneficiary cost sharing, such as deductibles, coinsurance, and copayment amounts, and

(iii) any beneficiary liability for balance billing.

(B) Election procedures. Information and instructions on how to exercise election options under this section.

(C) Rights. A general description of procedural rights (including grievance and appeals procedures) of beneficiaries under the original medicare fee-for-service program and the Medicare + Choice program and the right to be protected against discrimination based on health status-related factors under section 1852(b) [*42 USCS § 1395w-22(b)*].

(D) Information on medigap and medicare select. A general description of the benefits, enrollment rights, and other requirements applicable to medicare supplemental policies under section 1882 [*42 USCS § 1395ss*] and provisions relating to medicare select policies described in section 1882(t) [*42 USCS § 1395ss(t)*].

(E) Potential for contract termination. The fact that a Medicare + Choice organization may terminate its contract, refuse to renew its contract, or reduce the service area included in its contract, under this part [*42 USCS §§ 1395w-21* et seq.], and the effect of such a termination, nonrenewal, or service area reduction may have on individuals enrolled with the Medicare + Choice plan under this part [*42 USCS §§ 1395w-21* et seq.].

(F) Catastrophic coverage and single deductible. In the case of an MA regional plan, a description of the catastrophic coverage and single deductible applicable under the plan.

(4) Information comparing plan options. Information under this paragraph, with respect to a Medicare + Choice plan for a year, shall include the following:

(A) Benefits. The benefits covered under the plan, including the following:

(i) Covered items and services beyond those provided under the original medicare fee-for-service program.

(ii) Any beneficiary cost sharing, including information on the single deductible (if applicable) under section 1858(b)(1) [*42 USCS § 1395w-27a(b)(1)*].

(iii) Any maximum limitations on out-of-pocket expenses.

(iv) In the case of an MSA plan, differences in cost sharing, premiums, and balance billing under such a plan compared to under other Medicare + Choice plans.

(v) In the case of a Medicare + Choice private fee-for-service plan, differences in cost sharing, premiums, and balance billing under such a plan compared to under other Medicare + Choice plans.

(vi) The extent to which an enrollee may obtain benefits through out-of-network health care providers.

(vii) The extent to which an enrollee may select among in-network providers and the types of providers participating in the plan's network.

(viii) The organization's coverage of emergency and urgently needed care.

(B) Premiums.

(i) In general. The monthly amount of the premium charged to an individual.

(ii) Reductions. The reduction in part B [*42 USCS §§ 1395j* et seq.] premiums, if any.

(C) Service area. The service area of the plan.

(D) Quality and performance. To the extent available, plan quality and performance indicators for the benefits under the plan (and how they compare to such indicators under the original medicare fee-for-service program under parts A and B [*42 USCS §§ 1395c* et seq. and *1395j* et seq.] in the area involved), including--

(i) disenrollment rates for medicare enrollees electing to receive benefits through the plan for the previous 2 years (excluding disenrollment due to death or moving outside the plan's service area),

(ii) information on medicare enrollee satisfaction,

(iii) information on health outcomes, and

(iv) the recent record regarding compliance of the plan with requirements of this part [*42 USCS §§ 1395w-21* et seq.] (as determined by the Secretary).

(E) Supplemental benefits. Supplemental health care benefits, including any reductions in cost-sharing under section 1852(a)(3) [*42 USCS § 1395w-22(a)(3)*] and the terms and conditions (including premiums) for such benefits.

(5) Maintaining a toll-free number and internet site. The Secretary shall maintain a toll-free number for inquiries regarding Medicare + Choice options and the operation of this part [*42 USCS §§ 1395w-21* et seq.] in all areas in which Medicare + Choice plans are offered and an Internet site through which individuals may electronically obtain information on such options and Medicare + Choice plans.

(6) Use of non-Federal entities. The Secretary may enter into contracts with non-Federal entities to carry out activities under this subsection.

(7) Provision of information. A Medicare + Choice organization shall provide the Secretary with such information on the organization and each Medicare + Choice plan it offers as may be required for the preparation of the information referred to in paragraph (2)(A).

(e) Coverage election periods.

(1) Initial choice upon eligibility to make election if Medicare + Choice plans available to individual. If, at the time an individual first becomes entitled to benefits under part A [*42 USCS §§ 1395c* et seq.] and enrolled under part B [*42 USCS §§ 1395j* et seq.], there is one or more Medicare + Choice plans offered in the area in which the individual resides, the individual shall make the election under this section during a period specified by the Secretary such that if the individual elects a Medicare + Choice plan during the period, coverage under the plan becomes effective as of the first date on which the individual may receive such coverage. If any portion of an individual's initial enrollment period under part B [*42 USCS §§ 1395j* et seq.] occurs after the end of the annual, coordinated election period described in paragraph (3)(B)(iii), the initial enrollment period under this part [*42 USCS §§ 1395w-21* et seq.] shall further extend through the end of the individual's initial enrollment period under part B [*42 USCS §§ 1395j* et seq.].

(2) Open enrollment and disenrollment opportunities. Subject to paragraph (5)--

(A) Continuous open enrollment and disenrollment through 2005. At any time during the period beginning January 1, 1998, and ending on December 31, 2005, a Medicare + Choice eligible individual may change the election under subsection (a)(1).

(B) Continuous open enrollment and disenrollment for first 6 months during 2006.

(i) In general. Subject to clause (ii), subparagraph (C)(iii), and subparagraph (D), at any time during the first 6 months of 2006, or, if the individual first becomes a Medicare + Choice eligible individual during 2006, during the first 6 months during 2006 in which the individual is a Medicare + Choice eligible individual, a Medicare + Choice eligible individual may change the election under subsection (a)(1).

(ii) Limitation of one change. An individual may exercise the right under clause (i) only once. The limitation under this clause shall not apply to changes in elections effected during an annual, coordinated election period under paragraph (3) or during a special enrollment period under the first sentence of paragraph (4).

(C) Continuous open enrollment and disenrollment for first 3 months in subsequent years.

(i) In general. Subject to clauses (ii) and (iii) and subparagraph (D), at any time during the first 3 months of a year after 2006, or, if the individual first becomes a Medicare + Choice eligible individual during a year after 2006, during the first 3 months of such year in which the individual is a Medicare + Choice eligible individual, a Medicare + Choice eligible individual may change the election under subsection (a)(1).

(ii) Limitation of one change during open enrollment period each year. An individual may exercise the right under clause (i) only once during the applicable 3-month period described in such clause in each year. The limitation under this clause shall not apply to changes in elections effected during an annual, coordinated election period under paragraph (3) or during a special enrollment period under paragraph (4).

(iii) Limitation on exercise of right with respect to prescription drug coverage. Effective for plan years beginning on or after January 1, 2006, in applying clause (i) (and clause (i) of subparagraph (B)) in the case of an individual who--

(I) is enrolled in an MA plan that does provide qualified prescription drug coverage, the individual may exercise the right under such clause only with respect to coverage under the original fee-for-service plan or coverage under another MA plan that does not provide such coverage and may not exercise such right to obtain coverage under an MA-PD plan or under a prescription drug plan under part D [*42 USCS §§ 1395w-101* et seq.]; or

(II) is enrolled in an MA-PD plan, the individual may exercise the right under such clause only with respect to coverage under another MA-PD plan (and not an MA plan that does not provide qualified prescription drug coverage) or under the original fee-for-service plan and coverage under a prescription drug plan under part D [*42 USCS §§ 1395w-101* et seq.].

(D) Continuous open enrollment for institutionalized individuals. At any time after 2005 in the case of a Medicare + Choice eligible individual who is institutionalized (as defined by the Secretary), the individual may elect under subsection (a)(1)--

(i) to enroll in a Medicare + Choice plan; or

(ii) to change the Medicare + Choice plan in which the individual is enrolled.

(E) Limited continuous open enrollment of original fee-for-service enrollees in medicare advantage non-prescription drug plans.

(i) In general. On any date during the period beginning on January 1, 2007, and ending on July 31, 2007, on which a Medicare Advantage eligible individual is an unenrolled fee-for-service individual (as defined in clause (ii)), the individual may elect under subsection (a)(1) to enroll in a Medicare Advantage plan that is not an MA-PD plan.

(ii) Unenrolled fee-for-service individual defined. In this subparagraph, the term "unenrolled fee-for-service individual" means, with respect to a date, a Medicare Advantage eligible individual who--

(I) is receiving benefits under this title through enrollment in the original medicare fee-for-service program under parts A and B [*42 USCS §§ 1395c* et seq. and *1395j* et seq.];

(II) is not enrolled in an MA plan on such date; and

(III) as of such date is not otherwise eligible to elect to enroll in an MA plan.

(iii) Limitation of one change during the applicable period. An individual may exercise the right under clause (i) only once during the period described in such clause.

(iv) No effect on coverage under a prescription drug plan. Nothing in this subparagraph shall be construed as permitting an individual exercising the right under clause (i)--

(I) who is enrolled in a prescription drug plan under part D [*42 USCS §§ 1395w-101* et seq.], to disenroll from such plan or to enroll in a different prescription drug plan; or

(II) who is not enrolled in a prescription drug plan, to enroll in such a plan.

(3) Annual, coordinated election period.

(A) In general. Subject to paragraph (5), each individual who is eligible to make an election under this section may change such election during an annual, coordinated election period.

(B) Annual, coordinated election period. For purposes of this section, the term "annual, coordinated election period" means--

(i) with respect to a year before 2002, the month of November before such year;

(ii) with respect to 2002, 2003, 2004, and 2005, the period beginning on November 15 and ending on December 31 of the year before such year;

(iii) with respect to 2006, the period beginning on November 15, 2005, and ending on May 15, 2006; and

(iv) with respect to 2007 and succeeding years, the period beginning on November 15 and ending on December 31 of the year before such year.

(C) Medicare + Choice health information fairs. During the fall season of each year (beginning with 1999) and during the period described in subparagraph (B)(iii), in conjunction with the annual coordinated election period defined in subparagraph (B), the Secretary shall provide for a nationally coordinated educational and publicity campaign to inform Medicare + Choice eligible individuals about Medicare + Choice plans and the election process provided under this section.

(D) Special information campaigns. During November 1998 the Secretary shall provide for an educational and publicity campaign to inform Medicare + Choice eligible individuals about the availability of Medicare + Choice plans, and eligible organizations with risk-sharing contracts under section 1876 [*42 USCS § 1395mm*], offered in different areas and the election process provided under this section. During the period described in subparagraph (B)(iii), the Secretary shall provide for an educational and publicity campaign to inform MA eligible individuals about the availability of MA plans (including MA-PD plans) offered in different areas and the election process provided under this section.

(4) Special election periods. Effective as of January 1, 2006, an individual may discontinue an election of a Medicare + Choice plan offered by a Medicare + Choice organization other than during an annual, coordinated election period and make a new election under this section if--

(A)

(i) the certification of the organization or plan under this part [*42 USCS §§ 1395w-21* et seq.] has been terminated, or the organization or plan has notified the individual of an impending termination of such certification; or

(ii) the organization has terminated or otherwise discontinued providing the plan in the area in which the individual resides, or has notified the individual of an impending termination or discontinuation of such plan;

(B) the individual is no longer eligible to elect the plan because of a change in the individual's place of residence or other change in circumstances (specified by the Secretary, but not including termination of the individual's enrollment on the basis described in clause (i) or (ii) of subsection (g)(3)(B));

(C) the individual demonstrates (in accordance with guidelines established by the Secretary) that--

(i) the organization offering the plan substantially violated a material provision of the organization's contract under this part [*42 USCS §§ 1395w-21* et seq.] in relation to the individual (including the failure to provide an enrollee on a timely basis medically necessary care for which benefits are available under the plan or the failure to provide such covered care in accordance with applicable quality standards); or

(ii) the organization (or an agent or other entity acting on the organization's behalf) materially misrepresented the plan's provisions in marketing the plan to the individual; or

(D) the individual meets such other exceptional conditions as the Secretary may provide.

Effective as of January 1, 2006, an individual who, upon first becoming eligible for benefits under part A [*42 USCS §§ 1395c* et seq.] at age 65, enrolls in a Medicare + Choice plan under this part [*42 USCS §§ 1395w-21* et seq.], the individual may discontinue the election of such plan, and elect coverage under the original fee-for-service plan, at any time during the 12-month period beginning on the effective date of such enrollment.

(5) Special rules for MSA plans. Notwithstanding the preceding provisions of this subsection, an individual--

(A) may elect an MSA plan only during--

(i) an initial open enrollment period described in paragraph (1), or

(ii) an annual, coordinated election period described in paragraph (3)(B);

(B) subject to subparagraph (C), may not discontinue an election of an MSA plan except during the periods described in clause (ii) or (iii) of subparagraph (A) and under the first sentence of paragraph (4); and

(C) who elects an MSA plan during an annual, coordinated election period, and who never previously had elected such a plan, may revoke such election, in a manner determined by the Secretary, by not later than December 15 following the date of the election.

(6) Open enrollment periods. Subject to paragraph (5), a Medicare + Choice organization--

(A) shall accept elections or changes to elections during the initial enrollment periods described in paragraph (1), during the month of November 1998 and during the annual, coordinated election period under paragraph (3) for each subsequent year, and during special election periods described in the first sentence of paragraph (4); and

(B) may accept other changes to elections at such other times as the organization provides.

(f) Effectiveness of elections and changes of elections.

(1) During initial coverage election period. An election of coverage made during the initial coverage election period under subsection (e)(1) shall take effect upon the date the individual becomes entitled to benefits under part A [*42 USCS §§ 1395c* et seq.] and enrolled under part B [*42 USCS §§ 1395j* et seq.], except as the Secretary may provide (consistent with section 1838 [*42 USCS § 1395q*]) in order to prevent retroactive coverage.

(2) During continuous open enrollment periods. An election or change of coverage made under subsection (e)(2) shall take effect with the first day of the first calendar month following the date on which the election or change is made.

(3) Annual, coordinated election period. An election or change of coverage made during an annual, coordinated election period (as defined in subsection (e)(3)(B), other than the period described in clause (iii) of such subsection) in a year shall take effect as of the first day of the following year.

(4) Other periods. An election or change of coverage made during any other period under subsection (e)(4) shall take effect in such manner as the Secretary provides in a manner consistent (to the extent practicable) with protecting continuity of health benefit coverage.

(g) Guaranteed issue and renewal.

(1) In general. Except as provided in this subsection, a Medicare + Choice organization shall provide that at any time during which elections are accepted under this section with respect to a Medicare + Choice plan offered by the organization, the organization will accept without restrictions individuals who are eligible to make such election.

(2) Priority. If the Secretary determines that a Medicare + Choice organization, in relation to a Medicare + Choice plan it offers, has a capacity limit and the number of Medicare + Choice eligible individuals who elect the plan under this section exceeds the capacity limit, the organization may limit the election of individuals of the plan under this section but only if priority in election is provided--

(A) first to such individuals as have elected the plan at the time of the determination, and

(B) then to other such individuals in such a manner that does not discriminate, on a basis described in section 1852(b) [*42 USCS § 1395w-22(b)*], among the individuals (who seek to elect the plan).

The preceding sentence shall not apply if it would result in the enrollment of enrollees substantially nonrepresentative, as determined in accordance with regulations of the Secretary, of the medicare population in the service area of the plan.

(3) Limitation on termination of election.

(A) In general. Subject to subparagraph (B), a Medicare + Choice organization may not for any reason terminate the election of any individual under this section for a Medicare + Choice plan it offers.

(B) Basis for termination of election. A Medicare + Choice organization may terminate an individual's election under this section with respect to a Medicare + Choice plan it offers if--

(i) any Medicare + Choice monthly basic and supplemental beneficiary premiums required with respect to such plan are not paid on a timely basis (consistent with standards under section 1856 [*42 USCS § 1395w-26*] that provide for a grace period for late payment of such premiums),

(ii) the individual has engaged in disruptive behavior (as specified in such standards), or

(iii) the plan is terminated with respect to all individuals under this part [*42 USCS §§ 1395w-21* et seq.] in the area in which the individual resides.

(C) Consequence of termination.

(i) Terminations for cause. Any individual whose election is terminated under clause (i) or (ii) of subparagraph (B) is deemed to have elected the original medicare fee-for-service program option described in subsection (a)(1)(A).

(ii) Termination based on plan termination or service area reduction. Any individual whose election is terminated under subparagraph (B)(iii) shall have a special election period under subsection (e)(4)(A) in which to change coverage to coverage under another Medicare + Choice plan. Such an individual who fails to make an election during such period is deemed to have chosen to change coverage to the original medicare fee-for-service program option described in subsection (a)(1)(A).

(D) Organization obligation with respect to election forms. Pursuant to a contract under section 1857 [*42 USCS § 1395w-27*], each Medicare + Choice organization receiving an election form under subsection (c)(2) shall transmit to the Secretary (at such time and in such manner as the Secretary may specify) a copy of such form or such other information respecting the election as the Secretary may specify.

(h) Approval of marketing material and application forms.

(1) Submission. No marketing material or application form may be distributed by a Medicare + Choice organization to (or for the use of) Medicare + Choice eligible individuals unless--

(A) at least 45 days (or 10 days in the case described in paragraph (5)) before the date of distribution the organization has submitted the material or form to the Secretary for review, and

(B) the Secretary has not disapproved the distribution of such material or form.

(2) Review. The standards established under section 1856 [*42 USCS § 1395w-26*] shall include guidelines for the review of any material or form submitted and under such guidelines the Secretary shall disapprove (or later require the correction of) such material or form if the material or form is materially inaccurate or misleading or otherwise makes a material misrepresentation.

(3) Deemed approval (1-stop shopping). In the case of material or form that is submitted under paragraph (1)(A) to the Secretary or a regional office of the Department of Health and Human Services and the Secretary or the office has not disapproved the distribution of marketing material or form under paragraph (1)(B) with respect to a Medicare + Choice plan in an area, the Secretary is deemed not to have disapproved such distribution in all other areas covered by the plan and organization except with regard to that portion of such material or form that is specific only to an area involved.

(4) Prohibition of certain marketing practices. Each Medicare + Choice organization shall conform to fair marketing standards, in relation to Medicare + Choice plans offered under this part [*42 USCS §§ 1395w-21* et seq.], included in the standards established under section 1856 [*42 USCS § 1395w-26*]. Such standards--

(A) shall not permit a Medicare + Choice organization to provide for, subject to subsection (j)(2)(C), cash, gifts, prizes, or other monetary rebates as an inducement for enrollment or otherwise;

(B) may include a prohibition against a Medicare + Choice organization (or agent of such an organization) completing any portion of any election form used to carry out elections under this section on behalf of any individual;

(C) shall not permit a Medicare Advantage organization (or the agents, brokers, and other third parties representing such organization) to conduct the prohibited activities described in subsection (j)(1); and

(D) shall only permit a Medicare Advantage organization (and the agents, brokers, and other third parties representing such organization) to conduct the activities described in subsection (j)(2) in accordance with the limitations established under such subsection.

(5) Special treatment of marketing material following model marketing language. In the case of marketing material of an organization that uses, without modification, proposed model language specified by the Secretary, the period specified in paragraph (1)(A) shall be reduced from 45 days to 10 days.

(6) Required inclusion of plan type in plan name. For plan years beginning on or after January 1, 2010, a Medicare Advantage organization must ensure that the name of each Medicare Advantage plan offered by the Medicare Advantage organization includes the plan type of the plan (using standard terminology developed by the Secretary).

(7) Strengthening the ability of States to act in collaboration with the Secretary to address fraudulent or inappropriate marketing practices.

(A) Appointment of agents and brokers. Each Medicare Advantage organization shall--

(i) only use agents and brokers who have been licensed under State law to sell Medicare Advantage plans offered by the Medicare Advantage organization;

(ii) in the case where a State has a State appointment law, abide by such law; and

(iii) report to the applicable State the termination of any such agent or broker, including the reasons for such termination (as required under applicable State law).

(B) Compliance with State information requests. Each Medicare Advantage organization shall comply in a timely manner with any request by a State for information regarding the performance of a licensed agent, broker, or other third party representing the Medicare Advantage organization as part of an investigation by the State into the conduct of the agent, broker, or other third party.

(i) Effect of election of Medicare + Choice plan option.

(1) Payments to organizations. Subject to sections 1852(a)(5), 1853(a)(4), 1853(g), 1853(h), 1886(d)(11), and 1886(h)(3)(D) [*42 USCS §§ 1395w-22(a)(5)*, *1395w-23(a)(4)*, *1395w-23(g)*, *1395w-23(h)*, *1395ww(d)(11)*, and *1395ww(h)(3)(D)*], payments under a contract with a Medicare + Choice organization under section 1853(a) [*42 USCS § 1395w-23(a)*] with respect to an individual electing a Medicare + Choice plan offered by the organization shall be instead of the amounts which (in the absence of the contract) would otherwise be payable under parts A and B [*42 USCS §§ 1395c* et seq. and *1395j* et seq.] for items and services furnished to the individual.

(2) Only organization entitled to payment. Subject to sections 1853(a)(4), 1853(e), 1853(g), 1853(h), 1857(f)(2), 1858(h), 1886(d)(11), and 1886(h)(3)(D) [*42 USCS §§ 1395w-23(a)(4)*, *1395w-23(e)*, *1395w-23(g)*, *1395w-23(h)*, *1395w-27(f)(2)*, *1395w-27a(h)*, *1395ww(d)(11)*, and *1395ww(h)(3)(D)*], only the Medicare + Choice organization shall be entitled to receive payments from the Secretary under this *title [42 USCS §§ 1395* et seq.] for services furnished to the individual.

(j) Prohibited activities described and limitations on the conduct of certain other activities.

(1) Prohibited activities described. The following prohibited activities are described in this paragraph:

(A) Unsolicited means of direct contact. Any unsolicited means of direct contact of prospective enrollees, including soliciting door-to-door or any outbound telemarketing without the prospective enrollee initiating contact.

(B) Cross-selling. The sale of other non-health related products (such as annuities and life insurance) during any sales or marketing activity or presentation conducted with respect to a Medicare Advantage plan.

(C) Meals. The provision of meals of any sort, regardless of value, to prospective enrollees at promotional and sales activities.

(D) Sales and marketing in health care settings and at educational events. Sales and marketing activities for the enrollment of individuals in Medicare Advantage plans that are conducted--

(i) in health care settings in areas where health care is delivered to individuals (such as physician offices and pharmacies), except in the case where such activities are conducted in common areas in health care settings; and

(ii) at educational events.

(2) Limitations. The Secretary shall establish limitations with respect to at least the following:

(A) Scope of marketing appointments. The scope of any appointment with respect to the marketing of a Medicare Advantage plan. Such limitation shall require advance agreement with a prospective enrollee on the scope of the marketing appointment and documentation of such agreement by the Medicare Advantage organization. In the case where the marketing appointment is in person, such documentation shall be in writing.

(B) Co-branding. The use of the name or logo of a co-branded network provider on Medicare Advantage plan membership and marketing materials.

(C) Limitation of gifts to nominal dollar value. The offering of gifts and other promotional items other than those that are of nominal value (as determined by the Secretary) to prospective enrollees at promotional activities.

(D) Compensation. The use of compensation other than as provided under guidelines established by the Secretary. Such guidelines shall ensure that the use of compensation creates incentives for agents and brokers to enroll individuals in the Medicare Advantage plan that is intended to best meet their health care needs.

(E) Required training, annual retraining, and testing of agents, brokers, and other third parties. The use by a Medicare Advantage organization of any individual as an agent, broker, or other third party representing the organization that has not completed an initial training and testing program and does not complete an annual retraining and testing program.

HISTORY:

(Aug. 14, 1935, ch 531, Title XVIII, Part C, § 1851, as added Aug. 5, 1997, P.L. 105-33, Title IV, Subtitle A, Ch 1, Subch A, § 4001, 111 Stat. 276; Nov. 29, 1999, P.L. 106-113, Div B, § 1000(a)(6), 113 Stat. 1536; Dec. 21, 2000, P.L. 106-554, § 1(a)(6), 114 Stat. 2763; June 12, 2002, P.L. 107-188, Title V, Subtitle C, § 532(a), (c)(1), 116 Stat. 696; Dec. 8, 2003, P.L. 108-173, Title I, § 102(a), (c)(1), Title II, Subtitle C, §§ 221(a)(1), (d)(5), 222(l)(3)(A), (B), (D), (E), Subtitle D, §§ 231(a), 233(b), (d), 237(b)(2)(A), 117 Stat. 2152, 2154, 2180, 2193, 2206, 2207, 2209, 2213.)

(As amended Dec. 20, 2006, P.L. 109-432, Div B, Title II, § 206(a), 120 Stat. 2990; July 18, 2007, P.L. 110-48, § 2, 121 Stat. 244; July 15, 2008, P.L. 110-275, Title I, Subtitle A, Part I, § 103(a)(1), (b)(1), (c)(1), (d)(1), 122 Stat. 2498, 2499, 2500, 2501.)

§ 1395w-22. Benefits and beneficiary protections

(a) Basic benefits.

(1) Requirement.

(A) In general. Except as provided in section 1859(b)(3) [*42 USCS § 1395w-28(b)(3)*] for MSA plans and except as provided in paragraph (6) for MA regional plans, each Medicare + Choice plan shall provide to members enrolled under this part [*42 USCS §§ 1395w-21* et seq.], through providers and other persons that meet the applicable requirements of this *title [42 USCS §§ 1395* et seq.] and part A of title XI [*42 USCS §§ 1301* et seq.], benefits under the original medicare fee-for-service program option (and, for plan years before 2006, additional benefits required under section 1854(f)(1)(A) [*42 USCS § 1395w-24(f)(1)(A)*]).

(B) Benefits under the original medicare fee-for-service program option defined.

(i) In general. For purposes of this part [*42 USCS §§ 1395w-21* et seq.], the term "benefits under the original medicare fee-for-service program option" means those items and services (other than hospice care) for which benefits are available under parts A and B [*42 USCS §§ 1395c* et seq. and *1395j* et seq.] to individuals entitled to benefits under part A [*42 USCS §§ 1395c* et seq.] and enrolled under part B [*42 USCS §§ 1395j* et seq.], with cost-sharing for those services as required under parts A and B [*42 USCS §§ 1395c* et seq. and *1395j* et seq.] or an actuarially equivalent level of cost-sharing as determined in this part [*42 USCS §§ 1395w-21* et seq.],.

(ii) Special rule for regional plans. In the case of an MA regional plan in determining an actuarially equivalent level of cost-sharing with respect to benefits under the original medicare fee-for-service program option, there shall only be taken into account, with respect to the application of section 1858(b)(2) [*42 USCS § 1395w-27a(b)(2)*], such expenses only with respect to subparagraph (A) of such section.

(2) Satisfaction of requirement.

(A) In general. A Medicare + Choice plan (other than an MSA plan) offered by a Medicare + Choice organization satisfies paragraph (1)(A), with respect to benefits for items and services furnished other than through a provider or other person that has a contract with the organization offering the plan, if the plan provides payment in an amount so that--

(i) the sum of such payment amount and any cost sharing provided for under the plan, is equal to at least

(ii) the total dollar amount of payment for such items and services as would otherwise be authorized under parts A and B [*42 USCS §§ 1395c* et seq. and *1395j* et seq.] (including any balance billing permitted under such parts).

(B) Reference to related provisions. For provision relating to--

(i) limitations on balance billing against Medicare + Choice organizations for non-contract providers, see sections 1852(k) and 1866(a)(1)(O) [*42 USCS §§ 1395w-22(k)* and *1395cc(a)(1)(O)*], and

(ii) limiting actuarial value of enrollee liability for covered benefits, see section 1854(e) [*42 USCS § 1395w-24(e)*].

(C) Election of uniform coverage determination. In the case of a Medicare + Choice organization that offers a Medicare + Choice plan in an area in which more than one local coverage determination is applied with respect to different parts of the area, the organization may elect to have the local coverage determination for the part of the area that is most beneficial to Medicare + Choice enrollees (as identified by the Secretary) apply with respect to all Medicare + Choice enrollees enrolled in the plan.

(3) Supplemental benefits.

(A) Benefits included subject to Secretary's approval. Each Medicare + Choice organization may provide to individuals enrolled under this part [*42 USCS §§ 1395w-21* et seq.], other than under an MSA plan (without affording those individuals an option to decline the coverage), supplemental health care benefits that the Secretary may approve. The Secretary shall approve any such supplemental benefits unless the Secretary determines that including such supplemental benefits would substantially discourage enrollment by Medicare + Choice eligible individuals with the organization.

(B) At enrollees' option.

(i) In general. Subject to clause (ii), a Medicare + Choice organization may provide to individuals enrolled under this part [*42 USCS §§ 1395w-21* et seq.] supplemental health care benefits that the individuals may elect, at their option, to have covered.

(ii) Special rule for MSA plans. A Medicare + Choice organization may not provide, under an MSA plan, supplemental health care benefits that cover the deductible described in section 1859(b)(2)(B) [*42 USCS § 1395w-28(b)(2)(B)*]. In applying the previous sentence, health benefits described in section 1882(u)(2)(B) [*42 USCS § 1395ss(u)(2)(B)*] shall not be treated as covering such deductible.

(C) Application to Medicare + Choice private fee-for-service plans. Nothing in this paragraph shall be construed as preventing a Medicare + Choice private fee-for-service plan from offering supplemental benefits that include payment for some or all of the balance billing amounts permitted consistent with section 1852(k) [*42 USCS § 1395w-22(k)*] and coverage of additional services that the plan finds to be medically necessary.

Such benefits may include reductions in cost-sharing below the actuarial value specified in section 1854(e)(4)(B) [*42 USCS § 1395w-24(e)(4)(B)*].

(4) Organization as secondary payer. Notwithstanding any other provision of law, a Medicare + Choice organization may (in the case of the provision of items and services to an individual under a Medicare + Choice plan under circumstances in which payment under this *title [42 USCS §§ 1395* et seq.] is made secondary pursuant to section 1862(b)(2) [*42 USCS § 1395y(b)(2)*]) charge or authorize the provider of such services to charge, in accordance with the charges allowed under a law, plan, or policy described in such section--

(A) the insurance carrier, employer, or other entity which under such law, plan, or policy is to pay for the provision of such services, or

(B) such individual to the extent that the individual has been paid under such law, plan, or policy for such services.

(5) National coverage determinations and legislative changes in benefits. If there is a national coverage determination or legislative change in benefits required to be provided under this part [*42 USCS §§ 1395w-21* et seq.] made in the period beginning on the date of an announcement under section 1853(b) [*42 USCS § 1395w-23(b)*] and ending on the date of the next announcement under such section and the Secretary projects that the determination will result in a significant change in the costs to a Medicare + Choice organization of providing the benefits that are the subject of such national coverage determination and that such change in costs was not incorporated in the determination of the annual Medicare + Choice capitation rate under section 1853 [*42 USCS § 1395w-23*] included in the announcement made at the beginning of such period, then, unless otherwise required by law--

(A) such determination or legislative change in benefits shall not apply to contracts under this part [*42 USCS §§ 1395w-21* et seq.] until the first contract year that begins after the end of such period, and

(B) if such coverage determination or legislative change provides for coverage of additional benefits or coverage under additional circumstances, section 1851(i)(1) [*42 USCS § 1395w-21(i)(1)*] shall not apply to payment for such additional benefits or benefits provided under such additional circumstances until the first contract year that begins after the end of such period.

The projection under the previous sentence shall be based on an analysis by the Chief Actuary of the Centers for Medicare & Medicaid Services of the actuarial costs associated with the coverage determination or legislative change in benefits.

(6) Special benefit rules for regional plans. In the case of an MA plan that is an MA regional plan, benefits under the plan shall include the benefits described in paragraphs (1) and (2) of section 1858(b) [*42 USCS § 1395w-27a(b)*].

(7) Limitation on cost-sharing for dual eligibles and qualified medicare beneficiaries **[Caution: This paragraph applies to plan years beginning on or after January 1, 2010, as provided by § 165(b) of Act July 15, 2008, P.L. 110-275, which appears as a note to this section.]**. In the case of an individual who is a full-benefit dual eligible individual (as defined in section 1935(c)(6) [*42 USCS § 1396u-5(c)(6)*]) or a qualified medicare beneficiary (as defined in section 1905(p)(1) [*42 USCS § 1396d(p)(1)*]) and who is enrolled in a specialized Medicare Advantage plan for special needs individuals described in section 1859(b)(6)(B)(ii) [*42 USCS § 1395w-28(b)(6)(B)(ii)*], the plan may not impose cost-sharing that exceeds the amount of cost-sharing that would be permitted with respect to the individual under title XIX [*42 USCS §§ 1396* et seq.] if the individual were not enrolled in such plan.

(b) Antidiscrimination.

(1) Beneficiaries.

(A) In general. A Medicare + Choice organization may not deny, limit, or condition the coverage or provision of benefits under this part [*42 USCS §§ 1395w-21* et seq.], for individuals permitted to be enrolled with the organization under this part [*42 USCS §§ 1395w-21* et seq.], based on any health status-related factor described in section 2702(a)(1) of the Public Health Service Act [*42 USCS § 300gg-1(a)(1)*]. The Secretary shall not approve a plan of an organization if the Secretary determines that the design of the plan and its benefits are likely to substantially discourage enrollment by certain MA eligible individuals with the organization.

(B) Construction. Subparagraph (A) shall not be construed as requiring a Medicare + Choice organization to enroll individuals who are determined to have end-stage renal disease, except as provided under section 1851(a)(3)(B) [*42 USCS § 1395w-21(a)(3)(B)*].

(2) Providers. A Medicare + Choice organization shall not discriminate with respect to participation, reimbursement, or indemnification as to any provider who is acting within the scope of the provider's license or certification under applicable State law, solely on the basis of such license or certification. This paragraph shall not be construed to prohibit a plan from including providers only to the extent necessary to meet the needs of the plan's enrollees or from establishing any measure designed to maintain quality and control costs consistent with the responsibilities of the plan.

(c) Disclosure requirements.

(1) Detailed description of plan provisions. A Medicare + Choice organization shall disclose, in clear, accurate, and standardized form to each enrollee with a Medicare + Choice plan offered by the organization under this part [*42 USCS §§ 1395w-21* et seq.] at the time of enrollment and at least annually thereafter, the following information regarding such plan:

(A) Service area. The plan's service area.

(B) Benefits. Benefits offered under the plan, including information described in section 1851(d)(3)(A) [*42 USCS § 1395w-21(d)(3)(A)*] and exclusions from coverage and, if it is an MSA plan, a comparison of benefits under such a plan with benefits under other Medicare + Choice plans.

(C) Access. The number, mix, and distribution of plan providers, out-of-network coverage (if any) provided by the plan, and any point-of-service option (including the supplemental premium for such option).

(D) Out-of-area coverage. Out-of-area coverage provided by the plan.

(E) Emergency coverage. Coverage of emergency services, including--

(i) the appropriate use of emergency services, including use of the 911 telephone system or its local equivalent in emergency situations and an explanation of what constitutes an emergency situation;

(ii) the process and procedures of the plan for obtaining emergency services; and

(iii) the locations of (I) emergency departments, and (II) other settings, in which plan physicians and hospitals provide emergency services and post-stabilization care.

(F) Supplemental benefits. Supplemental benefits available from the organization offering the plan, including--

(i) whether the supplemental benefits are optional,

(ii) the supplemental benefits covered, and

(iii) the Medicare + Choice monthly supplemental beneficiary premium for the supplemental benefits.

(G) Prior authorization rules. Rules regarding prior authorization or other review requirements that could result in nonpayment.

(H) Plan grievance and appeals procedures. All plan appeal or grievance rights and procedures.

(I) Quality improvement program. A description of the organization's quality improvement program under subsection (e).

(2) Disclosure upon request. Upon request of a Medicare + Choice eligible individual, a Medicare + Choice organization must provide the following information to such individual:

(A) The general coverage information and general comparative plan information made available under clauses (i) and (ii) of section 1851(d)(2)(A) [*42 USCS § 1395w-21(d)(2)(A)*].

(B) Information on procedures used by the organization to control utilization of services and expenditures.

(C) Information on the number of grievances, redeterminations, and appeals and on the disposition in the aggregate of such matters.

(D) An overall summary description as to the method of compensation of participating physicians.

(d) Access to services.

(1) In general. A Medicare + Choice organization offering a Medicare + Choice plan may select the providers from whom the benefits under the plan are provided so long as--

(A) the organization makes such benefits available and accessible to each individual electing the plan within the plan service area with reasonable promptness and in a manner which assures continuity in the provision of benefits;

(B) when medically necessary the organization makes such benefits available and accessible 24 hours a day and 7 days a week;

(C) the plan provides for reimbursement with respect to services which are covered under subparagraphs (A) and (B) and which are provided to such an individual other than through the organization, if--

(i) the services were not emergency services (as defined in paragraph (3)), but (I) the services were medically necessary and immediately required because of an unforeseen illness, injury, or condition, and (II) it was not reasonable given the circumstances to obtain the services through the organization,

(ii) the services were renal dialysis services and were provided other than through the organization because the individual was temporarily out of the plan's service area, or

(iii) the services are maintenance care or post-stabilization care covered under the guidelines established under paragraph (2);

(D) the organization provides access to appropriate providers, including credentialed specialists, for medically necessary treatment and services; and

(E) coverage is provided for emergency services (as defined in paragraph (3)) without regard to prior authorization or the emergency care provider's contractual relationship with the organization.

(2) Guidelines respecting coordination of post-stabilization care. A Medicare + Choice plan shall comply with such guidelines as the Secretary may prescribe relating to promoting efficient and timely coordination of appropriate maintenance and post-stabilization care of an enrollee after the enrollee has been determined to be stable under section 1867 [*42 USCS § 1395dd*].

(3) Definition of emergency services. In this subsection--

(A) In general. The term "emergency services" means, with respect to an individual enrolled with an organization, covered inpatient and outpatient services that--

(i) are furnished by a provider that is qualified to furnish such services under this *title [42 USCS §§ 1395* et seq.], and

(ii) are needed to evaluate or stabilize an emergency medical condition (as defined in subparagraph (B)).

(B) Emergency medical condition based on prudent layperson. The term "emergency medical condition" means a medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain) such that a prudent layperson, who possesses an average knowledge of health and medicine, could reasonably expect the absence of immediate medical attention to result in--

(i) placing the health of the individual (or, with respect to a pregnant woman, the health of the woman or her unborn child) in serious jeopardy,

(ii) serious impairment to bodily functions, or

(iii) serious dysfunction of any bodily organ or part.

(4) Assuring access to services in Medicare + Choice private fee-for-service plans. In addition to any other requirements under this part [*42 USCS §§ 1395w-21* et seq.], in the case of a Medicare + Choice private fee-for-service plan, the organization offering the plan must demonstrate to the Secretary that the organization has sufficient number and range of health care professionals and providers willing to provide services under the terms of the plan. Subject to paragraphs (5) and (6), the Secretary shall find that an organization has met such requirement with respect to any category of health care professional or provider if, with respect to that category of provider--

(A) the plan has established payment rates for covered services furnished by that category of provider that are not less than the payment rates provided for under part A [*42 USCS §§ 1395c* et seq.], part B [*42 USCS §§ 1395j* et seq.], or both, for such services, or

(B) **[Caution: For provisions applicable to plan years before 2010, see 2008 amendment note below.]** the plan has contracts or agreements (other than deemed contracts or agreements under subsection (j)(6)) with a sufficient number and range of providers within such category to meet the access standards in subparagraphs (A) through (E) of paragraph (1),

or a combination of both. The previous sentence shall not be construed as restricting the persons from whom enrollees under such a plan may obtain covered benefits, except that, if a plan entirely meets such requirement with respect to a category of health care professional or provider on the basis of subparagraph (B), it may provide for a higher beneficiary copayment in the case of health care professionals and providers of that category who do not have contracts or agreements (other than deemed contracts or agreements under subsection (j)(6)) to provide covered services under the terms of the plan.

(5) Requirement of certain nonemployer medicare advantage private fee-for-service plans to use contracts with providers.

(A) In general. For plan year 2011 and subsequent plan years, in the case of a Medicare Advantage private fee-for-service plan not described in paragraph (1) or (2) of section 1857(i) [*42 USCS § 1395w-27(i)*] operating in a network area (as defined in subparagraph (B)), the plan shall meet the access standards under paragraph (4) in that area only through entering into written contracts as provided for under subparagraph (B) of such paragraph and not, in whole or in part, through the establishment of payment rates meeting the requirements under subparagraph (A) of such paragraph.

(B) Network area defined. For purposes of subparagraph (A), the term "network area" means, for a plan year, an area which the Secretary identifies (in the Secretary's announcement of the proposed payment rates for the previous plan year under section 1853(b)(1)(B) [*42 USCS § 1395w-23(b)(1)(B)*]) as having at least 2 network-based plans (as defined in subparagraph (C)) with enrollment under this part as of the first day of the year in which such announcement is made.

(C) Network-based plan defined.

(i) In general. For purposes of subparagraph (B), the term "network-based plan" means--

(I) except as provided in clause (ii), a Medicare Advantage plan that is a coordinated care plan described in section 1851(a)(2)(A)(i) [USCS § 1395w-21(a)(2)(A)(i)];

(II) a network-based MSA plan; and

(III) a reasonable cost reimbursement plan under section 1876 [*42 USCS § 1395mm*].

(ii) Exclusion of non-network regional PPOs. The term "network-based plan" shall not include an MA regional plan that, with respect to the area, meets access adequacy standards under this part [*42 USCS §§ 1395w-21* et seq.] substantially through the authority of *section 422.112(a)(1)(ii) of title 42, Code of Federal R*egulations, rather than through written contracts.

(6) Requirement of all employer Medicare Advantage private fee-for-service plans to use contracts with providers. For plan year 2011 and subsequent plan years, in the case of a Medicare Advantage private fee-for-service plan that is described in paragraph (1) or (2) of section 1857(i) [*42 USCS § 1395w-27(i)*], the plan shall meet the access standards under paragraph (4) only through entering into written contracts as provided for under subparagraph (B) of such paragraph and not, in whole or in part, through the establishment of payment rates meeting the requirements under subparagraph (A) of such paragraph.

(e) Quality improvement program.

(1) In general **[Caution: For provisions applicable to plan years beginning before January 1, 2010, see 2008 amendment note below.]**. Each MA organization shall have an ongoing quality improvement program for the purpose of improving the quality of care provided to enrollees in each MA plan offered by such organization.

(2) Chronic care improvement programs. As part of the quality improvement program under paragraph (1), each MA organization shall have a chronic care improvement program. Each chronic care improvement program shall have a method for monitoring and identifying enrollees with multiple or sufficiently severe chronic conditions that meet criteria established by the organization for participation under the program.

(3) Data.

(A) Collection, analysis, and reporting **[Caution: For provisions applicable to plan years beginning before January 1, 2010, see 2008 amendment note below.]**.

(i) In general. Except as provided in clauses (ii) and (iii) with respect to plans described in such clauses and subject to subparagraph (B), as part of the quality improvement program under paragraph (1), each MA organization shall provide for the collection, analysis, and reporting of data that permits the measurement of health outcomes and other indices of quality. With respect to MA private fee-for-service plans and MSA plans, the requirements under the preceding sentence may not exceed the requirements under this subparagraph with respect to MA local plans that are preferred provider organization plans, except that, for plan year 2010, the limitation under clause (iii) shall not apply and such requirements shall apply only with respect to administrative claims data.

(ii) Special requirements for specialized MA plans for special needs individuals **[Caution: This clause takes effect on a date specified by the Secretary (but in no case later than January 1, 2010), as provided by § 164(f)(2) of Act July 15, 2008, P.L. 110-275, which appears as a note to this section.]**. In addition to the data required to be collected, analyzed, and reported under clause (i) and notwithstanding the limitations under subparagraph (B), as part of the quality improvement program under paragraph (1), each MA organization offering a specialized Medicare

Advantage plan for special needs individuals shall provide for the collection, analysis, and reporting of data that permits the measurement of health outcomes and other indices of quality with respect to the requirements described in paragraphs (2) through (5) of subsection (f). Such data may be based on claims data and shall be at the plan level.

(iii) Application to local preferred provider organizations and MA regional plans. Clause (i) shall apply to MA organizations with respect to MA local plans that are preferred provider organization plans and to MA regional plans only insofar as services are furnished by providers or services, physicians, and other health care practitioners and suppliers that have contracts with such organization to furnish services under such plans.

(iv) Definition of preferred provider organization plan. In this subparagraph, the term "preferred provider organization plan" means an MA plan that--

(I) has a network of providers that have agreed to a contractually specified reimbursement for covered benefits with the organization offering the plan;

(II) provides for reimbursement for all covered benefits regardless of whether such benefits are provided within such network of providers; and

(III) is offered by an organization that is not licensed or organized under State law as a health maintenance organization.

(B) Limitations.

(i) Types of data. The Secretary shall not collect under subparagraph (A) data on quality, outcomes, and beneficiary satisfaction to facilitate consumer choice and program administration other than the types of data that were collected by the Secretary as of November 1, 2003.

(ii) Changes in types of data. Subject to subclause (iii), the Secretary may only change the types of data that are required to be submitted under subparagraph (A) after submitting to Congress a report on the reasons for such changes that was prepared in consultation with MA organizations and private accrediting bodies.

(iii) Construction. Nothing in the subsection shall be construed as restricting the ability of the Secretary to carry out the duties under section 1851(d)(4)(D) [*42 USCS § 1395w-21(d)(4)(D)*].

(4) Treatment of accreditation.

(A) In general The Secretary shall provide that a Medicare + Choice organization is deemed to meet all the requirements described in any specific clause of subparagraph (B) if the organization is accredited (and periodically reaccredited) by a private accrediting organization under a process that the Secretary has determined assures that the accrediting organization applies and enforces standards that meet or exceed the standards established under section 1856 [*42 USCS § 1395w-26*] to carry out the requirements in such clause.

(B) Requirements described. The provisions described in this subparagraph are the following:

(i) Paragraphs (1) through (3) of this subsection (relating to quality improvement programs).

(ii) Subsection (b) (relating to antidiscrimination).

(iii) Subsection (d) (relating to access to services).

(iv) Subsection (h) (relating to confidentiality and accuracy of enrollee records).

(v) Subsection (i) (relating to information on advance directives).

(vi) Subsection (j) (relating to provider participation rules).

(vii) The requirements described in section 1860D-4(j) [*42 USCS § 1395w-104(j)*], to the extent such requirements apply under section 1860D-21(c) [*42 USCS § 1395w-131(c)*].

(C) Timely action on applications **[Caution: For provisions applicable to accreditations of hospitals granted before July 15, 2010, see 2008 amendment note below.]**. The Secretary shall determine, within 210 days after the date the Secretary receives an application by a private accrediting organization and using the criteria specified in section 1865(a)(2) [*42 USCS § 1395bb(a)(2)*], whether the process of the private accrediting organization meets the requirements with respect to any specific clause in subparagraph (B) with respect to which the application is made. The Secretary may not deny such an application on the basis that it seeks to meet the requirements with respect to only one, or more than one, such specific clause.

(D) Construction. Nothing in this paragraph shall be construed as limiting the authority of the Secretary under section 1857 [*42 USCS § 1395w-27*], including the authority to terminate contracts with Medicare + Choice organizations under subsection (c)(2) of such section.

(f) Grievance mechanism. Each Medicare + Choice organization must provide meaningful procedures for hearing and resolving grievances between the organization (including any entity or individual through which the organization provides health care services) and enrollees with Medicare + Choice plans of the organization under this part [*42 USCS §§ 1395w-21* et seq.].

(g) Coverage determinations, reconsiderations, and appeals.

(1) Determinations by organization.

(A) In general. A Medicare + Choice organization shall have a procedure for making determinations regarding whether an individual enrolled with the plan of the organization under this part [*42 USCS §§ 1395w-21* et seq.] is entitled to receive a health service under this section and the amount (if any) that the individual is required to pay with respect to such service. Subject to paragraph (3), such procedures shall provide for such determination to be made on a timely basis.

(B) Explanation of determination. Such a determination that denies coverage, in whole or in part, shall be in writing and shall include a statement in understandable language of the reasons for the denial and a description of the reconsideration and appeals processes.

(2) Reconsiderations.

(A) In general. The organization shall provide for reconsideration of a determination described in paragraph (1)(B) upon request by the enrollee involved. The reconsideration shall be within a time period specified by the Secretary, but shall be made, subject to paragraph (3), not later than 60 days after the date of the receipt of the request for reconsideration.

(B) Physician decision on certain reconsiderations. A reconsideration relating to a determination to deny coverage based on a lack of medical necessity shall be made only by a physician with appropriate expertise in the field of medicine which necessitates treatment who is other than a physician involved in the initial determination.

(3) Expedited determinations and reconsiderations.

(A) Receipt of requests.

(i) Enrollee requests. An enrollee in a Medicare + Choice plan may request, either in writing or orally, an expedited determination under paragraph (1) or an expedited reconsideration under paragraph (2) by the Medicare + Choice organization.

(ii) Physician requests. A physician, regardless whether the physician is affiliated with the organization or not, may request, either in writing or orally, such an expedited determination or reconsideration.

(B) Organization procedures.

(i) In general. The Medicare + Choice organization shall maintain procedures for expediting organization determinations and reconsiderations when, upon request of an enrollee, the organization determines that the application of the normal time frame for making a determination (or a reconsideration involving a determination) could seriously jeopardize the life or health of the enrollee or the enrollee's ability to regain maximum function.

(ii) Expedition required for physician requests. In the case of a request for an expedited determination or reconsideration made under subparagraph (A)(ii), the organization shall expedite the determination or reconsideration if the request indicates that the application of the normal time frame for making a determination (or a reconsideration involving a determination) could seriously jeopardize the life or health of the enrollee or the enrollee's ability to regain maximum function.

(iii) Timely response. In cases described in clauses (i) and (ii), the organization shall notify the enrollee (and the physician involved, as appropriate) of the determination or reconsideration under time limitations established by the Secretary, but not later than 72 hours of the time of receipt of the request for the determination or reconsideration (or receipt of the information necessary to make the determination or reconsideration), or such longer period as the Secretary may permit in specified cases.

(4) Independent review of certain coverage denials. The Secretary shall contract with an independent, outside entity to review and resolve in a timely manner reconsiderations that affirm denial of coverage, in whole or in part. The provisions of section 1869(c)(5) [*42 USCS § 1395ff(c)(5)*] shall apply to independent outside entities under contract with the Secretary under this paragraph.

(5) An enrollee with a Medicare + Choice plan of a Medicare + Choice organization under this part [*42 USCS §§ 1395w-21* et seq.] who is dissatisfied by reason of the enrollee's failure to receive any health service to which the enrollee believes the enrollee is entitled and at no greater charge than the enrollee believes the enrollee is required to pay is entitled, if the amount in controversy is $ 100 or more, to a hearing before the Secretary to the same extent as is provided in section 205(b) [*42 USCS § 405(b)*], and in any such hearing the Secretary shall make the organization a party. If the amount in controversy is $ 1,000 or more, the individual or organization shall, upon notifying the other party, be entitled to judicial review of the Secretary's final decision as provided in section 205(g) [*42 USCS § 405(g)*], and both the individual and the organization shall be entitled to be parties to that judicial review. In applying subsections (b) and (g) of section 205 [*42 USCS § 405(b)* and (g)] as provided in this paragraph, and in applying section 205(l) [*42 USCS § 405(l)*] thereto, any reference therein to the Commissioner of Social Security or the Social Security Administration shall be considered a reference to the Secretary or the Department of Health and Human Services, respectively. The provisions of section 1869(b)(1)(E)(iii) [*42 USCS § 1395ff(b)(1)(E)(iii)*] shall apply with respect to dollar amounts specified in the first 2 sentences of this paragraph in the same manner as they apply to the dollar amounts specified in section 1869(b)(1)(E)(i) [*42 USCS § 1395ff(b)(1)(E)(i)*].

(h) Confidentiality and accuracy of enrollee records. Insofar as a Medicare + Choice organization maintains medical records or other health information regarding enrollees under this part [*42 USCS §§ 1395w-21* et seq.], the Medicare + Choice organization shall establish procedures--

(1) to safeguard the privacy of any individually identifiable enrollee information;

(2) to maintain such records and information in a manner that is accurate and timely; and

(3) to assure timely access of enrollees to such records and information.

(i) Information on advance directives. Each Medicare + Choice organization shall meet the requirement of section 1866(f) [*42 USCS § 1395cc(f)*] (relating to maintaining written policies and procedures respecting advance directives).

(j) Rules regarding provider participation.

(1) Procedures. Insofar as a Medicare + Choice organization offers benefits under a Medicare + Choice plan through agreements with physicians, the organization shall establish reasonable procedures relating to the participation (under an agreement between a physician and the organization) of physicians under such a plan. Such procedures shall include--

(A) providing notice of the rules regarding participation,

(B) providing written notice of participation decisions that are adverse to physicians, and

(C) providing a process within the organization for appealing such adverse decisions, including the presentation of information and views of the physician regarding such decision.

(2) Consultation in medical policies. A Medicare + Choice organization shall consult with physicians who have entered into participation agreements with the organization regarding the organization's medical policy, quality, and medical management procedures.

(3) Prohibiting interference with provider advice to enrollees.

(A) In general. Subject to subparagraphs (B) and (C), a Medicare + Choice organization (in relation to an individual enrolled under a Medicare + Choice plan offered by the organization under this part [*42 USCS §§ 1395w-21* et seq.]) shall not prohibit or otherwise restrict a covered health care professional (as defined in subparagraph (D)) from advising such an individual who is a patient of the professional about the health status of the individual or medical care or treatment for the individual's condition or disease, regardless of whether benefits for such care or treatment are provided under the plan, if the professional is acting within the lawful scope of practice.

(B) Conscience protection. Subparagraph (A) shall not be construed as requiring a Medicare + Choice plan to provide, reimburse for, or provide coverage of a counseling or referral service if the Medicare + Choice organization offering the plan--

(i) objects to the provision of such service on moral or religious grounds; and

(ii) in the manner and through the written instrumentalities such Medicare + Choice organization deems appropriate, makes available information on its policies regarding such service to prospective enrollees before or during enrollment and to enrollees within 90 days after the date that the organization or plan adopts a change in policy regarding such a counseling or referral service.

(C) Construction. Nothing in subparagraph (B) shall be construed to affect disclosure requirements under State law or under the Employee Retirement Income Security Act of 1974.

(D) Health care professional defined. For purposes of this paragraph, the term "health care professional" means a physician (as defined in section 1861(r) [*42 USCS § 1395x(r)*]) or other health care professional if coverage for the professional's services is provided under the Medicare + Choice plan for the services of the professional. Such term includes a podiatrist, optometrist, chiropractor, psychologist, dentist, physician assistant, physical or occupational therapist and therapy assistant, speech-language pathologist, audiologist, registered or licensed practical nurse (including nurse practitioner, clinical nurse specialist, certified registered nurse anesthetist, and certified nurse-midwife), licensed certified social worker, registered respiratory therapist, and certified respiratory therapy technician.

(4) Limitations on physician incentive plans.

(A) In general. No Medicare + Choice organization may operate any physician incentive plan (as defined in subparagraph (B)) unless the organization provides assurances satisfactory to the Secretary that the following requirements are met:

(i) No specific payment is made directly or indirectly under the plan to a physician or physician group as an inducement to reduce or limit medically necessary services provided with respect to a specific individual enrolled with the organization.

(ii) If the plan places a physician or physician group at substantial financial risk (as determined by the Secretary) for services not provided by the physician or physician group, the organization provides stop-loss protection for the physician or group that is adequate and appropriate, based on standards developed by the Secretary that take into account the number of physicians placed at such substantial financial risk in the group or under the plan and the number of individuals enrolled with the organization who receive services from the physician or group.

(B) Physician incentive plan defined. In this paragraph, the term "physician incentive plan" means any compensation arrangement between a Medicare + Choice organization and a physician or physician group that may directly or indirectly have the effect of reducing or limiting services provided with respect to individuals enrolled with the organization under this part [*42 USCS §§ 1395w-21* et seq.].

(5) Limitation on provider indemnification. A Medicare + Choice organization may not provide (directly or indirectly) for a health care professional, provider of services, or other entity providing health care services (or group of such professionals, providers, or entities) to indemnify the organization against any liability resulting from a civil action brought for any damage caused to an enrollee with a Medicare + Choice plan of the organization under this part [*42 USCS §§ 1395w-21* et seq.] by the organization's denial of medically necessary care.

(6) Special rules for Medicare + Choice private fee-for-service plans. For purposes of applying this part [*42 USCS §§ 1395w-21* et seq.] (including subsection (k)(1)) and section 1866(a)(1)(O) [*42 USCS § 1395cc(a)(1)(O)*], a hospital (or other provider of services), a physician or other health care professional, or other entity furnishing health care services is treated as having an agreement or contract in effect with a Medicare + Choice organization (with respect to an individual enrolled in a Medicare + Choice private fee-for-service plan it offers), if--

(A) the provider, professional, or other entity furnishes services that are covered under the plan to such an enrollee; and

(B) before providing such services, the provider, professional, or other entity--

(i) has been informed of the individual's enrollment under the plan, and

(ii) either--

(I) has been informed of the terms and conditions of payment for such services under the plan, or

(II) is given a reasonable opportunity to obtain information concerning such terms and conditions,

in a manner reasonably designed to effect informed agreement by a provider.

The previous sentence shall only apply in the absence of an explicit agreement between such a provider, professional, or other entity and the Medicare + Choice organization.

(7) Promotion of e-prescribing by MA plans.

(A) In general. An MA-PD plan may provide for a separate payment or otherwise provide for a differential payment for a participating physician that prescribes covered part D drugs in accordance with an electronic prescription drug program that meets standards established under section 1860D-4(e) [*42 USCS § 1395w-104(e)*].

(B) Considerations. Such payment may take into consideration the costs of the physician in implementing such a program and may also be increased for those participating physicians who significantly increase--

(i) formulary compliance;

(ii) lower cost, therapeutically equivalent alternatives;

(iii) reductions in adverse drug interactions; and

(iv) efficiencies in filing prescriptions through reduced administrative costs.

(C) Structure. Additional or increased payments under this subsection may be structured in the same manner as medication therapy management fees are structured under section 1860D-4(c)(2)(E) [*42 USCS § 1395w-104(c)(2)(E)*].

(k) Treatment of services furnished by certain providers.

(1) In general. Except as provided in paragraph (2), a physician or other entity (other than a provider of services) that does not have a contract establishing payment amounts for services furnished to an individual enrolled under this part [*42 USCS §§ 1395w-21* et seq.] with a Medicare + Choice organization described in section 1851(a)(2)(A) [*42 USCS § 1395w-21(a)(2)(A)*] or with an organization offering an MSA plan shall accept as payment in full for covered services under this *title [42 USCS §§ 1395* et seq.] that are furnished to such an individual the amounts that the physician or other entity could collect if the individual were not so enrolled. Any penalty or other provision of law that applies to such a payment with respect to an individual entitled to benefits under this *title [42 USCS §§ 1395* et seq.] (but not enrolled with a Medicare + Choice organization under this part [*42 USCS §§ 1395w-21* et seq.]) also applies with respect to an individual so enrolled.

(2) Application to Medicare + Choice private fee-for-service plans.

(A) Balance billing limits under Medicare + Choice private fee-for-service plans in case of contract providers.

(i) In general. In the case of an individual enrolled in a Medicare + Choice private fee-for-service plan under this part [*42 USCS §§ 1395w-21* et seq.], a physician, provider of services, or other entity that has a contract (including through the operation of subsection (j)(6)) establishing a payment rate for services furnished to the enrollee shall accept as payment in full for covered services under this *title [42 USCS §§ 1395* et seq.] that are furnished to such an individual an amount not to exceed (including any deductibles, coinsurance, copayments, or balance billing otherwise permitted under the plan) an amount equal to 115 percent of such payment rate.

(ii) Procedures to enforce limits. The Medicare + Choice organization that offers such a plan shall establish procedures, similar to the procedures described in section 1848(g)(1)(A) [*42 USCS § 1395w-4(g)(1)(A)*], in order to carry out the previous sentence.

(iii) Assuring enforcement. If the Medicare + Choice organization fails to establish and enforce procedures required under clause (ii), the organization is subject to intermediate sanctions under section 1857(g) [*42 USCS § 1395w-27(g)*].

(B) Enrollee liability for noncontract providers. For provision--

(i) establishing minimum payment rate in the case of noncontract providers under a Medicare + Choice private fee-for-service plan, see section 1852(a)(2) [*42 USCS § 1395w-22(a)(2)*]; or

(ii) limiting enrollee liability in the case of covered services furnished by such providers, see paragraph (1) and section 1866(a)(1)(O) [*42 USCS § 1395cc(a)(1)(O)*].

(C) Information on beneficiary liability.

(i) In general. Each Medicare + Choice organization that offers a Medicare + Choice private fee-for-service plan shall provide that enrollees under the plan who are furnished services for which payment is sought under the plan are provided an appropriate explanation of benefits (consistent with that provided under parts A and B [*42 USCS §§ 1395c* et seq. and *1395j* et seq.] and, if applicable, under medicare supplemental policies) that includes a clear statement of the amount of the enrollee's liability (including any liability for balance billing consistent with this subsection) with respect to payments for such services.

(ii) Advance notice before receipt of inpatient hospital services and certain other services. In addition, such organization shall, in its terms and conditions of payments to hospitals for inpatient hospital services and for other services identified by the Secretary for which the amount of the balance billing under subparagraph (A) could be substantial, require the hospital to provide to the enrollee, before furnishing such services and if the hospital imposes balance billing under subparagraph (A)--

(I) notice of the fact that balance billing is permitted under such subparagraph for such services, and

(II) a good faith estimate of the likely amount of such balance billing (if any), with respect to such services, based upon the presenting condition of the enrollee.

(l) Return to home skilled nursing facilities for covered post-hospital extended care services.

(1) Ensuring return to home SNF.

(A) In general. In providing coverage of post-hospital extended care services, a Medicare + Choice plan shall provide for such coverage through a home skilled nursing facility if the following conditions are met:

(i) Enrollee election. The enrollee elects to receive such coverage through such facility.

(ii) SNF agreement. The facility has a contract with the Medicare + Choice organization for the provision of such services, or the facility agrees to accept substantially similar payment under the same terms and conditions that apply to similarly situated skilled nursing facilities that are under contract with the Medicare + Choice organization for the provision of such services and through which the enrollee would otherwise receive such services.

(B) Manner of payment to home SNF. The organization shall provide payment to the home skilled nursing facility consistent with the contract or the agreement described in subparagraph (A)(ii), as the case may be.

(2) No less favorable coverage. The coverage provided under paragraph (1) (including scope of services, cost-sharing, and other criteria of coverage) shall be no less favorable to the enrollee than the coverage that would be provided to the enrollee with respect to a skilled nursing facility the post-hospital extended care services of which are otherwise covered under the Medicare + Choice plan.

(3) Rule of construction. Nothing in this subsection shall be construed to do the following:

(A) To require coverage through a skilled nursing facility that is not otherwise qualified to provide benefits under part A [1395c et seq.] for medicare beneficiaries not enrolled in a Medicare + Choice plan.

(B) To prevent a skilled nursing facility from refusing to accept, or imposing conditions upon the acceptance of, an enrollee for the receipt of post-hospital extended care services.

(4) Definitions. In this subsection:

(A) Home skilled nursing facility. The term "home skilled nursing facility" means, with respect to an enrollee who is entitled to receive post-hospital extended care services under a Medicare + Choice plan, any of the following skilled nursing facilities:

(i) SNF residence at time of admission. The skilled nursing facility in which the enrollee resided at the time of admission to the hospital preceding the receipt of such post-hospital extended care services.

(ii) SNF in continuing care retirement community. A skilled nursing facility that is providing such services through a continuing care retirement community (as defined in subparagraph (B)) which provided residence to the enrollee at the time of such admission.

(iii) SNF residence of spouse at time of discharge. The skilled nursing facility in which the spouse of the enrollee is residing at the time of discharge from such hospital.

(B) Continuing care retirement community. The term "continuing care retirement community" means, with respect to an enrollee in a Medicare + Choice plan, an arrangement under which housing and health-related services are provided (or arranged) through an organization for the enrollee under an agreement that is effective for the life of the enrollee or for a specified period.

HISTORY:

(Aug. 14, 1935, ch 531, Title XVIII, Part C, § 1852, as added Aug. 5, 1997, P.L. 105-33, Title IV, Subtitle A, Ch 1, Subch A, § 4001, 111 Stat. 286; Nov. 29, 1999, P.L. 106-113, Div B, § 1000(a)(6), 113 Stat. 1536; Dec. 21, 2000, P.L. 106-554, § 1(a)(6), 114 Stat. 2763; Dec. 8, 2003, P.L. 108-173, Title I, § 102(b), Title II, Subtitle B, § 211(j), Subtitle C, §§ 221(d)(3), 222(a)(2), (3), (h), (l)(1), Subtitle D, § 233(a)(1), (2), (c), Title VII, Subtitle C, § 722(a), (b), Title IX, § 900(e)(1)(F), Subtitle D, § 940(b)(2)(A), Title E, § 948(b)(2), 117 Stat. 2153, 2180, 2193, 2195, 2204, 2206, 2209, 2347, 2371, 2417, 2426.)

(As amended July 15, 2008, P.L. 110-275, Title I, Subtitle B, § 125(b)(6), Subtitle D, §§ 162(a)(1)-(3)(A), 163(a), (b), 164(f)(1), 165(a), 122 Stat. 2519, 2569, 2571, 2574, 2575.)

§ 1395w-23. Payments to Medicare + Choice organizations

(a) Payments to organizations.

(1) Monthly payments.

(A) In general. Under a contract under section 1857 [*42 USCS § 1395w-27*] and subject to subsections (e), (g), and (i) and section 1859(e)(4) [*42 USCS § 1395w-28(e)(4)*], the Secretary shall make monthly payments under this section in advance to each Medicare + Choice organization, with respect to coverage of an individual under this part [*42 USCS §§ 1395w-21* et seq.] in a Medicare + Choice payment area for a month, in an amount determined as follows:

(i) Payment before 2006. For years before 2006, the payment amount shall be equal to 1/12 of the annual MA capitation rate (as calculated under subsection (c)(1)) with respect to that individual for that area, adjusted under subparagraph (C) and reduced by the amount of any reduction elected under section 1854(f)(1)(E) [*42 USCS § 1395w-24(f)(1)(E)*].

(ii) Payment for original fee-for-service benefits beginning with 2006. For years beginning with 2006, the amount specified in subparagraph (B).

(B) Payment amount for original fee-for-service benefits beginning with 2006.

(i) Payment of bid for plans with bids below benchmark. In the case of a plan for which there are average per capita monthly savings described in section 1854(b)(3)(C) or 1854(b)(4)(C) [*42 USCS § 1395w-24(b)(3)(C)* or (4)(C)], as the case may be, the amount specified in this subparagraph is equal to the unadjusted MA statutory non-drug monthly bid amount, adjusted under subparagraph (C) and (if applicable) under subparagraphs (F) and (G), plus the amount (if any) of any rebate under subparagraph (E).

(ii) Payment of benchmark for plans with bids at or above benchmark. In the case of a plan for which there are no average per capita monthly savings described in section 1854(b)(3)(C) or 1854(b)(4)(C) [*42 USCS § 1395w-24(b)(3)(C)* or (4)(C)], as the case may be, the amount specified in this subparagraph is equal to the MA area-specific non-drug monthly benchmark amount, adjusted under subparagraph (C) and (if applicable) under subparagraphs (F) and (G).

(iii) Payment of benchmark for MSA plans. Notwithstanding clauses (i) and (ii), in the case of an MSA plan, the amount specified in this subparagraph is equal to the MA area-specific non-drug monthly benchmark amount, adjusted under subparagraph (C).

(C) Demographic adjustment, including adjustment for health status.

(i) In general. The Secretary shall adjust the payment amount under subparagraph (A)(i) and the amount specified under subparagraph (B)(i), (B)(ii), and (B)(iii) for such risk factors as age, disability status, gender, institutional status, and such other factors as the Secretary determines to be appropriate, including adjustment for health status under paragraph (3), so as to ensure actuarial equivalence. The Secretary may add to, modify, or substitute for such adjustment factors if such changes will improve the determination of actuarial equivalence.

(ii) Application during phase-out of budget neutrality factor. For 2006 through 2010:

(I) In applying the adjustment under clause (i) for health status to payment amounts, the Secretary shall ensure that such adjustment reflects changes in treatment and coding practices in the fee-for-service sector and reflects differences in coding patterns between Medicare Advantage plans and providers under part A and B [*42 USCS §§ 1395c* et seq. and *1395j* et seq.] to the extent that the Secretary has identified such differences.

(II) In order to ensure payment accuracy, the Secretary shall conduct an analysis of the differences described in subclause (I). The Secretary shall complete such analysis by a date necessary to ensure that the results of such analysis

are incorporated into the risk scores only for 2008, 2009, and 2010. In conducting such analysis, the Secretary shall use data submitted with respect to 2004 and subsequent years, as available.

(D) Separate payment for Federal drug subsidies. In the case of an enrollee in an MA-PD plan, the MA organization offering such plan also receives--

(i) subsidies under section 1860D-15 [*42 USCS § 1395w-115*] (other than under subsection (g)); and

(ii) reimbursement for premium and cost-sharing reductions for low-income individuals under section 1860D-14(c)(1)(C) [*42 USCS § 1395w-114(c)(1)(C)*].

(E) Payment of rebate for plans with bids below benchmark. In the case of a plan for which there are average per capita monthly savings described in section 1854(b)(3)(C) or 1854(b)(4)(C) [*42 USCS § 1395w-24(b)(3)(C)* or (4)(C)], as the case may be, the amount specified in this subparagraph is the amount of the monthly rebate computed under section 1854(b)(1)(C)(i) [*42 USCS § 1395w-24(b)(1)(C)(i)*] for that plan and year (as reduced by the amount of any credit provided under section 1854(b)(1)(C)(iv) [*42 USCS § 1395w-24(b)(1)(C)(iv)*]).

(F) Adjustment for intra-area variations.

(i) Intra-regional variations. In the case of payment with respect to an MA regional plan for an MA region, the Secretary shall also adjust the amounts specified under subparagraphs (B)(i) and (B)(ii) in a manner to take into account variations in MA local payment rates under this part among the different MA local areas included in such region.

(ii) Intra-service area variations. In the case of payment with respect to an MA local plan for a service area that covers more than one MA local area, the Secretary shall also adjust the amounts specified under subparagraphs (B)(i) and (B)(ii) in a manner to take into account variations in MA local payment rates under this part among the different MA local areas included in such service area.

(G) Adjustment relating to risk adjustment. The Secretary shall adjust payments with respect to MA plans as necessary to ensure that--

(i) the sum of--

(I) the monthly payment made under subparagraph (A)(ii); and

(II) the MA monthly basic beneficiary premium under section 1854(b)(2)(A) [*42 USCS § 1395w-24(b)(2)(A)*]; equals

(ii) the unadjusted MA statutory non-drug monthly bid amount, adjusted in the manner described in subparagraph (C) and, for an MA regional plan, subparagraph (F).

(H) Special rule for end-stage renal disease. The Secretary shall establish separate rates of payment to a Medicare + Choice organization with respect to classes of individuals determined to have end-stage renal disease and enrolled in a Medicare + Choice plan of the organization. Such rates of payment shall be actuarially equivalent to rates that would have been paid with respect to other enrollees in the MA payment area (or such other area as specified by the Secretary) under the provisions of this section as in effect before the date of the enactment of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 [enacted Dec. 8, 2003]. In accordance with regulations, the Secretary shall provide for the application of the seventh sentence of section 1881(b)(7) [*42 USCS § 1395rr(b)(7)*] to payments under this section covering the provision of renal dialysis treatment in the same manner as such sentence applies to composite rate payments described in such sentence. In establishing such rates, the Secretary shall provide for appropriate adjustments to increase each rate to reflect the demonstration rate (including the risk adjustment methodology associated with such rate) of the social health maintenance organization end-stage renal disease capitation demonstrations (established by section 2355 of the Deficit Reduction Act of 1984 [unclassified], as amended by section 13567(b) of the Omnibus Budget Reconciliation Act of 1993), and shall compute such rates by taking into account such factors as renal treatment modality, age, and the underlying cause of the end-stage renal disease. The Secretary may apply the competitive bidding methodology provided for in this section, with appropriate adjustments to account for the risk adjustment methodology applied to end stage renal disease payments.

(2) Adjustment to reflect number of enrollees.

(A) In general. The amount of payment under this subsection may be retroactively adjusted to take into account any difference between the actual number of individuals enrolled with an organization under this part [*42 USCS §§ 1395w-21* et seq.] and the number of such individuals estimated to be so enrolled in determining the amount of the advance payment.

(B) Special rule for certain enrollees.

(i) In general. Subject to clause (ii), the Secretary may make retroactive adjustments under subparagraph (A) to take into account individuals enrolled during the period beginning on the date on which the individual enrolls with a Medicare + Choice organization under a plan operated, sponsored, or contributed to by the individual's employer or former employer (or the employer or former employer of the individual's spouse) and ending on the date on which the individual is enrolled in the organization under this part [*42 USCS §§ 1395w-21* et seq.], except that for purposes of making such retroactive adjustments under this subparagraph, such period may not exceed 90 days.

(ii) Exception. No adjustment may be made under clause (i) with respect to any individual who does not certify that the organization provided the individual with the disclosure statement described in section 1852(c) [*42 USCS § 1395w-22(c)*] at the time the individual enrolled with the organization.

(3) Establishment of risk adjustment factors.

(A) Report. The Secretary shall develop, and submit to Congress by not later than March 1, 1999, a report on the method of risk adjustment of payment rates under this section, to be implemented under subparagraph (C), that accounts for variations in per capita costs based on health status. Such report shall include an evaluation of such method by an outside, independent actuary of the actuarial soundness of the proposal.

(B) Data collection. In order to carry out this paragraph, the Secretary shall require Medicare + Choice organizations (and eligible organizations with risk-sharing contracts under section 1876 [*42 USCS § 1395mm*]) to submit data regarding inpatient hospital services for periods beginning on or after July 1, 1997, and data regarding other services and other information as the Secretary deems necessary for periods beginning on or after July 1, 1998. The Secretary may not require an organization to submit such data before January 1, 1998.

(C) Initial implementation.

(i) In general. The Secretary shall first provide for implementation of a risk adjustment methodology that accounts for variations in per capita costs based on health status and other demographic factors for payments by no later than January 1, 2000.

(ii) Phase-in. Except as provided in clause (iv), such risk adjustment methodology shall be implemented in a phased-in manner so that the methodology insofar as it makes adjustments to capitation rates for health status applies to--

(I) 10 percent of 1/12 of the annual Medicare + Choice capitation rate in 2000 and each succeeding year through 2003;

(II) 30 percent of such capitation rate in 2004;

(III) 50 percent of such capitation rate in 2005;

(IV) 75 percent of such capitation rate in 2006; and

(V) 100 percent of such capitation rate in 2007 and succeeding years.

(iii) Data for risk adjustment methodology. Such risk adjustment methodology for 2004 and each succeeding year, shall be based on data from inpatient hospital and ambulatory settings.

(iv) Full implementation of risk adjustment for congestive heart failure enrollees for 2001.

(I) Exemption from phase-in. Subject to subclause (II), the Secretary shall fully implement the risk adjustment methodology described in clause (i) with respect to each individual who has had a qualifying congestive heart failure inpatient diagnosis (as determined by the Secretary under such risk adjustment methodology) during the period beginning on July 1, 1999, and ending on June 30, 2000, and who is enrolled in a coordinated care plan that is the only coordinated care plan offered on January 1, 2001, in the service area of the individual.

(II) Period of application. Subclause (I) shall only apply during the 1-year period beginning on January 1, 2001.

(D) Uniform application to all types of plans. Subject to section 1859(e)(4) [*42 USCS § 1395w-28(e)(4)*], the methodology shall be applied uniformly without regard to the type of plan.

(4) Payment rule for federally qualified health center services. If an individual who is enrolled with an MA plan under this part receives a service from a federally qualified health center that has a written agreement with the MA organization that offers such plan for providing such a service (including any agreement required under section 1857(e)(3) [*42 USCS § 1395w-27(e)(3)*])--

(A) the Secretary shall pay the amount determined under section 1833(a)(3)(B) [*42 USCS § 1395l(a)(3)(B)*] directly to the federally qualified health center not less frequently than quarterly; and

(B) the Secretary shall not reduce the amount of the monthly payments under this subsection as a result of the application of subparagraph (A).

(b) Annual announcement of payment rates.

(1) Annual announcements.

(A) For 2005. The Secretary shall determine, and shall announce (in a manner intended to provide notice to interested parties), not later than the second Monday in May of 2004, with respect to each MA payment area, the following:

(i) MA capitation rates. The annual MA capitation rate for each MA payment area for 2005.

(ii) Adjustment factors. The risk and other factors to be used in adjusting such rates under subsection (a)(1)(C) for payments for months in 2005.

(B) For 2006 and subsequent years. For a year after 2005--

(i) Initial announcement. The Secretary shall determine, and shall announce (in a manner intended to provide notice to interested parties), not later than the first Monday in April before the calendar year concerned, with respect to each MA payment area, the following:

(I) MA capitation rates; ma local area benchmark. The annual MA capitation rate for each MA payment area for the year.

(II) Adjustment factors. The risk and other factors to be used in adjusting such rates under subsection (a)(1)(C) for payments for months in such year.

(ii) Regional benchmark announcement. The Secretary shall determine, and shall announce (in a manner intended to provide notice to interested parties), on a timely basis before the calendar year concerned, with respect to each MA region and each MA regional plan for which a bid was submitted under section 1854 [*42 USCS § 1395w-24*], the MA region-specific non-drug monthly benchmark amount for that region for the year involved.

(iii) Benchmark announcement for CCA local areas. The Secretary shall determine, and shall announce (in a manner intended to provide notice to interested parties), on a timely basis before the calendar year concerned, with respect to each CCA area (as defined in section 1860C-1(b)(1)(A) [*42 USCS § 1395w-29(b)(1)(A)*]), the CCA non-drug monthly benchmark amount under section 1860C-1(e)(1) [*42 USCS § 1395w-29(e)(1)*] for that area for the year involved.

(2) Advance notice of methodological changes. At least 45 days before making the announcement under paragraph (1) for a year, the Secretary shall provide for notice to Medicare + Choice organizations of proposed changes to be made in the methodology from the methodology and assumptions used in the previous announcement and shall provide such organizations an opportunity to comment on such proposed changes.

(3) Explanation of assumptions. In each announcement made under paragraph (1), the Secretary shall include an explanation of the assumptions and changes in methodology used in such announcement.

(4) Continued computation and publication of county-specific per capita fee-for-service expenditure information. The Secretary, through the Chief Actuary of the Centers for Medicare & Medicaid Services, shall provide for the computation and publication, on an annual basis beginning with 2001 at the time of publication of the annual Medicare + Choice capitation rates under paragraph (1), of the following information for the original medicare fee-for-service program under parts A and B [*42 USCS §§ 1395c* et seq. and *1395j* et seq.] (exclusive of individuals eligible for coverage under section 226A [*42 USCS § 426-1*]) for each Medicare + Choice payment area for the second calendar year ending before the date of publication:

(A) Total expenditures per capita per month, computed separately for part A [*42 USCS §§ 1395c* et seq.] and for part B [*42 USCS §§ 1395j* et seq.].

(B) The expenditures described in subparagraph (A) reduced by the best estimate of the expenditures (such as graduate medical education and disproportionate share hospital payments) not related to the payment of claims.

(C) The average risk factor for the covered population based on diagnoses reported for medicare inpatient services, using the same methodology as is expected to be applied in making payments under subsection (a).

(D) Such average risk factor based on diagnoses for inpatient and other sites of service, using the same methodology as is expected to be applied in making payments under subsection (a).

(c) Calculation of annual Medicare + Choice capitation rates.

(1) In general. For purposes of this part [*42 USCS §§ 1395w-21* et seq.], subject to paragraphs (6)(C) and (7), each annual Medicare + Choice capitation rate, for a Medicare + Choice payment area that is an MA local area for a contract year consisting of a calendar year, is equal to the largest of the amounts specified in the following subparagraph (A), (B), (C), or (D):

(A) Blended capitation rate. For a year before 2005, the sum of--

(i) the area-specific percentage (as specified under paragraph (2) for the year) of the annual area-specific Medicare + Choice capitation rate for the Medicare + Choice payment area, as determined under paragraph (3) for the year, and

(ii) the national percentage (as specified under paragraph (2) for the year) of the input-price-adjusted annual national Medicare + Choice capitation rate, as determined under paragraph (4) for the year,

multiplied (for a year other than 2004) by the budget neutrality adjustment factor determined under paragraph (5).

(B) Minimum amount. 12 multiplied by the following amount:

(i) For 1998, $ 367 (but not to exceed, in the case of an area outside the 50 States and the District of Columbia, 150 percent of the annual per capita rate of payment for 1997 determined under section 1876(a)(1)(C) [*42 USCS § 1395mm(a)(1)(C)*] for the area).

(ii) For 1999 and 2000, the minimum amount determined under clause (i) or this clause, respectively, for the preceding year, increased by the national per capita Medicare + Choice growth percentage described in paragraph (6)(A) applicable to 1999 or 2000, respectively.

(iii) (I) Subject to subclause (II), for 2001, for any area in a Metropolitan Statistical Area with a population of more than 250,000, $ 525, and for any other area $ 475.

(II) In the case of an area outside the 50 States and the District of Columbia, the amount specified in this clause shall not exceed 120 percent of the amount determined under clause (ii) for such area for 2000.

(iv) For 2002, 2003, and 2004, the minimum amount specified in this clause (or clause (iii)) for the preceding year increased by the national per capita Medicare + Choice growth percentage, described in paragraph (6)(A) for that succeeding year.

(C) Minimum percentage increase.

(i) For 1998, 102 percent of the annual per capita rate of payment for 1997 determined under section 1876(a)(1)(C) [*42 USCS § 1395mm(a)(1)(C)*] for the Medicare + Choice payment area.

(ii) For 1999 and 2000, 102 percent of the annual Medicare + Choice capitation rate under this paragraph for the area for the previous year.

(iii) For 2001, 103 percent of the annual Medicare + Choice capitation rate under this paragraph for the area for 2000.

(iv) For 2002 and 2003, 102 percent of the annual Medicare + Choice capitation rate under this paragraph for the area for the previous year.

(v) For 2004 and each succeeding year, the greater of--

(I) 102 percent of the annual MA capitation rate under this paragraph for the area for the previous year; or

(II) the annual MA capitation rate under this paragraph for the area for the previous year increased by the national per capita MA growth percentage, described in paragraph (6) for that succeeding year, but not taking into account any adjustment under paragraph (6)(C) for a year before 2004.

(D) 100 percent of fee-for-service costs.

(i) In general. For each year specified in clause (ii), the adjusted average per capita cost for the year involved, determined under section 1876(a)(4) [*42 USCS § 1395mm(a)(4)*] and adjusted as appropriate for the purpose of risk adjustment, for the MA payment area for individuals who are not enrolled in an MA plan under this part for the year, but adjusted to exclude costs attributable to payments under section 1886(h) [*42 USCS § 1395ww(h)*].

(ii) Periodic rebasing. The provisions of clause (i) shall apply for 2004 and for subsequent years as the Secretary shall specify (but not less than once every 3 years).

(iii) Inclusion of costs of VA and DOD military facility services to medicare-eligible beneficiaries. In determining the adjusted average per capita cost under clause (i) for a year, such cost shall be adjusted to include the Secretary's estimate, on a per capita basis, of the amount of additional payments that would have been made in the area involved under this title if individuals entitled to benefits under this title had not received services from facilities of the Department of Defense or the Department of Veterans Affairs.

(2) Area-specific and national percentages. For purposes of paragraph (1)(A)--

(A) for 1998, the "area-specific percentage" is 90 percent and the "national percentage" is 10 percent,

(B) for 1999, the "area-specific percentage" is 82 percent and the "national percentage" is 18 percent,

(C) for 2000, the "area-specific percentage" is 74 percent and the "national percentage" is 26 percent,

(D) for 2001, the "area-specific percentage" is 66 percent and the "national percentage" is 34 percent,

(E) for 2002, the "area-specific percentage" is 58 percent and the "national percentage" is 42 percent, and

(F) for a year after 2002, the "area-specific percentage" is 50 percent and the "national percentage" is 50 percent.

(3) Annual area-specific Medicare + Choice capitation rate.

(A) In general. For purposes of paragraph (1)(A), subject to subparagraphs (B) and (E), the annual area-specific Medicare + Choice capitation rate for a Medicare + Choice payment area--

(i) for 1998 is, subject to subparagraph (D), the annual per capita rate of payment for 1997 determined under section 1876(a)(1)(C) [*42 USCS § 1395mm(a)(1)(C)*] for the area, increased by the national per capita Medicare + Choice growth percentage for 1998 (described in paragraph (6)(A)); or

(ii) for a subsequent year is the annual area-specific Medicare + Choice capitation rate for the previous year determined under this paragraph for the area, increased by the national per capita Medicare + Choice growth percentage for such subsequent year.

(B) Removal of medical education from calculation of adjusted average per capita cost.

(i) In general. In determining the area-specific Medicare + Choice capitation rate under subparagraph (A) for a year (beginning with 1998), the annual per capita rate of payment for 1997 determined under section 1876(a)(1)(C) [*42 USCS § 1395mm(a)(1)(C)*] shall be adjusted to exclude from the rate the applicable percent (specified in clause (ii)) of the payment adjustments described in subparagraph (C).

(ii) Applicable percent. For purposes of clause (i), the applicable percent for--

(I) 1998 is 20 percent,

(II) 1999 is 40 percent,

(III) 2000 is 60 percent,

(IV) 2001 is 80 percent, and

(V) a succeeding year is 100 percent.

(C) Payment adjustment.

(i) In general. Subject to clause (ii), the payment adjustments described in this subparagraph are payment adjustments which the Secretary estimates were payable during 1997--

(I) for the indirect costs of medical education under section 1886(d)(5)(B) [*42 USCS § 1395ww(d)(5)(B)*], and

(II) for direct graduate medical education costs under section 1886(h) [*42 USCS § 1395ww(h)*].

(ii) Treatment of payments covered under state hospital reimbursement system. To the extent that the Secretary estimates that an annual per capita rate of payment for 1997 described in clause (i) reflects payments to hospitals reimbursed under section 1814(b)(3) [*42 USCS § 1395f(b)(3)*], the Secretary shall estimate a payment adjustment that is comparable to the payment adjustment that would have been made under clause (i) if the hospitals had not been reimbursed under such section.

(D) Treatment of areas with highly variable payment rates. In the case of a Medicare + Choice payment area for which the annual per capita rate of payment determined under section 1876(a)(1)(C) [*42 USCS § 1395mm(a)(1)(C)*] for 1997 varies by more than 20 percent from such rate for 1996, for purposes of this subsection the Secretary may substitute for such rate for 1997 a rate that is more representative of the costs of the enrollees in the area.

(E) Inclusion of costs of DOD and VA military facility services to medicare-eligible beneficiaries. In determining the area-specific MA capitation rate under subparagraph (A) for a year (beginning with 2004), the annual per capita rate of payment for 1997 determined under section 1876(a)(1)(C) [*42 USCS § 1395mm(a)(1)(C)*] shall be adjusted to include in the rate the Secretary's estimate, on a per capita basis, of the amount of additional payments that would have been made in the area involved under this title if individuals entitled to benefits under this title had not received services from facilities of the Department of Defense or the Department of Veterans Affairs.

(4) Input-price-adjusted annual national Medicare + Choice capitation rate.

(A) In general. For purposes of paragraph (1)(A), the input-price-adjusted annual national Medicare + Choice capitation rate for a Medicare + Choice payment area for a year is equal to the sum, for all the types of medicare services (as classified by the Secretary), of the product (for each such type of service) of--

(i) the national standardized annual Medicare + Choice capitation rate (determined under subparagraph (B)) for the year,

(ii) the proportion of such rate for the year which is attributable to such type of services, and

(iii) an index that reflects (for that year and that type of services) the relative input price of such services in the area compared to the national average input price of such services.

In applying clause (iii), the Secretary may, subject to subparagraph (C), apply those indices under this *title [42 USCS §§ 1395* et seq.]that are used in applying (or updating) national payment rates for specific areas and localities.

(B) National standardized annual Medicare + Choice capitation rate. In subparagraph (A)(i), the "national standardized annual Medicare + Choice capitation rate" for a year is equal to--

(i) the sum (for all Medicare + Choice payment areas) of the product of--

(I) the annual area-specific Medicare + Choice capitation rate for that year for the area under paragraph (3), and

(II) the average number of medicare beneficiaries residing in that area in the year, multiplied by the average of the risk factor weights used to adjust payments under subsection (a)(1)(A) for such beneficiaries in such area; divided by

(ii) the sum of the products described in clause (i)(II) for all areas for that year.

(C) Special rules for 1998. In applying this paragraph for 1998--

(i) medicare services shall be divided into 2 types of services: part A [*42 USCS §§ 1395c* et seq.] services and part B [*42 USCS §§ 1395j* et seq.] services;

(ii) the proportions described in subparagraph (A)(ii)--

(I) for part A [*42 USCS §§ 1395c* et seq.] services shall be the ratio (expressed as a percentage) of the national average annual per capita rate of payment for part A [*42 USCS §§ 1395c* et seq.] for 1997 to the total national average annual per capita rate of payment for parts A and B [*42 USCS §§ 1395c* et seq. and *1395j* et seq.] for 1997, and

(II) for part B [*42 USCS §§ 1395j* et seq.] services shall be 100 percent minus the ratio described in subclause (I);

(iii) for part A [*42 USCS §§ 1395c* et seq.] services, 70 percent of payments attributable to such services shall be adjusted by the index used under section 1886(d)(3)(E) [*42 USCS § 1395ww(d)(3)(E)*] to adjust payment rates for relative hospital wage levels for hospitals located in the payment area involved;

(iv) for part B [*42 USCS §§ 1395j* et seq.] services--

(I) 66 percent of payments attributable to such services shall be adjusted by the index of the geographic area factors under section 1848(e) [*42 USCS § 1395w-4(e)*] used to adjust payment rates for physicians' services furnished in the payment area, and

(II) of the remaining 34 percent of the amount of such payments, 40 percent shall be adjusted by the index described in clause (iii); and

(v) the index values shall be computed based only on the beneficiary population who are 65 years of age or older and who are not determined to have end stage renal disease.

The Secretary may continue to apply the rules described in this subparagraph (or similar rules) for 1999.

(5) Payment adjustment budget neutrality factor. For purposes of paragraph (1)(A), for each year (other than 2004), the Secretary shall determine a budget neutrality adjustment factor so that the aggregate of the payments under this part [*42 USCS §§ 1395w-21* et seq.] (other than those attributable to subsections (a)(c)(3)(iv), (a)(4), and (i)) shall equal the aggregate payments that would have been made under this part [*42 USCS §§ 1395w-21* et seq.] if payment were based entirely on area-specific capitation rates.

(6) National per capita Medicare + Choice growth percentage defined.

(A) In general. In this part [*42 USCS §§ 1395w-21* et seq.], the "national per capita Medicare + Choice growth percentage" for a year is the percentage determined by the Secretary, by March 1st before the beginning of the year involved, to reflect the Secretary's estimate of the projected per capita rate of growth in expenditures under this *title [42 USCS §§ 1395* et seq.] for an individual entitled to benefits under part A [*42 USCS §§ 1395c* et seq.] and enrolled under part B [*42 USCS §§ 1395j* et seq.], reduced by the number of percentage points specified in subparagraph (B) for the year. Separate determinations may be made for aged enrollees, disabled enrollees, and enrollees with end-stage renal disease.

(B) Adjustment. The number of percentage points specified in this subparagraph is--

(i) for 1998, 0.8 percentage points,

(ii) for 1999, 0.5 percentage points,

(iii) for 2000, 0.5 percentage points,

(iv) for 2001, 0.5 percentage points,

(v) for 2002, 0.3 percentage points, and

(vi) for a year after 2002, 0 percentage points.

(C) Adjustment for over or under projection of national per capita Medicare + Choice growth percentage. Beginning with rates calculated for 1999, before computing rates for a year as described in paragraph (1), the Secretary shall adjust all area-specific and national Medicare + Choice capitation rates (and beginning in 2000, the minimum amount) for the previous year for the differences between the projections of the national per capita Medicare + Choice growth percentage for that year and previous years and the current estimate of such percentage for such years, except that for purposes of paragraph (1)(C)(v)(II), no such adjustment shall be made for a year before 2004.

(7) Adjustment for national coverage determinations and legislative changes in benefits. If the Secretary makes a determination with respect to coverage under this title or there is a change in benefits required to be provided under this part that the Secretary projects will result in a significant increase in the costs to Medicare + Choice of providing benefits under contracts under this part (for periods after any period described in section 1852(a)(5) [*42 USCS § 1395w-22(a)(5)*]), the Secretary shall adjust appropriately the payments to such organizations under this part. Such projection and adjustment shall be based on an analysis by the Chief Actuary of the Centers for Medicare & Medicaid Services of the actuarial costs associated with the new benefits.

(d) MA payment area; MA local area; MA region defined.

(1) MA payment area. In this part [*42 USCS §§ 1395w-21* et seq.], except as provided in this subsection, the term "MA payment area" means--

(A) with respect to an MA local plan, an MA local area (as defined in paragraph (2)); and

(B) with respect to an MA regional plan, an MA region (as established under section 1858(a)(2) [*42 USCS § 1395w-27a(a)(2)*]).

(2) MA local area. The term "MA local area" means a county or equivalent area specified by the Secretary.

(3) Rule for ESRD beneficiaries. In the case of individuals who are determined to have end stage renal disease, the Medicare + Choice payment area shall be a State or such other payment area as the Secretary specifies.

(4) Geographic adjustment.

(A) In general. Upon written request of the chief executive officer of a State for a contract year (beginning after 1998) made by not later than February 1 of the previous year, the Secretary shall make a geographic adjustment to a Medicare + Choice payment area in the State otherwise determined under paragraph (1) for local MA plans--

(i) to a single statewide Medicare + Choice payment area,

(ii) to the metropolitan based system described in subparagraph (C), or

(iii) to consolidating into a single Medicare + Choice payment area noncontiguous counties (or equivalent areas described in paragraph (1)(A)) within a State.

Such adjustment shall be effective for payments for months beginning with January of the year following the year in which the request is received.

(B) Budget neutrality adjustment. In the case of a State requesting an adjustment under this paragraph, the Secretary shall initially (and annually thereafter) adjust the payment rates otherwise established under this section with respect to MA local plans for Medicare + Choice payment areas in the State in a manner so that the aggregate of the payments under this section for such plans in the State shall not exceed the aggregate payments that would have been made under this section for such plans for Medicare + Choice payment areas in the State in the absence of the adjustment under this paragraph.

(C) Metropolitan based system. The metropolitan based system described in this subparagraph is one in which--

(i) all the portions of each metropolitan statistical area in the State or in the case of a consolidated metropolitan statistical area, all of the portions of each primary metropolitan statistical area within the consolidated area within the State, are treated as a single Medicare + Choice payment area, and

(ii) all areas in the State that do not fall within a metropolitan statistical area are treated as a single Medicare + Choice payment area.

(D) Areas. In subparagraph (C), the terms "metropolitan statistical area", "consolidated metropolitan statistical area", and "primary metropolitan statistical area" mean any area designated as such by the Secretary of Commerce.

(e) Special rules for individuals electing MSA plans.

(1) In general. If the amount of the Medicare + Choice monthly MSA premium (as defined in section 1854(b)(2)(C) [*42 USCS § 1395w-24(b)(2)(C)*]) for an MSA plan for a year is less than 1/12 of the annual Medicare + Choice capitation rate applied under this section for the area and year involved, the Secretary shall deposit an amount equal to 100 percent of such difference in a Medicare + Choice MSA established (and, if applicable, designated) by the individual under paragraph (2).

(2) Establishment and designation of Medicare + Choice medical savings account as requirement for payment of contribution. In the case of an individual who has elected coverage under an MSA plan, no payment shall be made under paragraph (1) on behalf of an individual for a month unless the individual--

(A) has established before the beginning of the month (or by such other deadline as the Secretary may specify) a Medicare + Choice MSA (as defined in *section 138(b)(2) of the Internal Revenue Code of 1986* [*26 USCS § 138(b)(2)*]), and

(B) if the individual has established more than one such Medicare + Choice MSA, has designated one of such accounts as the individual's Medicare + Choice MSA for purposes of this part [*42 USCS §§ 1395w-21* et seq.].

Under rules under this section, such an individual may change the designation of such account under subparagraph (B) for purposes of this part [*42 USCS §§ 1395w-21* et seq.].

(3) Lump-sum deposit of medical savings account contribution. In the case of an individual electing an MSA plan effective beginning with a month in a year, the amount of the contribution to the Medicare + Choice MSA on behalf of the individual for that month and all successive months in the year shall be deposited during that first month. In the case of a termination of such an election as of a month before the end of a year, the Secretary shall provide for a procedure for the recovery of deposits attributable to the remaining months in the year.

(f) Payments from trust funds. The payment to a Medicare + Choice organization under this section for individuals enrolled under this part [*42 USCS §§ 1395w-21* et seq.] with the organization and payments to a Medicare + Choice MSA under subsection (e)(1) shall be made from the Federal Hospital Insurance Trust Fund and the Federal Supplementary Medical Insurance Trust Fund in such proportion as the Secretary determines reflects the relative weight that benefits under part A [*42 USCS §§ 1395c* et seq.] and under part B [*42 USCS §§ 1395j* et seq.] represents of the actuarial value of the total benefits under this *title [42 USCS §§ 1395* et seq.]. Payments to MA organizations for statutory drug benefits provided under this *title [42 USCS §§ 1395* et seq.] are made from the Medicare Prescription Drug Account in the Federal Supplementary Medical Insurance Trust Fund. Monthly payments otherwise payable under this section for October 2000 shall be paid on the first business day of such month. Monthly payments otherwise payable under this section for October 2001 shall be paid on the last business day of September 2001. Monthly payments otherwise payable under this section for October 2006 shall be paid on the first business day of October 2006.

(g) Special rule for certain inpatient hospital stays. In the case of an individual who is receiving inpatient hospital services from a subsection (d) hospital (as defined in section 1886(d)(1)(B) [*42 USCS § 1395ww(d)(1)(B)*]), a rehabilitation hospital described in section 1886(d)(1)(B)(ii) [*42 USCS § 1395ww(d)(1)(B)(ii)*] or a distinct part rehabilitation unit described in the matter following clause (v) of section 1886(d)(1)(B) [*42 USCS § 1395ww(d)(1)(B)*], or a long-term care hospital (described in section 1886(d)(1)(B)(iv) [*42 USCS § 1395ww(d)(1)(B)(iv)*]) as of the effective date of the individual's--

(1) election under this part [*42 USCS §§ 1395w-21* et seq.] of a Medicare + Choice plan offered by a Medicare + Choice organization--

(A) payment for such services until the date of the individual's discharge shall be made under this *title [42 USCS §§ 1395* et seq.] through the Medicare + Choice plan or the original medicare fee-for-service program option described in section 1851(a)(1)(A) [*42 USCS § 1395w-21(a)(1)(A)*] (as the case may be) elected before the election with such organization,

(B) the elected organization shall not be financially responsible for payment for such services until the date after the date of the individual's discharge, and

(C) the organization shall nonetheless be paid the full amount otherwise payable to the organization under this part [*42 USCS §§ 1395w-21* et seq.]; or

(2) termination of election with respect to a Medicare + Choice organization under this part [*42 USCS §§ 1395w-21* et seq.]--

(A) the organization shall be financially responsible for payment for such services after such date and until the date of the individual's discharge,

(B) payment for such services during the stay shall not be made under section 1886(d) [*42 USCS § 1395ww(d)*] or other payment provision under this title for inpatient services for the type of facility, hospital, or unit involved, described in the matter preceding paragraph (1), as the case may be, or by any succeeding Medicare + Choice organization, and

(C) the terminated organization shall not receive any payment with respect to the individual under this part [*42 USCS §§ 1395w-21* et seq.] during the period the individual is not enrolled.

(h) Special rule for hospice care.

(1) Information. A contract under this part [*42 USCS §§ 1395w-21* et seq.] shall require the Medicare + Choice organization to inform each individual enrolled under this part [*42 USCS §§ 1395w-21* et seq.] with a Medicare + Choice plan offered by the organization about the availability of hospice care if--

(A) a hospice program participating under this *title [42 USCS §§ 1395* et seq.] is located within the organization's service area; or

(B) it is common practice to refer patients to hospice programs outside such service area.

(2) Payment. If an individual who is enrolled with a Medicare + Choice organization under this part [*42 USCS §§ 1395w-21* et seq.] makes an election under section 1812(d)(1) [*42 USCS § 1395d(d)(1)*] to receive hospice care from a particular hospice program--

(A) payment for the hospice care furnished to the individual shall be made to the hospice program elected by the individual by the Secretary;

(B) payment for other services for which the individual is eligible notwithstanding the individual's election of hospice care under section 1812(d)(1) [*42 USCS § 1395d(d)(1)*], including services not related to the individual's terminal illness, shall be made by the Secretary to the Medicare + Choice organization or the provider or supplier of the service instead of payments calculated under subsection (a); and

(C) the Secretary shall continue to make monthly payments to the Medicare + Choice organization in an amount equal to the value of the additional benefits required under section 1854(f)(1)(A) [*42 USCS § 1395w-24(f)(1)(A)*].

(i) New entry bonus.

(1) In general. Subject to paragraphs (2) and (3), in the case of Medicare + Choice payment area in which a Medicare + Choice plan has not been offered since 1997 (or in which all organizations that offered a plan since such date have filed notice with the Secretary, as of October 13, 1999, that they will not be offering such a plan as of January 1, 2000, or filed notice with the Secretary as of October 3, 2000, that they will not be offering such a plan as of January 1, 2001), the amount of the monthly payment otherwise made under this section shall be increased--

(A) only for the first 12 months in which any Medicare + Choice plan is offered in the area, by 5 percent of the total monthly payment otherwise computed for such payment area; and

(B) only for the subsequent 12 months, by 3 percent of the total monthly payment otherwise computed for such payment area.

(2) Period of application. Paragraph (1) shall only apply to payment for Medicare + Choice plans which are first offered in a Medicare + Choice payment area during the 2-year period beginning on January 1, 2000.

(3) Limitation to organization offering first plan in an area. Paragraph (1) shall only apply to payment to the first Medicare + Choice organization that offers a Medicare + Choice plan in each Medicare + Choice payment area, except that if more than one such organization first offers such a plan in an area on the same date, paragraph (1) shall apply to payment for such organizations.

(4) Construction. Nothing in paragraph (1) shall be construed as affecting the calculation of the annual Medicare + Choice capitation rate under subsection (c) for any payment area or as applying to payment for any period not described in such paragraph and paragraph (2).

(5) Offered defined. In this subsection, the term "offered" means, with respect to a Medicare + Choice plan as of a date, that a Medicare + Choice eligible individual may enroll with the plan on that date, regardless of when the enrollment takes effect or when the individual obtains benefits under the plan.

(j) Computation of benchmark amounts. For purposes of this part [*42 USCS §§ 1395w-21* et seq.], the term "MA area-specific non-drug monthly benchmark amount" means for a month in a year--

(1) with respect to--

(A) a service area that is entirely within an MA local area, subject to section 1860C-1(d)(2)(A) [*42 USCS § 1395w-29(d)(2)(A)*], an amount equal to 1/12 of the annual MA capitation rate under section 1853(c)(1) [*42 USCS § 1395w-23(c)(1)*] (or, beginning with 2007, 1/12 of the applicable amount determined under subsection (k)(1)) for the area for the year, adjusted as appropriate (for years before 2007) for the purpose of risk adjustment; or

(B) a service area that includes more than one MA local area, an amount equal to the average of the amounts described in subparagraph (A) for each such local MA area, weighted by the projected number of enrollees in the plan residing in the respective local MA areas (as used by the plan for purposes of the bid and disclosed to the Secretary under section 1854(a)(6)(A)(iii) [*42 USCS § 1395w-24(a)(6)(A)(iii)*]), adjusted as appropriate (for years before 2007) for the purpose of risk adjustment; or

(2) with respect to an MA region for a month in a year, the MA region-specific non-drug monthly benchmark amount, as defined in section 1858(f) [*42 USCS § 1395w-27a*] for the region for the year.

(k) Determination of applicable amount for purposes of calculating the benchmark amounts.

(1) Applicable amount defined. For purposes of subsection (j), subject to paragraphs (2) and (4), the term "applicable amount" means for an area--

(A) for 2007--

(i) if such year is not specified under subsection (c)(1)(D)(ii), an amount equal to the amount specified in subsection (c)(1)(C) for the area for 2006--

(I) first adjusted by the rescaling factor for 2006 for the area (as made available by the Secretary in the announcement of the rates on April 4, 2005, under subsection (b)(1), but excluding any national adjustment factors for coding intensity and risk adjustment budget neutrality that were included in such factor); and

(II) then increased by the national per capita MA growth percentage, described in subsection (c)(6) for 2007, but not taking into account any adjustment under subparagraph (C) of such subsection for a year before 2004;

(ii) if such year is specified under subsection (c)(1)(D)(ii), an amount equal to the greater of--

(I) the amount determined under clause (i) for the area for the year; or

(II) the amount specified in subsection (c)(1)(D) for the area for the year; and

(B) for a subsequent year--

(i) if such year is not specified under subsection (c)(1)(D)(ii), an amount equal to the amount determined under this paragraph for the area for the previous year (determined without regard to paragraphs (2) and (4)), increased by the national per capita MA growth percentage, described in subsection (c)(6) for that succeeding year, but not taking into account any adjustment under subparagraph (C) of such subsection for a year before 2004; and

(ii) if such year is specified under subsection (c)(1)(D)(ii), an amount equal to the greater of--

(I) the amount determined under clause (i) for the area for the year; or

(II) the amount specified in subsection (c)(1)(D) for the area for the year.

(2) Phase-out of budget neutrality factor.

(A) In general. Except as provided in subparagraph (D), in the case of 2007 through 2010, the applicable amount determined under paragraph (1) shall be multiplied by a factor equal to 1 plus the product of--

(i) the percent determined under subparagraph (B) for the year; and

(ii) the applicable phase-out factor for the year under subparagraph (C).

(B) Percent determined.

(i) In general. For purposes of subparagraph (A)(i), subject to clause (iv), the percent determined under this subparagraph for a year is a percent equal to a fraction the numerator of which is described in clause (ii) and the denominator of which is described in clause (iii).

(ii) Numerator based on difference between demographic rate and risk rate.

(I) In general. The numerator described in this clause is an amount equal to the amount by which the demographic rate described in subclause (II) exceeds the risk rate described in subclause (III).

(II) Demographic rate. The demographic rate described in this subclause is the Secretary's estimate of the total payments that would have been made under this part in the year if all the monthly payment amounts for all MA plans were equal to 1/12 of the annual MA capitation rate under subsection (c)(1) for the area and year, adjusted pursuant to subsection (a)(1)(C).

(III) Risk rate. The risk rate described in this subclause is the Secretary's estimate of the total payments that would have been made under this part in the year if all the monthly payment amounts for all MA plans were equal to the amount described in subsection (j)(1)(A) (determined as if this paragraph had not applied) under subsection (j) for the area and year, adjusted pursuant to subsection (a)(1)(C).

(iii) Denominator based on risk rate. The denominator described in this clause is equal to the total amount estimated for the year under clause (ii)(III).

(iv) Requirements. In estimating the amounts under the previous clauses, the Secretary shall--

(I) use a complete set of the most recent and representative Medicare Advantage risk scores under subsection (a)(3) that are available from the risk adjustment model announced for the year;

(II) adjust the risk scores to reflect changes in treatment and coding practices in the fee-for-service sector;

(III) adjust the risk scores for differences in coding patterns between Medicare Advantage plans and providers under the original Medicare fee-for-service program under parts A and B to the extent that the Secretary has identified such differences, as required in subsection (a)(1)(C);

(IV) as necessary, adjust the risk scores for late data submitted by Medicare Advantage organizations;

(V) as necessary, adjust the risk scores for lagged cohorts; and

(VI) as necessary, adjust the risk scores for changes in enrollment in Medicare Advantage plans during the year.

(v) Authority. In computing such amounts the Secretary may take into account the estimated health risk of enrollees in preferred provider organization plans (including MA regional plans) for the year.

(C) Applicable phase-out factor. For purposes of subparagraph (A)(ii), the term "applicable phase-out factor" means--

(i) for 2007, 0.55;

(ii) for 2008, 0.40;

(iii) for 2009, 0.25; and

(iv) for 2010, 0.05.

(D) Termination of application. Subparagraph (A) shall not apply in a year if the amount estimated under subparagraph (B)(ii)(III) for the year is equal to or greater than the amount estimated under subparagraph (B)(ii)(II) for the year.

(3) No revision in percent.

(A) In general. The Secretary may not make any adjustment to the percent determined under paragraph (2)(B) for any year.

(B) Rule of construction. Nothing in this subsection shall be construed to limit the authority of the Secretary to make adjustments to the applicable amounts determined under paragraph (1) as appropriate for purposes of updating data or for purposes of adopting an improved risk adjustment methodology.

(4) Phase-out of the indirect costs of medical education from capitation rates.

(A) In general. After determining the applicable amount for an area for a year under paragraph (1) (beginning with 2010), the Secretary shall adjust such applicable amount to exclude from such applicable amount the phase-in percentage (as defined in subparagraph (B)(i)) for the year of the Secretary's estimate of the standardized costs for payments under section 1886(d)(5)(B) [*42 USCS § 1395ww(d)(5)(B)*] in the area for the year. Any adjustment under the preceding sentence shall be made prior to the application of paragraph (2).

(B) Percentages defined. For purposes of this paragraph:

(i) Phase-in percentage. The term "phase-in percentage" means, for an area for a year, the ratio (expressed as a percentage, but in no case greater than 100 percent) of--

(I) the maximum cumulative adjustment percentage for the year (as defined in clause (ii)); to

(II) the standardized IME cost percentage (as defined in clause (iii)) for the area and year.

(ii) Maximum cumulative adjustment percentage. The term "maximum cumulative adjustment percentage" means, for--

(I) 2010, 0.60 percent; and

(II) a subsequent year, the maximum cumulative adjustment percentage for the previous year increased by 0.60 percentage points.

(iii) Standardized ime cost percentage. The term "standardized IME cost percentage" means, for an area for a year, the per capita costs for payments under section 1886(d)(5)(B) [*42 USCS § 1395ww(d)(5)(B)*] (expressed as a percentage of the fee-for-service amount specified in subparagraph (C)) for the area and the year.

(C) Fee-for-service amount. The fee-for-service amount specified in this subparagraph for an area for a year is the amount specified under subsection (c)(1)(D) for the area and the year.

HISTORY:

(Aug. 14, 1935, ch 531, Title XVIII, Part C, § 1853, as added Aug. 5, 1997, P.L. 105-33, Title IV, Subtitle A, Ch 1, Subch A, § 4001, 111 Stat. 299; Nov. 29, 1999, P.L. 106-113, Div B, § 1000(a)(6), 113 Stat. 1536; Dec. 21, 2000, P.L. 106-554, § 1(a)(6), 114 Stat. 2763; June 12, 2002, P.L. 107-188, Title V, Subtitle C, § 532(d)(1), 116 Stat. 696; Dec. 8, 2003, P.L. 108-173, Title I, § 101(e)(3)(D), Title II, Subtitle B, § 211(a)-(e)(1), Subtitle C, §§ 221(d)(1), (4), 222(d)-(f), (i), Subtitle D, § 237(b)(1), (2)(B), Subtitle E, § 241(b)(1), Title VII, Subtitle D, § 736(d)(1), Title IX, § 900(e)(1)(G), 117 Stat. 2151, 2176, 2192, 2193, 2200, 2204, 2212, 2213, 2220, 2357, 2371.)

(As amended Feb. 8, 2006, P.L. 109-171, Title V, Subtitle D, § 5301, 120 Stat. 48; July 15, 2008, P.L. 110-275, Title I, Subtitle D, § 161(a), (b), 122 Stat. 2568.)

§ 1395w-24. Premiums and bid amounts

(a) Submission of proposed premiums, bid amounts, and related information.

(1) In general.

(A) Initial submission. Not later than the second Monday in September of 2002, 2003, and 2004 (or the first Monday in June of each subsequent year), each MA organization shall submit to the Secretary, in a form and manner specified by the Secretary and for each MA plan for the service area (or segment of such an area if permitted under subsection (h)) in which it intends to be offered in the following year the following:

(i) The information described in paragraph (2), (3), (4), or (6)(A) for the type of plan and year involved.

(ii) The plan type for each plan.

(iii) The enrollment capacity (if any) in relation to the plan and area.

(B) Beneficiary rebate information. In the case of a plan required to provide a monthly rebate under subsection (b)(1)(C) for a year, the MA organization offering the plan shall submit to the Secretary, in such form and manner and at such time as the Secretary specifies, information on--

(i) the manner in which such rebate will be provided under clause (ii) of such subsection; and

(ii) the MA monthly prescription drug beneficiary premium (if any) and the MA monthly supplemental beneficiary premium (if any).

(C) Paperwork reduction for offering of MA regional plans nationally or in multi-region areas. The Secretary shall establish requirements for information submission under this subsection in a manner that promotes the offering of MA regional plans in more than one region (including all regions) through the filing of consolidated information.

(2) Information required for coordinated care plans before 2006. For a Medicare + Choice plan described in section 1851(a)(2)(A) [*42 USCS § 1395w-21(a)(2)(A)*] for a year before 2006, the information described in this paragraph is as follows:

(A) Basic (and additional) benefits. For benefits described in section 1852(a)(1)(A) [*42 USCS § 1395w-22(a)(1)(A)*]--

(i) the adjusted community rate (as defined in subsection (f)(3));

(ii) the Medicare + Choice monthly basic beneficiary premium (as defined in subsection (b)(2)(A));

(iii) a description of deductibles, coinsurance, and copayments applicable under the plan and the actuarial value of such deductibles, coinsurance, and copayments, described in subsection (e)(1)(A); and

(iv) if required under subsection (f)(1), a description of the additional benefits to be provided pursuant to such subsection and the value determined for such proposed benefits under such subsection.

(B) Supplemental benefits. For benefits described in section 1852(a)(3) [*42 USCS § 1395w-22(a)(3)*]--

(i) the adjusted community rate (as defined in subsection (f)(3));

(ii) the Medicare + Choice monthly supplemental beneficiary premium (as defined in subsection (b)(2)(B)); and

(iii) a description of deductibles, coinsurance, and copayments applicable under the plan and the actuarial value of such deductibles, coinsurance, and copayments, described in subsection (e)(2).

(3) Requirements for MSA plans. For an MSA plan for any year, the information described in this paragraph is as follows:

(A) Basic (and additional) benefits. For benefits described in section 1852(a)(1)(A) [*42 USCS § 1395w-22(a)(1)(A)*], the amount of the Medicare + Choice monthly MSA premium.

(B) Supplemental benefits. For benefits described in section 1852(a)(3) [*42 USCS § 1395w-22(a)(3)*], the amount of the Medicare + Choice monthly supplementary beneficiary premium.

(4) Requirements for private fee-for-service plans before 2006. For a Medicare + Choice plan described in section 1851(a)(2)(C) [*42 USCS § 1395w-21(a)(2)(C)*] for benefits described in section 1852(a)(1)(A) [*42 USCS § 1395w-22(a)(1)(A)*] for a year before 2006, the information described in this paragraph is as follows:

(A) Basic (and additional) benefits. For benefits described in section 1852(a)(1)(A) [*42 USCS § 1395w-22(a)(1)(A)*]--

(i) the adjusted community rate (as defined in subsection (f)(3));

(ii) the amount of the Medicare + Choice monthly basic beneficiary premium;

(iii) a description of the deductibles, coinsurance, and copayments applicable under the plan, and the actuarial value of such deductibles, coinsurance, and copayments, as described in subsection (e)(4)(A); and

(iv) if required under subsection (f)(1), a description of the additional benefits to be provided pursuant to such subsection and the value determined for such proposed benefits under such subsection.

(B) Supplemental benefits. For benefits described in section 1852(a)(3) [*42 USCS § 1395w-22(a)(3)*], the amount of the Medicare + Choice monthly supplemental beneficiary premium (as defined in subsection (b)(2)(B)).

(5) Review.

(A) In general. Subject to subparagraph (B), the Secretary shall review the adjusted community rates, the amounts of the basic and supplemental premiums, and values filed under paragraphs (2) and (4) of this subsection and shall approve or disapprove such rates, amounts, and values so submitted. The Chief Actuary of the Centers for Medicare & Medicaid Services shall review the actuarial assumptions and data used by the Medicare + Choice organization with respect to such rates, amounts, and values so submitted to determine the appropriateness of such assumptions and data.

(B) Exception. The Secretary shall not review, approve, or disapprove the amounts submitted under paragraph (3) or, in the case of an MA private fee-for-service plan, subparagraphs (A)(ii) and (B) of paragraph (4).

(6) Submission of bid amounts by MA organizations beginning in 2006.

(A) Information to be submitted. For an MA plan (other than an MSA plan) for a plan year beginning on or after January 1, 2006, the information described in this subparagraph is as follows:

(i) The monthly aggregate bid amount for the provision of all items and services under the plan, which amount shall be based on average revenue requirements (as used for purposes of section 1302(8) of the Public Health Service Act [*42 USCS § 300e-1(8)*]) in the payment area for an enrollee with a national average risk profile for the factors described in section 1853(a)(1)(C) [*42 USCS § 1395w-23(a)(1)(C)*] (as specified by the Secretary).

(ii) The proportions of such bid amount that are attributable to--

(I) the provision of benefits under the original medicare fee-for-service program option (as defined in section 1852(a)(1)(B) [*42 USCS § 1395w-22(a)(1)(B)*]);

(II) the provision of basic prescription drug coverage; and

(III) the provision of supplemental health care benefits.

(iii) The actuarial basis for determining the amount under clause (i) and the proportions described in clause (ii) and such additional information as the Secretary may require to verify such actuarial bases and the projected number of enrollees in each MA local area.

(iv) A description of deductibles, coinsurance, and copayments applicable under the plan and the actuarial value of such deductibles, coinsurance, and copayments, described in subsection (e)(4)(A).

(v) With respect to qualified prescription drug coverage, the information required under section 1860D-4 [*42 USCS § 1395w-104*], as incorporated under section 1860D-11(b)(2) [*42 USCS § 1395w-111(b)(2)*], with respect to such coverage.

In the case of a specialized MA plan for special needs individuals, the information described in this subparagraph is such information as the Secretary shall specify.

(B) Acceptance and negotiation of bid amounts.

(i) Authority. Subject to clauses (iii) and (iv), the Secretary has the authority to negotiate regarding monthly bid amounts submitted under subparagraph (A) (and the proportions described in subparagraph (A)(ii)), including supplemental benefits provided under subsection (b)(1)(C)(ii)(I) and in exercising such authority the Secretary shall have authority similar to the authority of the Director of the Office of Personnel Management with respect to health benefits plans under chapter 89 of title 5, United States Code [*5 USCS §§ 8901* et seq.].

(ii) Application of FEHBP standard. Subject to clause (iv), the Secretary may only accept such a bid amount or proportion if the Secretary determines that such amount and proportions are supported by the actuarial bases provided under subparagraph (A) and reasonably and equitably reflects the revenue requirements (as used for purposes of section 1302(8) of the Public Health Service Act [*42 USCS § 300e-1(8)*]) of benefits provided under that plan.

(iii) Noninterference. In order to promote competition under this part and part D and in carrying out such parts, the Secretary may not require any MA organization to contract with a particular hospital, physician, or other entity or individual to furnish items and services under this title or require a particular price structure for payment under such a contract to the extent consistent with the Secretary's authority under this part.

(iv) Exception. In the case of a plan described in section 1851(a)(2)(C) [*42 USCS § 1395w-21(a)(2)(C)*], the provisions of clauses (i) and (ii) shall not apply and the provisions of paragraph (5)(B), prohibiting the review, approval, or disapproval of amounts described in such paragraph, shall apply to the negotiation and rejection of the monthly bid amounts and the proportions referred to in subparagraph (A).

(b) Monthly premium charged.

(1) In general.

(A) Rule for other than MSA plans. Subject to the rebate under subparagraph (C), the monthly amount (if any) of the premium charged to an individual enrolled in a Medicare + Choice plan (other than an MSA plan) offered by a Medicare + Choice organization shall be equal to the sum of the Medicare + Choice monthly basic beneficiary premium, the Medicare + Choice monthly supplementary beneficiary premium (if any), and, if the plan provides qualified prescription drug coverage, the MA monthly prescription drug beneficiary premium.

(B) MSA plans. The monthly amount of the premium charged to an individual enrolled in an MSA plan offered by a Medicare + Choice organization shall be equal to the Medicare + Choice monthly supplemental beneficiary premium (if any).

(C) Beneficiary rebate rule.

(i) Requirement. The MA plan shall provide to the enrollee a monthly rebate equal to 75 percent of the average per capita savings (if any) described in paragraph (3)(C) or (4)(C), as applicable to the plan and year involved.

(ii) Form of rebate. A rebate required under this subparagraph shall be provided through the application of the amount of the rebate toward one or more of the following:

(I) Provision of supplemental health care benefits and payment for premium for supplemental benefits. The provision of supplemental health care benefits described in section 1852(a)(3) [*42 USCS § 1395w-22(a)(3)*] in a manner specified under the plan, which may include the reduction of cost-sharing otherwise applicable as well as additional health care benefits which are not benefits under the original medicare fee-for-service program option, or crediting toward an MA monthly supplemental beneficiary premium (if any).

(II) Payment for premium for prescription drug coverage. Crediting toward the MA monthly prescription drug beneficiary premium.

(III) Payment toward part B premium. Crediting toward the premium imposed under part B [*42 USCS §§ 1395j* et seq.] (determined without regard to the application of subsections (b), (h), and (i) of section 1839 [*42 USCS § 1395r*]).

(iii) Disclosure relating to rebates. The plan shall disclose to the Secretary information on the form and amount of the rebate provided under this subparagraph or the actuarial value in the case of supplemental health care benefits.

(iv) Application of part B premium reduction. Insofar as an MA organization elects to provide a rebate under this subparagraph under a plan as a credit toward the part B premium under clause (ii)(III), the Secretary shall apply such credit to reduce the premium under section 1839 [*42 USCS § 1395r*] of each enrollee in such plan as provided in section 1840(i) [*42 USCS § 1395s(i)*].

(2) Premium and bid terminology defined. For purposes of this part [*42 USCS §§ 1395w-21* et seq.]:

(A) MA monthly basic beneficiary premium. The term "MA monthly basic beneficiary premium" means, with respect to an MA plan--

(i) described in section 1853(a)(1)(B)(i) [*42 USCS § 1395w-23(a)(1)(B)(i)*] (relating to plans providing rebates), zero; or

(ii) described in section 1853(a)(1)(B)(ii) [*42 USCS § 1395w-23(a)(1)(B)(ii)*], the amount (if any) by which the unadjusted MA statutory non-drug monthly bid amount (as defined in subparagraph (E)) exceeds the applicable unadjusted MA area-specific non-drug monthly benchmark amount (as defined in section 1853(j) [*42 USCS § 1395w-23(j)*]).

(B) MA monthly prescription drug beneficiary premium. The term "MA monthly prescription drug beneficiary premium" means, with respect to an MA plan, the base beneficiary premium (as determined under section 1860D-13(a)(2) [*42 USCS § 1395w-113(a)(2)*] and as adjusted under section 1860D-13(a)(1)(B) [*42 USCS § 1395w-113(a)(1)(B)*]), less the amount of rebate credited toward such amount under section 1854(b)(1)(C)(ii)(II) [*42 USCS § 1395w-24(b)(1)(C)(ii)(II)*].

(C) MA monthly supplemental beneficiary premium. The term "MA monthly supplemental beneficiary premium" means, with respect to an MA plan, the portion of the aggregate monthly bid amount submitted under clause (i) of subsection (a)(6)(A) for the year that is attributable under clause (ii)(III) of such subsection to the provision of supplemental health care benefits, less the amount of rebate credited toward such portion under section 1854(b)(1)(C)(ii)(I) [*42 USCS § 1395w-24(b)(1)(C)(ii)(I)*].

(D) Medicare + Choice monthly MSA premium. The term "Medicare + Choice monthly MSA premium" means, with respect to a Medicare + Choice plan, the amount of such premium filed under subsection (a)(3)(A) for the plan.

(E) Unadjusted MA statutory non-drug monthly bid amount. The term "unadjusted MA statutory non-drug monthly bid amount" means the portion of the bid amount submitted under clause (i) of subsection (a)(6)(A) for the year that is attributable under clause (ii)(I) of such subsection to the provision of benefits under the original medicare fee-for-service program option (as defined in section 1852(a)(1)(B) [*42 USCS § 1395w-22(a)(1)(B)*]).

(3) Computation of average per capita monthly savings for local plans. For purposes of paragraph (1)(C)(i), the average per capita monthly savings referred to in such paragraph for an MA local plan and year is computed as follows:

(A) Determination of statewide average risk adjustment for local plans.

(i) In general. Subject to clause (iii), the Secretary shall determine, at the same time rates are promulgated under section 1853(b)(1) [*42 USCS § 1395w-23(b)(1)*] (beginning with 2006) for each State, the average of the risk adjustment factors to be applied under section 1853(a)(1)(C) [*42 USCS § 1395w-23(a)(1)(C)*] to payment for enrollees in that State for MA local plans.

(ii) Treatment of States for first year in which local plan offered. In the case of a State in which no MA local plan was offered in the previous year, the Secretary shall estimate such average. In making such estimate, the Secretary may use average risk adjustment factors applied to comparable States or applied on a national basis.

(iii) Authority to determine risk adjustment for areas other than States. The Secretary may provide for the determination and application of risk adjustment factors under this subparagraph on the basis of areas other than States or on a plan-specific basis.

(B) Determination of risk adjusted benchmark and risk-adjusted bid for local plans. For each MA plan offered in a local area in a State, the Secretary shall--

(i) adjust the applicable MA area-specific non-drug monthly benchmark amount (as defined in section 1853(j)(1) [*42 USCS § 1395w-23(j)(1)*]) for the area by the average risk adjustment factor computed under subparagraph (A); and

(ii) adjust the unadjusted MA statutory non-drug monthly bid amount by such applicable average risk adjustment factor.

(C) Determination of average per capita monthly savings. The average per capita monthly savings described in this subparagraph for an MA local plan is equal to the amount (if any) by which--

(i) the risk-adjusted benchmark amount computed under subparagraph (B)(i); exceeds

(ii) the risk-adjusted bid computed under subparagraph (B)(ii).

(4) Computation of average per capita monthly savings for regional plans. For purposes of paragraph (1)(C)(i), the average per capita monthly savings referred to in such paragraph for an MA regional plan and year is computed as follows:

(A) Determination of regionwide average risk adjustment for regional plans.

(i) In general. The Secretary shall determine, at the same time rates are promulgated under section 1853(b)(1) [*42 USCS § 1395w-23(b)(1)*] (beginning with 2006) for each MA region the average of the risk adjustment factors to be applied under section 1853(a)(1)(C) [*42 USCS § 1395w-23(a)(1)(C)*] to payment for enrollees in that region for MA regional plans.

(ii) Treatment of regions for first year in which regional plan offered. In the case of an MA region in which no MA regional plan was offered in the previous year, the Secretary shall estimate such average. In making such estimate, the Secretary may use average risk adjustment factors applied to comparable regions or applied on a national basis.

(iii) Authority to determine risk adjustment for areas other than regions. The Secretary may provide for the determination and application of risk adjustment factors under this subparagraph on the basis of areas other than MA regions or on a plan-specific basis.

(B) Determination of risk-adjusted benchmark and risk-adjusted bid for regional plans. For each MA regional plan offered in a region, the Secretary shall--

(i) adjust the applicable MA area-specific non-drug monthly benchmark amount (as defined in section 1853(j)(2) [*42 USCS § 1395w-23(j)(2)*]) for the region by the average risk adjustment factor computed under subparagraph (A); and

(ii) adjust the unadjusted MA statutory non-drug monthly bid amount by such applicable average risk adjustment factor.

(C) Determination of average per capita monthly savings. The average per capita monthly savings described in this subparagraph for an MA regional plan is equal to the amount (if any) by which--

(i) the risk-adjusted benchmark amount computed under subparagraph (B)(i); exceeds

(ii) the risk-adjusted bid computed under subparagraph (B)(ii).

(c) Uniform premium and bid amounts. Except as permitted under section 1857(i) [*42 USCS § 1395w-27(i)*], the MA monthly bid amount submitted under subsection (a)(6), the amounts of the MA monthly basic, prescription drug, and supplemental beneficiary premiums, and the MA monthly MSA premium charged under subsection (b) of an MA organization under this part may not vary among individuals enrolled in the plan.

(d) Terms and conditions of imposing premiums.

(1) In general. Each Medicare + Choice organization shall permit the payment of Medicare + Choice monthly basic, prescription drug, and supplemental beneficiary premiums on a monthly basis, may terminate election of individuals for a Medicare + Choice plan for failure to make premium payments only in accordance with section 1851(g)(3)(B)(i) [*42 USCS § 1395w-21(g)(3)(B)(i)*], and may not provide for cash or other monetary rebates as an inducement for enrollment or otherwise.

(2) Beneficiary's option of payment through withholding from social security payment or use of electronic funds transfer mechanism. In accordance with regulations, an MA organization shall permit each enrollee, at the enrollee's option, to make payment of premiums (if any) under this part to the organization through--

(A) withholding from benefit payments in the manner provided under section 1840 [*42 USCS § 1395s*] with respect to monthly premiums under section 1839 [*42 USCS § 1395r*];

(B) an electronic funds transfer mechanism (such as automatic charges of an account at a financial institution or a credit or debit card account); or

(C) such other means as the Secretary may specify, including payment by an employer or under employment-based retiree health coverage (as defined in section 1860D-22(c)(1) [*42 USCS § 1395w-132(c)(1)*]) on behalf of an employee or former employee (or dependent).

All premium payments that are withheld under subparagraph (A) shall be credited to the appropriate Trust Fund (or Account thereof), as specified by the Secretary, under this title and shall be paid to the MA organization involved. No charge may be imposed under an MA plan with respect to the election of the payment option described in subparagraph (A). The Secretary shall consult with the Commissioner of Social Security and the Secretary of the Treasury regarding methods for allocating premiums withheld under subparagraph (A) among the appropriate Trust Funds and Account.

(3) Information necessary for collection. In order to carry out paragraph (2)(A) with respect to an enrollee who has elected such paragraph to apply, the Secretary shall transmit to the Commissioner of Social Security--

(A) by the beginning of each year, the name, social security account number, consolidated monthly beneficiary premium described in paragraph (4) owed by such enrollee for each month during the year, and other information determined appropriate by the Secretary, in consultation with the Commissioner of Social Security; and

(B) periodically throughout the year, information to update the information previously transmitted under this paragraph for the year.

(4) Consolidated monthly beneficiary premium. In the case of an enrollee in an MA plan, the Secretary shall provide a mechanism for the consolidation of--

(A) the MA monthly basic beneficiary premium (if any);

(B) the MA monthly supplemental beneficiary premium (if any); and

(C) the MA monthly prescription drug beneficiary premium (if any).

(e) Limitation on enrollee liability.

(1) For basic and additional benefits before 2006. For periods before 2006, in no event may--

(A) the Medicare + Choice monthly basic beneficiary premium (multiplied by 12) and the actuarial value of the deductibles, coinsurance, and copayments applicable on average to individuals enrolled under this part [*42 USCS §§ 1395w-21* et seq.] with a Medicare + Choice plan described in section 1851(a)(2)(A) [*42 USCS § 1395w-21(a)(2)(A)*] of an organization with respect to required benefits described in section 1852(a)(1)(A) [*42 USCS § 1395w-22(a)(1)(A)*] and additional benefits (if any) required under subsection (f)(1)(A) for a year, exceed

(B) the actuarial value of the deductibles, coinsurance, and copayments that would be applicable on average to individuals entitled to benefits under part A [*42 USCS §§ 1395c* et seq.] and enrolled under part B [*42 USCS §§ 1395j* et seq.] if they were not members of a Medicare + Choice organization for the year.

(2) For supplemental benefits before 2006. For periods before 2006, if the Medicare + Choice organization provides to its members enrolled under this part [*42 USCS §§ 1395w-21* et seq.] in a Medicare + Choice plan described in section 1851(a)(2)(A) [*42 USCS § 1395w-21(a)(2)(A)*] with respect to supplemental benefits described in section 1852(a)(3) [*42 USCS § 1395w-22(a)(3)*], the sum of the Medicare + Choice monthly supplemental beneficiary premium (multiplied by 12) charged and the actuarial value of its deductibles, coinsurance, and copayments charged with respect to such benefits may not exceed the adjusted community rate for such benefits (as defined in subsection (f)(3)).

(3) Determination on other basis. If the Secretary determines that adequate data are not available to determine the actuarial value under paragraph (1)(A), (2), or (4), the Secretary may determine such amount with respect to all individuals in same geographic area, the State, or in the United States, eligible to enroll in the Medicare + Choice plan involved under this part [*42 USCS §§ 1395w-21* et seq.] or on the basis of other appropriate data.

(4) Special rule for private fee-for-service plans and for basic benefits beginning in 2006. With respect to a Medicare + Choice private fee-for-service plan (other than a plan that is an MSA plan) and for periods beginning with 2006, with respect to an MA plan described in section 1851(a)(2)(A) *[42 USCS § 13952-21*(a)(2)(A)], in no event may--

(A) the actuarial value of the deductibles, coinsurance, and copayments applicable on average to individuals enrolled under this part [*42 USCS §§ 1395w-21* et seq.] with such a plan of an organization with respect to benefits under the original medicare fee-for-service program option, exceed

(B) the actuarial value of the deductibles, coinsurance, and copayments that would be applicable with respect to such benefits on average to individuals entitled to benefits under part A [*42 USCS §§ 1395c* et seq.] and enrolled under part B [*42 USCS §§ 1395j* et seq.] if they were not members of a Medicare + Choice organization for the year.

(f) Requirement for additional benefits before 2006.

(1) Requirement.

(A) In general. For years before 2006, each Medicare + Choice organization (in relation to a Medicare + Choice plan, other than an MSA plan, it offers) shall provide that if there is an excess amount (as defined in subparagraph (B)) for the plan for a contract year, subject to the succeeding provisions of this subsection, the organization shall provide to individuals such additional benefits (as the organization may specify) in a value which the Secretary determines is at least equal to the adjusted excess amount (as defined in subparagraph (C)).

(B) Excess amount. For purposes of this paragraph, the "excess amount", for an organization for a plan, is the amount (if any) by which--

(i) the average of the capitation payments made to the organization under section 1853 [*42 USCS § 1395w-23*] for the plan at the beginning of contract year, exceeds

(ii) the actuarial value of the required benefits described in section 1852(a)(1)(A) [*42 USCS § 1395w-22(a)(1)(A)*] under the plan for individuals under this part [*42 USCS §§ 1395w-21* et seq.], as determined based upon an adjusted community rate described in paragraph (3) (as reduced for the actuarial value of the coinsurance, copayments, and deductibles under parts A and B [*42 USCS §§ 1395c* et seq. and *1395j* et seq.]).

(C) Adjusted excess amount. For purposes of this paragraph, the "adjusted excess amount", for an organization for a plan, is the excess amount reduced to reflect any amount withheld and reserved for the organization for the year under paragraph (2).

(D) Uniform application. This paragraph shall be applied uniformly for all enrollees for a plan.

(E) Premium reductions.

(i) In general. Subject to clause (ii), as part of providing any additional benefits required under subparagraph (A), a Medicare + Choice organization may elect a reduction in its payments under section 1853(a)(1)(A) [*42 USCS § 1395w-23(a)(1)(A)*] with respect to a Medicare + Choice plan and the Secretary shall apply such reduction to reduce the premium under section 1839 [*42 USCS § 1395r*] of each enrollee in such plan as provided in section 1840(i) [*42 USCS § 1395s(i)*].

(ii) Amount of reduction. The amount of the reduction under clause (i) with respect to any enrollee in a Medicare + Choice plan--

(I) may not exceed 125 percent of the premium described under section 1839(a)(3) [*42 USCS § 1395r(a)(3)*]; and

(II) shall apply uniformly to each enrollee of the Medicare + Choice plan to which such reduction applies.

(F) Construction. Nothing in this subsection shall be construed as preventing a Medicare + Choice organization from providing supplemental benefits (described in section 1852(a)(3) [*42 USCS § 1395w-22(a)(3)*]) that are in addition to the health care benefits otherwise required to be provided under this paragraph and from imposing a premium for such supplemental benefits.

(2) Stabilization fund. A Medicare + Choice organization may provide that a part of the value of an excess amount described in paragraph (1) be withheld and reserved in the Federal Hospital Insurance Trust Fund and in the Federal Supplementary Medical Insurance Trust Fund (in such proportions as the Secretary determines to be appropriate) by the Secretary for subsequent annual contract periods, to the extent required to stabilize and prevent undue fluctuations in the additional benefits offered in those subsequent periods by the organization in accordance with such paragraph. Any of such value of the amount reserved which is not provided as additional benefits described in paragraph (1)(A) to individuals electing the Medicare + Choice plan of the organization in accordance with such paragraph prior to the end of such periods, shall revert for the use of such trust funds.

(3) Adjusted community rate. For purposes of this subsection, subject to paragraph (4), the term "adjusted community rate" for a service or services means, at the election of a Medicare + Choice organization, either--

(A) the rate of payment for that service or services which the Secretary annually determines would apply to an individual electing a Medicare + Choice plan under this part [*42 USCS §§ 1395w-21* et seq.] if the rate of payment were

determined under a "community rating system" (as defined in section 1302(8) of the Public Health Service Act [*42 USCS § 300e-1(8)*], other than subparagraph (C)), or

(B) such portion of the weighted aggregate premium, which the Secretary annually estimates would apply to such an individual, as the Secretary annually estimates is attributable to that service or services,

but adjusted for differences between the utilization characteristics of the individuals electing coverage under this part [*42 USCS §§ 1395w-21* et seq.] and the utilization characteristics of the other enrollees with the plan (or, if the Secretary finds that adequate data are not available to adjust for those differences, the differences between the utilization characteristics of individuals selecting other Medicare + Choice coverage, or Medicare + Choice eligible individuals in the area, in the State, or in the United States, eligible to elect Medicare + Choice coverage under this part [*42 USCS §§ 1395w-21* et seq.] and the utilization characteristics of the rest of the population in the area, in the State, or in the United States, respectively).

(4) Determination based on insufficient data. For purposes of this subsection, if the Secretary finds that there is insufficient enrollment experience to determine an average of the capitation payments to be made under this part [*42 USCS §§ 1395w-21* et seq.] at the beginning of a contract period or to determine (in the case of a newly operated provider-sponsored organization or other new organization) the adjusted community rate for the organization, the Secretary may determine such an average based on the enrollment experience of other contracts entered into under this part [*42 USCS §§ 1395w-21* et seq.] and may determine such a rate using data in the general commercial marketplace.

(g) Prohibition of State imposition of premium taxes. No State may impose a premium tax or similar tax with respect to payments to Medicare + Choice organizations under section 1853 [*42 USCS § 1395w-23*] or premiums paid to such organizations under this part [*42 USCS §§ 1395w-21* et seq.].

(h) Permitting use of segments of service areas. The Secretary shall permit a Medicare + Choice organization to elect to apply the provisions of this section uniformly to separate segments of a service area (rather than uniformly to an entire service area) as long as such segments are composed of one or more Medicare + Choice payment areas.

HISTORY:

(Aug. 14, 1935, ch 531, Title XVIII, Part C, § 1854, as added Aug. 5, 1997, P.L. 105-33, Title IV, Subtitle A, Ch 1, Subch A, § 4001, 111 Stat. 308; Nov. 29, 1999, P.L. 106-113, Div B, § 1000(a)(6), 113 Stat. 1536; Dec. 21, 2000, P.L. 106-554, § 1(a)(6), 114 Stat. 2763; June 12, 2002, P.L. 107-188, Title V, Subtitle C, § 532(b)(1), 116 Stat. 696; Dec. 8, 2003, P.L. 108-173, Title II, Subtitle C, § 222(a)(1), (b), (c), (g), Subtitle D, § 232(b), Title IX, § 900(e)(1)(H), 117 Stat. 2193, 2196, 2203, 2208, 2371.)

§ 1395w-25. Organizational and financial requirements for Medicare + Choice organizations; provider-sponsored organizations

(a) Organized and licensed under State law.

(1) In general. Subject to paragraphs (2) and (3), a Medicare + Choice organization shall be organized and licensed under State law as a risk-bearing entity eligible to offer health insurance or health benefits coverage in each State in which it offers a Medicare + Choice plan.

(2) Special exception for provider-sponsored organizations.

(A) In general. In the case of a provider-sponsored organization that seeks to offer a Medicare + Choice plan in a State, the Secretary shall waive the requirement of paragraph (1) that the organization be licensed in that State if--

(i) the organization files an application for such waiver with the Secretary by not later than November 1, 2002, and

(ii) the Secretary determines, based on the application and other evidence presented to the Secretary, that any of the grounds for approval of the application described in subparagraph (B), (C), or (D) has been met.

(B) Failure to act on licensure application on a timely basis. The ground for approval of such a waiver application described in this subparagraph is that the State has failed to complete action on a licensing application of the organization within 90 days of the date of the State's receipt of a substantially complete application. No period before the date of the enactment of this section shall be included in determining such 90-day period.

(C) Denial of application based on discriminatory treatment. The ground for approval of such a waiver application described in this subparagraph is that the State has denied such a licensing application and--

(i) the standards or review process imposed by the State as a condition of approval of the license imposes any material requirements, procedures, or standards (other than solvency requirements) to such organizations that are not generally applicable to other entities engaged in a substantially similar business, or

(ii) the State requires the organization, as a condition of licensure, to offer any product or plan other than a Medicare + Choice plan.

(D) Denial of application based on application of solvency requirements. With respect to waiver applications filed on or after the date of publication of solvency standards under section 1856(a) [*42 USCS § 1395w-26(a)*], the ground for approval of such a waiver application described in this subparagraph is that the State has denied such a licensing application based (in whole or in part) on the organization's failure to meet applicable solvency requirements and--

(i) such requirements are not the same as the solvency standards established under section 1856(a) [*42 USCS § 1395w-26(a)*]; or

(ii) the State has imposed as a condition of approval of the license documentation or information requirements relating to solvency or other material requirements, procedures, or standards relating to solvency that are different from the requirements, procedures, and standards applied by the Secretary under subsection (d)(2).

For purposes of this paragraph, the term "solvency requirements" means requirements relating to solvency and other matters covered under the standards established under section 1856(a) [*42 USCS § 1395w-26(a)*].

(E) Treatment of waiver. In the case of a waiver granted under this paragraph for a provider-sponsored organization with respect to a State--

(i) Limitation to State. The waiver shall be effective only with respect to that State and does not apply to any other State.

(ii) Limitation to 36-month period. The waiver shall be effective only for a 36-month period and may not be renewed.

(iii) Conditioned on compliance with consumer protection and quality standards. The continuation of the waiver is conditioned upon the organization's compliance with the requirements described in subparagraph (G).

(iv) Preemption of State law. Any provisions of law of that State which relate to the licensing of the organization and which prohibit the organization from providing coverage pursuant to a contract under this part [*42 USCS §§ 1395w-21* et seq.] shall be superseded.

(F) Prompt action on application. The Secretary shall grant or deny such a waiver application within 60 days after the date the Secretary determines that a substantially complete waiver application has been filed. Nothing in this section shall be construed as preventing an organization which has had such a waiver application denied from submitting a subsequent waiver application.

(G) Application and enforcement of State consumer protection and quality standards.

(i) In general. A waiver granted under this paragraph to an organization with respect to licensing under State law is conditioned upon the organization's compliance with all consumer protection and quality standards insofar as such standards--

(I) would apply in the State to the organization if it were licensed under State law;

(II) are generally applicable to other Medicare + Choice organizations and plans in the State; and

(III) are consistent with the standards established under this part [*42 USCS §§ 1395w-21* et seq.].

Such standards shall not include any standard preempted under section 1856(b)(3)(B) [*42 USCS § 1395w-26(b)(3)(B)*].

(ii) Incorporation into contract. In the case of such a waiver granted to an organization with respect to a State, the Secretary shall incorporate the requirement that the organization (and Medicare + Choice plans it offers) comply with standards under clause (i) as part of the contract between the Secretary and the organization under section 1857 [*42 USCS § 1395w-27*].

(iii) Enforcement. In the case of such a waiver granted to an organization with respect to a State, the Secretary may enter into an agreement with the State under which the State agrees to provide for monitoring and enforcement activities with respect to compliance of such an organization and its Medicare + Choice plans with such standards. Such monitoring and enforcement shall be conducted by the State in the same manner as the State enforces such standards with respect to other Medicare + Choice organizations and plans, without discrimination based on the type of organization to which the standards apply. Such an agreement shall specify or establish mechanisms by which compliance activities are undertaken, while not lengthening the time required to review and process applications for waivers under this paragraph.

(H) Report. By not later than December 31, 2001, the Secretary shall submit to the Committee on Ways and Means and the Committee on Commerce of the House of Representatives and the Committee on Finance of the Senate a report regarding whether the waiver process under this paragraph should be continued after December 31, 2002. In making such recommendation, the Secretary shall consider, among other factors, the impact of such process on beneficiaries and on the long-term solvency of the program under this *title [42 USCS §§ 1395* et seq.].

(3) Licensure does not substitute for or constitute certification. The fact that an organization is licensed in accordance with paragraph (1) does not deem the organization to meet other requirements imposed under this part [*42 USCS §§ 1395w-21* et seq.].

(b) Assumption of full financial risk. The Medicare + Choice organization shall assume full financial risk on a prospective basis for the provision of the health care services for which benefits are required to be provided under section 1852(a)(1) [*42 USCS § 1395w-22(a)(1)*], except that the organization--

(1) may obtain insurance or make other arrangements for the cost of providing to any enrolled member such services the aggregate value of which exceeds such aggregate level as the Secretary specifies from time to time,

(2) may obtain insurance or make other arrangements for the cost of such services provided to its enrolled members other than through the organization because medical necessity required their provision before they could be secured through the organization,

(3) may obtain insurance or make other arrangements for not more than 90 percent of the amount by which its costs for any of its fiscal years exceed 115 percent of its income for such fiscal year, and

(4) may make arrangements with physicians or other health care professionals, health care institutions, or any combination of such individuals or institutions to assume all or part of the financial risk on a prospective basis for the provision of basic health services by the physicians or other health professionals or through the institutions.

(c) Certification of provision against risk of insolvency for unlicensed PSOs.

(1) In general. Each Medicare + Choice organization that is a provider-sponsored organization, that is not licensed by a State under subsection (a), and for which a waiver application has been approved under subsection (a)(2), shall meet standards established under section 1856(a) [*42 USCS § 1395w-26(a)*] relating to the financial solvency and capital adequacy of the organization.

(2) Certification process for solvency standards for PSOS. The Secretary shall establish a process for the receipt and approval of applications of a provider-sponsored organization described in paragraph (1) for certification (and periodic recertification) of the organization as meeting such solvency standards. Under such process, the Secretary shall act upon such a certification application not later than 60 days after the date the application has been received.

(d) "Provider-sponsored organization" defined.

(1) In general. In this part [*42 USCS §§ 1395w-21* et seq.], the term "provider-sponsored organization" means a public or private entity--

(A) that is established or organized, and operated, by a health care provider, or group of affiliated health care providers,

(B) that provides a substantial proportion (as defined by the Secretary in accordance with paragraph (2)) of the health care items and services under the contract under this part [*42 USCS §§ 1395w-21* et seq.] directly through the provider or affiliated group of providers, and

(C) with respect to which the affiliated providers share, directly or indirectly, substantial financial risk with respect to the provision of such items and services and have at least a majority financial interest in the entity.

(2) Substantial proportion. In defining what is a "substantial proportion" for purposes of paragraph (1)(B), the Secretary--

(A) shall take into account the need for such an organization to assume responsibility for providing--

(i) significantly more than the majority of the items and services under the contract under this section through its own affiliated providers; and

(ii) most of the remainder of the items and services under the contract through providers with which the organization has an agreement to provide such items and services,

in order to assure financial stability and to address the practical considerations involved in integrating the delivery of a wide range of service providers;

(B) shall take into account the need for such an organization to provide a limited proportion of the items and services under the contract through providers that are neither affiliated with nor have an agreement with the organization; and

(C) may allow for variation in the definition of substantial proportion among such organizations based on relevant differences among the organizations, such as their location in an urban or rural area.

(3) Affiliation. For purposes of this subsection, a provider is "affiliated" with another provider if, through contract, ownership, or otherwise--

(A) one provider, directly or indirectly, controls, is controlled by, or is under common control with the other,

(B) both providers are part of a controlled group of corporations under *section 1563 of the Internal Revenue Code of 1986* [*26 USCS § 1563*],

(C) each provider is a participant in a lawful combination under which each provider shares substantial financial risk in connection with the organization's operations, or

(D) both providers are part of an affiliated service group under section 414 of such Code [*26 USCS § 414*].

(4) Control. For purposes of paragraph (3), control is presumed to exist if one party, directly or indirectly, owns, controls, or holds the power to vote, or proxies for, not less than 51 percent of the voting rights or governance rights of another.

(5) Health care provider defined. In this subsection, the term "health care provider" means--

(A) any individual who is engaged in the delivery of health care services in a State and who is required by State law or regulation to be licensed or certified by the State to engage in the delivery of such services in the State, and

(B) any entity that is engaged in the delivery of health care services in a State and that, if it is required by State law or regulation to be licensed or certified by the State to engage in the delivery of such services in the State, is so licensed.

(6) Regulations. The Secretary shall issue regulations to carry out this subsection.

HISTORY:

(Aug. 14, 1935, ch 531, Title XVIII, Part C, § 1855, as added Aug. 5, 1997, P.L. 105-33, Title IV, Subtitle A, Ch 1, Subch A, § 4001, 111 Stat. 312.)

§ 1395w-26. Establishment of standards

(a) Establishment of solvency standards for provider-sponsored organizations.

(1) Establishment.

(A) In general. The Secretary shall establish, on an expedited basis and using a negotiated rulemaking process under subchapter III of chapter 5 of title 5, United States Code [*5 USCS §§ 571* et seq.], standards described in section 1855(c)(1) [*42 USCS § 1395w-25(c)(1)*] (relating to the financial solvency and capital adequacy of the organization) that entities must meet to qualify as provider-sponsored organizations under this part [*42 USCS §§ 1395w-21* et seq.].

(B) Factors to consider for solvency standards. In establishing solvency standards under subparagraph (A) for provider-sponsored organizations, the Secretary shall consult with interested parties and shall take into account--

(i) the delivery system assets of such an organization and ability of such an organization to provide services directly to enrollees through affiliated providers,

(ii) alternative means of protecting against insolvency, including reinsurance, unrestricted surplus, letters of credit, guarantees, organizational insurance coverage, partnerships with other licensed entities, and valuation attributable to the ability of such an organization to meet its service obligations through direct delivery of care, and

(iii) any standards developed by the National Association of Insurance Commissioners specifically for risk-based health care delivery organizations.

(C) Enrollee protection against insolvency. Such standards shall include provisions to prevent enrollees from being held liable to any person or entity for the Medicare + Choice organization's debts in the event of the organization's insolvency.

(2) Publication of notice. In carrying out the rulemaking process under this subsection, the Secretary, after consultation with the National Association of Insurance Commissioners, the American Academy of Actuaries, organizations representative of medicare beneficiaries, and other interested parties, shall publish the notice provided for under *section 564(a) of title 5, United States Code*, by not later than 45 days after the date of the enactment of this section [enacted Aug. 5, 1997].

(3) Target date for publication of rule. As part of the notice under paragraph (2), and for purposes of this subsection, the "target date for publication" (referred to in section 564(a)(5) of such title) shall be April 1, 1998.

(4) Abbreviated period for submission of comments. In applying section 564(c) of such title under this subsection, "15 days" shall be substituted for "30 days".

(5) Appointment of negotiated rulemaking committee and facilitator. The Secretary shall provide for--

(A) the appointment of a negotiated rulemaking committee under section 565(a) of such title by not later than 30 days after the end of the comment period provided for under section 564(c) of such title (as shortened under paragraph (4)), and

(B) the nomination of a facilitator under section 566(c) of such title by not later than 10 days after the date of appointment of the committee.

(6) Preliminary committee report. The negotiated rulemaking committee appointed under paragraph (5) shall report to the Secretary, by not later than January 1, 1998, regarding the committee's progress on achieving a consensus with regard to the rulemaking proceeding and whether such consensus is likely to occur before 1 month before the target date for publication of the rule. If the committee reports that the committee has failed to make significant progress towards such consensus or is unlikely to reach such consensus by the target date, the Secretary may terminate such process and provide for the publication of a rule under this subsection through such other methods as the Secretary may provide.

(7) Final committee report. If the committee is not terminated under paragraph (6), the rulemaking committee shall submit a report containing a proposed rule by not later than 1 month before the target date of publication.

(8) Interim, final effect. The Secretary shall publish a rule under this subsection in the Federal Register by not later than the target date of publication. Such rule shall be effective and final immediately on an interim basis, but is subject to change and revision after public notice and opportunity for a period (of not less than 60 days) for public comment. In connection with such rule, the Secretary shall specify the process for the timely review and approval of applications of entities to be certified as provider-sponsored organizations pursuant to such rules and consistent with this subsection.

(9) Publication of rule after public comment. The Secretary shall provide for consideration of such comments and republication of such rule by not later than 1 year after the target date of publication.

(b) Establishment of other standards.

(1) In general. The Secretary shall establish by regulation other standards (not described in subsection (a)) for Medicare + Choice organizations and plans consistent with, and to carry out, this part [*42 USCS §§ 1395w-21* et seq.]. The Secretary shall publish such regulations by June 1, 1998. In order to carry out this requirement in a timely manner, the Secretary may promulgate regulations that take effect on an interim basis, after notice and pending opportunity for public comment.

(2) Use of current standards. Consistent with the requirements of this part [*42 USCS §§ 1395w-21* et seq.], standards established under this subsection shall be based on standards established under section 1876 [*42 USCS § 1395mm*] to carry out analogous provisions of such section.

(3) Relation to State laws. The standards established under this part [*42 USCS §§ 1395w-21* et seq.] shall supersede any State law or regulation (other than State licensing laws or State laws relating to plan solvency) with respect to MA plans which are offered by MA organizations under this part [*42 USCS §§ 1395w-21* et seq.].

(4) Prohibition of midyear implementation of significant new regulatory requirements. The Secretary may not implement, other than at the beginning of a calendar year, regulations under this section that impose new, significant regulatory requirements on a Medicare + Choice organization or plan.

HISTORY:

(Aug. 14, 1935, ch 531, Title XVIII, Part C, § 1856, as added Aug. 5, 1997, P.L. 105-33, Title IV, Subtitle A, Ch 1, Subch A, § 4001, 111 Stat. 317; Dec. 21, 2000, P.L. 106-554, § 1(a)(6), 114 Stat. 2763; Dec. 8, 2003, P.L. 108-173, Title II, Subtitle D, § 232(a), 117 Stat. 2208.)

§ 1395w-27. Contracts with Medicare + Choice organizations

(a) In general. The Secretary shall not permit the election under section 1851 [*42 USCS § 1395w-21*] of a Medicare + Choice plan offered by a Medicare + Choice organization under this part [*42 USCS §§ 1395w-21* et seq.], and no payment shall be made under section 1853 [*42 USCS § 1395w-23*] to an organization, unless the Secretary has entered into a contract under this section with the organization with respect to the offering of such plan. Such a contract with an organization may cover more than 1 Medicare + Choice plan. Such contract shall provide that the organization agrees to comply with the applicable requirements and standards of this part [*42 USCS §§ 1395w-21* et seq.] and the terms and conditions of payment as provided for in this part [*42 USCS §§ 1395w-21* et seq.].

(b) Minimum enrollment requirements.

(1) In general. Subject to paragraph (2), the Secretary may not enter into a contract under this section with a Medicare + Choice organization unless the organization has--

(A) at least 5,000 individuals (or 1,500 individuals in the case of an organization that is a provider-sponsored organization) who are receiving health benefits through the organization, or

(B) at least 1,500 individuals (or 500 individuals in the case of an organization that is a provider-sponsored organization) who are receiving health benefits through the organization if the organization primarily serves individuals residing outside of urbanized areas.

(2) Application to MSA plans. In applying paragraph (1) in the case of a Medicare + Choice organization that is offering an MSA plan, paragraph (1) shall be applied by substituting covered lives for individuals.

(3) Allowing transition. The Secretary may waive the requirement of paragraph (1) during the first 3 contract years with respect to an organization.

(c) Contract period and effectiveness.

(1) Period. Each contract under this section shall be for a term of at least 1 year, as determined by the Secretary, and may be made automatically renewable from term to term in the absence of notice by either party of intention to terminate at the end of the current term.

(2) Termination authority. In accordance with procedures established under subsection (h), the Secretary may at any time terminate any such contract if the Secretary determines that the organization--

(A) has failed substantially to carry out the contract;

(B) is carrying out the contract in a manner inconsistent with the efficient and effective administration of this part [*42 USCS §§ 1395w-21* et seq.]; or

(C) no longer substantially meets the applicable conditions of this part [*42 USCS §§ 1395w-21* et seq.].

(3) Effective date of contracts. The effective date of any contract executed pursuant to this section shall be specified in the contract, except that in no case shall a contract under this section which provides for coverage under an MSA plan be effective before January 1999 with respect to such coverage.

(4) Previous terminations.

(A) In general. The Secretary may not enter into a contract with a Medicare + Choice organization if a previous contract with that organization under this section was terminated at the request of the organization within the preceding 2-year period, except as provided in subparagraph (B) and except in such other circumstances which warrant special consideration, as determined by the Secretary.

(B) Earlier re-entry permitted where change in payment policy. Subparagraph (A) shall not apply with respect to the offering by a Medicare + Choice organization of a Medicare + Choice plan in a Medicare + Choice payment area if during the 6-month period beginning on the date the organization notified the Secretary of the intention to terminate the most recent previous contract, there was a legislative change enacted (or a regulatory change adopted) that has the effect of increasing payment amounts under section 1853 [*42 USCS § 1395w-23*] for that Medicare + Choice payment area.

(5) Contracting authority. The authority vested in the Secretary by this part [*42 USCS §§ 1395w-21* et seq.] may be performed without regard to such provisions of law or regulations relating to the making, performance, amendment, or modification of contracts of the United States as the Secretary may determine to be inconsistent with the furtherance of the purpose of this *title [42 USCS §§ 1395* et seq.].

(d) Protections against fraud and beneficiary protections.

(1) Periodic auditing. The Secretary shall provide for the annual auditing of the financial records (including data relating to medicare utilization and costs, including allowable costs under section 1858(c) [*42 USCS § 1395w-27a(c)*]) of at least one-third of the Medicare + Choice organizations offering Medicare + Choice plans under this part [*42 USCS §§ 1395w-21* et seq.]. The Comptroller General shall monitor auditing activities conducted under this subsection.

(2) Inspection and audit. Each contract under this section shall provide that the Secretary, or any person or organization designated by the Secretary--

(A) shall have the right to inspect or otherwise evaluate (i) the quality, appropriateness, and timeliness of services performed under the contract, and (ii) the facilities of the organization when there is reasonable evidence of some need for such inspection, and

(B) shall have the right to audit and inspect any books and records of the Medicare + Choice organization that pertain (i) to the ability of the organization to bear the risk of potential financial losses, or (ii) to services performed or determinations of amounts payable under the contract.

(3) Enrollee notice at time of termination. Each contract under this section shall require the organization to provide (and pay for) written notice in advance of the contract's termination, as well as a description of alternatives for obtaining benefits under this *title [42 USCS §§ 1395* et seq.], to each individual enrolled with the organization under this part [*42 USCS §§ 1395w-21* et seq.].

(4) Disclosure.

(A) In general. Each Medicare + Choice organization shall, in accordance with regulations of the Secretary, report to the Secretary financial information which shall include the following:

(i) Such information as the Secretary may require demonstrating that the organization has a fiscally sound operation.

(ii) A copy of the report, if any, filed with the Secretary containing the information required to be reported under section 1124 [*42 USCS § 1320a-3*] by disclosing entities.

(iii) A description of transactions, as specified by the Secretary, between the organization and a party in interest. Such transactions shall include--

(I) any sale or exchange, or leasing of any property between the organization and a party in interest;

(II) any furnishing for consideration of goods, services (including management services), or facilities between the organization and a party in interest, but not including salaries paid to employees for services provided in the normal course of their employment and health services provided to members by hospitals and other providers and by staff, medical group (or groups), individual practice association (or associations), or any combination thereof; and

(III) any lending of money or other extension of credit between an organization and a party in interest.

The Secretary may require that information reported respecting an organization which controls, is controlled by, or is under common control with, another entity be in the form of a consolidated financial statement for the organization and such entity.

(B) Party in interest defined. For the purposes of this paragraph, the term "party in interest" means--

(i) any director, officer, partner, or employee responsible for management or administration of a Medicare + Choice organization, any person who is directly or indirectly the beneficial owner of more than 5 percent of the equity of the organization, any person who is the beneficial owner of a mortgage, deed of trust, note, or other interest secured by, and valuing more than 5 percent of the organization, and, in the case of a Medicare + Choice organization organized as a nonprofit corporation, an incorporator or member of such corporation under applicable State corporation law;

(ii) any entity in which a person described in clause (i)--

(I) is an officer or director;

(II) is a partner (if such entity is organized as a partnership);

(III) has directly or indirectly a beneficial interest of more than 5 percent of the equity; or

(IV) has a mortgage, deed of trust, note, or other interest valuing more than 5 percent of the assets of such entity;

(iii) any person directly or indirectly controlling, controlled by, or under common control with an organization; and

(iv) any spouse, child, or parent of an individual described in clause (i).

(C) Access to information. Each Medicare + Choice organization shall make the information reported pursuant to subparagraph (A) available to its enrollees upon reasonable request.

(5) Loan information. The contract shall require the organization to notify the Secretary of loans and other special financial arrangements which are made between the organization and subcontractors, affiliates, and related parties.

(6) Review to ensure compliance with care management requirements for specialized Medicare Advantage plans for special needs individuals. In conjunction with the periodic audit of a specialized Medicare Advantage plan for special needs individuals under paragraph (1), the Secretary shall conduct a review to ensure that such organization offering the plan meets the requirements described in section 1859(f)(5) [*42 USCS § 1395w-28(f)(5)*].

(e) Additional contract terms.

(1) In general. The contract shall contain such other terms and conditions not inconsistent with this part [*42 USCS §§ 1395w-21* et seq.] (including requiring the organization to provide the Secretary with such information) as the Secretary may find necessary and appropriate.

(2) Cost-sharing in enrollment-related costs.

(A) In general. A Medicare + Choice organization and a PDP sponsor under part D [*42 USCS §§ 1395w-101* et seq.] shall pay the fee established by the Secretary under subparagraph (B).

(B) Authorization. The Secretary is authorized to charge a fee to each Medicare + Choice organization with a contract under this part [*42 USCS §§ 1395w-21* et seq.] and each PDP sponsor with a contract under part D [*42 USCS §§ 1395w-101* et seq.] that is equal to the organization's or sponsor's pro rata share (as determined by the Secretary) of the aggregate amount of fees which the Secretary is directed to collect in a fiscal year. Any amounts collected shall be available without further appropriation to the Secretary for the purpose of carrying out section 1851 [*42 USCS § 1395w-21*] (relating to enrollment and dissemination of information), section 1860D-1(c) [*42 USCS § 1395w-101(c)*], and section 4360 of the Omnibus Budget Reconciliation Act of 1990 [*42 USCS § 1395b-4*] (relating to the health insurance counseling and assistance program).

(C) Authorization of appropriations. There are authorized to be appropriated for the purposes described in subparagraph (B) for each fiscal year beginning with fiscal year 2001 and ending with fiscal year 2005 an amount equal to $ 100,000,000, and for each fiscal year beginning with fiscal year 2006 an amount equal to $ 200,000,000, reduced by the amount of fees authorized to be collected under this paragraph and section 1860D-12(b)(3)(D) [*42 USCS § 1395w-112(b)(3)(D)*] for the fiscal year.

(D) Limitation. In any fiscal year the fees collected by the Secretary under subparagraph (B) shall not exceed the lesser of--

(i) the estimated costs to be incurred by the Secretary in the fiscal year in carrying out the activities described in section 1851 [*42 USCS § 1395w-21*] and section 1860D-1(c) [*42 USCS § 1395w-101(c)*] and section 4360 of the Omnibus Budget Reconciliation Act of 1990 [*42 USCS § 1395b-4*]; or

(ii) (I) $ 200,000,000 in fiscal year 1998;

(II) $ 150,000,000 in fiscal year 1999;

(III) $ 100,000,000 in fiscal year 2000;

(IV) the Medicare + Choice portion (as defined in subparagraph (E)) of $ 100,000,000 in fiscal year 2001 and each succeeding fiscal year before fiscal year 2006; and

(V) the applicable portion (as defined in subparagraph (F)) of $ 200,000,000 in fiscal year 2006 and each succeeding fiscal year.

(E) Medicare + Choice portion defined. In this paragraph, the term "Medicare + Choice portion" means, for a fiscal year, the ratio, as estimated by the Secretary, of--

(i) the average number of individuals enrolled in Medicare + Choice plans during the fiscal year, to

(ii) the average number of individuals entitled to benefits under part A [*42 USCS §§ 1395c* et seq.], and enrolled under part B [*42 USCS §§ 1395j* et seq.], during the fiscal year.

(F) Applicable portion defined. In this paragraph, the term "applicable portion" means, for a fiscal year--

(i) with respect to MA organizations, the Secretary's estimate of the total proportion of expenditures under this title that are attributable to expenditures made under this part (including payments under part D [*42 USCS §§ 1395w-101* et seq.] that are made to such organizations); or

(ii) with respect to PDP sponsors, the Secretary's estimate of the total proportion of expenditures under this title that are attributable to expenditures made to such sponsors under part D [*42 USCS §§ 1395w-101* et seq.].

(3) Agreements with federally qualified health centers.

(A) Payment levels and amounts. A contract under this section with an MA organization shall require the organization to provide, in any written agreement described in section 1853(a)(4) [*42 USCS § 1395w-23(a)(4)*] between the organization and a federally qualified health center, for a level and amount of payment to the federally qualified health center for services provided by such health center that is not less than the level and amount of payment that the plan would make for such services if the services had been furnished by a entity providing similar services that was not a federally qualified health center.

(B) Cost-sharing. Under the written agreement referred to in subparagraph (A), a federally qualified health center must accept the payment amount referred to in such subparagraph plus the Federal payment provided for in section 1833(a)(3)(B) [*42 USCS § 1395l(a)(3)(B)*] as payment in full for services covered by the agreement, except that such a health center may collect any amount of cost-sharing permitted under the contract under this section, so long as the amounts of any deductible, coinsurance, or copayment comply with the requirements under section 1854(e) [*42 USCS § 1395w-24(e)*].

(f) Prompt payment by Medicare + Choice organization.

(1) Requirement. A contract under this part [*42 USCS §§ 1395w-21* et seq.] shall require a Medicare + Choice organization to provide prompt payment (consistent with the provisions of sections 1816(c)(2) and 1842(c)(2) [*42 USCS §§ 1395h(c)(2)* and *1395u(c)(2)*]) of claims submitted for services and supplies furnished to enrollees pursuant to the contract, if the services or supplies are not furnished under a contract between the organization and the provider or supplier (or in the case of a Medicare + Choice private fee-for-service plan, if a claim is submitted to such organization by an enrollee).

(2) Secretary's option to bypass noncomplying organization. In the case of a Medicare + Choice eligible organization which the Secretary determines, after notice and opportunity for a hearing, has failed to make payments of amounts in compliance with paragraph (1), the Secretary may provide for direct payment of the amounts owed to providers and suppliers (or, in the case of a Medicare + Choice private fee-for-service plan, amounts owed to the enrollees) for covered services and supplies furnished to individuals enrolled under this part [*42 USCS §§ 1395w-21* et seq.] under the contract. If the Secretary provides for the direct payments, the Secretary shall provide for an appropriate reduction in the amount of payments otherwise made to the organization under this part [*42 USCS §§ 1395w-21* et seq.] to reflect the amount of the Secretary's payments (and the Secretary's costs in making the payments).

(3) Incorporation of certain prescription drug plan contract requirements. The following provisions shall apply to contracts with a Medicare Advantage organization offering an MA-PD plan in the same manner as they apply to contracts with a PDP sponsor offering a prescription drug plan under part D [*42 USCS §§ 1395w-101* et seq.]:

(A) Prompt payment. Section 1860D-12(b)(4) [*42 USCS § 1395w-112(b)(4)*].

(B) Submission of claims by pharmacies located in or contracting with long-term care facilities. Section 1860D-12(b)(5) [*42 USCS § 1395w-112(b)(5)*].

(C) Regular update of prescription drug pricing standard. Section 1860D-12(b)(6) [*42 USCS § 1395w-112(b)(6)*].

(g) Intermediate sanctions.

(1) In general. If the Secretary determines that a Medicare + Choice organization with a contract under this section--

(A) fails substantially to provide medically necessary items and services that are required (under law or under the contract) to be provided to an individual covered under the contract, if the failure has adversely affected (or has substantial likelihood of adversely affecting) the individual;

(B) imposes premiums on individuals enrolled under this part [*42 USCS §§ 1395w-21* et seq.] in excess of the amount of the Medicare + Choice monthly basic and supplemental beneficiary premiums permitted under section 1854 [*42 USCS § 1395w-24*];

(C) acts to expel or to refuse to re-enroll an individual in violation of the provisions of this part [*42 USCS §§ 1395w-21* et seq.];

(D) engages in any practice that would reasonably be expected to have the effect of denying or discouraging enrollment (except as permitted by this part [*42 USCS §§ 1395w-21* et seq.]) by eligible individuals with the organization whose medical condition or history indicates a need for substantial future medical services;

(E) misrepresents or falsifies information that is furnished--

(i) to the Secretary under this part [*42 USCS §§ 1395w-21* et seq.], or

(ii) to an individual or to any other entity under this part [*42 USCS §§ 1395w-21* et seq.];

(F) fails to comply with the applicable requirements of section 1852(j)(3) or 1852(k)(2)(A)(ii) [*42 USCS § 1395w-22(j)(3)* or (k)(2)(A)(ii)]; or

(G) employs or contracts with any individual or entity that is excluded from participation under this *title [42 USCS §§ 1395* et seq.] under section 1128 or 1128A [*42 USCS § 1320a-7* or *1320a-7a*] for the provision of health care, utilization review, medical social work, or administrative services or employs or contracts with any entity for the provision (directly or indirectly) through such an excluded individual or entity of such services;

the Secretary may provide, in addition to any other remedies authorized by law, for any of the remedies described in paragraph (2).

(2) Remedies. The remedies described in this paragraph are--

(A) civil money penalties of not more than $ 25,000 for each determination under paragraph (1) or, with respect to a determination under subparagraph (D) or (E)(i) of such paragraph, of not more than $ 100,000 for each such determination, plus, with respect to a determination under paragraph (1)(B), double the excess amount charged in violation of such paragraph (and the excess amount charged shall be deducted from the penalty and returned to the individual concerned), and plus, with respect to a determination under paragraph (1)(D), $ 15,000 for each individual not enrolled as a result of the practice involved,

(B) suspension of enrollment of individuals under this part [*42 USCS §§ 1395w-21* et seq.] after the date the Secretary notifies the organization of a determination under paragraph (1) and until the Secretary is satisfied that the basis for such determination has been corrected and is not likely to recur, or

(C) suspension of payment to the organization under this part [*42 USCS §§ 1395w-21* et seq.] for individuals enrolled after the date the Secretary notifies the organization of a determination under paragraph (1) and until the Secretary is satisfied that the basis for such determination has been corrected and is not likely to recur.

(3) Other intermediate sanctions. In the case of a Medicare + Choice organization for which the Secretary makes a determination under subsection (c)(2) the basis of which is not described in paragraph (1), the Secretary may apply the following intermediate sanctions:

(A) Civil money penalties of not more than $ 25,000 for each determination under subsection (c)(2) if the deficiency that is the basis of the determination has directly adversely affected (or has the substantial likelihood of adversely affecting) an individual covered under the organization's contract.

(B) Civil money penalties of not more than $ 10,000 for each week beginning after the initiation of civil money penalty procedures by the Secretary during which the deficiency that is the basis of a determination under subsection (c)(2) exists.

(C) Suspension of enrollment of individuals under this part [*42 USCS §§ 1395w-21* et seq.] after the date the Secretary notifies the organization of a determination under subsection (c)(2) and until the Secretary is satisfied that the deficiency that is the basis for the determination has been corrected and is not likely to recur.

(D) Civil monetary penalties of not more than $ 100,000, or such higher amount as the Secretary may establish by regulation, where the finding under subsection (c)(2)(A) is based on the organization's termination of its contract under this section other than at a time and in a manner provided for under subsection (a).

(4) Civil money penalties. The provisions of section 1128A [*42 USCS § 1320a-7a*] (other than subsections (a) and (b)) shall apply to a civil money penalty under paragraph (2) or (3) in the same manner as they apply to a civil money penalty or proceeding under section 1128A(a) [*42 USCS § 1320a-7a(a)*].

(h) Procedures for termination.

(1) In general. The Secretary may terminate a contract with a Medicare + Choice organization under this section in accordance with formal investigation and compliance procedures established by the Secretary under which--

(A) the Secretary provides the organization with the reasonable opportunity to develop and implement a corrective action plan to correct the deficiencies that were the basis of the Secretary's determination under subsection (c)(2); and

(B) the Secretary provides the organization with reasonable notice and opportunity for hearing (including the right to appeal an initial decision) before terminating the contract.

(2) Exception for imminent and serious risk to health. Paragraph (1) shall not apply if the Secretary determines that a delay in termination, resulting from compliance with the procedures specified in such paragraph prior to termination, would pose an imminent and serious risk to the health of individuals enrolled under this part [*42 USCS §§ 1395w-21* et seq.] with the organization.

(i) Medicare + Choice program compatibility with employer or union group health plans.

(1) Contracts with MA organizations. To facilitate the offering of Medicare + Choice plans under contracts between Medicare + Choice organizations and employers, labor organizations, or the trustees of a fund established by 1 or more employers or labor organizations (or combination thereof) to furnish benefits to the entity's employees, former employees (or combination thereof) or members or former members (or combination thereof) of the labor organizations, the Secretary may waive or modify requirements that hinder the design of, the offering of, or the enrollment in such Medicare + Choice plans.

(2) Employer sponsored MA plans. To facilitate the offering of MA plans by employers, labor organizations, or the trustees of a fund established by one or more employers or labor organizations (or combination thereof) to furnish benefits to the entity's employees, former employees (or combination thereof) or members or former members (or combination thereof) of the labor organizations, the Secretary may waive or modify requirements that hinder the design of, the offering of, or the enrollment in such MA plans. Notwithstanding section 1851(g) [*42 USCS § 1395w-21(g)*], an MA plan described in the previous sentence may restrict the enrollment of individuals under this part to individuals who are beneficiaries and participants in such plan.

HISTORY:

(Aug. 14, 1935, ch 531, Title XVIII, Part C, § 1857, as added Aug. 5, 1997, P.L. 105-33, Title IV, Subtitle A, Ch 1, Subch A, § 4001, 111 Stat. 319; Nov. 29, 1999, P.L. 106-113, Div B, § 1000(a)(6), 113 Stat. 1536; Dec. 21, 2000, P.L. 106-554, § 1(a)(6), 114 Stat. 2763; Dec. 8, 2003, P.L. 108-173, Title II, Subtitle C, § 222(j), (k), (l)(3)(C), Subtitle D, § 237(c), Title IX, § 900(e)(1)(I), 117 Stat. 2205, 2207, 2213, 2372.)

(As amended July 15, 2008, P.L. 110-275, Title I, Subtitle D, § 164(d)(2), Subtitle E, Part I, §§ 171(b), 172(a)(2), 173(b), 122 Stat. 2574, 2580, 2581.)

§ 1395w-27a. Special rules for MA regional plans

(a) Regional service area; establishment of MA regions.

(1) Coverage of entire MA region. The service area for an MA regional plan shall consist of an entire MA region established under paragraph (2) and the provisions of section 1854(h) [*42 USCS § 1395w-24(h)*] shall not apply to such a plan.

(2) Establishment of MA regions.

(A) MA region. For purposes of this *title [42 USCS §§ 1395* et seq.], the term "MA region" means such a region within the 50 States and the District of Columbia as established by the Secretary under this paragraph.

(B) Establishment.

(i) Initial establishment. Not later than January 1, 2005, the Secretary shall first establish and publish MA regions.

(ii) Periodic review and revision of service areas. The Secretary may periodically review MA regions under this paragraph and, based on such review, may revise such regions if the Secretary determines such revision to be appropriate.

(C) Requirements for MA regions. The Secretary shall establish, and may revise, MA regions under this paragraph in a manner consistent with the following:

(i) Number of regions. There shall be no fewer than 10 regions, and no more than 50 regions.

(ii) Maximizing availability of plans. The regions shall maximize the availability of MA regional plans to all MA eligible individuals without regard to health status, especially those residing in rural areas.

(D) Market survey and analysis. Before establishing MA regions, the Secretary shall conduct a market survey and analysis, including an examination of current insurance markets, to determine how the regions should be established.

(3) National plan. Nothing in this subsection shall be construed as preventing an MA regional plan from being offered in more than one MA region (including all regions).

(b) Application of single deductible and catastrophic limit on out-of-pocket expenses. An MA regional plan shall include the following:

(1) Single deductible. Any deductible for benefits under the original medicare fee-for-service program option shall be a single deductible (instead of a separate inpatient hospital deductible and a part B deductible) and may be applied differentially for in-network services and may be waived for preventive or other items and services.

(2) Catastrophic limit.

(A) In-network. A catastrophic limit on out-of-pocket expenditures for in-network benefits under the original medicare fee-for-service program option.

(B) Total. A catastrophic limit on out-of-pocket expenditures for all benefits under the original medicare fee-for-service program option.

(c) Portion of total payments to an organization subject to risk for 2006 and 2007.

(1) Application of risk corridors.

(A) In general. This subsection shall only apply to MA regional plans offered during 2006 or 2007.

(B) Notification of allowable costs under the plan. In the case of an MA organization that offers an MA regional plan in an MA region in 2006 or 2007, the organization shall notify the Secretary, before such date in the succeeding year as the Secretary specifies, of--

(i) its total amount of costs that the organization incurred in providing benefits covered under the original medicare fee-for-service program option for all enrollees under the plan in the region in the year and the portion of such costs that is attributable to administrative expenses described in subparagraph (C); and

(ii) its total amount of costs that the organization incurred in providing rebatable integrated benefits (as defined in subparagraph (D)) and with respect to such benefits the portion of such costs that is attributable to administrative expenses described in subparagraph (C) and not described in clause (i) of this subparagraph.

(C) Allowable costs defined. For purposes of this subsection, the term "allowable costs" means, with respect to an MA regional plan for a year, the total amount of costs described in subparagraph (B) for the plan and year, reduced by the portion of such costs attributable to administrative expenses incurred in providing the benefits described in such subparagraph.

(D) Rebatable integrated benefits. For purposes of this subsection, the term "rebatable integrated benefits" means such non-drug supplemental benefits under subclause (I) of section 1854(b)(1)(C)(ii) [*42 USCS § 1395w-24(b)(1)(C)(ii)*] pursuant to a rebate under such section that the Secretary determines are integrated with the benefits described in subparagraph (B)(i).

(2) Adjustment of payment.

(A) No adjustment if allowable costs within 3 percent of target amount. If the allowable costs for the plan for the year are at least 97 percent, but do not exceed 103 percent, of the target amount for the plan and year, there shall be no payment adjustment under this subsection for the plan and year.

(B) Increase in payment if allowable costs above 103 percent of target amount.

(i) Costs between 103 and 108 percent of target amount. If the allowable costs for the plan for the year are greater than 103 percent, but not greater than 108 percent, of the target amount for the plan and year, the Secretary shall increase the total of the monthly payments made to the organization offering the plan for the year under section 1853(a) [*42 USCS § 1395w-23(a)*] by an amount equal to 50 percent of the difference between such allowable costs and 103 percent of such target amount.

(ii) Costs above 108 percent of target amount. If the allowable costs for the plan for the year are greater than 108 percent of the target amount for the plan and year, the Secretary shall increase the total of the monthly payments made to the organization offering the plan for the year under section 1853(a) [*42 USCS § 1395w-23(a)*] by an amount equal to the sum of--

(I) 2.5 percent of such target amount; and

(II) 80 percent of the difference between such allowable costs and 108 percent of such target amount.

(C) Reduction in payment if allowable costs below 97 percent of target amount.

(i) Costs between 92 and 97 percent of target amount. If the allowable costs for the plan for the year are less than 97 percent, but greater than or equal to 92 percent, of the target amount for the plan and year, the Secretary shall reduce the total of the monthly payments made to the organization offering the plan for the year under section 1853(a) [*42 USCS § 1395w-23(a)*] by an amount (or otherwise recover from the plan an amount) equal to 50 percent of the difference between 97 percent of the target amount and such allowable costs.

(ii) Costs below 92 percent of target amount. If the allowable costs for the plan for the year are less than 92 percent of the target amount for the plan and year, the Secretary shall reduce the total of the monthly payments made to the organization offering the plan for the year under section 1853(a) [*42 USCS § 1395w-23(a)*] by an amount (or otherwise recover from the plan an amount) equal to the sum of--

(I) 2.5 percent of such target amount; and

(II) 80 percent of the difference between 92 percent of such target amount and such allowable costs.

(D) Target amount described. For purposes of this paragraph, the term "target amount" means, with respect to an MA regional plan offered by an organization in a year, an amount equal to--

(i) the sum of--

(I) the total monthly payments made to the organization for enrollees in the plan for the year that are attributable to benefits under the original medicare fee-for-service program option (as defined in section 1852(a)(1)(B) [*42 USCS § 1395w-22(a)(1)(B)*]);

(II) the total of the MA monthly basic beneficiary premium collectable for such enrollees for the year; and

(III) the total amount of the rebates under section 1854(b)(1)(C)(ii) [*42 USCS § 1395w-24(b)(1)(C)(ii)*] that are attributable to rebatable integrated benefits; reduced by

(ii) the amount of administrative expenses assumed in the bid insofar as the bid is attributable to benefits described in clause (i)(I) or (i)(III).

(3) Disclosure of information.

(A) In general. Each contract under this part [*42 USCS §§ 1395w-21* et seq.] shall provide--

(i) that an MA organization offering an MA regional plan shall provide the Secretary with such information as the Secretary determines is necessary to carry out this subsection; and

(ii) that, pursuant to section 1857(d)(2)(B) [*42 USCS § 1395w-27(d)(2)(B)*], the Secretary has the right to inspect and audit any books and records of the organization that pertain to the information regarding costs provided to the Secretary under paragraph (1)(B).

(B) Restriction on use of information. Information disclosed or obtained pursuant to the provisions of this subsection may be used by officers, employees, and contractors of the Department of Health and Human Services only for the purposes of, and to the extent necessary in, carrying out this subsection.

(d) Organizational and financial requirements.

(1) In general. In the case of an MA organization that is offering an MA regional plan in an MA region and--

(A) meets the requirements of section 1855(a)(1) [*42 USCS § 1395w-25(a)(1)*] with respect to at least one such State in such region; and

(B) with respect to each other State in such region in which it does not meet requirements, it demonstrates to the satisfaction of the Secretary that it has filed the necessary application to meet such requirements,

the Secretary may waive such requirement with respect to each State described in subparagraph (B) for such period of time as the Secretary determines appropriate for the timely processing of such an application by the State (and, if such application is denied, through the end of such plan year as the Secretary determines appropriate to provide for a transition).

(2) Selection of appropriate State. In applying paragraph (1) in the case of an MA organization that meets the requirements of section 1855(a)(1) [*42 USCS § 1395w-25(a)(1)*] with respect to more than one State in a region, the organization shall select, in a manner specified by the Secretary among such States, one State the rules of which shall apply in the case of the States described in paragraph (1)(B).

(e) Stabilization Fund.

(1) Establishment. The Secretary shall establish under this subsection an MA Regional Plan Stabilization Fund (in this subsection referred to as the "Fund") which shall be available for two purposes:

(A) Plan entry. To provide incentives to have MA regional plans offered in each MA region under paragraph (3).

(B) Plan retention. To provide incentives to retain MA regional plans in certain MA regions with below-national-average MA market penetration under paragraph (4).

(2) Funding.

(A) Initial funding.

(i) In general. There shall be available to the Fund, for expenditures from the Fund during 2014 $ 1.

(ii) Payment from Trust Funds. Such amount shall be available to the Fund, as expenditures are made from the Fund, from the Federal Hospital Insurance Trust Fund and the Federal Supplementary Medical Insurance Trust Fund in the proportion specified in section 1853(f) [*42 USCS § 1395w-23(f)*].

(B) Additional funding from savings.

(i) In general. There shall also be made available to the Fund, 50 percent of savings described in clause (ii).

(ii) Savings. The savings described in this clause are 25 percent of the average per capita savings described in section 1854(b)(4)(C) [*42 USCS § 1395w-24(b)(4)(C)*] for which monthly rebates are provided under section 1854(b)(1)(C) [*42 USCS § 1395w-24(b)(1)(C)*] in the fiscal year involved that are attributable to MA regional plans.

(iii) Availability. Funds made available under this subparagraph shall be transferred into a special account in the Treasury from the Federal Hospital Insurance Trust Fund and the Federal Supplementary Medical Insurance Trust Fund in the proportion specified in section 1853(f) [*42 USCS § 1395w-23(f)*] on a monthly basis.

(C) Obligations. Amounts in the Fund shall be available in advance of appropriations to MA regional plans in qualifying MA regions only in accordance with paragraph (5).

(D) Ordering. Expenditures from the Fund shall first be made from amounts made available under subparagraph (A).

(3) Plan entry funding.

(A) In general. Funding is available under this paragraph for a year only as follows:

(i) National plan. For a national bonus payment described in subparagraph (B) for the offering by a single MA organization of an MA regional plan in each MA region in the year, but only if there was not such a plan offered in each such region in the previous year. Funding under this clause is only available with respect to any individual MA organization for a single year, but may be made available to more than one such organization in the same year.

(ii) Regional plans. Subject to clause (iii), for an increased amount under subparagraph (C) for an MA regional plan offered in an MA region which did not have any MA regional plan offered in the prior year.

(iii) Limitation on regional plan funding in case of national plan. In no case shall there be any payment adjustment under subparagraph (C) for a year for which a national payment adjustment is made under subparagraph (B).

(B) National bonus payment. The national bonus payment under this subparagraph shall--

(i) be available to an MA organization only if the organization offers MA regional plans in every MA region;

(ii) be available with respect to all MA regional plans of the organization regardless of whether any other MA regional plan is offered in any region; and

(iii) subject to amounts available under paragraph (5) for a year, be equal to 3 percent of the benchmark amount otherwise applicable for each MA regional plan offered by the organization.

(C) Regional payment adjustment.

(i) In general. The increased amount under this subparagraph for an MA regional plan in an MA region for a year shall be an amount, determined by the Secretary, based on the bid submitted for such plan (or plans) and shall be available to all MA regional plans offered in such region and year. Such amount may be based on the mean, mode, or median, or other measure of such bids and may vary from region to region. The Secretary may not limit the number of plans or bids in a region.

(ii) Multi-year funding.

(I) In general. Subject to amounts available under paragraph (5), funding under this subparagraph shall be available for a period determined by the Secretary.

(II) Report. If the Secretary determines that funding will be provided for a second consecutive year with respect to an MA region, the Secretary shall submit to the Congress a report that describes the underlying market dynamics in the region and that includes recommendations concerning changes in the payment methodology otherwise provided for MA regional plans under this part [*42 USCS §§ 1395w-21* et seq.].

(iii) Application to all plans in a region. Funding under this subparagraph with respect to an MA region shall be made available with respect to all MA regional plans offered in the region.

(iv) Limitation on availability of plan retention funding in next year. If an increased amount is made available under this subparagraph with respect to an MA region for a period determined by the Secretary under clause (ii)(I), in no case shall funding be available under paragraph (4) with respect to MA regional plans offered in the region in the year following such period.

(D) Application. Any additional payment under this paragraph provided for an MA regional plan for a year shall be treated as if it were an addition to the benchmark amount otherwise applicable to such plan and year, but shall not be taken into account in the computation of any benchmark amount for any subsequent year.

(4) Plan retention funding.

(A) In general. Funding is available under this paragraph for a year with respect to MA regional plans offered in an MA region for the increased amount specified in subparagraph (B) but only if the region meets the requirements of subparagraphs (C) and (E).

(B) Payment increase. The increased amount under this subparagraph for an MA regional plan in an MA region for a year shall be an amount, determined by the Secretary, that does not exceed the greater of--

(i) 3 percent of the benchmark amount applicable in the region; or

(ii) such amount as (when added to the benchmark amount applicable to the region) will result in the ratio of--

(I) such additional amount plus the benchmark amount computed under section 1854(b)(4)(B)(i) [*42 USCS § 1395w-24(b)(4)(B)(i)*] for the region and year, to the adjusted average per capita cost for the region and year, as estimated by the Secretary under section 1876(a)(4) [*42 USCS § 1395mm(a)(4)*] and adjusted as appropriate for the purpose of risk adjustment; being equal to

(II) the weighted average of such benchmark amounts for all the regions and such year, to the average per capita cost for the United States and such year, as estimated by the Secretary under section 1876(a)(4) [*42 USCS § 1395mm(a)(4)*] and adjusted as appropriate for the purpose of risk adjustment.

(C) Regional requirements. The requirements of this subparagraph for an MA region for a year are as follows:

(i) Notification of plan exit. The Secretary has received notice (in such form and manner as the Secretary specifies) before a year that one or more MA regional plans that were offered in the region in the previous year will not be offered in the succeeding year.

(ii) Regional plans available from fewer than 2 MA organizations in the region. The Secretary determines that if the plans referred to in clause (i) are not offered in the year, fewer than 2 MA organizations will be offering MA regional plans in the region in the year involved.

(iii) Percentage enrollment in MA regional plans below national average. For the previous year, the Secretary determines that the average percentage of MA eligible individuals residing in the region who are enrolled in MA regional plans is less than the average percentage of such individuals in the United States enrolled in such plans.

(D) Application. Any additional payment under this paragraph provided for an MA regional plan for a year shall be treated as if it were an addition to the benchmark amount otherwise applicable to such plan and year, but shall not be taken into account in the computation of any benchmark amount for any subsequent year.

(E) 2-consecutive-year limitation.

(i) In general. In no case shall any funding be available under this paragraph in an MA region in a period of consecutive years that exceeds 2 years.

(ii) Report. If the Secretary determines that funding will be provided under this paragraph for a second consecutive year with respect to an MA region, the Secretary shall submit to the Congress a report that describes the underlying market dynamics in the region and that includes recommendations concerning changes in the payment methodology otherwise provided for MA regional plans under this part [*42 USCS §§ 1395w-21* et seq.].

(5) Funding limitation.

(A) In general. The total amount expended from the Fund as a result of the application of this subsection through the end of a calendar year may not exceed the amount available to the Fund as of the first day of such year. For purposes of this subsection, amounts that are expended under this *title [42 USCS §§ 1395* et seq.] insofar as such amounts would not have been expended but for the application of this subsection shall be counted as amounts expended as a result of such application.

(B) Application of limitation. The Secretary may obligate funds from the Fund for a year only if the Secretary determines (and the Chief Actuary of the Centers for Medicare & Medicaid Services and the appropriate budget officer certify) that there are available in the Fund at the beginning of the year sufficient amounts to cover all such obligations incurred during the year consistent with subparagraph (A). The Secretary shall take such steps, in connection with computing additional payment amounts under paragraphs (3) and (4) and including limitations on enrollment in MA regional plans receiving such payments, as will ensure that sufficient funds are available to make such payments for the entire year. Funds shall only be made available from the Fund pursuant to an apportionment made in accordance with applicable procedures.

(6) Secretary reports. Not later than April 1 of each year (beginning in 2008), the Secretary shall submit a report to Congress and the Comptroller General of the United States that includes--

(A) a detailed description of--

(i) the total amount expended as a result of the application of this subsection in the previous year compared to the total amount that would have been expended under this *title [42 USCS §§ 1395* et seq.] in the year if this subsection had not been enacted;

(ii) the projections of the total amount that will be expended as a result of the application of this subsection in the year in which the report is submitted compared to the total amount that would have been expended under this *title [42 USCS §§ 1395* et seq.] in the year if this subsection had not been enacted;

(iii) amounts remaining within the funding limitation specified in paragraph (5); and

(iv) the steps that the Secretary will take under paragraph (5)(B) to ensure that the application of this subsection will not cause expenditures to exceed the amount available in the Fund; and

(B) a certification from the Chief Actuary of the Centers for Medicare & Medicaid Services that the description provided under subparagraph (A) is reasonable, accurate, and based on generally accepted actuarial principles and methodologies.

(7) Biennial GAO reports. Not later than January 1 of 2009, 2011, 2013, and 2015, the Comptroller General of the United States shall submit to the Secretary and Congress a report on the application of additional payments under this subsection. Each report shall include--

(A) an evaluation of--

(i) the quality of care provided to individuals enrolled in MA regional plans for which additional payments were made under this subsection;

(ii) the satisfaction of such individuals with benefits under such a plan;

(iii) the costs to the medicare program for payments made to such plans; and

(iv) any improvements in the delivery of health care services under such a plan;

(B) a comparative analysis of the performance of MA regional plans receiving payments under this subsection with MA regional plans not receiving such payments; and

(C) recommendations for such legislation or administrative action as the Comptroller General determines to be appropriate.

(f) Computation of applicable MA region-specific non-drug monthly benchmark amounts.

(1) Computation for regions. For purposes of section 1853(j)(2) [*42 USCS § 1395w-23(j)(2)*] and this section, subject to subsection (e), the term "MA region-specific non-drug monthly benchmark amount" means, with respect to an MA region for a month in a year, the sum of the 2 components described in paragraph (2) for the region and year. The Secretary shall compute such benchmark amount for each MA region before the beginning of each annual, coordinated election period under section 1851(e)(3)(B) [*42 USCS § 1395w-21(e)(3)(B)*] for each year (beginning with 2006).

(2) 2 components. For purposes of paragraph (1), the 2 components described in this paragraph for an MA region and a year are the following:

(A) Statutory component. The product of the following:

(i) Statutory region-specific non-drug amount. The statutory region-specific non-drug amount (as defined in paragraph (3)) for the region and year.

(ii) Statutory national market share. The statutory national market share percentage, determined under paragraph (4) for the year.

(B) Plan-bid component. The product of the following:

(i) Weighted average of MA plan bids in region. The weighted average of the plan bids for the region and year (as determined under paragraph (5)(A)).

(ii) Non-statutory market share. 1 minus the statutory national market share percentage, determined under paragraph (4) for the year.

(3) Statutory region-specific non-drug amount. For purposes of paragraph (2)(A)(i), the term "statutory region-specific non-drug amount" means, for an MA region and year, an amount equal the sum (for each MA local area within the region) of the product of--

(A) MA area-specific non-drug monthly benchmark amount under section 1853(j)(1)(A) [*42 USCS § 1395w-23(j)(1)(A)*] for that area and year; and

(B) the number of MA eligible individuals residing in the local area, divided by the total number of MA eligible individuals residing in the region.

(4) Computation of statutory market share percentage.

(A) In general. The Secretary shall determine for each year a statutory national market share percentage that is equal to the proportion of MA eligible individuals nationally who were not enrolled in an MA plan during the reference month.

(B) Reference month defined. For purposes of this part [*42 USCS §§ 1395w-21* et seq.], the term "reference month" means, with respect to a year, the most recent month during the previous year for which the Secretary determines that data are available to compute the percentage specified in subparagraph (A) and other relevant percentages under this part [*42 USCS §§ 1395w-21* et seq.].

(5) Determination of weighted average MA bids for a region.

(A) In general. For purposes of paragraph (2)(B)(i), the weighted average of plan bids for an MA region and a year is the sum, for MA regional plans described in subparagraph (D) in the region and year, of the products (for each such plan) of the following:

(i) Monthly MA statutory non-drug bid amount. The unadjusted MA statutory non-drug monthly bid amount for the plan.

(ii) Plan's share of MA enrollment in region. The factor described in subparagraph (B) for the plan.

(B) Plan's share of MA enrollment in region.

(i) In general. Subject to the succeeding provisions of this subparagraph, the factor described in this subparagraph for a plan is equal to the number of individuals described in subparagraph (C) for such plan, divided by the total number of such individuals for all MA regional plans described in subparagraph (D) for that region and year.

(ii) Single plan rule. In the case of an MA region in which only a single MA regional plan is being offered, the factor described in this subparagraph shall be equal to 1.

(iii) Equal division among multiple plans in year in which plans are first available. In the case of an MA region in the first year in which any MA regional plan is offered, if more than one MA regional plan is offered in such year, the factor described in this subparagraph for a plan shall (as specified by the Secretary) be equal to--

(I) 1 divided by the number of such plans offered in such year; or

(II) a factor for such plan that is based upon the organization's estimate of projected enrollment, as reviewed and adjusted by the Secretary to ensure reasonableness and as is certified by the Chief Actuary of the Centers for Medicare & Medicaid Services.

(C) Counting of individuals. For purposes of subparagraph (B)(i), the Secretary shall count for each MA regional plan described in subparagraph (D) for an MA region and year, the number of individuals who reside in the region and who were enrolled under such plan under this part [*42 USCS §§ 1395w-21* et seq.] during the reference month.

(D) Plans covered. For an MA region and year, an MA regional plan described in this subparagraph is an MA regional plan that is offered in the region and year and was offered in the region in the reference month.

(g) Election of uniform coverage determination. Instead of applying section 1852(a)(2)(C) [*42 USCS § 1395w-22(a)(2)(C)*] with respect to an MA regional plan, the organization offering the plan may elect to have a local coverage determination for the entire MA region be the local coverage determination applied for any part of such region (as selected by the organization).

(h) Assuring network adequacy.

(1) In general. For purposes of enabling MA organizations that offer MA regional plans to meet applicable provider access requirements under section 1852 [*42 USCS § 1395w-22*] with respect to such plans, the Secretary may provide for payment under this section to an essential hospital that provides inpatient hospital services to enrollees in such a plan where the MA organization offering the plan certifies to the Secretary that the organization was unable to reach an agreement between the hospital and the organization regarding provision of such services under the plan. Such payment shall be available only if--

(A) the organization provides assurances satisfactory to the Secretary that the organization will make payment to the hospital for inpatient hospital services of an amount that is not less than the amount that would be payable to the hospital under section 1886 [*42 USCS § 1395ww*] with respect to such services; and

(B) with respect to specific inpatient hospital services provided to an enrollee, the hospital demonstrates to the satisfaction of the Secretary that the hospital's costs of such services exceed the payment amount described in subparagraph (A).

(2) Payment amounts. The payment amount under this subsection for inpatient hospital services provided by a subsection (d) hospital to an enrollee in an MA regional plan shall be, subject to the limitation of funds under paragraph (3), the amount (if any) by which--

(A) the amount of payment that would have been paid for such services under this *title [42 USCS §§ 1395* et seq.] if the enrollees were covered under the original medicare fee-for-service program option and the hospital were a critical access hospital; exceeds

(B) the amount of payment made for such services under paragraph (1)(A).

(3) Available amounts. There shall be available for payments under this subsection--

(A) in 2006, $ 25,000,000; and

(B) in each succeeding year the amount specified in this paragraph for the preceding year increased by the market basket percentage increase (as defined in section 1886(b)(3)(B)(iii) [*42 USCS § 1395ww(b)(3)(B)(iii)*]) for the fiscal year ending in such succeeding year.

Payments under this subsection shall be made from the Federal Hospital Insurance Trust Fund.

(4) Essential hospital. In this subsection, the term "essential hospital" means, with respect to an MA regional plan offered by an MA organization, a subsection (d) hospital (as defined in section 1886(d) [*42 USCS § 1395ww(d)*]) that the Secretary determines, based upon an application filed by the organization with the Secretary, is necessary to meet the requirements referred to in paragraph (1) for such plan.

HISTORY:

(Aug. 14, 1935, ch 531, Title XVIII, Part C, § 1858, as added Dec. 8, 2003, P.L. 108-173, Title II, Subtitle C, § 221(c), 117 Stat. 2181.)

(As amended Dec. 20, 2006, P.L. 109-432, Div B, Title III, § 301, 120 Stat. 2990; July 18, 2007, P.L. 110-48, § 3, 121 Stat. 244; Dec. 29, 2007, P.L. 110-173, Title I, § 110, 121 Stat. 2497; July 15, 2008, P.L. 110-275, Title I, Subtitle D, § 166, 122 Stat. 2575.)

§ 1395w-28. Definitions; miscellaneous provisions

(a) Definitions relating to Medicare + Choice organizations. In this part [*42 USCS §§ 1395w-21* et seq.]--

(1) Medicare + Choice organization. The term "Medicare + Choice organization" means a public or private entity that is certified under section 1856 [*42 USCS § 1395w-26*] as meeting the requirements and standards of this part [*42 USCS §§ 1395w-21* et seq.] for such an organization.

(2) Provider-sponsored organization. The term "provider-sponsored organization" is defined in section 1855(d)(1) [*42 USCS § 1395w-25(d)(1)*].

(b) Definitions relating to Medicare + Choice plans.

(1) Medicare + choice plan. The term "Medicare + Choice plan" means health benefits coverage offered under a policy, contract, or plan by a Medicare + Choice organization pursuant to and in accordance with a contract under section 1857 [*42 USCS § 1395w-27*].

(2) Medicare + Choice private fee-for-service plan. The term "Medicare + Choice private fee-for-service plan" means a Medicare + Choice plan that--

(A) reimburses hospitals, physicians, and other providers at a rate determined by the plan on a fee-for-service basis without placing the provider at financial risk;

(B) does not vary such rates for such a provider based on utilization relating to such provider; and

(C) does not restrict the selection of providers among those who are lawfully authorized to provide the covered services and agree to accept the terms and conditions of payment established by the plan.

Nothing in subparagraph (B) shall be construed to preclude a plan from varying rates for such a provider based on the specialty of the provider, the location of the provider, or other factors related to such provider that are not related to utilization, or to preclude a plan from increasing rates for such a provider based on increased utilization of specified preventive or screening services.

(3) MSA plan.

(A) In general. The term "MSA plan" means a Medicare + Choice plan that--

(i) provides reimbursement for at least the items and services described in section 1852(a)(1) [*42 USCS § 1395w-22(a)(1)*] in a year but only after the enrollee incurs countable expenses (as specified under the plan) equal to the amount of an annual deductible (described in subparagraph (B));

(ii) counts as such expenses (for purposes of such deductible) at least all amounts that would have been payable under parts A and B [*42 USCS §§ 1395c* et seq. and *1395j* et seq.], and that would have been payable by the enrollee as deductibles, coinsurance, or copayments, if the enrollee had elected to receive benefits through the provisions of such parts; and

(iii) provides, after such deductible is met for a year and for all subsequent expenses for items and services referred to in clause (i) in the year, for a level of reimbursement that is not less than--

(I) 100 percent of such expenses, or

(II) 100 percent of the amounts that would have been paid (without regard to any deductibles or coinsurance) under parts A and B [*42 USCS §§ 1395c* et seq. and *1395j* et seq.] with respect to such expenses,

whichever is less.

(B) Deductible. The amount of annual deductible under an MSA plan--

(i) for contract year 1999 shall be not more than $ 6,000; and

(ii) for a subsequent contract year shall be not more than the maximum amount of such deductible for the previous contract year under this subparagraph increased by the national per capita Medicare + Choice growth percentage under section 1853(c)(6) [*42 USCS § 1395w-23(c)(6)*] for the year.

If the amount of the deductible under clause (ii) is not a multiple of $ 50, the amount shall be rounded to the nearest multiple of $ 50.

(4) MA regional plan. The term "MA regional plan" means an MA plan described in section 1851(a)(2)(A)(i) [*42 USCS § 1395w-21(a)(2)(A)(i)*]--

(A) that has a network of providers that have agreed to a contractually specified reimbursement for covered benefits with the organization offering the plan;

(B) that provides for reimbursement for all covered benefits regardless of whether such benefits are provided within such network of providers; and

(C) the service area of which is one or more entire MA regions.

(5) MA local plan. The term "MA local plan" means an MA plan that is not an MA regional plan.

(6) Specialized MA plans for special needs individuals.

(A) In general. The term "specialized MA plan for special needs individuals" means an MA plan that exclusively serves special needs individuals (as defined in subparagraph (B)) and that, as of January 1, 2010, meets the applicable requirements of paragraph (2), (3), or (4) of subsection (f), as the case may be.

(B) Special needs individual. The term "special needs individual" means an MA eligible individual who--

(i) is institutionalized (as defined by the Secretary);

(ii) is entitled to medical assistance under a State plan under title XIX [*42 USCS §§ 1396* et seq.]; or

(iii) **[Caution: For provisions applicable to plan years beginning before January 1, 2010, see 2008 amendment note below.]** meets such requirements as the Secretary may determine would benefit from enrollment in such a specialized MA plan described in subparagraph (A) for individuals with severe or disabling chronic conditions who have one or more comorbid and medically complex chronic conditions that are substantially disabling or life threatening, have a high risk of hospitalization or other significant adverse health outcomes, and require specialized delivery systems across domains of care.

The Secretary may waive application of section 1851(a)(3)(B) [*42 USCS § 1395w-21(a)(3)(B)*] in the case of an individual described in clause (i), (ii), or (iii) of this subparagraph and may apply rules similar to the rules of section 1894(c)(4) [*42 USCS § 1395eee(c)(4)*] for continued eligibility of special needs individuals.

(c) Other references to other terms.

(1) Medicare + choice eligible individual. The term "Medicare + Choice eligible individual" is defined in section 1851(a)(3) [*42 USCS § 1395w-21(a)(3)*].

(2) Medicare + choice payment area. The term "Medicare + Choice payment area" is defined in section 1853(d) [*42 USCS § 1395w-23(d)*].

(3) National per capita Medicare + Choice growth percentage. The "national per capita Medicare + Choice growth percentage" is defined in section 1853(c)(6) [*42 USCS § 1395w-23(c)(6)*].

(4) Medicare + choice monthly basic beneficiary premium; Medicare + Choice monthly supplemental beneficiary premium. The terms "Medicare + Choice monthly basic beneficiary premium" and "Medicare + Choice monthly supplemental beneficiary premium" are defined in section 1854(a)(2) [*42 USCS § 1395w-24(a)(2)*].

(5) MA local area. The term "MA local area" is defined in section 1853(d)(2) [*42 USCS § 1395w-23(d)(2)*].

(d) Coordinated acute and long-term care benefits under a Medicare + Choice plan. Nothing in this part [*42 USCS §§ 1395w-21* et seq.] shall be construed as preventing a State from coordinating benefits under a medicaid plan under title XIX with those provided under a Medicare + Choice plan in a manner that assures continuity of a full-range of acute care and long-term care services to poor elderly or disabled individuals eligible for benefits under this *title [42 USCS §§ 1395* et seq.] and under such plan.

(e) Restriction on enrollment for certain Medicare + Choice plans.

(1) In general. In the case of a Medicare + Choice religious fraternal benefit society plan described in paragraph (2), notwithstanding any other provision of this part [*42 USCS §§ 1395w-21* et seq.] to the contrary and in accordance with regulations of the Secretary, the society offering the plan may restrict the enrollment of individuals under this part [*42 USCS §§ 1395w-21* et seq.] to individuals who are members of the church, convention, or group described in paragraph (3)(B) with which the society is affiliated.

(2) Medicare + choice religious fraternal benefit society plan described. For purposes of this subsection, a Medicare + Choice religious fraternal benefit society plan described in this paragraph is a Medicare + Choice plan described in section 1851(a)(2) [*42 USCS § 1395w-21(a)(2)*] that--

(A) is offered by a religious fraternal benefit society described in paragraph (3) only to members of the church, convention, or group described in paragraph (3)(B); and

(B) permits all such members to enroll under the plan without regard to health status-related factors.

Nothing in this subsection shall be construed as waiving any plan requirements relating to financial solvency.

(3) Religious fraternal benefit society defined. For purposes of paragraph (2)(A), a "religious fraternal benefit society" described in this section is an organization that--

(A) is described in *section 501(c)(8) of the Internal Revenue Code of 1986* [*26 USCS § 501(c)(8)*] and is exempt from taxation under section 501(a) of such Act [*26 USCS § 501(a)*];

(B) is affiliated with, carries out the tenets of, and shares a religious bond with, a church or convention or association of churches or an affiliated group of churches;

(C) offers, in addition to a Medicare + Choice religious fraternal benefit society plan, health coverage to individuals not entitled to benefits under this *title [42 USCS §§ 1395* et seq.] who are members of such church, convention, or group; and

(D) does not impose any limitation on membership in the society based on any health status-related factor.

(4) Payment adjustment. Under regulations of the Secretary, in the case of individuals enrolled under this part [*42 USCS §§ 1395w-21* et seq.] under a Medicare + Choice religious fraternal benefit society plan described in paragraph (2), the Secretary shall provide for such adjustment to the payment amounts otherwise established under section 1854 [*42 USCS § 1395w-24*] as may be appropriate to assure an appropriate payment level, taking into account the actuarial characteristics and experience of such individuals.

(f) Requirements regarding enrollment in specialized MA plans for special needs individuals [Caution: For provisions applicable to plan years beginning before January 1, 2010, see 2008 amendment note below.].

(1) Requirements for enrollment. In the case of a specialized MA plan for special needs individuals (as defined in subsection (b)(6)), notwithstanding any other provision of this part and in accordance with regulations of the Secretary and for periods before January 1, 2011, the plan may restrict the enrollment of individuals under the plan to individuals who are within one or more classes of special needs individuals.

(2) Additional requirements for institutional SNPs. In the case of a specialized MA plan for special needs individuals described in subsection (b)(6)(B)(i), the applicable requirements described in this paragraph are as follows:

(A) Each individual that enrolls in the plan on or after January 1, 2010, is a special needs individuals described in subsection (b)(6)(B)(i). In the case of an individual who is living in the community but requires an institutional level of care, such individual shall not be considered a special needs individual described in subsection (b)(6)(B)(i) unless the determination that the individual requires an institutional level of care was made--

(i) using a State assessment tool of the State in which the individual resides; and

(ii) by an entity other than the organization offering the plan.

(B) The plan meets the requirements described in paragraph (5).

(3) Additional requirements for dual SNPs. In the case of a specialized MA plan for special needs individuals described in subsection (b)(6)(B)(ii), the applicable requirements described in this paragraph are as follows:

(A) Each individual that enrolls in the plan on or after January 1, 2010, is a special needs individuals described in subsection (b)(6)(B)(ii).

(B) The plan meets the requirements described in paragraph (5).

(C) The plan provides each prospective enrollee, prior to enrollment, with a comprehensive written statement (using standardized content and format established by the Secretary) that describes--

(i) the benefits and cost-sharing protections that the individual is entitled to under the State Medicaid program under title XIX [*42 USCS §§ 1396* et seq.]; and

(ii) which of such benefits and cost-sharing protections are covered under the plan.

Such statement shall be included with any description of benefits offered by the plan.

(D) The plan has a contract with the State Medicaid agency to provide benefits, or arrange for benefits to be provided, for which such individual is entitled to receive as medical assistance under title XIX [*42 USCS §§ 1396* et seq.]. Such benefits may include long-term care services consistent with State policy.

(4) Additional requirements for severe or disabling chronic condition SNPs. In the case of a specialized MA plan for special needs individuals described in subsection (b)(6)(B)(iii), the applicable requirements described in this paragraph are as follows:

(A) Each individual that enrolls in the plan on or after January 1, 2010, is a special needs individual described in subsection (b)(6)(B)(iii).

(B) The plan meets the requirements described in paragraph (5).

(5) Care management requirements for all SNPs. The requirements described in this paragraph are that the organization offering a specialized MA plan for special needs individuals described in subsection (b)(6)(B)(i)--

(A) have in place an evidenced-based model of care with appropriate networks of providers and specialists; and

(B) with respect to each individual enrolled in the plan--

(i) conduct an initial assessment and an annual reassessment of the individual's physical, psychosocial, and functional needs;

(ii) develop a plan, in consultation with the individual as feasible, that identifies goals and objectives, including measurable outcomes as well as specific services and benefits to be provided; and

(iii) use an interdisciplinary team in the management of care.

HISTORY:

(Aug. 14, 1935, ch 531, Title XVIII, Part C, § 1859, as added Aug. 5, 1997, P.L. 105-33, Title IV, Subtitle A, Ch 1, Subch A, § 4001, 111 Stat. 325; Nov. 29, 1999, P.L. 106-113, Div B, § 1000(a)(6), 113 Stat. 1536; Dec. 8, 2003, P.L. 108-173, Title II, Subtitle C, § 221(b)(1), (d)(2), Subtitle D, § 231(b), (c), 117 Stat. 2181, 2193, 2207.)

(As amended Dec. 29, 2007, P.L. 110-173, Title I, § 108(a), 121 Stat. 2496; July 15, 2008, P.L. 110-275, Title I, Subtitle D, §§ 162(b), 164(a), (c)(1), (d)(1), (e)(1), 122 Stat. 2571, 2572, 2573, 2574.)

§ 1395w-29. Comparative cost adjustment (CCA) program

(a) Establishment of program.

(1) In general. The Secretary shall establish a program under this section (in this section referred to as the "CCA program") for the application of comparative cost adjustment in CCA areas selected under this section.

(2) Duration. The CCA program shall begin January 1, 2010, and shall extend over a period of 6 years, and end on December 31, 2015.

(3) Report. Upon the completion of the CCA program, the Secretary shall submit a report to Congress. Such report shall include the following, with respect to both this part [*42 USCS §§ 1395w-21* et seq.] and the original medicare fee-for-service program:

(A) An evaluation of the financial impact of the CCA program.

(B) An evaluation of changes in access to physicians and other health care providers.

(C) Beneficiary satisfaction.

(D) Recommendations regarding any extension or expansion of the CCA program.

(b) Requirements for selection of CCA areas.

(1) CCA area defined.

(A) In general. For purposes of this section, the term "CCA area" means an MSA that meets the requirements of paragraph (2) and is selected by the Secretary under subsection (c).

(B) MSA defined. For purposes of this section, the term "MSA" means a Metropolitan Statistical Area (or such similar area as the Secretary recognizes).

(2) Requirements for CCA areas. The requirements of this paragraph for an MSA to be a CCA area are as follows:

(A) MA enrollment requirement. For the reference month (as defined under section 1858(f)(4)(B) [*42 USCS § 1395w-27a(f)(4)(B)*]) with respect to 2010, at least 25 percent of the total number of MA eligible individuals who reside in the MSA were enrolled in an MA local plan described in section 1851(a)(2)(A)(i) [*42 USCS § 1395w-21(a)(2)(A)(i)*].

(B) 2 plan requirement. There will be offered in the MSA during the annual, coordinated election period under section 1851(e)(3)(B) [*42 USCS § 1395w-21(e)(3)(B)*] before the beginning of 2010 at least 2 MA local plans described in section 1851(a)(2)(A)(i) [*42 USCS § 1395w-21(a)(2)(A)(i)*] (in addition to the fee-for-service program under parts A and B [*42 USCS §§ 1395c* et seq. and *1395j* et seq.]), each offered by a different MA organization and each of which met the minimum enrollment requirements of paragraph (1) of section 1857(b) [*42 USCS § 1395w-27(b)*] (as applied without regard to paragraph (3) thereof) as of the reference month.

(c) Selection of CCA areas.

(1) General selection criteria. The Secretary shall select CCA areas from among those MSAs qualifying under subsection (b) in a manner that--

(A) seeks to maximize the opportunity to test the application of comparative cost adjustment under this title;

(B) does not seek to maximize the number of MA eligible individuals who reside in such areas; and

(C) provides for geographic diversity consistent with the criteria specified in paragraph (2).

(2) Selection criteria. With respect to the selection of MSAs that qualify to be CCA areas under subsection (b), the following rules apply, to the maximum extent feasible:

(A) Maximum number. The number of such MSAs selected may not exceed the lesser of (i) 6, or (ii) 25 percent of the number of MSAs that meet the requirement of subsection (b)(2)(A).

(B) One of 4 largest areas by population. At least one such qualifying MSA shall be selected from among the 4 such qualifying MSAs with the largest total population of MA eligible individuals.

(C) One of 4 areas with lowest population density. At least one such qualifying MSA shall be selected from among the 4 such qualifying MSAs with the lowest population density (as measured by residents per square mile or similar measure of density).

(D) Multistate area. At least one such qualifying MSA shall be selected that includes a multi-State area. Such an MSA may be an MSA described in subparagraph (B) or (C).

(E) Limitation within same geographic region. No more than 2 such MSAs shall be selected that are, in whole or in part, within the same geographic region (as specified by the Secretary) of the United States.

(F) Priority to areas not within certain demonstration projects. Priority shall be provided for those qualifying MSAs that do not have a demonstration project in effect as of the date of the enactment of this section [enacted Dec. 8, 2003] for medicare preferred provider organization plans under this part [*42 USCS §§ 1395w-21* et seq.].

(d) Application of comparative cost adjustment.

(1) In general. In the case of a CCA area for a year--

(A) for purposes of applying this part [*42 USCS §§ 1395w-21* et seq.] with respect to payment for MA local plans, any reference to an MA area-specific non-drug monthly benchmark amount shall be treated as a reference to such benchmark computed as if the CCA area-specific non-drug monthly benchmark amount (as defined in subsection (e)(1))

were substituted for the amount described in section 1853(j)(1)(A) [*42 USCS § 1395w-23(j)(1)(A)*] for the CCA area and year involved, as phased in under paragraph (3); and

(B) with respect to months in the year for individuals residing in the CCA area who are not enrolled in an MA plan, the amount of the monthly premium under section 1839 [*42 USCS § 1395r*] is subject to adjustment under subsection (f).

(2) Exclusion of MA local areas with fewer than 2 organizations offering MA plans.

(A) In general. In no case shall an MA local area that is within an MSA be included as part of a CCA area unless for 2010 (and, except as provided in subparagraph (B), for a subsequent year) there is offered in each part of such MA local area at least 2 MA local plans described in section 1851(a)(2)(A)(i) [*42 USCS § 1395w-21(a)(2)(A)(i)*] each of which is offered by a different MA organization.

(B) Continuation. If an MA local area meets the requirement of subparagraph (A) and is included in a CCA area for 2010, such local area shall continue to be included in such CCA area for a subsequent year notwithstanding that it no longer meets such requirement so long as there is at least one MA local plan described in section 1851(a)(2)(A)(i) [*42 USCS § 1395w-21(a)(2)(A)(i)*] that is offered in such local area.

(3) Phase-in of CCA benchmark.

(A) In general. In applying this section for a year before 2013, paragraph (1)(A) shall be applied as if the phase-in fraction under subparagraph (B) of the CCA non-drug monthly benchmark amount for the year were substituted for such fraction of the MA area-specific non-drug monthly benchmark amount.

(B) Phase-in fraction. The phase-in fraction under this subparagraph is--

(i) for 2010 1/4 ; and

(ii) for a subsequent year is the phase-in fraction under this subparagraph for the previous year increased by 1/4 , but in no case more than 1.

(e) Computation of CCA benchmark amount.

(1) CCA non-drug monthly benchmark amount. For purposes of this section, the term "CCA non-drug monthly benchmark amount" means, with respect to a CCA area for a month in a year, the sum of the 2 components described in paragraph (2) for the area and year. The Secretary shall compute such benchmark amount for each such CCA area before the beginning of each annual, coordinated election period under section 1851(e)(3)(B) [*42 USCS § 1395w-21(e)(3)(B)*] for each year (beginning with 2010) in which the CCA area is so selected.

(2) 2 components. For purposes of paragraph (1), the 2 components described in this paragraph for a CCA area and a year are the following:

(A) MA local component. The product of the following:

(i) Weighted average of medicare advantage plan bids in area. The weighted average of the plan bids for the area and year (as determined under paragraph (3)(A)).

(ii) Non-ffs market share. One minus the fee-for-service market share percentage, determined under paragraph (4) for the area and year.

(B) Fee-for-service component. The product of the following:

(i) Fee-for-service area-specific non-drug amount. The fee-for-service area-specific non-drug amount (as defined in paragraph (5)) for the area and year.

(ii) Fee-for-service market share. The fee-for-service market share percentage, determined under paragraph (4) for the area and year.

(3) Determination of weighted average MA bids for a CCA area.

(A) In general. For purposes of paragraph (2)(A)(i), the weighted average of plan bids for a CCA area and a year is, subject to subparagraph (D), the sum of the following products for MA local plans described in subparagraph (C) in the area and year:

(i) Monthly medicare advantage statutory non-drug bid amount. The accepted unadjusted MA statutory non-drug monthly bid amount.

(ii) Plan's share of medicare advantage enrollment in area. The number of individuals described in subparagraph (B), divided by the total number of such individuals for all MA plans described in subparagraph (C) for that area and year.

(B) Counting of individuals. The Secretary shall count, for each MA local plan described in subparagraph (C) for an area and year, the number of individuals who reside in the area and who were enrolled under such plan under this part [*42 USCS §§ 1395w-21* et seq.] during the reference month for that year.

(C) Exclusion of plans not offered in previous year. For an area and year, the MA local plans described in this subparagraph are MA local plans described in section 1851(a)(2)(A)(i) [*42 USCS § 1395w-21(a)(2)(A)(i)*] that are offered in the area and year and were offered in the CCA area in the reference month.

(D) Computation of weighted average of plan bids. In calculating the weighted average of plan bids for a CCA area under subparagraph (A)--

(i) in the case of an MA local plan that has a service area only part of which is within such CCA area, the MA organization offering such plan shall submit a separate bid for such plan for the portion within such CCA area; and

(ii) the Secretary shall adjust such separate bid (or, in the case of an MA local plan that has a service area entirely within such CCA area, the plan bid) as may be necessary to take into account differences between the service area of such plan within the CCA area and the entire CCA area and the distribution of plan enrollees of all MA local plans offered within the CCA area.

(4) Computation of fee-for-service market share percentage. The Secretary shall determine, for a year and a CCA area, the proportion (in this subsection referred to as the "fee-for-service market share percentage") equal to--

(A) the total number of MA eligible individuals residing in such area who during the reference month for the year were not enrolled in any MA plan; divided by

(B) the sum of such number and the total number of MA eligible individuals residing in such area who during such reference month were enrolled in an MA local plan described in section 1851(a)(2)(A)(i) [*42 USCS § 1395w-21(a)(2)(A)(i)*],

or, if greater, such proportion determined for individuals nationally.

(5) Fee-for-service area-specific non-drug amount.

(A) In general. For purposes of paragraph (2)(B)(i) and subsection (f)(2)(A), subject to subparagraph (C), the term "fee-for-service area-specific non-drug amount" means, for a CCA area and a year, the adjusted average per capita cost for such area and year involved, determined under section 1876(a)(4) [*42 USCS § 1395mm(a)(4)*] and adjusted as appropriate for the purpose of risk adjustment for benefits under the original medicare fee-for-service program option for individuals entitled to benefits under part A [*42 USCS §§ 1395c* et seq.] and enrolled under part B [*42 USCS §§ 1395j* et seq.] who are not enrolled in an MA plan for the year, but adjusted to exclude costs attributable to payments under section 1886(h) [*42 USCS § 1395ww(h)*].

(B) Use of full risk adjustment to standardize fee-for-service costs to typical beneficiary. In determining the adjusted average per capita cost for an area and year under subparagraph (A), such costs shall be adjusted to fully take into account the demographic and health status risk factors established under section 1853(a)(1)(A)(iv) [*42 USCS § 1395w-23(a)(1)(A)(iv)*] so that such per capita costs reflect the average costs for a typical beneficiary residing in the CCA area.

(C) Inclusion of costs of VA and DOD military facility services to medicare-eligible beneficiaries. In determining the adjusted average per capita cost under subparagraph (A) for a year, such cost shall be adjusted to include the Secretary's estimate, on a per capita basis, of the amount of additional payments that would have been made in the area involved under this title if individuals entitled to benefits under this title had not received services from facilities of the Department of Veterans Affairs or the Department of Defense.

(f) Premium adjustment.

(1) Application.

(A) In general. Except as provided in subparagraph (B), in the case of an individual who is enrolled under part B [*42 USCS §§ 1395j* et seq.], who resides in a CCA area, and who is not enrolled in an MA plan under this part [*42 USCS §§ 1395w-21* et seq.], the monthly premium otherwise applied under part B [*42 USCS §§ 1395j* et seq.] (determined without regard to subsections (b), (f), and (i) of section 1839 [*42 USCS § 1395r*] or any adjustment under this subsection) shall be adjusted in accordance with paragraph (2), but only in the case of premiums for months during the period in which the CCA program under this section for such area is in effect.

(B) No premium adjustment for subsidy eligible beneficiaries. No premium adjustment shall be made under this subsection for a premium for a month if the individual is determined to be a subsidy eligible individual (as defined in section 1860D-14(a)(3)(A) [*42 USCS § 1395w-114(a)(3)(A)*]) for the month.

(2) Amount of adjustment.

(A) In general. Under this paragraph, subject to the exemption under paragraph (1)(B) and the limitation under subparagraph (B), if the fee-for-service area-specific non-drug amount (as defined in section (e)(5)) for a CCA area in which an individual resides for a month--

(i) does not exceed the CCA non-drug monthly benchmark amount (as determined under subsection (e)(1)) for such area and month, the amount of the premium for the individual for the month shall be reduced, by an amount equal to 75 percent of the amount by which such CCA benchmark exceeds such fee-for-service area-specific non-drug amount; or

(ii) exceeds such CCA non-drug benchmark, the amount of the premium for the individual for the month shall be adjusted to ensure, that--

(I) the sum of the amount of the adjusted premium and the CCA non-drug benchmark for the area; is equal to

(II) the sum of the unadjusted premium plus the amount of such fee-for-service area-specific non-drug amount for the area.

(B) Limitation. In no case shall the actual amount of an adjustment under subparagraph (A) for an area and month in a year result in an adjustment that exceeds the maximum adjustment permitted under subparagraph (C) for the area and year, or, if less, the maximum annual adjustment permitted under subparagraph (D) for the area and year.

(C) Phase-in of adjustment. The amount of an adjustment under subparagraph (A) for a CCA area and year may not exceed the product of the phase-in fraction for the year under subsection (d)(3)(B) multiplied by the amount of the adjustment otherwise computed under subparagraph (A) for the area and year, determined without regard to this subparagraph and subparagraph (D).

(D) 5-percent limitation on adjustment. The amount of the adjustment under this subsection for months in a year shall not exceed 5 percent of the amount of the monthly premium amount determined for months in the year under section 1839 [*42 USCS § 1395r*] without regard to subsections (b), (f), and (i) of such section and this subsection.

HISTORY:

(Aug. 14, 1935, ch 531, Title XVIII, Part C, § 1860C-1, as added Dec. 8, 2003, P.L. 108-173, Title II, Subtitle E, § 241(a), 117 Stat. 2214.)

§ 1395w-101. Eligibility, enrollment, and information

(a) Provision of qualified prescription drug coverage through enrollment in plans.

(1) In general. Subject to the succeeding provisions of this part [*42 USCS §§ 1395w-101* et seq.], each part D eligible individual (as defined in paragraph (3)(A)) is entitled to obtain qualified prescription drug coverage (described in section 1860D-2(a) [*42 USCS § 1395w-102(a)*]) as follows:

(A) Fee-for-service enrollees may receive coverage through a prescription drug plan. A part D eligible individual who is not enrolled in an MA plan may obtain qualified prescription drug coverage through enrollment in a prescription drug plan (as defined in section 1860D-41(a)(14) [*42 USCS § 1395w-151(a)(14)*]).

(B) Medicare Advantage enrollees.

(i) Enrollees in a plan providing qualified prescription drug coverage receive coverage through the plan. A part D eligible individual who is enrolled in an MA-PD plan obtains such coverage through such plan.

(ii) Limitation on enrollment of MA plan enrollees in prescription drug plans. Except as provided in clauses (iii) and (iv), a part D eligible individual who is enrolled in an MA plan may not enroll in a prescription drug plan under this part [*42 USCS §§ 1395w-101* et seq.].

(iii) Private fee-for-service enrollees in ma plans not providing qualified prescription drug coverage permitted to enroll in a prescription drug plan. A part D eligible individual who is enrolled in an MA private fee-for-service plan (as defined in section 1859(b)(2) [*42 USCS § 1395w-28(b)(2)*]) that does not provide qualified prescription drug coverage may obtain qualified prescription drug coverage through enrollment in a prescription drug plan.

(iv) Enrollees in MSA plans permitted to enroll in a prescription drug plan. A part D eligible individual who is enrolled in an MSA plan (as defined in section 1859(b)(3) [*42 USCS § 1395w-28(b)(3)*]) may obtain qualified prescription drug coverage through enrollment in a prescription drug plan.

(2) Coverage first effective January 1, 2006. Coverage under prescription drug plans and MA-PD plans shall first be effective on January 1, 2006.

(3) Definitions. For purposes of this part [*42 USCS §§ 1395w-101* et seq.]:

(A) Part D eligible individual. The term "part D eligible individual" means an individual who is entitled to benefits under part A [*42 USCS §§ 1395c* et seq.] or enrolled under part B [*42 USCS §§ 1395j* et seq.].

(B) MA plan. The term "MA plan" has the meaning given such term in section 1859(b)(1) [*42 USCS § 1395w-28(b)(1)*].

(C) MA-PD plan. The term "MA-PD plan" means an MA plan that provides qualified prescription drug coverage.

(b) Enrollment process for prescription drug plans.

(1) Establishment of process.

(A) In general. The Secretary shall establish a process for the enrollment, disenrollment, termination, and change of enrollment of part D eligible individuals in prescription drug plans consistent with this subsection.

(B) Application of MA rules. In establishing such process, the Secretary shall use rules similar to (and coordinated with) the rules for enrollment, disenrollment, termination, and change of enrollment with an MA-PD plan under the following provisions of section 1851 [*42 USCS § 1395w-21*]:

(i) Residence requirements. Section 1851(b)(1)(A) [*42 USCS § 1395w-21(b)(1)(A)*], relating to residence requirements.

(ii) Exercise of choice. Section 1851(c) [*42 USCS § 1395w-21(c)*] (other than paragraph (3)(A) of such section), relating to exercise of choice.

(iii) Coverage election periods. Subject to paragraphs (2) and (3) of this subsection, section 1851(e) [*42 USCS § 1395w-21(e)*] (other than subparagraphs (B), (C), and (E) of paragraph (2) and the second sentence of paragraph (4) of such section), relating to coverage election periods, including initial periods, annual coordinated election periods, special election periods, and election periods for exceptional circumstances.

(iv) Coverage periods. Section 1851(f) [*42 USCS § 1395w-21(f)*], relating to effectiveness of elections and changes of elections.

(v) Guaranteed issue and renewal. Section 1851(g) [*42 USCS § 1395w-21(g)*] (other than paragraph (2) of such section and clause (i) and the second sentence of clause (ii) of paragraph (3)(C) of such section), relating to guaranteed issue and renewal.

(vi) Marketing material and application forms. Section 1851(h) [*42 USCS § 1395w-21(h)*], relating to approval of marketing material and application forms.

In applying clauses (ii), (iv), and (v) of this subparagraph, any reference to section 1851(e) [*42 USCS § 1395w-21(e)*] shall be treated as a reference to such section as applied pursuant to clause (iii) of this subparagraph.

(C) Special rule. The process established under subparagraph (A) shall include, in the case of a part D eligible individual who is a full-benefit dual eligible individual (as defined in section 1935(c)(6) [*42 USCS § 1396u-5(c)(6)*]) who has failed to enroll in a prescription drug plan or an MA-PD plan, for the enrollment in a prescription drug plan that has a monthly beneficiary premium that does not exceed the premium assistance available under section 1860D-14(a)(1)(A) [*42 USCS § 1395w-114(a)(1)(A)*]). If there is more than one such plan available, the Secretary shall enroll such an individual on a random basis among all such plans in the PDP region. Nothing in the previous sentence shall prevent such an individual from declining or changing such enrollment.

(2) Initial enrollment period.

(A) Program initiation. In the case of an individual who is a part D eligible individual as of November 15, 2005, there shall be an initial enrollment period that shall be the same as the annual, coordinated open election period described in section 1851(e)(3)(B)(iii) [*42 USCS § 1395w-21(e)(3)(B)(iii)*], as applied under paragraph (1)(B)(iii).

(B) Continuing periods. In the case of an individual who becomes a part D eligible individual after November 15, 2005, there shall be an initial enrollment period which is the period under section 1851(e)(1) [*42 USCS § 1395w-21(e)(1)*], as applied under paragraph (1)(B)(iii) of this section, as if "entitled to benefits under part A [*42 USCS §§ 1395c* et seq.] or enrolled under part B [*42 USCS §§ 1395j* et seq.]" were substituted for "entitled to benefits under part A [*42 USCS §§ 1395c* et seq.] and enrolled under part B [*42 USCS §§ 1395j* et seq.]", but in no case shall such period end before the period described in subparagraph (A).

(3) Additional special enrollment periods. The Secretary shall establish special enrollment periods, including the following:

(A) Involuntary loss of creditable prescription drug coverage.

(i) In general. In the case of a part D eligible individual who involuntarily loses creditable prescription drug coverage (as defined in section 1860D-13(b)(4) [*42 USCS § 1395w-113(b)(4)*]).

(ii) Notice. In establishing special enrollment periods under clause (i), the Secretary shall take into account when the part D eligible individuals are provided notice of the loss of creditable prescription drug coverage.

(iii) Failure to pay premium. For purposes of clause (i), a loss of coverage shall be treated as voluntary if the coverage is terminated because of failure to pay a required beneficiary premium.

(iv) Reduction in coverage. For purposes of clause (i), a reduction in coverage so that the coverage no longer meets the requirements under section 1860D-13(b)(5) [*42 USCS § 1395w-113(b)(5)*] (relating to actuarial equivalence) shall be treated as an involuntary loss of coverage.

(B) Errors in enrollment. In the case described in section 1837(h) [*42 USCS § 1395p(h)*] (relating to errors in enrollment), in the same manner as such section applies to part B [*42 USCS §§ 1395j* et seq.].

(C) Exceptional circumstances. In the case of part D eligible individuals who meet such exceptional conditions (in addition to those conditions applied under paragraph (1)(B)(iii)) as the Secretary may provide.

(D) Medicaid coverage. In the case of an individual (as determined by the Secretary) who is a full-benefit dual eligible individual (as defined in section 1935(c)(6) [*42 USCS § 1396u-5(c)(6)*]).

(E) Discontinuance of MA-PD election during first year of eligibility. In the case of a part D eligible individual who discontinues enrollment in an MA-PD plan under the second sentence of section 1851(e)(4) [*42 USCS § 1395w-21(e)(4)*] at the time of the election of coverage under such sentence under the original medicare fee-for-service program.

(4) Information to facilitate enrollment.

(A) In general. Notwithstanding any other provision of law but subject to subparagraph (B), the Secretary may provide to each PDP sponsor and MA organization such identifying information about part D eligible individuals as the

Secretary determines to be necessary to facilitate efficient marketing of prescription drug plans and MA-PD plans to such individuals and enrollment of such individuals in such plans.

(B) Limitation.

(i) Provision of information. The Secretary may provide the information under subparagraph (A) only to the extent necessary to carry out such subparagraph.

(ii) Use of information. Such information provided by the Secretary to a PDP sponsor or an MA organization may be used by such sponsor or organization only to facilitate marketing of, and enrollment of part D eligible individuals in, prescription drug plans and MA-PD plans.

(5) Reference to enrollment procedures for MA-PD plans. For rules applicable to enrollment, disenrollment, termination, and change of enrollment of part D eligible individuals in MA-PD plans, see section 1851 [*42 USCS § 1395w-21*].

(6) Reference to penalties for late enrollment. Section 1860D-13(b) [*42 USCS § 1395w-113(b)*] imposes a late enrollment penalty for part D eligible individuals who--

(A) enroll in a prescription drug plan or an MA-PD plan after the initial enrollment period described in paragraph (2); and

(B) fail to maintain continuous creditable prescription drug coverage during the period of non-enrollment.

(c) Providing information to beneficiaries.

(1) Activities. The Secretary shall conduct activities that are designed to broadly disseminate information to part D eligible individuals (and prospective part D eligible individuals) regarding the coverage provided under this part [*42 USCS §§ 1395w-101* et seq.]. Such activities shall ensure that such information is first made available at least 30 days prior to the initial enrollment period described in subsection (b)(2)(A).

(2) Requirements. The activities described in paragraph (1) shall--

(A) be similar to the activities performed by the Secretary under section 1851(d) [*42 USCS § 1395w-21(d)*], including dissemination (including through the toll-free telephone number 1-800-MEDICARE) of comparative information for prescription drug plans and MA-PD plans; and

(B) be coordinated with the activities performed by the Secretary under such section and under section 1804 [*42 USCS § 1395b-2*].

(3) Comparative information.

(A) In general. Subject to subparagraph (B), the comparative information referred to in paragraph (2)(A) shall include a comparison of the following with respect to qualified prescription drug coverage:

(i) Benefits. The benefits provided under the plan.

(ii) Monthly beneficiary premium. The monthly beneficiary premium under the plan.

(iii) Quality and performance. The quality and performance under the plan.

(iv) Beneficiary cost-sharing. The cost-sharing required of part D eligible individuals under the plan.

(v) Consumer satisfaction surveys. The results of consumer satisfaction surveys regarding the plan conducted pursuant to section 1860D-4(d) [*42 USCS § 1395w-104(d)*].

(B) Exception for unavailability of information. The Secretary is not required to provide comparative information under clauses (iii) and (v) of subparagraph (A) with respect to a plan--

(i) for the first plan year in which it is offered; and

(ii) for the next plan year if it is impracticable or the information is otherwise unavailable.

(4) Information on late enrollment penalty. The information disseminated under paragraph (1) shall include information concerning the methodology for determining the late enrollment penalty under section 1860D-13(b) [*42 USCS § 1395w-113(b)*].

HISTORY:

(Aug. 4, 1935, ch 531, Title XVIII, Part D, Subpart 1, § 1860D-1, as added Dec. 8, 2003, P.L. 108-173, Title I, § 101(a)(2), 117 Stat. 2071.)

(As amended Dec. 20, 2006, P.L. 109-432, Div B, Title II, § 206(b), 120 Stat. 2990.)

§ 1395w-102. Prescription drug benefits

(a) Requirements.

(1) In general. For purposes of this part and part C [*42 USCS §§ 1395w-101* et seq. and *1395w-21* et seq.], the term "qualified prescription drug coverage" means either of the following:

(A) Standard prescription drug coverage with access to negotiated prices. Standard prescription drug coverage (as defined in subsection (b)) and access to negotiated prices under subsection (d).

(B) Alternative prescription drug coverage with at least actuarially equivalent benefits and access to negotiated prices. Coverage of covered part D drugs which meets the alternative prescription drug coverage requirements of subsection (c) and access to negotiated prices under subsection (d), but only if the benefit design of such coverage is approved by the Secretary, as provided under subsection (c).

(2) Permitting supplemental prescription drug coverage.

(A) In general. Subject to subparagraph (B), qualified prescription drug coverage may include supplemental prescription drug coverage consisting of either or both of the following:

(i) Certain reductions in cost-sharing.

(I) In general. A reduction in the annual deductible, a reduction in the coinsurance percentage, or an increase in the initial coverage limit with respect to covered part D drugs, or any combination thereof, insofar as such a reduction or increase increases the actuarial value of benefits above the actuarial value of basic prescription drug coverage.

(II) Construction. Nothing in this paragraph shall be construed as affecting the application of subsection (c)(3).

(ii) Optional drugs. Coverage of any product that would be a covered part D drug but for the application of subsection (e)(2)(A).

(B) Requirement. A PDP sponsor may not offer a prescription drug plan that provides supplemental prescription drug coverage pursuant to subparagraph (A) in an area unless the sponsor also offers a prescription drug plan in the area that only provides basic prescription drug coverage.

(3) Basic prescription drug coverage. For purposes of this part and part C [*42 USCS §§ 1395w-101* et seq. and *1395w-21* et seq.], the term "basic prescription drug coverage" means either of the following:

(A) Coverage that meets the requirements of paragraph (1)(A).

(B) Coverage that meets the requirements of paragraph (1)(B) but does not have any supplemental prescription drug coverage described in paragraph (2)(A).

(4) Application of secondary payor provisions. The provisions of section 1852(a)(4) [*42 USCS § 1395w-22(a)(4)*] shall apply under this part [*42 USCS §§ 1395w-101* et seq.] in the same manner as they apply under part C [*42 USCS §§ 1395w-21* et seq.].

(5) Construction. Nothing in this subsection shall be construed as changing the computation of incurred costs under subsection (b)(4).

(b) Standard prescription drug coverage. For purposes of this part and part C [*42 USCS §§ 1395w-101* et seq. and *1395w-21* et seq.], the term "standard prescription drug coverage" means coverage of covered part D drugs that meets the following requirements:

(1) Deductible.

(A) In general. The coverage has an annual deductible--

(i) for 2006, that is equal to $ 250; or

(ii) for a subsequent year, that is equal to the amount specified under this paragraph for the previous year increased by the percentage specified in paragraph (6) for the year involved.

(B) Rounding. Any amount determined under subparagraph (A)(ii) that is not a multiple of $ 5 shall be rounded to the nearest multiple of $ 5.

(2) Benefit structure.

(A) 25 percent coinsurance. The coverage has coinsurance (for costs above the annual deductible specified in paragraph (1) and up to the initial coverage limit under paragraph (3)) that is--

(i) equal to 25 percent; or

(ii) actuarially equivalent (using processes and methods established under section 1860D-11(c) [*42 USCS § 1395w-111(c)*]) to an average expected payment of 25 percent of such costs.

(B) Use of tiers. Nothing in this part [*42 USCS §§ 1395w-101* et seq.] shall be construed as preventing a PDP sponsor or an MA organization from applying tiered copayments under a plan, so long as such tiered copayments are consistent with subparagraph (A)(ii).

(3) Initial coverage limit.

(A) In general. Except as provided in paragraph (4), the coverage has an initial coverage limit on the maximum costs that may be recognized for payment purposes (including the annual deductible)--

(i) for 2006, that is equal to $ 2,250; or

(ii) for a subsequent year, that is equal to the amount specified in this paragraph for the previous year, increased by the annual percentage increase described in paragraph (6) for the year involved.

(B) Rounding. Any amount determined under subparagraph (A)(ii) that is not a multiple of $ 10 shall be rounded to the nearest multiple of $ 10.

(4) Protection against high out-of-pocket expenditures.

(A) In general.

(i) In general. The coverage provides benefits, after the part D eligible individual has incurred costs (as described in subparagraph (C)) for covered part D drugs in a year equal to the annual out-of-pocket threshold specified in subparagraph (B), with cost-sharing that is equal to the greater of--

(I) a copayment of $ 2 for a generic drug or a preferred drug that is a multiple source drug (as defined in section 1927(k)(7)(A)(i) [*42 USCS § 1396r-8(k)(7)(A)(i)*]) and $ 5 for any other drug; or

(II) coinsurance that is equal to 5 percent.

(ii) Adjustment of amount. For a year after 2006, the dollar amounts specified in clause (i)(I) shall be equal to the dollar amounts specified in this subparagraph for the previous year, increased by the annual percentage increase described in paragraph (6) for the year involved. Any amount established under this clause that is not a multiple of a 5 cents shall be rounded to the nearest multiple of 5 cents.

(B) Annual out-of-pocket threshold.

(i) In general. For purposes of this part [*42 USCS §§ 1395w-101* et seq.], the "annual out-of-pocket threshold" specified in this subparagraph--

(I) for 2006, is equal to $ 3,600; or

(II) for a subsequent year, is equal to the amount specified in this subparagraph for the previous year, increased by the annual percentage increase described in paragraph (6) for the year involved.

(ii) Rounding. Any amount determined under clause (i)(II) that is not a multiple of $ 50 shall be rounded to the nearest multiple of $ 50.

(C) Application. In applying subparagraph (A)--

(i) incurred costs shall only include costs incurred with respect to covered part D drugs for the annual deductible described in paragraph (1), for cost-sharing described in paragraph (2), and for amounts for which benefits are not provided because of the application of the initial coverage limit described in paragraph (3), but does not include any costs incurred for covered part D drugs which are not included (or treated as being included) in the plan's formulary; and

(ii) such costs shall be treated as incurred only if they are paid by the part D eligible individual (or by another person, such as a family member, on behalf of the individual), under section 1860D-14 [*42 USCS § 1395w-114*], or under a State Pharmaceutical Assistance Program and the part D eligible individual (or other person) is not reimbursed through insurance or otherwise, a group health plan, or other third-party payment arrangement (other than under such section or such a Program) for such costs.

(D) Information regarding third-party reimbursement.

(i) Procedures for exchanging information. In order to accurately apply the requirements of subparagraph (C)(ii), the Secretary is authorized to establish procedures, in coordination with the Secretary of the Treasury and the Secretary of Labor--

(I) for determining whether costs for part D eligible individuals are being reimbursed through insurance or otherwise, a group health plan, or other third-party payment arrangement; and

(II) for alerting the PDP sponsors and MA organizations that offer the prescription drug plans and MA-PD plans in which such individuals are enrolled about such reimbursement arrangements.

(ii) Authority to request information from enrollees. A PDP sponsor or an MA organization may periodically ask part D eligible individuals enrolled in a prescription drug plan or an MA-PD plan offered by the sponsor or organization whether such individuals have or expect to receive such third-party reimbursement. A material misrepresentation of the information described in the preceding sentence by an individual (as defined in standards set by the Secretary and determined through a process established by the Secretary) shall constitute grounds for termination of enrollment in any plan under section 1851(g)(3)(B) [*42 USCS § 1395w-21(g)(3)(B)*] (and as applied under this part [*42 USCS §§ 1395w-101* et seq.] under section 1860D-1(b)(1)(B)(v) [*42 USCS § 1395w-101(b)(1)(B)(v)*]) for a period specified by the Secretary.

(5) Construction. Nothing in this part [*42 USCS §§ 1395w-101* et seq.] shall be construed as preventing a PDP sponsor or an MA organization offering an MA-PD plan from reducing to zero the cost-sharing otherwise applicable to preferred or generic drugs.

(6) Annual percentage increase. The annual percentage increase specified in this paragraph for a year is equal to the annual percentage increase in average per capita aggregate expenditures for covered part D drugs in the United States for part D eligible individuals, as determined by the Secretary for the 12-month period ending in July of the previous year using such methods as the Secretary shall specify.

(c) Alternative prescription drug coverage requirements. A prescription drug plan or an MA-PD plan may provide a different prescription drug benefit design from standard prescription drug coverage so long as the Secretary determines (consistent with section 1860D-11(c) [*42 USCS § 1395w-111(c)*]) that the following requirements are met and the plan applies for, and receives, the approval of the Secretary for such benefit design:

(1) Assuring at least actuarially equivalent coverage.

(A) Assuring equivalent value of total coverage. The actuarial value of the total coverage is at least equal to the actuarial value of standard prescription drug coverage.

(B) Assuring equivalent unsubsidized value of coverage. The unsubsidized value of the coverage is at least equal to the unsubsidized value of standard prescription drug coverage. For purposes of this subparagraph, the unsubsidized value of coverage is the amount by which the actuarial value of the coverage exceeds the actuarial value of the subsidy payments under section 1860D-15 [*42 USCS § 1395w-115*] with respect to such coverage.

(C) Assuring standard payment for costs at initial coverage limit. The coverage is designed, based upon an actuarially representative pattern of utilization, to provide for the payment, with respect to costs incurred that are equal to the initial coverage limit under subsection (b)(3) for the year, of an amount equal to at least the product of--

(i) the amount by which the initial coverage limit described in subsection (b)(3) for the year exceeds the deductible described in subsection (b)(1) for the year; and

(ii) 100 percent minus the coinsurance percentage specified in subsection (b)(2)(A)(i).

(2) Maximum required deductible. The deductible under the coverage shall not exceed the deductible amount specified under subsection (b)(1) for the year.

(3) Same protection against high out-of-pocket expenditures. The coverage provides the coverage required under subsection (b)(4).

(d) Access to negotiated prices.

(1) Access.

(A) In general. Under qualified prescription drug coverage offered by a PDP sponsor offering a prescription drug plan or an MA organization offering an MA-PD plan, the sponsor or organization shall provide enrollees with access to negotiated prices used for payment for covered part D drugs, regardless of the fact that no benefits may be payable under the coverage with respect to such drugs because of the application of a deductible or other cost-sharing or an initial coverage limit (described in subsection (b)(3)).

(B) Negotiated prices. For purposes of this part [*42 USCS §§ 1395w-101* et seq.], negotiated prices shall take into account negotiated price concessions, such as discounts, direct or indirect subsidies, rebates, and direct or indirect remunerations, for covered part D drugs, and include any dispensing fees for such drugs.

(C) Medicaid-related provisions. The prices negotiated by a prescription drug plan, by an MA-PD plan with respect to covered part D drugs, or by a qualified retiree prescription drug plan (as defined in section 1860D-22(a)(2) [*42 USCS § 1395w-132(a)(2)*]) with respect to such drugs on behalf of part D eligible individuals, shall (notwithstanding any other provision of law) not be taken into account for the purposes of establishing the best price under section 1927(c)(1)(C) [*42 USCS § 1396r-8(c)(1)(C)*].

(2) Disclosure. A PDP sponsor offering a prescription drug plan or an MA organization offering an MA-PD plan shall disclose to the Secretary (in a manner specified by the Secretary) the aggregate negotiated price concessions described in paragraph (1)(B) made available to the sponsor or organization by a manufacturer which are passed through in the form of lower subsidies, lower monthly beneficiary prescription drug premiums, and lower prices through pharmacies and other dispensers. The provisions of section 1927(b)(3)(D) [*42 USCS § 1396r-8(b)(3)(D)*] apply to information disclosed to the Secretary under this paragraph.

(3) Audits. To protect against fraud and abuse and to ensure proper disclosures and accounting under this part [*42 USCS §§ 1395w-101* et seq.] and in accordance with section 1857(d)(2)(B) [*42 USCS § 1395w-27(d)(2)(B)*] (as applied under section 1860D-12(b)(3)(C) [*42 USCS § 1395w-112(b)(3)(C)*]), the Secretary may conduct periodic audits, directly or through contracts, of the financial statements and records of PDP sponsors with respect to prescription drug plans and MA organizations with respect to MA-PD plans.

(e) Covered part D drug defined.

(1) In general. Except as provided in this subsection, for purposes of this part [*42 USCS §§ 1395w-101* et seq.], the term "covered part D drug" means--

(A) a drug that may be dispensed only upon a prescription and that is described in subparagraph (A)(i), (A)(ii), or (A)(iii) of section 1927(k)(2) [*42 USCS § 1396r-8(k)(2)*]; or

(B) a biological product described in clauses (i) through (iii) of subparagraph (B) of such section or insulin described in subparagraph (C) of such section and medical supplies associated with the injection of insulin (as defined in regulations of the Secretary),

and such term includes a vaccine licensed under section 351 of the Public Health Service Act [*42 USCS § 262*] (and, for vaccines administered on or after January 1, 2008, its administration) and any use of a covered part D drug for a medically accepted indication (as defined in paragraph (4)).

(2) Exclusions.

(A) In general **[Caution: For provisions applicable to prescriptions dispensed before January 1, 2013, see 2008 amendment note below.]**. Such term does not include drugs or classes of drugs, or their medical uses, which may be excluded from coverage or otherwise restricted under section 1927(d)(2) [*42 USCS § 1396r-8(d)(2)*], other than subparagraph (E) of such section (relating to smoking cessation agents), other than subparagraph (I) of such section (relating to barbiturates) if the barbiturate is used in the treatment of epilepsy, cancer, or a chronic mental health disorder, and other than subparagraph (J) of such section (relating to benzodiazepines), or under section 1927(d)(3) [*42 USCS § 1396r-8(d)(3)*], as such sections were in effect on the date of the enactment of this part [enacted Dec. 8, 2003]. Such term also does not include a drug when used for the treatment of sexual or erectile dysfunction, unless such drug were used to treat a condition, other than sexual or erectile dysfunction, for which the drug has been approved by the Food and Drug Administration.

(B) Medicare covered drugs. A drug prescribed for a part D eligible individual that would otherwise be a covered part D drug under this part [*42 USCS §§ 1395w-101* et seq.] shall not be so considered if payment for such drug as so prescribed and dispensed or administered with respect to that individual is available (or would be available but for the application of a deductible) under part A or B [*42 USCS §§ 1395c* et seq. or *1395j* et seq.] for that individual.

(3) Application of general exclusion provisions. A prescription drug plan or an MA-PD plan may exclude from qualified prescription drug coverage any covered part D drug--

(A) for which payment would not be made if section 1862(a) [*42 USCS § 1395y(a)*] applied to this part [*42 USCS §§ 1395w-101* et seq.]; or

(B) which is not prescribed in accordance with the plan or this part [*42 USCS §§ 1395w-101* et seq.].

Such exclusions are determinations subject to reconsideration and appeal pursuant to subsections (g) and (h), respectively, of section 1860D-4 [*42 USCS § 1395w-104*].

(4) Medically accepted indication defined.

(A) In general. For purposes of paragraph (1), the term "medically accepted indication"' has the meaning given that term--

(i) in the case of a covered part D drug used in an anticancer chemotherapeutic regimen, in section 1861(t)(2)(B) [*42 USCS § 1395x(t)(2)(B)*], except that in applying such section--

(I) "prescription drug plan or MA-PD plan" shall be substituted for "carrier" each place it appears; and

(II) subject to subparagraph (B), the compendia described in section 1927(g)(1)(B)(i)(III) [*42 USCS § 1396r-8(g)(1)(B)(i)(III)*] shall be included in the list of compendia described in clause (ii)(I) section 1861(t)(2)(B) [*42 USCS § 1395x(t)(2)(B)*]; and

(ii) in the case of any other covered part D drug, in section 1927(k)(6) [*42 USCS § 1396r-8(k)(6)*].

(B) Conflict of interest. On and after January 1, 2010, subparagraph (A)(i)(II) shall not apply unless the compendia described in section 1927(g)(1)(B)(i)(III) [*42 USCS § 1396r-8(g)(1)(B)(i)(III)*] meets the requirement in the third sentence of section 1861(t)(2)(B) [*42 USCS § 1395x(t)(2)(B)*].

(C) Update. For purposes of applying subparagraph (A)(ii), the Secretary shall revise the list of compendia described in section 1927(g)(1)(B)(i) [*42 USCS § 1396r-8(g)(1)(B)(i)*] as is appropriate for identifying medically accepted indications for drugs. Any such revision shall be done in a manner consistent with the process for revising compendia under section 1861(t)(2)(B) [*42 USCS § 1395x(t)(2)(B)*].

HISTORY:

(Aug. 4, 1935, ch 531, Title XVIII, Part D, Subpart 1, § 1860D-2, as added Dec. 8, 2003, P.L. 108-173, Title I, § 101(a)(2), 117 Stat. 2075.)

(As amended Oct. 20, 2005, P.L. 109-91, Title I, § 103(a), 119 Stat. 2092; Dec. 20, 2006, P.L. 109-432, Div B, Title II, § 202(b), 120 Stat. 2986; July 15, 2008, P.L. 110-275, Title I, Subtitle E, Part II, § 175(a), Subtitle F, § 182(a)(1), 122 Stat. 2581, 2583.)

§ 1395w-103. Access to a choice of qualified prescription drug coverage

(a) Assuring access to a choice of coverage.

(1) Choice of at least two plans in each area. The Secretary shall ensure that each part D eligible individual has available, consistent with paragraph (2), a choice of enrollment in at least 2 qualifying plans (as defined in paragraph (3)) in the area in which the individual resides, at least one of which is a prescription drug plan. In any such case in which such plans are not available, the part D eligible individual shall be given the opportunity to enroll in a fallback prescription drug plan.

(2) Requirement for different plan sponsors. The requirement in paragraph (1) is not satisfied with respect to an area if only one entity offers all the qualifying plans in the area.

(3) Qualifying plan defined. For purposes of this section, the term "qualifying plan" means--

(A) a prescription drug plan; or

(B) an MA-PD plan described in section 1851(a)(2)(A)(i) [*42 USCS § 1395w-21(a)(2)(A)(i)*] that provides--

(i) basic prescription drug coverage; or

(ii) qualified prescription drug coverage that provides supplemental prescription drug coverage so long as there is no MA monthly supplemental beneficiary premium applied under the plan, due to the application of a credit against such premium of a rebate under section 1854(b)(1)(C) [*42 USCS § 1395w-24(b)(1)(C)*].

(b) Flexibility in risk assumed and application of fallback plan. In order to ensure access pursuant to subsection (a) in an area--

(1) the Secretary may approve limited risk plans under section 1860D-11(f) [*42 USCS § 1395w-111(f)*] for the area; and

(2) only if such access is still not provided in the area after applying paragraph (1), the Secretary shall provide for the offering of a fallback prescription drug plan for that area under section 1860D-11(g) [*42 USCS § 1395w-111(g)*].

HISTORY:

(Aug. 4, 1935, ch 531, Title XVIII, Part D, Subpart 1, § 1860D-3, as added Dec. 8, 2003, P.L. 108-173, Title I, § 101(a)(2), 117 Stat. 2081.)

§ 1395w-104. Beneficiary protections for qualified prescription drug coverage

(a) Dissemination of information.

(1) General information.

(A) Application of MA information. A PDP sponsor shall disclose, in a clear, accurate, and standardized form to each enrollee with a prescription drug plan offered by the sponsor under this part [*42 USCS §§ 1395w-101* et seq.] at the time of enrollment and at least annually thereafter, the information described in section 1852(c)(1) [*42 USCS § 1395w-22(c)(1)*] relating to such plan, insofar as the Secretary determines appropriate with respect to benefits provided under this part [*42 USCS §§ 1395w-101* et seq.], and including the information described in subparagraph (B).

(B) Drug specific information. The information described in this subparagraph is information concerning the following:

(i) Access to specific covered part D drugs, including access through pharmacy networks.

(ii) How any formulary (including any tiered formulary structure) used by the sponsor functions, including a description of how a part D eligible individual may obtain information on the formulary consistent with paragraph (3).

(iii) Beneficiary cost-sharing requirements and how a part D eligible individual may obtain information on such requirements, including tiered or other copayment level applicable to each drug (or class of drugs), consistent with paragraph (3).

(iv) The medication therapy management program required under subsection (c).

(2) Disclosure upon request of general coverage, utilization, and grievance information. Upon request of a part D eligible individual who is eligible to enroll in a prescription drug plan, the PDP sponsor offering such plan shall provide information similar (as determined by the Secretary) to the information described in subparagraphs (A), (B), and (C) of section 1852(c)(2) [*42 USCS § 1395w-22(c)(2)*] to such individual.

(3) Provision of specific information.

(A) Response to beneficiary questions. Each PDP sponsor offering a prescription drug plan shall have a mechanism for providing specific information on a timely basis to enrollees upon request. Such mechanism shall include access to information through the use of a toll-free telephone number and, upon request, the provision of such information in writing.

(B) Availability of information on changes in formulary through the internet. A PDP sponsor offering a prescription drug plan shall make available on a timely basis through an Internet website information on specific changes in the formulary under the plan (including changes to tiered or preferred status of covered part D drugs).

(4) Claims information. A PDP sponsor offering a prescription drug plan must furnish to each enrollee in a form easily understandable to such enrollees--

(A) an explanation of benefits (in accordance with section 1806(a) [*42 USCS § 1395b-7(a)*] or in a comparable manner); and

(B) when prescription drug benefits are provided under this part [*42 USCS §§ 1395w-101* et seq.], a notice of the benefits in relation to--

(i) the initial coverage limit for the current year; and

(ii) the annual out-of-pocket threshold for the current year.

Notices under subparagraph (B) need not be provided more often than as specified by the Secretary and notices under subparagraph (B)(ii) shall take into account the application of section 1860D-2(b)(4)(C) [*42 USCS § 1395w-102(b)(4)(C)*] to the extent practicable, as specified by the Secretary.

(b) Access to covered part D drugs.

(1) Assuring pharmacy access.

(A) Participation of any willing pharmacy. A prescription drug plan shall permit the participation of any pharmacy that meets the terms and conditions under the plan.

(B) Discounts allowed for network pharmacies. For covered part D drugs dispensed through in-network pharmacies, a prescription drug plan may, notwithstanding subparagraph (A), reduce coinsurance or copayments for part D eligible individuals enrolled in the plan below the level otherwise required. In no case shall such a reduction result in an increase in payments made by the Secretary under section 1860D-15 [*42 USCS § 1395w-115*] to a plan.

(C) Convenient access for network pharmacies.

(i) In general. The PDP sponsor of the prescription drug plan shall secure the participation in its network of a sufficient number of pharmacies that dispense (other than by mail order) drugs directly to patients to ensure convenient access (consistent with rules established by the Secretary).

(ii) Application of TRICARE standards. The Secretary shall establish rules for convenient access to in-network pharmacies under this subparagraph that are no less favorable to enrollees than the rules for convenient access to pharmacies included in the statement of work of solicitation (#MDA906-03-R-0002) of the Department of Defense under the TRICARE Retail Pharmacy (TRRx) as of March 13, 2003.

(iii) Adequate emergency access. Such rules shall include adequate emergency access for enrollees.

(iv) Convenient access in long-term care facilities. Such rules may include standards with respect to access for enrollees who are residing in long-term care facilities and for pharmacies operated by the Indian Health Service, Indian tribes and tribal organizations, and urban Indian organizations (as defined in section 4 of the Indian Health Care Improvement Act [*25 USCS § 1603*]).

(D) Level playing field. Such a sponsor shall permit enrollees to receive benefits (which may include a 90-day supply of drugs or biologicals) through a pharmacy (other than a mail order pharmacy), with any differential in charge paid by such enrollees.

(E) Not required to accept insurance risk. The terms and conditions under subparagraph (A) may not require participating pharmacies to accept insurance risk as a condition of participation.

(2) Use of standardized technology.

(A) In general. The PDP sponsor of a prescription drug plan shall issue (and reissue, as appropriate) such a card (or other technology) that may be used by an enrollee to assure access to negotiated prices under section 1860D-2(d) [*42 USCS § 1395w-102(d)*].

(B) Standards.

(i) In general. The Secretary shall provide for the development, adoption, or recognition of standards relating to a standardized format for the card or other technology required under subparagraph (A). Such standards shall be compatible with part C of title XI [*42 USCS §§ 1320d* et seq.] and may be based on standards developed by an appropriate standard setting organization.

(ii) Consultation. In developing the standards under clause (i), the Secretary shall consult with the National Council for Prescription Drug Programs and other standard setting organizations determined appropriate by the Secretary.

(iii) Implementation. The Secretary shall develop, adopt, or recognize the standards under clause (i) by such date as the Secretary determines shall be sufficient to ensure that PDP sponsors utilize such standards beginning January 1, 2006.

(3) Requirements on development and application of formularies. If a PDP sponsor of a prescription drug plan uses a formulary (including the use of tiered cost-sharing), the following requirements must be met:

(A) Development and revision by a pharmacy and therapeutic (P&T) committee.

(i) In general. The formulary must be developed and reviewed by a pharmacy and therapeutic committee. A majority of the members of such committee shall consist of individuals who are practicing physicians or practicing pharmacists (or both).

(ii) Inclusion of independent experts. Such committee shall include at least one practicing physician and at least one practicing pharmacist, each of whom--

(I) is independent and free of conflict with respect to the sponsor and plan; and

(II) has expertise in the care of elderly or disabled persons.

(B) Formulary development. In developing and reviewing the formulary, the committee shall--

(i) base clinical decisions on the strength of scientific evidence and standards of practice, including assessing peer-reviewed medical literature, such as randomized clinical trials, pharmacoeconomic studies, outcomes research data, and on such other information as the committee determines to be appropriate; and

(ii) take into account whether including in the formulary (or in a tier in such formulary) particular covered part D drugs has therapeutic advantages in terms of safety and efficacy.

(C) Inclusion of drugs in all therapeutic categories and classes.

(i) In general. Subject to subparagraph (G), the formulary must include drugs within each therapeutic category and class of covered part D drugs, although not necessarily all drugs within such categories and classes.

(ii) Model guidelines. The Secretary shall request the United States Pharmacopeia to develop, in consultation with pharmaceutical benefit managers and other interested parties, a list of categories and classes that may be used by prescription drug plans under this paragraph and to revise such classification from time to time to reflect changes in therapeutic uses of covered part D drugs and the additions of new covered part D drugs.

(iii) Limitation on changes in therapeutic classification. The PDP sponsor of a prescription drug plan may not change the therapeutic categories and classes in a formulary other than at the beginning of each plan year except as the Secretary may permit to take into account new therapeutic uses and newly approved covered part D drugs.

(D) Provider and patient education. The PDP sponsor shall establish policies and procedures to educate and inform health care providers and enrollees concerning the formulary.

(E) Notice before removing drug from formulary or changing preferred or tier status of drug. Any removal of a covered part D drug from a formulary and any change in the preferred or tiered cost-sharing status of such a drug shall take effect only after appropriate notice is made available (such as under subsection (a)(3)) to the Secretary, affected enrollees, physicians, pharmacies, and pharmacists.

(F) Periodic evaluation of protocols. In connection with the formulary, the sponsor of a prescription drug plan shall provide for the periodic evaluation and analysis of treatment protocols and procedures.

The requirements of this paragraph may be met by a PDP sponsor directly or through arrangements with another entity.

(G) Required inclusion of drugs in certain categories and classes.

(i) Identification of drugs in certain categories and classes. Beginning with plan year 2010, the Secretary shall identify, as appropriate, categories and classes of drugs for which both of the following criteria are met:

(I) Restricted access to drugs in the category or class would have major or life threatening clinical consequences for individuals who have a disease or disorder treated by the drugs in such category or class.

(II) There is significant clinical need for such individuals to have access to multiple drugs within a category or class due to unique chemical actions and pharmacological effects of the drugs within the category or class, such as drugs used in the treatment of cancer.

(ii) Formulary requirements. Subject to clause (iii), PDP sponsors offering prescription drug plans shall be required to include all covered part D drugs in the categories and classes identified by the Secretary under clause (i).

(iii) Exceptions. The Secretary may establish exceptions that permits a PDP sponsor of a prescription drug plan to exclude from its formulary a particular covered part D drug in a category or class that is otherwise required to be included in the formulary under clause (ii) (or to otherwise limit access to such a drug, including through prior authorization or utilization management). Any exceptions established under the preceding sentence shall be provided under a process that--

(I) ensures that any exception to such requirement is based upon scientific evidence and medical standards of practice (and, in the case of antiretroviral medications, is consistent with the Department of Health and Human Services Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents); and

(II) includes a public notice and comment period.

(c) Cost and utilization management; quality assurance; medication therapy management program.

(1) In general. The PDP sponsor shall have in place, directly or through appropriate arrangements, with respect to covered part D drugs, the following:

(A) A cost-effective drug utilization management program, including incentives to reduce costs when medically appropriate, such as through the use of multiple source drugs (as defined in section 1927(k)(7)(A)(i) [*42 USCS § 1396r-8(k)(7)(A)(i)*]).

(B) Quality assurance measures and systems to reduce medication errors and adverse drug interactions and improve medication use.

(C) A medication therapy management program described in paragraph (2).

(D) A program to control fraud, abuse, and waste.

Nothing in this section shall be construed as impairing a PDP sponsor from utilizing cost management tools (including differential payments) under all methods of operation.

(2) Medication therapy management program.

(A) Description.

(i) In general. A medication therapy management program described in this paragraph is a program of drug therapy management that may be furnished by a pharmacist and that is designed to assure, with respect to targeted beneficiaries described in clause (ii), that covered part D drugs under the prescription drug plan are appropriately used to optimize therapeutic outcomes through improved medication use, and to reduce the risk of adverse events, including adverse drug interactions. Such a program may distinguish between services in ambulatory and institutional settings.

(ii) Targeted beneficiaries described. Targeted beneficiaries described in this clause are part D eligible individuals who--

(I) have multiple chronic diseases (such as diabetes, asthma, hypertension, hyperlipidemia, and congestive heart failure);

(II) are taking multiple covered part D drugs; and

(III) are identified as likely to incur annual costs for covered part D drugs that exceed a level specified by the Secretary.

(B) Elements. Such program may include elements that promote--

(i) enhanced enrollee understanding to promote the appropriate use of medications by enrollees and to reduce the risk of potential adverse events associated with medications, through beneficiary education, counseling, and other appropriate means;

(ii) increased enrollee adherence with prescription medication regimens through medication refill reminders, special packaging, and other compliance programs and other appropriate means; and

(iii) detection of adverse drug events and patterns of overuse and underuse of prescription drugs.

(C) Development of program in cooperation with licensed pharmacists. Such program shall be developed in cooperation with licensed and practicing pharmacists and physicians.

(D) Coordination with care management plans. The Secretary shall establish guidelines for the coordination of any medication therapy management program under this paragraph with respect to a targeted beneficiary with any care management plan established with respect to such beneficiary under a chronic care improvement program under section 1807 [*42 USCS § 1395b-8*].

(E) Considerations in pharmacy fees. The PDP sponsor of a prescription drug plan shall take into account, in establishing fees for pharmacists and others providing services under such plan, the resources used, and time required to, implement the medication therapy management program under this paragraph. Each such sponsor shall disclose to the Secretary upon request the amount of any such management or dispensing fees. The provisions of section 1927(b)(3)(D) [*42 USCS § 1396r-8(b)(3)(D)*] apply to information disclosed under this subparagraph.

(d) Consumer satisfaction surveys. In order to provide for comparative information under section 1860D-1(c)(3)(A)(v) [*42 USCS § 1395w-101(c)(3)(A)(v)*], the Secretary shall conduct consumer satisfaction surveys with respect to PDP sponsors and prescription drug plans in a manner similar to the manner such surveys are conducted for MA organizations and MA plans under part C [*42 USCS §§ 1395w-21* et seq.].

(e) Electronic prescription program.

(1) Application of standards. As of such date as the Secretary may specify, but not later than 1 year after the date of promulgation of final standards under paragraph (4)(D), prescriptions and other information described in paragraph (2)(A) for covered part D drugs prescribed for part D eligible individuals that are transmitted electronically shall be transmitted only in accordance with such standards under an electronic prescription drug program that meets the requirements of paragraph (2).

(2) Program requirements. Consistent with uniform standards established under paragraph (3)--

(A) Provision of information to prescribing health care professional and dispensing pharmacies and pharmacists. An electronic prescription drug program shall provide for the electronic transmittal to the prescribing health care professional and to the dispensing pharmacy and pharmacist of the prescription and information on eligibility and benefits (including the drugs included in the applicable formulary, any tiered formulary structure, and any requirements for prior authorization) and of the following information with respect to the prescribing and dispensing of a covered part D drug:

(i) Information on the drug being prescribed or dispensed and other drugs listed on the medication history, including information on drug-drug interactions, warnings or cautions, and, when indicated, dosage adjustments.

(ii) Information on the availability of lower cost, therapeutically appropriate alternatives (if any) for the drug prescribed.

(B) Application to medical history information. Effective on and after such date as the Secretary specifies and after the establishment of appropriate standards to carry out this subparagraph, the program shall provide for the electronic

transmittal in a manner similar to the manner under subparagraph (A) of information that relates to the medical history concerning the individual and related to a covered part D drug being prescribed or dispensed, upon request of the professional or pharmacist involved.

(C) Limitations. Information shall only be disclosed under subparagraph (A) or (B) if the disclosure of such information is permitted under the Federal regulations (concerning the privacy of individually identifiable health information) promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996 [*42 USCS § 1320d-2* note].

(D) Timing. To the extent feasible, the information exchanged under this paragraph shall be on an interactive, real-time basis.

(3) Standards.

(A) In general. The Secretary shall provide consistent with this subsection for the promulgation of uniform standards relating to the requirements for electronic prescription drug programs under paragraph (2).

(B) Objectives. Such standards shall be consistent with the objectives of improving--

(i) patient safety;

(ii) the quality of care provided to patients; and

(iii) efficiencies, including cost savings, in the delivery of care.

(C) Design criteria. Such standards shall--

(i) be designed so that, to the extent practicable, the standards do not impose an undue administrative burden on prescribing health care professionals and dispensing pharmacies and pharmacists;

(ii) be compatible with standards established under part C of title XI [*42 USCS §§ 1320d* et seq.], standards established under subsection (b)(2)(B)(i), and with general health information technology standards; and

(iii) be designed so that they permit electronic exchange of drug labeling and drug listing information maintained by the Food and Drug Administration and the National Library of Medicine.

(D) Permitting use of appropriate messaging. Such standards shall allow for the messaging of information only if it relates to the appropriate prescribing of drugs, including quality assurance measures and systems referred to in subsection (c)(1)(B).

(E) Permitting patient designation of dispensing pharmacy.

(i) In general. Consistent with clause (ii), such standards shall permit a part D eligible individual to designate a particular pharmacy to dispense a prescribed drug.

(ii) No change in benefits. Clause (i) shall not be construed as affecting--

(I) the access required to be provided to pharmacies by a prescription drug plan; or

(II) the application of any differences in benefits or payments under such a plan based on the pharmacy dispensing a covered part D drug.

(4) Development, promulgation, and modification of standards.

(A) Initial standards. Not later than September 1, 2005, the Secretary shall develop, adopt, recognize, or modify initial uniform standards relating to the requirements for electronic prescription drug programs described in paragraph (2) taking into consideration the recommendations (if any) from the National Committee on Vital and Health Statistics (as established under section 306(k) of the Public Health Service Act (*42 U.S.C. 242k(k)*)) under subparagraph (B).

(B) Role of NCVHS. The National Committee on Vital and Health Statistics shall develop recommendations for uniform standards relating to such requirements in consultation with the following:

(i) Standard setting organizations (as defined in section 1171(8) [*42 USCS § 1320d(8)*])[.]

(ii) Practicing physicians.

(iii) Hospitals.

(iv) Pharmacies.

(v) Practicing pharmacists.

(vi) Pharmacy benefit managers.

(vii) State boards of pharmacy.

(viii) State boards of medicine.

(ix) Experts on electronic prescribing.

(x) Other appropriate Federal agencies.

(C) Pilot project to test initial standards.

(i) In general. During the 1-year period that begins on January 1, 2006, the Secretary shall conduct a pilot project to test the initial standards developed under subparagraph (A) prior to the promulgation of the final uniform standards under subparagraph (D) in order to provide for the efficient implementation of the requirements described in paragraph (2).

(ii) Exception. Pilot testing of standards is not required under clause (i) where there already is adequate industry experience with such standards, as determined by the Secretary after consultation with effected standard setting organizations and industry users.

(iii) Voluntary participation of physicians and pharmacies. In order to conduct the pilot project under clause (i), the Secretary shall enter into agreements with physicians, physician groups, pharmacies, hospitals, PDP sponsors, MA organizations, and other appropriate entities under which health care professionals electronically transmit prescriptions to dispensing pharmacies and pharmacists in accordance with such standards.

(iv) Evaluation and report.

(I) Evaluation. The Secretary shall conduct an evaluation of the pilot project conducted under clause (i).

(II) Report to Congress. Not later than April 1, 2007, the Secretary shall submit to Congress a report on the evaluation conducted under subclause (I).

(D) Final standards. Based upon the evaluation of the pilot project under subparagraph (C)(iv)(I) and not later than April 1, 2008, the Secretary shall promulgate uniform standards relating to the requirements described in paragraph (2).

(5) Relation to State laws. The standards promulgated under this subsection shall supersede any State law or regulation that--

(A) is contrary to the standards or restricts the ability to carry out this part [*42 USCS §§ 1395w-101* et seq.]; and

(B) pertains to the electronic transmission of medication history and of information on eligibility, benefits, and prescriptions with respect to covered part D drugs under this part [*42 USCS §§ 1395w-101* et seq.].

(6) Establishment of safe harbor. The Secretary, in consultation with the Attorney General, shall promulgate regulations that provide for a safe harbor from sanctions under paragraphs (1) and (2) of section 1128B(b) [*42 USCS § 1320a-7b(b)*] and an exception to the prohibition under subsection (a)(1) of section 1877 [*42 USCS § 1395nn*] with respect to the provision of nonmonetary remuneration (in the form of hardware, software, or information technology and training services) necessary and used solely to receive and transmit electronic prescription information in accordance with the standards promulgated under this subsection--

(A) in the case of a hospital, by the hospital to members of its medical staff;

(B) in the case of a group practice (as defined in section 1877(h)(4) [*42 USCS § 1395nn(h)(4)*]), by the practice to prescribing health care professionals who are members of such practice; and

(C) in the case of a PDP sponsor or MA organization, by the sponsor or organization to pharmacists and pharmacies participating in the network of such sponsor or organization, and to prescribing health care professionals.

(f) Grievance mechanism. Each PDP sponsor shall provide meaningful procedures for hearing and resolving grievances between the sponsor (including any entity or individual through which the sponsor provides covered benefits) and enrollees with prescription drug plans of the sponsor under this part [*42 USCS §§ 1395w-101* et seq.] in accordance with section 1852(f) [*42 USCS § 1395w-22(f)*].

(g) Coverage determinations and reconsiderations.

(1) Application of coverage determination and reconsideration provisions. A PDP sponsor shall meet the requirements of paragraphs (1) through (3) of section 1852(g) [*42 USCS § 1395w-22(g)*] with respect to covered benefits under the prescription drug plan it offers under this part [*42 USCS §§ 1395w-101* et seq.] in the same manner as such requirements apply to an MA organization with respect to benefits it offers under an MA plan under part C [*42 USCS §§ 1395w-21* et seq.].

(2) Request for a determination for the treatment of tiered formulary drug. In the case of a prescription drug plan offered by a PDP sponsor that provides for tiered cost-sharing for drugs included within a formulary and provides lower cost-sharing for preferred drugs included within the formulary, a part D eligible individual who is enrolled in the plan may request an exception to the tiered cost-sharing structure. Under such an exception, a nonpreferred drug could be covered under the terms applicable for preferred drugs if the prescribing physician determines that the preferred drug for treatment of the same condition either would not be as effective for the individual or would have adverse effects for the individual or both. A PDP sponsor shall have an exceptions process under this paragraph consistent with guidelines established by the Secretary for making a determination with respect to such a request. Denial of such an exception shall be treated as a coverage denial for purposes of applying subsection (h).

(h) Appeals.

(1) In general. Subject to paragraph (2), a PDP sponsor shall meet the requirements of paragraphs (4) and (5) of section 1852(g) [*42 USCS § 1395w-22(g)*] with respect to benefits (including a determination related to the application of tiered cost-sharing described in subsection (g)(2)) in a manner similar (as determined by the Secretary) to the manner such requirements apply to an MA organization with respect to benefits under the original medicare fee-for-service

program option it offers under an MA plan under part C [*42 USCS §§ 1395w-21* et seq.]. In applying this paragraph only the part D eligible individual shall be entitled to bring such an appeal.

(2) Limitation in cases on nonformulary determinations. A part D eligible individual who is enrolled in a prescription drug plan offered by a PDP sponsor may appeal under paragraph (1) a determination not to provide for coverage of a covered part D drug that is not on the formulary under the plan only if the prescribing physician determines that all covered part D drugs on any tier of the formulary for treatment of the same condition would not be as effective for the individual as the nonformulary drug, would have adverse effects for the individual, or both.

(3) Treatment of nonformulary determinations. If a PDP sponsor determines that a plan provides coverage for a covered part D drug that is not on the formulary of the plan, the drug shall be treated as being included on the formulary for purposes of section 1860D-2(b)(4)(C)(i) [*42 USCS § 1395w-102(b)(4)(C)(i)*].

(i) Privacy, confidentiality, and accuracy of enrollee records. The provisions of section 1852(h) [*42 USCS § 1395w-22(h)*] shall apply to a PDP sponsor and prescription drug plan in the same manner as it applies to an MA organization and an MA plan.

(j) Treatment of accreditation. Subparagraph (A) of section 1852(e)(4) [*42 USCS § 1395w-22(e)(4)*] (relating to treatment of accreditation) shall apply to a PDP sponsor under this part [*42 USCS §§ 1395w-101* et seq.] with respect to the following requirements, in the same manner as it applies to an MA organization with respect to the requirements in subparagraph (B) (other than clause (vii) thereof) of such section:

(1) Subsection (b) of this section (relating to access to covered part D drugs).

(2) Subsection (c) of this section (including quality assurance and medication therapy management).

(3) Subsection (i) of this section (relating to confidentiality and accuracy of enrollee records).

(k) Public disclosure of pharmaceutical prices for equivalent drugs.

(1) In general. A PDP sponsor offering a prescription drug plan shall provide that each pharmacy that dispenses a covered part D drug shall inform an enrollee of any differential between the price of the drug to the enrollee and the price of the lowest priced generic covered part D drug under the plan that is therapeutically equivalent and bioequivalent and available at such pharmacy.

(2) Timing of notice.

(A) In general. Subject to subparagraph (B), the information under paragraph (1) shall be provided at the time of purchase of the drug involved, or, in the case of dispensing by mail order, at the time of delivery of such drug.

(B) Waiver. The Secretary may waive subparagraph (A) in such circumstances as the Secretary may specify.

(l) Requirements with respect to sales and marketing activities. The following provisions shall apply to a PDP sponsor (and the agents, brokers, and other third parties representing such sponsor) in the same manner as such provisions apply to a Medicare Advantage organization (and the agents, brokers, and other third parties representing such organization):

(1) **[Caution: This paragraph applies to plan years beginning on or after January 1, 2009, as provided by § 103(a)(3) of Act July 15, 2008, P.L. 110-275, which appears as *42 USCS § 1395w-21* note.]** The prohibition under section 1851(h)(4)(C) [*42 USCS § 1395w-21(h)(4)(C)*] on conducting activities described in section 1851(j)(1) [*42 USCS § 1395w-21(j)(1)*].

(2) **[Caution: This paragraph shall take effect on a date specified by the Secretary (but in no case later than November 15, 2008), as provided by § 103(b)(3) of Act July 15, 2008, P.L. 110-275, which appears as *42 USCS § 1395w-21* note.]** The requirement under section 1851(h)(4)(D) [*42 USCS § 1395w-21(h)(4)(D)*] to conduct activities described in section 1851(j)(2) [*42 USCS § 1395w-21(j)(2)*] in accordance with the limitations established under such subsection.

(3) The inclusion of the plan type in the plan name under section 1851(h)(6) [*42 USCS § 1395w-21(h)(6)*].

(4) **[Caution: This paragraph applies to plan years beginning on or after January 1, 2009, as provided by § 103(d)(3) of Act July 15, 2008, P.L. 110-275, which appears as *42 USCS § 1395w-21* note.]** The requirements regarding the appointment of agents and brokers and compliance with State information requests under subparagraphs (A) and (B), respectively, of section 1851(h)(7) [*42 USCS § 1395w-21(h)(7)*].

HISTORY:

(Aug. 4, 1935, ch 531, Title XVIII, Part D, Subpart 1, § 1860D-4, as added Dec. 8, 2003, P.L. 108-173, Title I, § 101(a)(2), 117 Stat. 2082.)

(As amended July 15, 2008, P.L. 110-275, Title I, Subtitle A, Part I, § 103(a)(2), (b)(2), (c)(2), (d)(2), Subtitle E, Part II, § 176, 122 Stat. 2499, 2500, 2501, 2581.)

§ 1395w-111. PDP regions; submission of bids; plan approval

(a) Establishment of PDP regions; service areas.

(1) Coverage of entire PDP region. The service area for a prescription drug plan shall consist of an entire PDP region established under paragraph (2).

(2) Establishment of PDP regions.

(A) In general. The Secretary shall establish, and may revise, PDP regions in a manner that is consistent with the requirements for the establishment and revision of MA regions under subparagraphs (B) and (C) of section 1858(a)(2) [*42 USCS § 1395w-27a(a)(2)*].

(B) Relation to MA regions. To the extent practicable, PDP regions shall be the same as MA regions under section 1858(a)(2) [*42 USCS § 1395w-27a(a)(2)*]. The Secretary may establish PDP regions which are not the same as MA regions if the Secretary determines that the establishment of different regions under this part [*42 USCS §§ 1395w-101* et seq.] would improve access to benefits under this part [*42 USCS §§ 1395w-101* et seq.].

(C) Authority for territories. The Secretary shall establish, and may revise, PDP regions for areas in States that are not within the 50 States or the District of Columbia.

(3) National plan. Nothing in this subsection shall be construed as preventing a prescription drug plan from being offered in more than one PDP region (including all PDP regions).

(b) Submission of bids, premiums, and related information.

(1) In general. A PDP sponsor shall submit to the Secretary information described in paragraph (2) with respect to each prescription drug plan it offers. Such information shall be submitted at the same time and in a similar manner to the manner in which information described in paragraph (6) of section 1854(a) [*42 USCS § 1395w-24(a)*] is submitted by an MA organization under paragraph (1) of such section.

(2) Information described. The information described in this paragraph is information on the following:

(A) Coverage provided. The prescription drug coverage provided under the plan, including the deductible and other cost-sharing.

(B) Actuarial value. The actuarial value of the qualified prescription drug coverage in the region for a part D eligible individual with a national average risk profile for the factors described in section 1860D-15(c)(1)(A) [*42 USCS § 1395w-115(c)(1)(A)*] (as specified by the Secretary).

(C) Bid. Information on the bid, including an actuarial certification of--

(i) the basis for the actuarial value described in subparagraph (B) assumed in such bid;

(ii) the portion of such bid attributable to basic prescription drug coverage and, if applicable, the portion of such bid attributable to supplemental benefits;

(iii) assumptions regarding the reinsurance subsidy payments provided under section 1860D-15(b) [*42 USCS § 1395w-115(b)*] subtracted from the actuarial value to produce such bid; and

(iv) administrative expenses assumed in the bid.

(D) Service area. The service area for the plan.

(E) Level of risk assumed.

(i) In general. Whether the PDP sponsor requires a modification of risk level under clause (ii) and, if so, the extent of such modification. Any such modification shall apply with respect to all prescription drug plans offered by a PDP sponsor in a PDP region. This subparagraph shall not apply to an MA-PD plan.

(ii) Risk levels described. A modification of risk level under this clause may consist of one or more of the following:

(I) Increase in Federal percentage assumed in initial risk corridor. An equal percentage point increase in the percents applied under subparagraphs (B)(i), (B)(ii)(I), (C)(i), and (C)(ii)(I) of section 1860D-15(e)(2) [*42 USCS § 1395w-115(e)(2)*]. In no case shall the application of previous sentence prevent the application of a higher percentage under section 1869D-15(e)(2)(B)(iii) [1860D-15(e)(2)(B)(iii)] [*42 USCS § 1395w-115(e)(2)(B)(iii)*].

(II) Increase in Federal percentage assumed in second risk corridor. An equal percentage point increase in the percents applied under subparagraphs (B)(ii)(II) and (C)(ii)(II) of section 1860D-15(e)(2) [*42 USCS § 1395w-115(e)(2)*].

(III) Decrease in size of risk corridors. A decrease in the threshold risk percentages specified in section 1860D-15(e)(3)(C) [*42 USCS § 1395w-115(e)(3)(C)*].

(F) Additional information. Such other information as the Secretary may require to carry out this part [*42 USCS §§ 1395w-101* et seq.].

(3) Paperwork reduction for offering of prescription drug plans nationally or in multi-region areas. The Secretary shall establish requirements for information submission under this subsection in a manner that promotes the offering of such plans in more than one PDP region (including all regions) through the filing of consolidated information.

(c) Actuarial valuation.

(1) Processes. For purposes of this part [*42 USCS §§ 1395w-101* et seq.], the Secretary shall establish processes and methods for determining the actuarial valuation of prescription drug coverage, including--

(A) an actuarial valuation of standard prescription drug coverage under section 1860D-2(b) [*42 USCS § 1395w-102(b)*];

(B) actuarial valuations relating to alternative prescription drug coverage under section 1860D-2(c)(1) [*42 USCS § 1395w-102(c)(1)*];

(C) an actuarial valuation of the reinsurance subsidy payments under section 1860D-15(b) [*42 USCS § 1395w-115(b)*];

(D) the use of generally accepted actuarial principles and methodologies; and

(E) applying the same methodology for determinations of actuarial valuations under subparagraphs (A) and (B).

(2) Accounting for drug utilization. Such processes and methods for determining actuarial valuation shall take into account the effect that providing alternative prescription drug coverage (rather than standard prescription drug coverage) has on drug utilization.

(3) Responsibilities.

(A) Plan responsibilities. PDP sponsors and MA organizations are responsible for the preparation and submission of actuarial valuations required under this part [*42 USCS §§ 1395w-101* et seq.] for prescription drug plans and MA-PD plans they offer.

(B) Use of outside actuaries. Under the processes and methods established under paragraph (1), PDP sponsors offering prescription drug plans and MA organizations offering MA-PD plans may use actuarial opinions certified by independent, qualified actuaries to establish actuarial values.

(d) Review of information and negotiation.

(1) Review of information. The Secretary shall review the information filed under subsection (b) for the purpose of conducting negotiations under paragraph (2).

(2) Negotiation regarding terms and conditions. Subject to subsection (i), in exercising the authority under paragraph (1), the Secretary--

(A) has the authority to negotiate the terms and conditions of the proposed bid submitted and other terms and conditions of a proposed plan; and

(B) has authority similar to the authority of the Director of the Office of Personnel Management with respect to health benefits plans under chapter 89 of title 5, United States Code [*5 USCS §§ 8901* et seq.].

(e) Approval of proposed plans.

(1) In general. After review and negotiation under subsection (d), the Secretary shall approve or disapprove the prescription drug plan.

(2) Requirements for approval. The Secretary may approve a prescription drug plan only if the following requirements are met:

(A) Compliance with requirements. The plan and the PDP sponsor offering the plan comply with the requirements under this part [*42 USCS §§ 1395w-101* et seq.], including the provision of qualified prescription drug coverage.

(B) Actuarial determinations. The Secretary determines that the plan and PDP sponsor meet the requirements under this part [*42 USCS §§ 1395w-101* et seq.] relating to actuarial determinations, including such requirements under section 1860D-2(c) [*42 USCS § 1395w-102(c)*].

(C) Application of FEHBP standard.

(i) In general. The Secretary determines that the portion of the bid submitted under subsection (b) that is attributable to basic prescription drug coverage is supported by the actuarial bases provided under such subsection and reasonably and equitably reflects the revenue requirements (as used for purposes of section 1302(8)(C) of the Public Health Service Act [*42 USCS § 300e-1(8)(C)*]) for benefits provided under that plan, less the sum (determined on a monthly per capita basis) of the actuarial value of the reinsurance payments under section 1860D-15(b) [*42 USCS § 1395w-115(b)*].

(ii) Supplemental coverage. The Secretary determines that the portion of the bid submitted under subsection (b) that is attributable to supplemental prescription drug coverage pursuant to section 1860D-2(a)(2) [*42 USCS § 1395w-102(a)(2)*] is supported by the actuarial bases provided under such subsection and reasonably and equitably reflects the revenue requirements (as used for purposes of section 1302(8)(C) of the Public Health Service Act [*42 USCS § 300e-1(8)(C)*]) for such coverage under the plan.

(D) Plan design.

(i) In general. The Secretary does not find that the design of the plan and its benefits (including any formulary and tiered formulary structure) are likely to substantially discourage enrollment by certain part D eligible individuals under the plan.

(ii) Use of categories and classes in formularies. The Secretary may not find that the design of categories and classes within a formulary violates clause (i) if such categories and classes are consistent with guidelines (if any) for such categories and classes established by the United States Pharmacopeia.

(f) Application of limited risk plans.

(1) Conditions for approval of limited risk plans. The Secretary may only approve a limited risk plan (as defined in paragraph (4)(A)) for a PDP region if the access requirements under section 1860D-3(a) [*42 USCS § 1395w-103(a)*] would not be met for the region but for the approval of such a plan (or a fallback prescription drug plan under subsection (g)).

(2) Rules. The following rules shall apply with respect to the approval of a limited risk plan in a PDP region:

(A) Limited exercise of authority. Only the minimum number of such plans may be approved in order to meet the access requirements under section 1860D-3(a) [*42 USCS § 1395w-103(a)*].

(B) Maximizing assumption of risk. The Secretary shall provide priority in approval for those plans bearing the highest level of risk (as computed by the Secretary), but the Secretary may take into account the level of the bids submitted by such plans.

(C) No full underwriting for limited risk plans. In no case may the Secretary approve a limited risk plan under which the modification of risk level provides for no (or a de minimis) level of financial risk.

(3) Acceptance of all full risk contracts. There shall be no limit on the number of full risk plans that are approved under subsection (e).

(4) Risk-plans defined. For purposes of this subsection:

(A) Limited risk plan. The term "limited risk plan" means a prescription drug plan that provides basic prescription drug coverage and for which the PDP sponsor includes a modification of risk level described in subparagraph (E) of subsection (b)(2) in its bid submitted for the plan under such subsection. Such term does not include a fallback prescription drug plan.

(B) Full risk plan. The term "full risk plan" means a prescription drug plan that is not a limited risk plan or a fallback prescription drug plan.

(g) Guaranteeing access to coverage.

(1) Solicitation of bids.

(A) In general. Separate from the bidding process under subsection (b), the Secretary shall provide for a process for the solicitation of bids from eligible fallback entities (as defined in paragraph (2)) for the offering in all fallback service areas (as defined in paragraph (3)) in one or more PDP regions of a fallback prescription drug plan (as defined in paragraph (4)) during the contract period specified in paragraph (5).

(B) Acceptance of bids.

(i) In general. Except as provided in this subparagraph, the provisions of subsection (e) shall apply with respect to the approval or disapproval of fallback prescription drug plans. The Secretary shall enter into contracts under this subsection with eligible fallback entities for the offering of fallback prescription drug plans so approved in fallback service areas.

(ii) Limitation of 1 plan for all fallback service areas in a PDP region. With respect to all fallback service areas in any PDP region for a contract period, the Secretary shall approve the offering of only 1 fallback prescription drug plan.

(iii) Competitive procedures. Competitive procedures (as defined in section 4(5) of the Office of Federal Procurement Policy Act (*41 U.S.C. 403(5)*)) shall be used to enter into a contract under this subsection. The provisions of subsection (d) of section 1874A [*42 USCS § 1395kk-1*] shall apply to a contract under this section in the same manner as they apply to a contract under such section.

(iv) Timing. The Secretary shall approve a fallback prescription drug plan for a PDP region in a manner so that, if there are any fallback service areas in the region for a year, the fallback prescription drug plan is offered at the same time as prescription drug plans would otherwise be offered.

(v) No national fallback plan. The Secretary shall not enter into a contract with a single fallback entity for the offering of fallback plans throughout the United States.

(2) Eligible fallback entity. For purposes of this section, the term "eligible fallback entity" means, with respect to all fallback service areas in a PDP region for a contract period, an entity that--

(A) meets the requirements to be a PDP sponsor (or would meet such requirements but for the fact that the entity is not a risk-bearing entity); and

(B) does not submit a bid under section 1860D-11(b) [*42 USCS § 1395w-111(b)*] for any prescription drug plan for any PDP region for the first year of such contract period.

For purposes of subparagraph (B), an entity shall be treated as submitting a bid with respect to a prescription drug plan if the entity is acting as a subcontractor of a PDP sponsor that is offering such a plan. The previous sentence shall not apply to entities that are subcontractors of an MA organization except insofar as such organization is acting as a PDP sponsor with respect to a prescription drug plan.

(3) Fallback service area. For purposes of this subsection, the term "fallback service area" means, for a PDP region with respect to a year, any area within such region for which the Secretary determines before the beginning of the year that the access requirements of the first sentence of section 1860D-3(a) [*42 USCS § 1395w-103(a)*] will not be met for part D eligible individuals residing in the area for the year.

(4) Fallback prescription drug plan. For purposes of this part [*42 USCS §§ 1395w-101* et seq.], the term "fallback prescription drug plan" means a prescription drug plan that--

(A) only offers the standard prescription drug coverage and access to negotiated prices described in section 1860D-2(a)(1)(A) [*42 USCS § 1395w-102(a)(1)(A)*] and does not include any supplemental prescription drug coverage; and

(B) meets such other requirements as the Secretary may specify.

(5) Payments under the contract.

(A) In general. A contract entered into under this subsection shall provide for--

(i) payment for the actual costs (taking into account negotiated price concessions described in section 1860D-2(d)(1)(B) [*42 USCS § 1395w-102(d)(1)(B)*]) of covered part D drugs provided to part D eligible individuals enrolled in a fallback prescription drug plan offered by the entity; and

(ii) payment of management fees that are tied to performance measures established by the Secretary for the management, administration, and delivery of the benefits under the contract.

(B) Performance measures. The performance measures established by the Secretary pursuant to subparagraph (A)(ii) shall include at least measures for each of the following:

(i) Costs. The entity contains costs to the Medicare Prescription Drug Account and to part D eligible individuals enrolled in a fallback prescription drug plan offered by the entity through mechanisms such as generic substitution and price discounts.

(ii) Quality programs. The entity provides such enrollees with quality programs that avoid adverse drug reactions and overutilization and reduce medical errors.

(iii) Customer service. The entity provides timely and accurate delivery of services and pharmacy and beneficiary support services.

(iv) Benefit administration and claims adjudication. The entity provides efficient and effective benefit administration and claims adjudication.

(6) Monthly beneficiary premium. Except as provided in section 1860D-13(b) [*42 USCS § 1395w-113(b)*] (relating to late enrollment penalty) and subject to section 1860D-14 [*42 USCS § 1395w-114*] (relating to low-income assistance), the monthly beneficiary premium to be charged under a fallback prescription drug plan offered in all fallback service areas in a PDP region shall be uniform and shall be equal to 25.5 percent of an amount equal to the Secretary's estimate of the average monthly per capita actuarial cost, including administrative expenses, under the fallback prescription drug plan of providing coverage in the region, as calculated by the Chief Actuary of the Centers for Medicare & Medicaid Services. In calculating such administrative expenses, the Chief Actuary shall use a factor that is based on similar expenses of prescription drug plans that are not fallback prescription drug plans.

(7) General contract terms and conditions.

(A) In general. Except as may be appropriate to carry out this section, the terms and conditions of contracts with eligible fallback entities offering fallback prescription drug plans under this subsection shall be the same as the terms and conditions of contracts under this part [*42 USCS §§ 1395w-101* et seq.] for prescription drug plans.

(B) Period of contract.

(i) In general. Subject to clause (ii), a contract approved for a fallback prescription drug plan for fallback service areas for a PDP region under this section shall be for a period of 3 years (except as may be renewed after a subsequent bidding process).

(ii) Limitation. A fallback prescription drug plan may be offered under a contract in an area for a year only if that area is a fallback service area for that year.

(C) Entity not permitted to market or brand fallback prescription drug plans. An eligible fallback entity with a contract under this subsection may not engage in any marketing or branding of a fallback prescription drug plan.

(h) Annual report on use of limited risk plans and fallback plans. The Secretary shall submit to Congress an annual report that describes instances in which limited risk plans and fallback prescription drug plans were offered under

subsections (f) and (g). The Secretary shall include in such report such recommendations as may be appropriate to limit the need for the provision of such plans and to maximize the assumption of financial risk under section subsection (f).

(i) Noninterference. In order to promote competition under this part [*42 USCS §§ 1395w-101* et seq.] and in carrying out this part [*42 USCS §§ 1395w-101* et seq.], the Secretary--

(1) may not interfere with the negotiations between drug manufacturers and pharmacies and PDP sponsors; and

(2) may not require a particular formulary or institute a price structure for the reimbursement of covered part D drugs.

(j) Coordination of benefits. A PDP sponsor offering a prescription drug plan shall permit State Pharmaceutical Assistance Programs and Rx plans under sections 1860D-23 and 1860D-24 [*42 USCS §§ 1395w-133* and *1395w-134*] to coordinate benefits with the plan and, in connection with such coordination with such a Program, not to impose fees that are unrelated to the cost of coordination.

HISTORY:

(Aug. 4, 1935, ch 531, Title XVIII, Part D, Subpart 2, § 1860D-11, as added Dec. 8, 2003, P.L. 108-173, Title I, § 101(a)(2), 117 Stat. 2092.)

§ 1395w-112. Requirements for and contracts with prescription drug plan (PDP) sponsors

(a) General requirements. Each PDP sponsor of a prescription drug plan shall meet the following requirements:

(1) Licensure. Subject to subsection (c), the sponsor is organized and licensed under State law as a risk-bearing entity eligible to offer health insurance or health benefits coverage in each State in which it offers a prescription drug plan.

(2) Assumption of financial risk for unsubsidized coverage.

(A) In general. Subject to subparagraph (B), to the extent that the entity is at risk the entity assumes financial risk on a prospective basis for benefits that it offers under a prescription drug plan and that is not covered under section 1860D-15(b) [*42 USCS § 1395w-115(b)*].

(B) Reinsurance permitted. The plan sponsor may obtain insurance or make other arrangements for the cost of coverage provided to any enrollee to the extent that the sponsor is at risk for providing such coverage.

(3) Solvency for unlicensed sponsors. In the case of a PDP sponsor that is not described in paragraph (1) and for which a waiver has been approved under subsection (c), such sponsor shall meet solvency standards established by the Secretary under subsection (d).

(b) Contract requirements.

(1) In general. The Secretary shall not permit the enrollment under section 1860D-1 [*42 USCS § 1395w-101*] in a prescription drug plan offered by a PDP sponsor under this part [*42 USCS §§ 1395w-101* et seq.], and the sponsor shall not be eligible for payments under section 1860D-14 or 1860D-15 [*42 USCS § 1395w-114* or *1395w-115*], unless the Secretary has entered into a contract under this subsection with the sponsor with respect to the offering of such plan. Such a contract with a sponsor may cover more than one prescription drug plan. Such contract shall provide that the sponsor agrees to comply with the applicable requirements and standards of this part [*42 USCS §§ 1395w-101* et seq.] and the terms and conditions of payment as provided for in this part [*42 USCS §§ 1395w-101* et seq.].

(2) Limitation on entities offering fallback prescription drug plans. The Secretary shall not enter into a contract with a PDP sponsor for the offering of a prescription drug plan (other than a fallback prescription drug plan) in a PDP region for a year if the sponsor--

(A) submitted a bid under section 1860D-11(g) [*42 USCS § 1395w-111(g)*] for such year (as the first year of a contract period under such section) to offer a fallback prescription drug plan in any PDP region;

(B) offers a fallback prescription drug plan in any PDP region during the year; or

(C) offered a fallback prescription drug plan in that PDP region during the previous year.

For purposes of this paragraph, an entity shall be treated as submitting a bid with respect to a prescription drug plan or offering a fallback prescription drug plan if the entity is acting as a subcontractor of a PDP sponsor that is offering such a plan. The previous sentence shall not apply to entities that are subcontractors of an MA organization except insofar as such organization is acting as a PDP sponsor with respect to a prescription drug plan.

(3) Incorporation of certain medicare advantage contract requirements. Except as otherwise provided, the following provisions of section 1857 [*42 USCS § 1395w-27*] shall apply to contracts under this section in the same manner as they apply to contracts under section 1857(a) [*42 USCS § 1395w-27(a)*]:

(A) Minimum enrollment. Paragraphs (1) and (3) of section 1857(b) [*42 USCS § 1395w-27(b)*], except that--

(i) the Secretary may increase the minimum number of enrollees required under such paragraph (1) as the Secretary determines appropriate; and

(ii) the requirement of such paragraph (1) shall be waived during the first contract year with respect to an organization in a region.

(B) Contract period and effectiveness. Section 1857(c) [*42 USCS § 1395w-27(c)*], except that in applying paragraph (4)(B) of such section any reference to payment amounts under section 1853 [*42 USCS § 1395w-23*] shall be deemed payment amounts under section 1860D-15 [*42 USCS § 1395w-115*].

(C) Protections against fraud and beneficiary protections. Section 1857(d) [*42 USCS § 1395w-27(d)*].

(D) Additional contract terms. Section 1857(e) [*42 USCS § 1395w-27(e)*]; except that section 1857(e)(2) [*42 USCS § 1395w-27(e)(2)*] shall apply as specified to PDP sponsors and payments under this part [*42 USCS §§ 1395w-101* et seq.] to an MA-PD plan shall be treated as expenditures made under part D [*42 USCS §§ 1395w-101* et seq.]. Notwithstanding any other provision of law, information provided to the Secretary under the application of section 1857(e)(1) [*42 USCS § 1395w-27(e)(1)*] to contracts under this section under the preceding sentence--

(i) may be used for the purposes of carrying out this part, improving public health through research on the utilization, safety, effectiveness, quality, and efficiency of health care services (as the Secretary determines appropriate); and

(ii) shall be made available to Congressional support agencies (in accordance with their obligations to support Congress as set out in their authorizing statutes) for the purposes of conducting Congressional oversight, monitoring, making recommendations, and analysis of the program under this *title [42 USCS §§ 1395* et seq.].

(E) Intermediate sanctions. Section 1857(g) [*42 USCS § 1395w-27(g)*] (other than paragraph (1)(F) of such section), except that in applying such section the reference in section 1857(g)(1)(B) [*42 USCS § 1395w-27(g)(1)(B)*] to *section 1854* [*42 USCS § 1395w-24*] is deemed a reference to this part [*42 USCS §§ 1395w-101* et seq.].

(F) Procedures for termination. Section 1857(h) [*42 USCS § 1395w-27(h)*].

(4) Prompt payment of clean claims **[Caution: This paragraph applies to plan years beginning on or after January 1, 2010, as provided by § 171(c) of Act July 15, 2008, P.L. 110-275, which appears as *42 USCS § 1395w-27* note.]**.

(A) Prompt payment.

(i) In general. Each contract entered into with a PDP sponsor under this part with respect to a prescription drug plan offered by such sponsor shall provide that payment shall be issued, mailed, or otherwise transmitted with respect to all clean claims submitted by pharmacies (other than pharmacies that dispense drugs by mail order only or are located in, or contract with, a long-term care facility) under this part within the applicable number of calendar days after the date on which the claim is received.

(ii) Clean claim defined. In this paragraph, the term "clean claim" means a claim that has no defect or impropriety (including any lack of any required substantiating documentation) or particular circumstance requiring special treatment that prevents timely payment from being made on the claim under this part.

(iii) Date of receipt of claim. In this paragraph, a claim is considered to have been received--

(I) with respect to claims submitted electronically, on the date on which the claim is transferred; and

(II) with respect to claims submitted otherwise, on the 5th day after the postmark date of the claim or the date specified in the time stamp of the transmission.

(B) Applicable number of calendar days defined. In this paragraph, the term "applicable number of calendar days" means--

(i) with respect to claims submitted electronically, 14 days; and

(ii) with respect to claims submitted otherwise, 30 days.

(C) Interest payment.

(i) In general. Subject to clause (ii), if payment is not issued, mailed, or otherwise transmitted within the applicable number of calendar days (as defined in subparagraph (B)) after a clean claim is received, the PDP sponsor shall pay interest to the pharmacy that submitted the claim at a rate equal to the weighted average of interest on 3-month marketable Treasury securities determined for such period, increased by 0.1 percentage point for the period beginning on the day after the required payment date and ending on the date on which payment is made (as determined under subparagraph (D)(iv)). Interest amounts paid under this subparagraph shall not be counted against the administrative costs of a prescription drug plan or treated as allowable risk corridor costs under section 1860D-15(e) [*42 USCS § 1395w-115(e)*].

(ii) Authority not to charge interest. The Secretary may provide that a PDP sponsor is not charged interest under clause (i) in the case where there are exigent circumstances, including natural disasters and other unique and unexpected events, that prevent the timely processing of claims.

(D) Procedures involving claims.

(i) Claim deemed to be clean. A claim is deemed to be a clean claim if the PDP sponsor involved does not provide notice to the claimant of any deficiency in the claim--

(I) with respect to claims submitted electronically, within 10 days after the date on which the claim is received; and

(II) with respect to claims submitted otherwise, within 15 days after the date on which the claim is received.

(ii) Claim determined to not be a clean claim.

(I) In general. If a PDP sponsor determines that a submitted claim is not a clean claim, the PDP sponsor shall, not later than the end of the period described in clause (i), notify the claimant of such determination. Such notification shall specify all defects or improprieties in the claim and shall list all additional information or documents necessary for the proper processing and payment of the claim.

(II) Determination after submission of additional information. A claim is deemed to be a clean claim under this paragraph if the PDP sponsor involved does not provide notice to the claimant of any defect or impropriety in the claim within 10 days of the date on which additional information is received under subclause (I).

(iii) Obligation to pay. A claim submitted to a PDP sponsor that is not paid or contested by the sponsor within the applicable number of days (as defined in subparagraph (B)) after the date on which the claim is received shall be deemed to be a clean claim and shall be paid by the PDP sponsor in accordance with subparagraph (A).

(iv) Date of payment of claim. Payment of a clean claim under such subparagraph is considered to have been made on the date on which--

(I) with respect to claims paid electronically, the payment is transferred; and

(II) with respect to claims paid otherwise, the payment is submitted to the United States Postal Service or common carrier for delivery.

(E) Electronic transfer of funds. A PDP sponsor shall pay all clean claims submitted electronically by electronic transfer of funds if the pharmacy so requests or has so requested previously. In the case where such payment is made electronically, remittance may be made by the PDP sponsor electronically as well.

(F) Protecting the rights of claimants.

(i) In general. Nothing in this paragraph shall be construed to prohibit or limit a claim or action not covered by the subject matter of this section that any individual or organization has against a provider or a PDP sponsor.

(ii) Anti-retaliation. Consistent with applicable Federal or State law, a PDP sponsor shall not retaliate against an individual or provider for exercising a right of action under this subparagraph.

(G) Rule of construction. A determination under this paragraph that a claim submitted by a pharmacy is a clean claim shall not be construed as a positive determination regarding eligibility for payment under this title, nor is it an indication of government approval of, or acquiescence regarding, the claim submitted. The determination shall not relieve any party of civil or criminal liability with respect to the claim, nor does it offer a defense to any administrative, civil, or criminal action with respect to the claim.

(5) Submission of claims by pharmacies located in or contracting with long-term care facilities **[Caution: This paragraph applies to plan years beginning on or after January 1, 2010, as provided by § 172(b) of Act July 15, 2008, P.L. 110-275, which appears as *42 USCS § 1395w-27* note.]**. Each contract entered into with a PDP sponsor under this part with respect to a prescription drug plan offered by such sponsor shall provide that a pharmacy located in, or having a contract with, a long-term care facility shall have not less than 30 days (but not more than 90 days) to submit claims to the sponsor for reimbursement under the plan.

(6) Regular update of prescription drug pricing standard. If the PDP sponsor of a prescription drug plan uses a standard for reimbursement of pharmacies based on the cost of a drug, each contract entered into with such sponsor under this part with respect to the plan shall provide that the sponsor shall update such standard not less frequently than once every 7 days, beginning with an initial update on January 1 of each year, to accurately reflect the market price of acquiring the drug.

(c) Waiver of certain requirements to expand choice.

(1) Authorizing waiver.

(A) In general. In the case of an entity that seeks to offer a prescription drug plan in a State, the Secretary shall waive the requirement of subsection (a)(1) that the entity be licensed in that State if the Secretary determines, based on the application and other evidence presented to the Secretary, that any of the grounds for approval of the application described in paragraph (2) have been met.

(B) Application of regional plan waiver rule. In addition to the waiver available under subparagraph (A), the provisions of section 1858(d) [*42 USCS § 1395w-27a(d)*] shall apply to PDP sponsors under this part [*42 USCS §§ 1395w-101* et seq.] in a manner similar to the manner in which such provisions apply to MA organizations under part C [*42 USCS §§ 1395w-21* et seq.], except that no application shall be required under paragraph (1)(B) of such section in the case of a State that does not provide a licensing process for such a sponsor.

(2) Grounds for approval.

(A) In general. The grounds for approval under this paragraph are--

(i) subject to subparagraph (B), the grounds for approval described in subparagraphs (B), (C), and (D) of section 1855(a)(2) [*42 USCS § 1395w-25(a)(2)*]; and

(ii) the application by a State of any grounds other than those required under Federal law.

(B) Special rules. In applying subparagraph (A)(i)--

(i) the ground of approval described in section 1855(a)(2)(B) [*42 USCS § 1395w-25(a)(2)(B)*] is deemed to have been met if the State does not have a licensing process in effect with respect to the PDP sponsor; and

(ii) for plan years beginning before January 1, 2008, if the State does have such a licensing process in effect, such ground for approval described in such section is deemed to have been met upon submission of an application described in such section.

(3) Application of waiver procedures. With respect to an application for a waiver (or a waiver granted) under paragraph (1)(A) of this subsection, the provisions of subparagraphs (E), (F), and (G) of section 1855(a)(2) [*42 USCS § 1395w-25(a)(2)*] shall apply, except that clauses (i) and (ii) of such subparagraph (E) shall not apply in the case of a State that does not have a licensing process described in paragraph (2)(B)(i) in effect.

(4) References to certain provisions. In applying provisions of section 1855(a)(2) [*42 USCS § 1395w-25(a)(2)*] under paragraphs (2) and (3) of this subsection to prescription drug plans and PDP sponsors--

(A) any reference to a waiver application under section 1855 [*42 USCS § 1395w-25*] shall be treated as a reference to a waiver application under paragraph (1)(A) of this subsection; and

(B) any reference to solvency standards shall be treated as a reference to solvency standards established under subsection (d) of this section.

(d) Solvency standards for non-licensed entities.

(1) Establishment and publication. The Secretary, in consultation with the National Association of Insurance Commissioners, shall establish and publish, by not later than January 1, 2005, financial solvency and capital adequacy standards for entities described in paragraph (2).

(2) Compliance with standards. A PDP sponsor that is not licensed by a State under subsection (a)(1) and for which a waiver application has been approved under subsection (c) shall meet solvency and capital adequacy standards established under paragraph (1). The Secretary shall establish certification procedures for such sponsors with respect to such solvency standards in the manner described in section 1855(c)(2) [*42 USCS § 1395w-25(c)(2)*].

(e) Licensure does not substitute for or constitute certification. The fact that a PDP sponsor is licensed in accordance with subsection (a)(1) or has a waiver application approved under subsection (c) does not deem the sponsor to meet other requirements imposed under this part [*42 USCS §§ 1395w-101* et seq.] for a sponsor.

(f) Periodic review and revision of standards.

(1) In general. Subject to paragraph (2), the Secretary may periodically review the standards established under this section and, based on such review, may revise such standards if the Secretary determines such revision to be appropriate.

(2) Prohibition of midyear implementation of significant new regulatory requirements. The Secretary may not implement, other than at the beginning of a calendar year, regulations under this section that impose new, significant regulatory requirements on a PDP sponsor or a prescription drug plan.

(g) Prohibition of State imposition of premium taxes; relation to State laws. The provisions of sections 1854(g) and 1856(b)(3) [*42 USCS §§ 1395w-24(g)* and *1395w-26(b)(3)*] shall apply with respect to PDP sponsors and prescription drug plans under this part [*42 USCS §§ 1395w-101* et seq.] in the same manner as such sections apply to MA organizations and MA plans under part C [*42 USCS §§ 1395w-21* et seq.].

HISTORY:

(Aug. 4, 1935, ch 531, Title XVIII, Part D, Subpart 2, § 1860D-12, as added Dec. 8, 2003, P.L. 108-173, Title I, § 101(a)(2), 117 Stat. 2099.)

(As amended July 15, 2008, P.L. 110-275, Title I, Subtitle E, Part I, §§ 171(a), 172(a)(1), 173(a), Subtitle F, § 181, 122 Stat. 2578, 2580, 2581, 2582.)

§ 1395w-113. Premiums; late enrollment penalty

(a) Monthly beneficiary premium.

(1) Computation.

(A) In general. The monthly beneficiary premium for a prescription drug plan is the base beneficiary premium computed under paragraph (2) as adjusted under this paragraph.

(B) Adjustment to reflect difference between bid and national average bid.

(i) Above average bid. If for a month the amount of the standardized bid amount (as defined in paragraph (5)) exceeds the amount of the adjusted national average monthly bid amount (as defined in clause (iii)), the base beneficiary premium for the month shall be increased by the amount of such excess.

(ii) Below average bid. If for a month the amount of the adjusted national average monthly bid amount for the month exceeds the standardized bid amount, the base beneficiary premium for the month shall be decreased by the amount of such excess.

(iii) Adjusted national average monthly bid amount defined. For purposes of this subparagraph, the term "adjusted national average monthly bid amount" means the national average monthly bid amount computed under paragraph (4), as adjusted under section 1860D-15(c)(2) [*42 USCS § 1395w-115(c)(2)*].

(C) Increase for supplemental prescription drug benefits. The base beneficiary premium shall be increased by the portion of the PDP approved bid that is attributable to supplemental prescription drug benefits.

(D) Increase for late enrollment penalty. The base beneficiary premium shall be increased by the amount of any late enrollment penalty under subsection (b).

(E) Decrease for low-income assistance. The monthly beneficiary premium is subject to decrease in the case of a subsidy eligible individual under section 1860D-14 [*42 USCS § 1395w-114*].

(F) Uniform premium. Except as provided in subparagraphs (D) and (E), the monthly beneficiary premium for a prescription drug plan in a PDP region is the same for all part D eligible individuals enrolled in the plan.

(2) Base beneficiary premium. The base beneficiary premium under this paragraph for a prescription drug plan for a month is equal to the product--

(A) the beneficiary premium percentage (as specified in paragraph (3)); and

(B) the national average monthly bid amount (computed under paragraph (4)) for the month.

(3) Beneficiary premium percentage. For purposes of this subsection, the beneficiary premium percentage for any year is the percentage equal to a fraction

(A) the numerator of which is 25.5 percent; and

(B) the denominator of which is 100 percent minus a percentage equal to--

(i) the total reinsurance payments which the Secretary estimates are payable under section 1860D-15(b) [*42 USCS § 1395w-115(b)*] with respect to the coverage year; divided by

(ii) the sum of--

(I) the amount estimated under clause (i) for the year; and

(II) the total payments which the Secretary estimates will be paid to prescription drug plans and MA-PD plans that are attributable to the standardized bid amount during the year, taking into account amounts paid by the Secretary and enrollees.

(4) Computation of national average monthly bid amount.

(A) In general. For each year (beginning with 2006) the Secretary shall compute a national average monthly bid amount equal to the average of the standardized bid amounts (as defined in paragraph (5)) for each prescription drug plan and for each MA-PD plan described in section 1851(a)(2)(A)(i) [*42 USCS § 1395w-21(a)(2)(A)(i)*]. Such average does not take into account the bids submitted for MSA plans, MA private fee-for-service plan, and specialized MA plans for special needs individuals, PACE programs under section 1894 [*42 USCS § 1395eee*] (pursuant to section 1860D-21(f) [*42 USCS § 1395w-131(f)*]), and under reasonable cost reimbursement contracts under section 1876(h) [*42 USCS § 1395mm(h)*] (pursuant to section 1860D-21(e) [*42 USCS § 1395w-131(e)*]).

(B) Weighted average.

(i) In general. The monthly national average monthly bid amount computed under subparagraph (A) for a year shall be a weighted average, with the weight for each plan being equal to the average number of part D eligible individuals enrolled in such plan in the reference month (as defined in section 1858(f)(4) [*42 USCS § 1395w-27a(f)(4)*]).

(ii) Special rule for 2006. For purposes of applying this paragraph for 2006, the Secretary shall establish procedures for determining the weighted average under clause (i) for 2005.

(5) Standardized bid amount defined. For purposes of this subsection, the term "standardized bid amount" means the following:

(A) Prescription drug plans.

(i) Basic coverage. In the case of a prescription drug plan that provides basic prescription drug coverage, the PDP approved bid (as defined in paragraph (6)).

(ii) Supplemental coverage. In the case of a prescription drug plan that provides supplemental prescription drug coverage, the portion of the PDP approved bid that is attributable to basic prescription drug coverage.

(B) MA-PD plans. In the case of an MA-PD plan, the portion of the accepted bid amount that is attributable to basic prescription drug coverage.

(6) PDP approved bid defined. For purposes of this part [*42 USCS §§ 1395w-101* et seq.], the term "PDP approved bid" means, with respect to a prescription drug plan, the bid amount approved for the plan under this part [*42 USCS §§ 1395w-101* et seq.].

(b) Late enrollment penalty.

(1) In general. Subject to the succeeding provisions of this subsection, in the case of a part D eligible individual described in paragraph (2) with respect to a continuous period of eligibility, there shall be an increase in the monthly beneficiary premium established under subsection (a) in an amount determined under paragraph (3).

(2) Individuals subject to penalty. A part D eligible individual described in this paragraph is, with respect to a continuous period of eligibility, an individual for whom there is a continuous period of 63 days or longer (all of which in such continuous period of eligibility) beginning on the day after the last date of the individual's initial enrollment period under section 1860D-1(b)(2) [*42 USCS § 1395w-101(b)(2)*] and ending on the date of enrollment under a prescription drug plan or MA-PD plan during all of which the individual was not covered under any creditable prescription drug coverage.

(3) Amount of penalty.

(A) In general. The amount determined under this paragraph for a part D eligible individual for a continuous period of eligibility is the greater of--

(i) an amount that the Secretary determines is actuarially sound for each uncovered month (as defined in subparagraph (B)) in the same continuous period of eligibility; or

(ii) 1 percent of the base beneficiary premium (computed under subsection (a)(2)) for each such uncovered month in such period.

(B) Uncovered month defined. For purposes of this subsection, the term "uncovered month" means, with respect to a part D eligible individual, any month beginning after the end of the initial enrollment period under section 1860D-1(b)(2) [*42 USCS § 1395w-101(b)(2)*] unless the individual can demonstrate that the individual had creditable prescription drug coverage (as defined in paragraph (4)) for any portion of such month.

(4) Creditable prescription drug coverage defined. For purposes of this part [*42 USCS §§ 1395w-101* et seq.], the term "creditable prescription drug coverage" means any of the following coverage, but only if the coverage meets the requirement of paragraph (5):

(A) Coverage under prescription drug plan or MA-PD plan. Coverage under a prescription drug plan or under an MA-PD plan.

(B) Medicaid. Coverage under a medicaid plan under title XIX [*42 USCS §§ 1396* et seq.] or under a waiver under section 1115 [*42 USCS § 1315*].

(C) Group health plan. Coverage under a group health plan, including a health benefits plan under chapter 89 of title 5, United States Code [*5 USCS §§ 8901* et seq.] (commonly known as the Federal employees health benefits program), and a qualified retiree prescription drug plan (as defined in section 1860D-22(a)(2) [*42 USCS § 1395w-132(a)(2)*]).

(D) State pharmaceutical assistance program. Coverage under a State pharmaceutical assistance program described in section 1860D-23(b)(1) [*42 USCS § 1395w-133(b)(1)*].

(E) Veterans' coverage of prescription drugs. Coverage for veterans, and survivors and dependents of veterans, under chapter 17 of title 38, United States Code [*38 USCS §§ 1701* et seq.].

(F) Prescription drug coverage under medigap policies. Coverage under a medicare supplemental policy under section 1882 [*42 USCS § 1395ss*] that provides benefits for prescription drugs (whether or not such coverage conforms to the standards for packages of benefits under section 1882(p)(1) [*42 USCS § 1395ss(p)(1)*]).

(G) Military coverage (including TRICARE). Coverage under chapter 55 of title 10, United States Code [*10 USCS §§ 1071* et seq.].

(H) Other coverage. Such other coverage as the Secretary determines appropriate.

(5) Actuarial equivalence requirement. Coverage meets the requirement of this paragraph only if the coverage is determined (in a manner specified by the Secretary) to provide coverage of the cost of prescription drugs the actuarial value of which (as defined by the Secretary) to the individual equals or exceeds the actuarial value of standard prescription drug coverage (as determined under section 1860D-11(c) [*42 USCS § 1395w-111(c)*]).

(6) Procedures to document creditable prescription drug coverage.

(A) In general. The Secretary shall establish procedures (including the form, manner, and time) for the documentation of creditable prescription drug coverage, including procedures to assist in determining whether coverage meets the requirement of paragraph (5).

(B) Disclosure by entities offering creditable prescription drug coverage.

(i) In general. Each entity that offers prescription drug coverage of the type described in subparagraphs (B) through (H) of paragraph (4) shall provide for disclosure, in a form, manner, and time consistent with standards established by the Secretary, to the Secretary and part D eligible individuals of whether the coverage meets the requirement of paragraph (5) or whether such coverage is changed so it no longer meets such requirement.

(ii) Disclosure of non-creditable coverage. In the case of such coverage that does not meet such requirement, the disclosure to part D eligible individuals under this subparagraph shall include information regarding the fact that because such coverage does not meet such requirement there are limitations on the periods in a year in which the individuals may enroll under a prescription drug plan or an MA-PD plan and that any such enrollment is subject to a late enrollment penalty under this subsection.

(C) Waiver of requirement. In the case of a part D eligible individual who was enrolled in prescription drug coverage of the type described in subparagraphs (B) through (H) of paragraph (4) which is not creditable prescription drug coverage because it does not meet the requirement of paragraph (5), the individual may apply to the Secretary to have such coverage treated as creditable prescription drug coverage if the individual establishes that the individual was not adequately informed that such coverage did not meet such requirement.

(7) Continuous period of eligibility.

(A) In general. Subject to subparagraph (B), for purposes of this subsection, the term "continuous period of eligibility" means, with respect to a part D eligible individual, the period that begins with the first day on which the individual is eligible to enroll in a prescription drug plan under this part [*42 USCS §§ 1395w-101* et seq.] and ends with the individual's death.

(B) Separate period. Any period during all of which a part D eligible individual is entitled to hospital insurance benefits under part A [*42 USCS §§ 1395c* et seq.] and--

(i) which terminated in or before the month preceding the month in which the individual attained age 65; or

(ii) for which the basis for eligibility for such entitlement changed between section 226(b) [*42 USCS § 426(b)*] and section 226(a) [*42 USCS § 426(a)*], between 226(b) [*42 USCS § 426(b)*] and section 226A [*42 USCS § 426-1*], or between section 226A [*42 USCS § 426-1*] and section 226(a) [*42 USCS § 426(a)*],

shall be a separate continuous period of eligibility with respect to the individual (and each such period which terminates shall be deemed not to have existed for purposes of subsequently applying this paragraph).

(8) Waiver of penalty for subsidy-eligible individuals. In no case shall a part D eligible individual who is determined to be a subsidy eligible individual (as defined in section 1860D-14(a)(3) [*42 USCS § 1395w-114(a)(3)*]) be subject to an increase in the monthly beneficiary premium established under subsection (a).

(c) Collection of monthly beneficiary premiums.

(1) In general. Subject to paragraphs (2) and (3), the provisions of section 1854(d) [*42 USCS § 1395w-24(d)*] shall apply to PDP sponsors and premiums (and any late enrollment penalty) under this part [*42 USCS §§ 1395w-101* et seq.] in the same manner as they apply to MA organizations and beneficiary premiums under part C [*42 USCS §§ 1395w-21* et seq.], except that any reference to a Trust Fund is deemed for this purpose a reference to the Medicare Prescription Drug Account.

(2) Crediting of late enrollment penalty.

(A) Portion attributable to increased actuarial costs. With respect to late enrollment penalties imposed under subsection (b), the Secretary shall specify the portion of such a penalty that the Secretary estimates is attributable to increased actuarial costs assumed by the PDP sponsor or MA organization (and not taken into account through risk adjustment provided under section 1860D-15(c)(1) [*42 USCS § 1395w-115(c)(1)*] or through reinsurance payments under section 1860D-15(b) [*42 USCS § 1395w-115(b)*]) as a result of such late enrollment.

(B) Collection through withholding. In the case of a late enrollment penalty that is collected from a part D eligible individual in the manner described in section 1854(d)(2)(A) [*42 USCS § 1395w-24(d)(2)(A)*], the Secretary shall provide that only the portion of such penalty estimated under subparagraph (A) shall be paid to the PDP sponsor or MA organization offering the part D plan in which the individual is enrolled.

(C) Collection by plan. In the case of a late enrollment penalty that is collected from a part D eligible individual in a manner other than the manner described in section 1854(d)(2)(A) [*42 USCS § 1395w-24(d)(2)(A)*], the Secretary shall establish procedures for reducing payments otherwise made to the PDP sponsor or MA organization by an amount equal to the amount of such penalty less the portion of such penalty estimated under subparagraph (A).

(3) Fallback plans. In applying this subsection in the case of a fallback prescription drug plan, paragraph (2) shall not apply and the monthly beneficiary premium shall be collected in the manner specified in section 1854(d)(2)(A) [*42 USCS § 1395w-24(d)(2)(A)*] (or such other manner as may be provided under section 1840 [*42 USCS § 1395s*] in the case of monthly premiums under section 1839 [*42 USCS § 1395r*]).

HISTORY:

(Aug. 4, 1935, ch 531, Title XVIII, Part D, Subpart 2, § 1860D-13, as added Dec. 8, 2003, P.L. 108-173, Title I, § 101(a)(2), 117 Stat. 2102.)

(As amended July 15, 2008, P.L. 110-275, Title I, Subtitle A, Part II, § 114(a)(1), 122 Stat. 2506.)

§ 1395w-114. Premium and cost-sharing subsidies for low-income individuals [Caution: See prospective amendment note below.]

(a) Income-related subsidies for individuals with income up to 150 percent of poverty line.

(1) Individuals with income below 135 percent of poverty line. In the case of a subsidy eligible individual (as defined in paragraph (3)) who is determined to have income that is below 135 percent of the poverty line applicable to a family of the size involved and who meets the resources requirement described in paragraph (3)(D) or who is covered under this paragraph under paragraph (3)(B)(i), the individual is entitled under this section to the following:

(A) Full premium subsidy. An income-related premium subsidy equal to 100 percent of the amount described in subsection (b)(1), but not to exceed the premium amount specified in subsection (b)(2)(B).

(B) Elimination of deductible. A reduction in the annual deductible applicable under section 1860D-2(b)(1) [*42 USCS § 1395w-102(b)(1)*] to $ 0.

(C) Continuation of coverage above the initial coverage limit. The continuation of coverage from the initial coverage limit (under paragraph (3) of section 1860D-2(b) [*42 USCS § 1395w-102(b)*]) for expenditures incurred through the total amount of expenditures at which benefits are available under paragraph (4) of such section, subject to the reduced cost-sharing described in subparagraph (D).

(D) Reduction in cost-sharing below out-of-pocket threshold.

(i) Institutionalized individuals. In the case of an individual who is a full-benefit dual eligible individual and who is an institutionalized individual or couple (as defined in section 1902(q)(1)(B) [*42 USCS § 1396a(q)(1)(B)*]), the elimination of any beneficiary coinsurance described in section 1860D-2(b)(2) [*42 USCS § 1395w-102(b)(2)*] (for all amounts through the total amount of expenditures at which benefits are available under section 1860D-2(b)(4) [*42 USCS § 1395w-102(b)(4)*]).

(ii) Lowest income dual eligible individuals. In the case of an individual not described in clause (i) who is a full-benefit dual eligible individual and whose income does not exceed 100 percent of the poverty line applicable to a family of the size involved, the substitution for the beneficiary coinsurance described in section 1860D-2(b)(2) [*42 USCS § 1395w-102(b)(2)*] (for all amounts through the total amount of expenditures at which benefits are available under section 1860D-2(b)(4) [*42 USCS § 1395w-102(b)(4)*]) of a copayment amount that does not exceed $ 1 for a generic drug or a preferred drug that is a multiple source drug (as defined in section 1927(k)(7)(A)(i) [*42 USCS § 1396r-8(k)(7)(A)(i)*]) and $ 3 for any other drug, or, if less, the copayment amount applicable to an individual under clause (iii).

(iii) Other individuals. In the case of an individual not described in clause (i) or (ii), the substitution for the beneficiary coinsurance described in section 1860D-2(b)(2) [*42 USCS § 1395w-102(b)(2)*] (for all amounts through the total amount of expenditures at which benefits are available under section 1860D-2(b)(4) [*42 USCS § 1395w-102(b)(4)*]) of a copayment amount that does not exceed the copayment amount specified under section 1860D-2(b)(4)(A)(i)(I) [*42 USCS § 1395w-102(b)(4)(A)(i)(I)*] for the drug and year involved.

(E) Elimination of cost-sharing above annual out-of-pocket threshold. The elimination of any cost-sharing imposed under section 1860D-2(b)(4)(A) [*42 USCS § 1395w-102(b)(4)(A)*].

(2) Other individuals with income below 150 percent of poverty line. In the case of a subsidy eligible individual who is not described in paragraph (1), the individual is entitled under this section to the following:

(A) Sliding scale premium subsidy. An income-related premium subsidy determined on a linear sliding scale ranging from 100 percent of the amount described in paragraph (1)(A) for individuals with incomes at or below 135 percent of such level to 0 percent of such amount for individuals with incomes at 150 percent of such level.

(B) Reduction of deductible. A reduction in the annual deductible applicable under section 1860D-2(b)(1) [*42 USCS § 1395w-102(b)(1)*] to $ 50.

(C) Continuation of coverage above the initial coverage limit. The continuation of coverage from the initial coverage limit (under paragraph (3) of section 1860D-2(b) [*42 USCS § 1395w-102(b)*]) for expenditures incurred through the total amount of expenditures at which benefits are available under paragraph (4) of such section, subject to the reduced coinsurance described in subparagraph (D).

(D) Reduction in cost-sharing below out-of-pocket threshold. The substitution for the beneficiary coinsurance described in section 1860D-2(b)(2) [*42 USCS § 1395w-102(b)(2)*] (for all amounts above the deductible under subparagraph (B) through the total amount of expenditures at which benefits are available under section 1860D-2(b)(4) [*42 USCS § 1395w-102(b)(4)*]) of coinsurance of "15 percent" instead of coinsurance of "25 percent" in section 1860D-2(b)(2) [*42 USCS § 1395w-102(b)(2)*].

(E) Reduction of cost-sharing above annual out-of-pocket threshold. Subject to subsection (c), the substitution for the cost-sharing imposed under section 1860D-2(b)(4)(A) [*42 USCS § 1395w-102(b)(4)(A)*] of a copayment or coinsurance not to exceed the copayment or coinsurance amount specified under section 1860D-2(b)(4)(A)(i)(I) [*42 USCS § 1395w-102(b)(4)(A)(i)(I)*] for the drug and year involved.

(3) Determination of eligibility.

(A) Subsidy eligible individual defined. For purposes of this part [*42 USCS §§ 1395w-101* et seq.], subject to subparagraph (F), the term "subsidy eligible individual" means a part D eligible individual who--

(i) is enrolled in a prescription drug plan or MA-PD plan;

(ii) has income below 150 percent of the poverty line applicable to a family of the size involved; and

(iii) meets the resources requirement described in subparagraph (D) or (E).

(B) Determinations.

(i) In general. The determination of whether a part D eligible individual residing in a State is a subsidy eligible individual and whether the individual is described in paragraph (1) shall be determined under the State plan under title XIX [*42 USCS §§ 1396* et seq.] for the State under section 1935(a) [*42 USCS § 1396u-5(a)*] or by the Commissioner of Social Security. There are authorized to be appropriated to the Social Security Administration such sums as may be necessary for the determination of eligibility under this subparagraph.

(ii) Effective period. Determinations under this subparagraph shall be effective beginning with the month in which the individual applies for a determination that the individual is a subsidy eligible individual and shall remain in effect for a period specified by the Secretary, but not to exceed 1 year.

(iii) Redeterminations and appeals through medicaid. Redeterminations and appeals, with respect to eligibility determinations under clause (i) made under a State plan under title XIX [*42 USCS §§ 1396* et seq.], shall be made in accordance with the frequency of, and manner in which, redeterminations and appeals of eligibility are made under such plan for purposes of medical assistance under such title.

(iv) Redeterminations and appeals through Commissioner. With respect to eligibility determinations under clause (i) made by the Commissioner of Social Security--

(I) redeterminations shall be made at such time or times as may be provided by the Commissioner;

(II) the Commissioner shall establish procedures for appeals of such determinations that are similar to the procedures described in the third sentence of section 1631(c)(1)(A) [*42 USCS § 1383(c)(1)(A)*]; and

(III) judicial review of the final decision of the Commissioner made after a hearing shall be available to the same extent, and with the same limitations, as provided in subsections (g) and (h) of section 205 [*42 USCS § 405*].

(v) Treatment of medicaid beneficiaries. Subject to subparagraph (F), the Secretary--

(I) shall provide that part D eligible individuals who are full-benefit dual eligible individuals (as defined in section 1935(c)(6) [*42 USCS § 1396u-5(c)(6)*]) or who are recipients of supplemental security income benefits under title XVI [*42 USCS §§ 1381* et seq.] shall be treated as subsidy eligible individuals described in paragraph (1); and

(II) may provide that part D eligible individuals not described in subclause (I) who are determined for purposes of the State plan under title XIX [*42 USCS §§ 1396* et seq.] to be eligible for medical assistance under clause (i), (iii), or (iv) of section 1902(a)(10)(E) [*42 USCS § 1396a(a)(10)(E)*] are treated as being determined to be subsidy eligible individuals described in paragraph (1). Insofar as the Secretary determines that the eligibility requirements under the State plan for medical assistance referred to in subclause (II) are substantially the same as the requirements for being treated as a subsidy eligible individual described in paragraph (1), the Secretary shall provide for the treatment described in such subclause.

(C) Income determinations. For purposes of applying this section--

(i) in the case of a part D eligible individual who is not treated as a subsidy eligible individual under subparagraph (B)(v), income shall be determined in the manner described in section 1905(p)(1)(B) [*42 USCS § 1396d(p)(1)(B)*], without regard to the application of section 1902(r)(2) [*42 USCS § 1396a(r)(2)*]; and

(ii) the term "poverty line" has the meaning given such term in section 673(2) of the Community Services Block Grant Act (*42 U.S.C. 9902(2)*), including any revision required by such section.

Nothing in clause (i) shall be construed to affect the application of section 1902(r)(2) [*42 USCS § 1396a(r)(2)*] for the determination of eligibility for medical assistance under title XIX [*42 USCS §§ 1396* et seq.].

(D) Resource standard applied to full low-income subsidy to be based on three times SSI resource standard. The resources requirement of this subparagraph is that an individual's resources (as determined under section 1613 [*42 USCS § 1382b*] for purposes of the supplemental security income program) do not exceed--

(i) for 2006 three times the maximum amount of resources that an individual may have and obtain benefits under that program; and

(ii) for a subsequent year the resource limitation established under this clause for the previous year increased by the annual percentage increase in the consumer price index (all items; U.S. city average) as of September of such previous year.

Any resource limitation established under clause (ii) that is not a multiple of $ 10 shall be rounded to the nearest multiple of $ 10.

(E) Alternative resource standard.

(i) In general. The resources requirement of this subparagraph is that an individual's resources (as determined under section 1613 [*42 USCS § 1382b*] for purposes of the supplemental security income program) do not exceed--

(I) for 2006, $ 10,000 (or $ 20,000 in the case of the combined value of the individual's assets or resources and the assets or resources of the individual's spouse); and

(II) for a subsequent year the dollar amounts specified in this subclause (or subclause (I)) for the previous year increased by the annual percentage increase in the consumer price index (all items; U.S. city average) as of September of such previous year.

Any dollar amount established under subclause (II) that is not a multiple of $ 10 shall be rounded to the nearest multiple of $ 10.

(ii) Use of simplified application form and process. The Secretary, jointly with the Commissioner of Social Security, shall--

(I) develop a model, simplified application form and process consistent with clause (iii) for the determination and verification of a part D eligible individual's assets or resources under this subparagraph; and

(II) provide such form to States.

(iii) Documentation and safeguards. Under such process--

(I) the application form shall consist of an attestation under penalty of perjury regarding the level of assets or resources (or combined assets and resources in the case of a married part D eligible individual) and valuations of general classes of assets or resources;

(II) such form shall be accompanied by copies of recent statements (if any) from financial institutions in support of the application; and

(III) matters attested to in the application shall be subject to appropriate methods of verification.

(iv) Methodology flexibility. The Secretary may permit a State in making eligibility determinations for premium and cost-sharing subsidies under this section to use the same asset or resource methodologies that are used with respect to eligibility for medical assistance for medicare cost-sharing described in section 1905(p) [*42 USCS § 1396d(p)*] so long as the Secretary determines that the use of such methodologies will not result in any significant differences in the number of individuals determined to be subsidy eligible individuals.

(F) Treatment of territorial residents. In the case of a part D eligible individual who is not a resident of the 50 States or the District of Columbia, the individual is not eligible to be a subsidy eligible individual under this section but may be eligible for financial assistance with prescription drug expenses under section 1935(e) [*42 USCS § 1396u-5(e)*].

(4) Indexing dollar amounts.

(A) Copayment for lowest income dual eligible individuals. The dollar amounts applied under paragraph (1)(D)(ii)--

(i) for 2007 shall be the dollar amounts specified in such paragraph increased by the annual percentage increase in the consumer price index (all items; U.S. city average) as of September of such previous year; or

(ii) for a subsequent year shall be the dollar amounts specified in this clause (or clause (i)) for the previous year increased by the annual percentage increase in the consumer price index (all items; U.S. city average) as of September of such previous year.

Any amount established under clause (i) or (ii), that is based on an increase of $ 1 or $ 3, that is not a multiple of 5 cents or 10 cents, respectively, shall be rounded to the nearest multiple of 5 cents or 10 cents, respectively.

(B) Reduced deductible. The dollar amount applied under paragraph (2)(B)--

(i) for 2007 shall be the dollar amount specified in such paragraph increased by the annual percentage increase described in section 1860D-2(b)(6) [*42 USCS § 1395w-102(b)(6)*] for 2007; or

(ii) for a subsequent year shall be the dollar amount specified in this clause (or clause (i)) for the previous year increased by the annual percentage increase described in section 1860D-2(b)(6) [*42 USCS § 1395w-102(b)(6)*] for the year involved.

Any amount established under clause (i) or (ii) that is not a multiple of $ 1 shall be rounded to the nearest multiple of $ 1.

(b) Premium subsidy amount.

(1) In general. The premium subsidy amount described in this subsection for a subsidy eligible individual residing in a PDP region and enrolled in a prescription drug plan or MA-PD plan is the low-income benchmark premium amount (as defined in paragraph (2)) for the PDP region in which the individual resides or, if greater, the amount specified in paragraph (3).

(2) Low-income benchmark premium amount defined.

(A) In general. For purposes of this subsection, the term "low-income benchmark premium amount" means, with respect to a PDP region in which--

(i) all prescription drug plans are offered by the same PDP sponsor, the weighted average of the amounts described in subparagraph (B)(i) for such plans; or

(ii) there are prescription drug plans offered by more than one PDP sponsor, the weighted average of amounts described in subparagraph (B) for prescription drug plans and MA-PD plans described in section 1851(a)(2)(A)(i) [*42 USCS § 1395w-21(a)(2)(A)(i)*] offered in such region.

(B) Premium amounts described. The premium amounts described in this subparagraph are, in the case of--

(i) a prescription drug plan that is a basic prescription drug plan, the monthly beneficiary premium for such plan;

(ii) a prescription drug plan that provides alternative prescription drug coverage the actuarial value of which is greater than that of standard prescription drug coverage, the portion of the monthly beneficiary premium that is attributable to basic prescription drug coverage; and

(iii) an MA-PD plan, the portion of the MA monthly prescription drug beneficiary premium that is attributable to basic prescription drug benefits (described in section 1852(a)(6)(B)(ii) [*42 USCS § 1395w-22(a)(6)(B)(ii)*]).

The premium amounts described in this subparagraph do not include any amounts attributable to late enrollment penalties under section 1860D-13(b) [*42 USCS § 1395w-113(b)*].

(3) Access to 0 premium plan. In no case shall the premium subsidy amount under this subsection for a PDP region be less than the lowest monthly beneficiary premium for a prescription drug plan that offers basic prescription drug coverage in the region.

(c) Administration of subsidy program.

(1) In general. The Secretary shall provide a process whereby, in the case of a part D eligible individual who is determined to be a subsidy eligible individual and who is enrolled in a prescription drug plan or is enrolled in an MA-PD plan--

(A) the Secretary provides for a notification of the PDP sponsor or the MA organization offering the plan involved that the individual is eligible for a subsidy and the amount of the subsidy under subsection (a);

(B) the sponsor or organization involved reduces the premiums or cost-sharing otherwise imposed by the amount of the applicable subsidy and submits to the Secretary information on the amount of such reduction;

(C) the Secretary periodically and on a timely basis reimburses the sponsor or organization for the amount of such reductions; and

(D) the Secretary ensures the confidentiality of individually identifiable information.

In applying subparagraph (C), the Secretary shall compute reductions based upon imposition under subsections (a)(1)(D) and (a)(2)(E) of unreduced copayment amounts applied under such subsections.

(2) Use of capitated form of payment. The reimbursement under this section with respect to cost-sharing subsidies may be computed on a capitated basis, taking into account the actuarial value of the subsidies and with appropriate adjustments to reflect differences in the risks actually involved.

(d) Relation to medicaid program. For special provisions under the medicaid program relating to medicare prescription drug benefits, see section 1935 [*42 USCS § 1396u-5*].

HISTORY:

(Aug. 4, 1935, ch 531, Title XVIII, Part D, Subpart 2, § 1860D-14, as added Dec. 8, 2003, P.L. 108-173, Title I, § 101(a)(2), 117 Stat. 2107.)

(As amended July 15, 2008, P.L. 110-275, Title I, Subtitle A, Part II, §§ 114(a)(2), 116(a), 117(a), 122 Stat. 2506, 2507.)

§ 1395w-115. Subsidies for part D eligible individuals for qualified prescription drug coverage

(a) Subsidy payment. In order to reduce premium levels applicable to qualified prescription drug coverage for part D eligible individuals consistent with an overall subsidy level of 74.5 percent for basic prescription drug coverage, to reduce adverse selection among prescription drug plans and MA-PD plans, and to promote the participation of PDP sponsors under this part [*42 USCS §§ 1395w-101* et seq.] and MA organizations under part C [*42 USCS §§ 1395w-21* et seq.], the Secretary shall provide for payment to a PDP sponsor that offers a prescription drug plan and an MA organization that offers an MA-PD plan of the following subsidies in accordance with this section:

(1) Direct subsidy. A direct subsidy for each part D eligible individual enrolled in a prescription drug plan or MA-PD plan for a month equal to--

(A) the amount of the plan's standardized bid amount (as defined in section 1860D-13(a)(5) [*42 USCS § 1395w-113(a)(5)*]), adjusted under subsection (c)(1), reduced by

(B) the base beneficiary premium (as computed under paragraph (2) of section 1860D-13(a) [*42 USCS § 1395w-113(a)*] and as adjusted under paragraph (1)(B) of such section).

(2) Subsidy through reinsurance. The reinsurance payment amount (as defined in subsection (b)).

This section constitutes budget authority in advance of appropriations Acts and represents the obligation of the Secretary to provide for the payment of amounts provided under this section.

(b) Reinsurance payment amount.

(1) In general. The reinsurance payment amount under this subsection for a part D eligible individual enrolled in a prescription drug plan or MA-PD plan for a coverage year is an amount equal to 80 percent of the allowable reinsurance costs (as specified in paragraph (2)) attributable to that portion of gross covered prescription drug costs as specified in paragraph (3) incurred in the coverage year after such individual has incurred costs that exceed the annual out-of-pocket threshold specified in section 1860D-2(b)(4)(B) [*42 USCS § 1395w-102(b)(4)(B)*].

(2) Allowable reinsurance costs. For purposes of this section, the term "allowable reinsurance costs" means, with respect to gross covered prescription drug costs under a prescription drug plan offered by a PDP sponsor or an MA-PD plan offered by an MA organization, the part of such costs that are actually paid (net of discounts, chargebacks, and average percentage rebates) by the sponsor or organization or by (or on behalf of) an enrollee under the plan, but in no case more than the part of such costs that would have been paid under the plan if the prescription drug coverage under the plan were basic prescription drug coverage, or, in the case of a plan providing supplemental prescription drug coverage, if such coverage were standard prescription drug coverage.

(3) Gross covered prescription drug costs. For purposes of this section, the term "gross covered prescription drug costs" means, with respect to a part D eligible individual enrolled in a prescription drug plan or MA-PD plan during a coverage year, the costs incurred under the plan, not including administrative costs, but including costs directly related to the dispensing of covered part D drugs during the year and costs relating to the deductible. Such costs shall be determined whether they are paid by the individual or under the plan, regardless of whether the coverage under the plan exceeds basic prescription drug coverage.

(4) Coverage year defined. For purposes of this section, the term "coverage year" means a calendar year in which covered part D drugs are dispensed if the claim for such drugs (and payment on such claim) is made not later than such period after the end of such year as the Secretary specifies.

(c) Adjustments relating to bids.

(1) Health status risk adjustment.

(A) Establishment of risk adjustors. The Secretary shall establish an appropriate methodology for adjusting the standardized bid amount under subsection (a)(1)(A) to take into account variation in costs for basic prescription drug coverage among prescription drug plans and MA-PD plans based on the differences in actuarial risk of different enrollees being served. Any such risk adjustment shall be designed in a manner so as not to result in a change in the aggregate amounts payable to such plans under subsection (a)(1) and through that portion of the monthly beneficiary prescription drug premiums described in subsection (a)(1)(B) and MA monthly prescription drug beneficiary premiums.

(B) Considerations. In establishing the methodology under subparagraph (A), the Secretary may take into account the similar methodologies used under section 1853(a)(3) [*42 USCS § 1395w-23(a)(3)*] to adjust payments to MA organizations for benefits under the original medicare fee-for-service program option.

(C) Data collection. In order to carry out this paragraph, the Secretary shall require--

(i) PDP sponsors to submit data regarding drug claims that can be linked at the individual level to part A and part B [*42 USCS §§ 1395c* et seq. and *1395j* et seq.] data and such other information as the Secretary determines necessary; and

(ii) MA organizations that offer MA-PD plans to submit data regarding drug claims that can be linked at the individual level to other data that such organizations are required to submit to the Secretary and such other information as the Secretary determines necessary.

(D) Publication. At the time of publication of risk adjustment factors under section 1853(b)(1)(B)(i)(II) [*42 USCS § 1395w-23(b)(1)(B)(i)(II)*], the Secretary shall publish the risk adjusters established under this paragraph for the succeeding year.

(2) Geographic adjustment.

(A) In general. Subject to subparagraph (B), for purposes of section 1860D-13(a)(1)(B)(iii) [*42 USCS § 1395w-113(a)(1)(B)(iii)*], the Secretary shall establish an appropriate methodology for adjusting the national average monthly

bid amount (computed under section 1860D-13(a)(4) [*42 USCS § 1395w-113(a)(4)*]) to take into account differences in prices for covered part D drugs among PDP regions.

(B) De minimis rule. If the Secretary determines that the price variations described in subparagraph (A) among PDP regions are de minimis, the Secretary shall not provide for adjustment under this paragraph.

(C) Budget neutral adjustment. Any adjustment under this paragraph shall be applied in a manner so as to not result in a change in the aggregate payments made under this part [*42 USCS §§ 1395w-101* et seq.] that would have been made if the Secretary had not applied such adjustment.

(d) Payment methods.

(1) In general. Payments under this section shall be based on such a method as the Secretary determines. The Secretary may establish a payment method by which interim payments of amounts under this section are made during a year based on the Secretary's best estimate of amounts that will be payable after obtaining all of the information.

(2) Requirement for provision of information.

(A) Requirement. Payments under this section to a PDP sponsor or MA organization are conditioned upon the furnishing to the Secretary, in a form and manner specified by the Secretary, of such information as may be required to carry out this section.

(B) Restriction on use of information. Information disclosed or obtained pursuant to subparagraph (A) may be used by officers, employees, and contractors of the Department of Health and Human Services only for the purposes of, and to the extent necessary in, carrying out this section.

(3) Source of payments. Payments under this section shall be made from the Medicare Prescription Drug Account.

(4) Application of enrollee adjustment. The provisions of section 1853(a)(2) [*42 USCS § 1395w-23(a)(2)*] shall apply to payments to PDP sponsors under this section in the same manner as they apply to payments to MA organizations under section 1853(a) [*42 USCS § 1395w-23(a)*].

(e) Portion of total payments to a sponsor or organization subject to risk (application of risk corridors).

(1) Computation of adjusted allowable risk corridor costs.

(A) In general. For purposes of this subsection, the term "adjusted allowable risk corridor costs" means, for a plan for a coverage year (as defined in subsection (b)(4))--

(i) the allowable risk corridor costs (as defined in subparagraph (B)) for the plan for the year, reduced by

(ii) the sum of (I) the total reinsurance payments made under subsection (b) to the sponsor of the plan for the year, and (II) the total subsidy payments made under section 1860D-14 [*42 USCS § 1395w-114*] to the sponsor of the plan for the year.

(B) Allowable risk corridor costs. For purposes of this subsection, the term "allowable risk corridor costs" means, with respect to a prescription drug plan offered by a PDP sponsor or an MA-PD plan offered by an MA organization, the part of costs (not including administrative costs, but including costs directly related to the dispensing of covered part D drugs during the year) incurred by the sponsor or organization under the plan that are actually paid (net of discounts, chargebacks, and average percentage rebates) by the sponsor or organization under the plan, but in no case more than the part of such costs that would have been paid under the plan if the prescription drug coverage under the plan were basic prescription drug coverage, or, in the case of a plan providing supplemental prescription drug coverage, if such coverage were basic prescription drug coverage taking into account the adjustment under section 1860D-11(c)(2) [*42 USCS § 1395w-111(c)(2)*]. In computing allowable costs under this paragraph, the Secretary shall compute such costs based upon imposition under paragraphs (1)(D) and (2)(E) of section 1860D-14(a) [*42 USCS § 1395w-114(a)*] of the maximum amount of copayments permitted under such paragraphs.

(2) Adjustment of payment.

(A) No adjustment if adjusted allowable risk corridor costs within risk corridor. If the adjusted allowable risk corridor costs (as defined in paragraph (1)) for the plan for the year are at least equal to the first threshold lower limit of the risk corridor (specified in paragraph (3)(A)(i)), but not greater than the first threshold upper limit of the risk corridor (specified in paragraph (3)(A)(iii)) for the plan for the year, then no payment adjustment shall be made under this subsection.

(B) Increase in payment if adjusted allowable risk corridor costs above upper limit of risk corridor.

(i) Costs between first and second threshold upper limits. If the adjusted allowable risk corridor costs for the plan for the year are greater than the first threshold upper limit, but not greater than the second threshold upper limit, of the risk corridor for the plan for the year, the Secretary shall increase the total of the payments made to the sponsor or organization offering the plan for the year under this section by an amount equal to 50 percent (or, for 2006 and 2007, 75 percent or 90 percent if the conditions described in clause (iii) are met for the year) of the difference between such adjusted allowable risk corridor costs and the first threshold upper limit of the risk corridor.

(ii) Costs above second threshold upper limits. If the adjusted allowable risk corridor costs for the plan for the year are greater than the second threshold upper limit of the risk corridor for the plan for the year, the Secretary shall increase the total of the payments made to the sponsor or organization offering the plan for the year under this section by an amount equal to the sum of--

(I) 50 percent (or, for 2006 and 2007, 75 percent or 90 percent if the conditions described in clause (iii) are met for the year) of the difference between the second threshold upper limit and the first threshold upper limit; and

(II) 80 percent of the difference between such adjusted allowable risk corridor costs and the second threshold upper limit of the risk corridor.

(iii) Conditions for application of higher percentage for 2006 and 2007. The conditions described in this clause are met for 2006 or 2007 if the Secretary determines with respect to such year that--

(I) at least 60 percent of prescription drug plans and MA-PD plans to which this subsection applies have adjusted allowable risk corridor costs for the plan for the year that are more than the first threshold upper limit of the risk corridor for the plan for the year; and

(II) such plans represent at least 60 percent of part D eligible individuals enrolled in any prescription drug plan or MA-PD plan.

(C) Reduction in payment if adjusted allowable risk corridor costs below lower limit of risk corridor.

(i) Costs between first and second threshold lower limits. If the adjusted allowable risk corridor costs for the plan for the year are less than the first threshold lower limit, but not less than the second threshold lower limit, of the risk corridor for the plan for the year, the Secretary shall reduce the total of the payments made to the sponsor or organization offering the plan for the year under this section by an amount (or otherwise recover from the sponsor or organization an amount) equal to 50 percent (or, for 2006 and 2007, 75 percent) of the difference between the first threshold lower limit of the risk corridor and such adjusted allowable risk corridor costs.

(ii) Costs below second threshold lower limit. If the adjusted allowable risk corridor costs for the plan for the year are less the second threshold lower limit of the risk corridor for the plan for the year, the Secretary shall reduce the total of the payments made to the sponsor or organization offering the plan for the year under this section by an amount (or otherwise recover from the sponsor or organization an amount) equal to the sum of--

(I) 50 percent (or, for 2006 and 2007, 75 percent) of the difference between the first threshold lower limit and the second threshold lower limit; and

(II) 80 percent of the difference between the second threshold upper limit of the risk corridor and such adjusted allowable risk corridor costs.

(3) Establishment of risk corridors.

(A) In general. For each plan year the Secretary shall establish a risk corridor for each prescription drug plan and each MA-PD plan. The risk corridor for a plan for a year shall be equal to a range as follows:

(i) First threshold lower limit. The first threshold lower limit of such corridor shall be equal to--

(I) the target amount described in subparagraph (B) for the plan; minus

(II) an amount equal to the first threshold risk percentage for the plan (as determined under subparagraph (C)(i)) of such target amount.

(ii) Second threshold lower limit. The second threshold lower limit of such corridor shall be equal to--

(I) the target amount described in subparagraph (B) for the plan; minus

(II) an amount equal to the second threshold risk percentage for the plan (as determined under subparagraph (C)(ii)) of such target amount.

(iii) First threshold upper limit. The first threshold upper limit of such corridor shall be equal to the sum of--

(I) such target amount; and

(II) the amount described in clause (i)(II).

(iv) Second threshold upper limit. The second threshold upper limit of such corridor shall be equal to the sum of--

(I) such target amount; and

(II) the amount described in clause (ii)(II).

(B) Target amount described. The target amount described in this paragraph is, with respect to a prescription drug plan or an MA-PD plan in a year, the total amount of payments paid to the PDP sponsor or MA-PD organization for the plan for the year, taking into account amounts paid by the Secretary and enrollees, based upon the standardized bid amount (as defined in section 1860D-13(a)(5) [*42 USCS § 1395w-113(a)(5)*] and as risk adjusted under subsection (c)(1)), reduced by the total amount of administrative expenses for the year assumed in such standardized bid.

(C) First and second threshold risk percentage defined.

(i) First threshold risk percentage. Subject to clause (iii), for purposes of this section, the first threshold risk percentage is--

(I) for 2006 and 2007, and 2.5 percent;

(II) for 2008 through 2011, 5 percent; and

(III) for 2012 and subsequent years, a percentage established by the Secretary, but in no case less than 5 percent.

(ii) Second threshold risk percentage. Subject to clause (iii), for purposes of this section, the second threshold risk percentage is--

(I) for 2006 and 2007, 5 percent;

(II) for 2008 through 2011, 10 percent; and

(III) for 2012 and subsequent years, a percentage established by the Secretary that is greater than the percent established for the year under clause (i)(III), but in no case less than 10 percent.

(iii) Reduction of risk percentage to ensure 2 plans in an area. Pursuant to section 1860D-11(b)(2)(E)(ii) [*42 USCS § 1395w-111(b)(2)(E)(ii)*], a PDP sponsor may submit a bid that requests a decrease in the applicable first or second threshold risk percentages or an increase in the percents applied under paragraph (2).

(4) Plans at risk for entire amount of supplemental prescription drug coverage. A PDP sponsor and MA organization that offers a plan that provides supplemental prescription drug benefits shall be at full financial risk for the provision of such supplemental benefits.

(5) No effect on monthly premium. No adjustment in payments made by reason of this subsection shall affect the monthly beneficiary premium or the MA monthly prescription drug beneficiary premium.

(f) Disclosure of information.

(1) In general. Each contract under this part [*42 USCS §§ 1395w-101* et seq.] and under part C [*42 USCS §§ 1395w-21* et seq.] shall provide that--

(A) the PDP sponsor offering a prescription drug plan or an MA organization offering an MA-PD plan shall provide the Secretary with such information as the Secretary determines is necessary to carry out this section; and

(B) the Secretary shall have the right in accordance with section 1857(d)(2)(B) [*42 USCS § 1395w-27(d)(2)(B)*] (as applied under section 1860D-12(b)(3)(C) [*42 USCS § 1395w-112(b)(3)(C)*]) to inspect and audit any books and records of a PDP sponsor or MA organization that pertain to the information regarding costs provided to the Secretary under subparagraph (A).

(2) Restriction on use of information. Information disclosed or obtained pursuant to the provisions of this section may be used by officers, employees, and contractors of the Department of Health and Human Services only for the purposes of, and to the extent necessary in, carrying out this section.

(g) Payment for fallback prescription drug plans. In lieu of the amounts otherwise payable under this section to a PDP sponsor offering a fallback prescription drug plan (as defined in section 1860D-3(c)(4) [*42 USCS § 1395w-103(c)(4)*]), the amount payable shall be the amounts determined under the contract for such plan pursuant to section 1860D-11(g)(5) [*42 USCS § 1395w-111(g)(5)*].

HISTORY:

(Aug. 4, 1935, ch 531, Title XVIII, Part D, Subpart 2, § 1860D-15, as added Dec. 8, 2003, P.L. 108-173, Title I, § 101(a)(2), 117 Stat. 2113.)

§ 1395w-116. Medicare Prescription Drug Account in the Federal Supplementary Medical Insurance Trust Fund

(a) Establishment and operation of account

(1) Establishment. There is created within the Federal Supplementary Medical Insurance Trust Fund established by section 1841 [*42 USCS § 1395t*] an account to be known as the "Medicare Prescription Drug Account" (in this section referred to as the "Account").

(2) Funding. The Account shall consist of such gifts and bequests as may be made as provided in section 201(i)(1) [*42 USCS § 401(i)(1)*], accrued interest on balances in the Account, and such amounts as may be deposited in, or appropriated to, such Account as provided in this part [*42 USCS §§ 1395w-101* et seq.].

(3) Separate from rest of Trust Fund. Funds provided under this part [*42 USCS §§ 1395w-101* et seq.] to the Account shall be kept separate from all other funds within the Federal Supplementary Medical Insurance Trust Fund, but shall be invested, and such investments redeemed, in the same manner as all other funds and investments within such Trust Fund.

(b) Payments from Account.

(1) In general. The Managing Trustee shall pay from time to time from the Account such amounts as the Secretary certifies are necessary to make payments to operate the program under this part [*42 USCS §§ 1395w-101* et seq.], including--

(A) payments under section 1860D-14 [*42 USCS § 1395w-114*] (relating to low-income subsidy payments);

(B) payments under section 1860D-15 [*42 USCS § 1395w-115*] (relating to subsidy payments and payments for fallback plans);

(C) payments to sponsors of qualified retiree prescription drug plans under section 1860D-22(a) [*42 USCS § 1395w-132(a)*]; and

(D) payments with respect to administrative expenses under this part [*42 USCS §§ 1395w-101* et seq.] in accordance with section 201(g) [*42 USCS § 401(g)*].

(2) Transfers to Medicaid account for increased administrative costs. The Managing Trustee shall transfer from time to time from the Account to the Grants to States for Medicaid account amounts the Secretary certifies are attributable to increases in payment resulting from the application of section 1935(b) [*42 USCS § 1396u-5(b)*].

(3) Payments of premiums withheld. The Managing Trustee shall make payment to the PDP sponsor or MA organization involved of the premiums (and the portion of late enrollment penalties) that are collected in the manner described in section 1854(d)(2)(A) [*42 USCS § 1395w-24(d)(2)(A)*] and that are payable under a prescription drug plan or MA-PD plan offered by such sponsor or organization.

(4) Treatment in relation to part b premium. Amounts payable from the Account shall not be taken into account in computing actuarial rates or premium amounts under section 1839 [*42 USCS § 1395r*].

(c) Deposits into Account.

(1) Low-income transfer. Amounts paid under section 1935(c) [*42 USCS § 1396u-5(c)*] (and any amounts collected or offset under paragraph (1)(C) of such section) are deposited into the Account.

(2) Amounts withheld. Pursuant to sections 1860D-13(c) and 1854(d) [*42 USCS §§ 1395w-113(c)* and *1395w-24(d)*] (as applied under this part [*42 USCS §§ 1395w-101* et seq.]), amounts that are withheld (and allocated) to the Account are deposited into the Account.

(3) Appropriations to cover government contributions. There are authorized to be appropriated from time to time, out of any moneys in the Treasury not otherwise appropriated, to the Account, an amount equivalent to the amount of payments made from the Account under subsection (b) plus such amounts as the Managing Trustee certifies is necessary to maintain an appropriate contingency margin, reduced by the amounts deposited under paragraph (1) or subsection (a)(2).

(4) Initial funding and reserve. In order to assure prompt payment of benefits provided under this part [*42 USCS §§ 1395w-101* et seq.] and the administrative expenses thereunder during the early months of the program established by this part [*42 USCS §§ 1395w-101* et seq.] and to provide an initial contingency reserve, there are authorized to be appropriated to the Account, out of any moneys in the Treasury not otherwise appropriated, such amount as the Secretary certifies are required, but not to exceed 10 percent of the estimated total expenditures from such Account in 2006.

(5) Transfer of any remaining balance from transitional assistance account. Any balance in the Transitional Assistance Account that is transferred under section 1860D-31(k)(5) [*42 USCS § 1395w-141(k)(5)*] shall be deposited into the Account.

HISTORY:

(Aug. 4, 1935, ch 531, Title XVIII, Part D, Subpart 2, § 1860D-16, as added Dec. 8, 2003, P.L. 108-173, Title I, § 101(a)(2), 117 Stat. 2120.)

§ 1395w-131. Application to Medicare Advantage program and related managed care programs

(a) Special rules relating to offering of qualified prescription drug coverage.

(1) In general. An MA organization on and after January 1, 2006--

(A) may not offer an MA plan described in section 1851(a)(2)(A) [*42 USCS § 1395w-21(a)(2)(A)*] in an area unless either that plan (or another MA plan offered by the organization in that same service area) includes required prescription drug coverage (as defined in paragraph (2)); and

(B) may not offer prescription drug coverage (other than that required under parts A and B [*42 USCS §§ 1395c* et seq. and *1395j* et seq.]) to an enrollee--

(i) under an MSA plan; or

(ii) under another MA plan unless such drug coverage under such other plan provides qualified prescription drug coverage and unless the requirements of this section with respect to such coverage are met.

(2) Qualifying coverage. For purposes of paragraph (1)(A), the term "required coverage" means with respect to an MA-PD plan--

(A) basic prescription drug coverage; or

(B) qualified prescription drug coverage that provides supplemental prescription drug coverage, so long as there is no MA monthly supplemental beneficiary premium applied under the plan (due to the application of a credit against such premium of a rebate under section 1854(b)(1)(C) [*42 USCS § 1395w-24(b)(1)(C)*]).

(b) Application of default enrollment rules.

(1) Seamless continuation. In applying section 1851(c)(3)(A)(ii) [*42 USCS § 1395w-21(c)(3)(A)(ii)*], an individual who is enrolled in a health benefits plan shall not be considered to have been deemed to make an election into an MA-PD plan unless such health benefits plan provides any prescription drug coverage.

(2) MA continuation. In applying section 1851(c)(3)(B) [*42 USCS § 1395w-21(c)(3)(B)*], an individual who is enrolled in an MA plan shall not be considered to have been deemed to make an election into an MA-PD plan unless--

(A) for purposes of the election as of January 1, 2006, the MA plan provided as of December 31, 2005, any prescription drug coverage; or

(B) for periods after January 1, 2006, such MA plan is an MA-PD plan.

(3) Discontinuance of MA-PD election during first year of eligibility. In applying the second sentence of section 1851(e)(4) [*42 USCS § 1395w-21(e)(4)*] in the case of an individual who is electing to discontinue enrollment in an MA-PD plan, the individual shall be permitted to enroll in a prescription drug plan under part D [*42 USCS §§ 1395w-101* et seq.] at the time of the election of coverage under the original medicare fee-for-service program.

(4) Rules regarding enrollees in MA plans not providing qualified prescription drug coverage. In the case of an individual who is enrolled in an MA plan (other than an MSA plan) that does not provide qualified prescription drug coverage, if the organization offering such coverage discontinues the offering with respect to the individual of all MA plans that do not provide such coverage--

(i) the individual is deemed to have elected the original medicare fee-for-service program option, unless the individual affirmatively elects to enroll in an MA-PD plan; and

(ii) in the case of such a deemed election, the disenrollment shall be treated as an involuntary termination of the MA plan described in subparagraph (B)(ii) of section 1882(s)(3) [*42 USCS § 1395ss(s)(3)*] for purposes of applying such section.

The information disclosed under section 1852(c)(1) [*42 USCS § 1395w-22(c)(1)*] for individuals who are enrolled in such an MA plan shall include information regarding such rules.

(c) Application of part D rules for prescription drug coverage. With respect to the offering of qualified prescription drug coverage by an MA organization under this part [*42 USCS §§ 1395w-101* et seq.] on and after January 1, 2006--

(1) In general. Except as otherwise provided, the provisions of this part [*42 USCS §§ 1395w-101* et seq.] shall apply under part C [*42 USCS §§ 1395w-21* et seq.] with respect to prescription drug coverage provided under MA-PD plans in lieu of the other provisions of part C [*42 USCS §§ 1395w-21* et seq.] that would apply to such coverage under such plans.

(2) Waiver. The Secretary shall waive the provisions referred to in paragraph (1) to the extent the Secretary determines that such provisions duplicate, or are in conflict with, provisions otherwise applicable to the organization or plan under part C [*42 USCS §§ 1395w-21* et seq.] or as may be necessary in order to improve coordination of this part [*42 USCS §§ 1395w-101* et seq.] with the benefits under this part [*42 USCS §§ 1395w-101* et seq.].

(3) Treatment of MA owned and operated pharmacies. The Secretary may waive the requirement of section 1860D-4(b)(1)(C) [*42 USCS § 1395w-104(b)(1)(C)*] in the case of an MA-PD plan that provides access (other than mail order) to qualified prescription drug coverage through pharmacies owned and operated by the MA organization, if the Secretary determines that the organization's pharmacy network is sufficient to provide comparable access for enrollees under the plan.

(d) Special rules for private fee-for-service plans that offer prescription drug coverage. With respect to an MA plan described in section 1851(a)(2)(C) [*42 USCS § 1395w-21(a)(2)(C)*] that offers qualified prescription drug coverage, on and after January 1, 2006, the following rules apply:

(1) Requirements regarding negotiated prices. Subsections (a)(1) and (d)(1) of section 1860D-2 [*42 USCS § 1395w-102*] and section 1860D-4(b)(2)(A) [*42 USCS § 1395w-104(b)(2)(A)*] shall not be construed to require the plan to provide negotiated prices (described in subsection (d)(1)(B) of such section), but shall apply to the extent the plan does so.

(2) Modification of pharmacy access standard and disclosure requirement. If the plan provides coverage for drugs purchased from all pharmacies, without charging additional cost-sharing, and without regard to whether they are participating pharmacies in a network or have entered into contracts or agreements with pharmacies to provide drugs to enrollees covered by the plan, subsections (b)(1)(C) and (k) of section 1860D-4 [*42 USCS § 1395w-104*] shall not apply to the plan.

(3) Drug utilization management program and medication therapy management program not required. The requirements of subparagraphs (A) and (C) of section 1860D-4(c)(1) [*42 USCS § 1395w-104(c)(1)*] shall not apply to the plan.

(4) Application of reinsurance. The Secretary shall determine the amount of reinsurance payments under section 1860D-15(b) [*42 USCS § 1395w-115(b)*] using a methodology that--

(A) bases such amount on the Secretary's estimate of the amount of such payments that would be payable if the plan were an MA-PD plan described in section 1851(a)(2)(A)(i) [*42 USCS § 1395w-21(a)(2)(A)(i)*] and the previous provisions of this subsection did not apply; and

(B) takes into account the average reinsurance payments made under section 1860D-15(b) [*42 USCS § 1395w-115(b)*] for populations of similar risk under MA-PD plans described in such section.

(5) Exemption from risk corridor provisions. The provisions of section 1860D-15(e) [*42 USCS § 1395w-115(e)*] shall not apply.

(6) Exemption from negotiations. Subsections (d) and (e)(2)(C) of section 1860D-11 [*42 USCS § 1395w-111*] shall not apply and the provisions of section 1854(a)(5)(B) [*42 USCS § 1395w-24(a)(5)(B)*] prohibiting the review, approval, or disapproval of amounts described in such section shall apply to the proposed bid and terms and conditions described in section 1860D-11(d) [*42 USCS § 1395w-111(d)*].

(7) Treatment of incurred costs without regard to formulary. The exclusion of costs incurred for covered part D drugs which are not included (or treated as being included) in a plan's formulary under section 1860D-2(b)(4)(B)(i) [*42 USCS § 1395w-102(b)(4)(B)(i)*] shall not apply insofar as the plan does not utilize a formulary.

(e) Application to reasonable cost reimbursement contractors.

(1) In general. Subject to paragraphs (2) and (3) and rules established by the Secretary, in the case of an organization that is providing benefits under a reasonable cost reimbursement contract under section 1876(h) [*42 USCS § 1395mm(h)*] and that elects to provide qualified prescription drug coverage to a part D eligible individual who is enrolled under such a contract, the provisions of this part [*42 USCS §§ 1395w-101* et seq.] (and related provisions of part C [*42 USCS §§ 1395w-21* et seq.]) shall apply to the provision of such coverage to such enrollee in the same manner as such provisions apply to the provision of such coverage under an MA-PD local plan described in section 1851(a)(2)(A)(i) [*42 USCS § 1395w-21(a)(2)(A)(i)*] and coverage under such a contract that so provides qualified prescription drug coverage shall be deemed to be an MA-PD local plan.

(2) Limitation on enrollment. In applying paragraph (1), the organization may not enroll part D eligible individuals who are not enrolled under the reasonable cost reimbursement contract involved.

(3) Bids not included in determining national average monthly bid amount. The bid of an organization offering prescription drug coverage under this subsection shall not be taken into account in computing the national average monthly bid amount and low-income benchmark premium amount under this part [*42 USCS §§ 1395w-101* et seq.].

(f) Application to PACE.

(1) In general. Subject to paragraphs (2) and (3) and rules established by the Secretary, in the case of a PACE program under section 1894 [*42 USCS § 1395eee*] that elects to provide qualified prescription drug coverage to a part D eligible individual who is enrolled under such program, the provisions of this part [*42 USCS §§ 1395w-101* et seq.] (and related provisions of part C [*42 USCS §§ 1395w-21* et seq.]) shall apply to the provision of such coverage to such enrollee in a manner that is similar to the manner in which such provisions apply to the provision of such coverage under an MA-PD local plan described in section 1851(a)(2)(A)(ii) [*42 USCS § 1395w-21(a)(2)(A)(ii)*] and a PACE program that so provides such coverage may be deemed to be an MA-PD local plan.

(2) Limitation on enrollment. In applying paragraph (1), the organization may not enroll part D eligible individuals who are not enrolled under the PACE program involved.

(3) Bids not included in determining standardized bid amount. The bid of an organization offering prescription drug coverage under this subsection is not be taken into account in computing any average benchmark bid amount and low-income benchmark premium amount under this part [*42 USCS §§ 1395w-101* et seq.].

HISTORY:

(Aug. 4, 1935, ch 531, Title XVIII, Part D, Subpart 3, § 1860D-21, as added Dec. 8, 2003, P.L. 108-173, Title I, § 101(a)(2), 117 Stat. 2122.)

§ 1395w-132. Special rules for employer-sponsored programs

(a) Subsidy payment.

(1) In general. The Secretary shall provide in accordance with this subsection for payment to the sponsor of a qualified retiree prescription drug plan (as defined in paragraph (2)) of a special subsidy payment equal to the amount specified in paragraph (3) for each qualified covered retiree under the plan (as defined in paragraph (4)). This subsection constitutes budget authority in advance of appropriations Acts and represents the obligation of the Secretary to provide for the payment of amounts provided under this section.

(2) Qualified retiree prescription drug plan defined. For purposes of this subsection, the term "qualified retiree prescription drug plan" means employment-based retiree health coverage (as defined in subsection (c)(1)) if, with respect to a part D eligible individual who is a participant or beneficiary under such coverage, the following requirements are met:

(A) Attestation of actuarial equivalence to standard coverage. The sponsor of the plan provides the Secretary, annually or at such other time as the Secretary may require, with an attestation that the actuarial value of prescription drug coverage under the plan (as determined using the processes and methods described in section 1860D-11(c) [*42 USCS § 1395w-111(c)*]) is at least equal to the actuarial value of standard prescription drug coverage.

(B) Audits. The sponsor of the plan, or an administrator of the plan designated by the sponsor, shall maintain (and afford the Secretary access to) such records as the Secretary may require for purposes of audits and other oversight activities necessary to ensure the adequacy of prescription drug coverage and the accuracy of payments made under this section. The provisions of section 1860D-2(d)(3) [*42 USCS § 1395w-102(d)(3)*] shall apply to such information under this section (including such actuarial value and attestation) in a manner similar to the manner in which they apply to financial records of PDP sponsors and MA organizations.

(C) Provision of disclosure regarding prescription drug coverage. The sponsor of the plan shall provide for disclosure of information regarding prescription drug coverage in accordance with section 1860D-13(b)(6)(B) [*42 USCS § 1395w-113(b)(6)(B)*].

(3) Employer and union special subsidy amounts.

(A) In general. For purposes of this subsection, the special subsidy payment amount under this paragraph for a qualifying covered retiree for a coverage year enrolled with the sponsor of a qualified retiree prescription drug plan is, for the portion of the retiree's gross covered retiree plan-related prescription drug costs (as defined in subparagraph (C)(ii)) for such year that exceeds the cost threshold amount specified in subparagraph (B) and does not exceed the cost limit under such subparagraph, an amount equal to 28 percent of the allowable retiree costs (as defined in subparagraph (C)(i)) attributable to such gross covered prescription drug costs.

(B) Cost threshold and cost limit applicable.

(i) In general. Subject to clause (ii)--

(I) the cost threshold under this subparagraph is equal to $ 250 for plan years that end in 2006; and

(II) the cost limit under this subparagraph is equal to $ 5,000 for plan years that end in 2006.

(ii) Indexing. The cost threshold and cost limit amounts specified in subclauses (I) and (II) of clause (i) for a plan year that ends after 2006 shall be adjusted in the same manner as the annual deductible and the annual out-of-pocket threshold, respectively, are annually adjusted under paragraphs (1) and (4)(B) of section 1860D-2(b) [*42 USCS § 1395w-102(b)*].

(C) Definitions. For purposes of this paragraph:

(i) Allowable retiree costs. The term "allowable retiree costs" means, with respect to gross covered prescription drug costs under a qualified retiree prescription drug plan by a plan sponsor, the part of such costs that are actually paid (net of discounts, chargebacks, and average percentage rebates) by the sponsor or by or on behalf of a qualifying covered retiree under the plan.

(ii) Gross covered retiree plan-related prescription drug costs. For purposes of this section, the term "gross covered retiree plan-related prescription drug costs" means, with respect to a qualifying covered retiree enrolled in a qualified retiree prescription drug plan during a coverage year, the costs incurred under the plan, not including administrative costs, but including costs directly related to the dispensing of covered part D drugs during the year. Such costs shall be determined whether they are paid by the retiree or under the plan.

(iii) Coverage year. The term "coverage year" has the meaning given such term in section 1860D-15(b)(4) [*42 USCS § 1395w-115(b)(4)*].

(4) Qualifying covered retiree defined. For purposes of this subsection, the term "qualifying covered retiree" means a part D eligible individual who is not enrolled in a prescription drug plan or an MA-PD plan but is covered under a qualified retiree prescription drug plan.

(5) Payment methods, including provision of necessary information. The provisions of section 1860D-15(d) [*42 USCS § 1395w-115(d)*] (including paragraph (2), relating to requirement for provision of information) shall apply to payments under this subsection in a manner similar to the manner in which they apply to payment under section 1860D-15(b) [*42 USCS § 1395w-115(b)*].

(6) Construction. Nothing in this subsection shall be construed as--

(A) precluding a part D eligible individual who is covered under employment-based retiree health coverage from enrolling in a prescription drug plan or in an MA-PD plan;

(B) precluding such employment-based retiree health coverage or an employer or other person from paying all or any portion of any premium required for coverage under a prescription drug plan or MA-PD plan on behalf of such an individual;

(C) preventing such employment-based retiree health coverage from providing coverage--

(i) that is better than standard prescription drug coverage to retirees who are covered under a qualified retiree prescription drug plan; or

(ii) that is supplemental to the benefits provided under a prescription drug plan or an MA-PD plan, including benefits to retirees who are not covered under a qualified retiree prescription drug plan but who are enrolled in such a prescription drug plan or MA-PD plan; or

(D) preventing employers to provide for flexibility in benefit design and pharmacy access provisions, without regard to the requirements for basic prescription drug coverage, so long as the actuarial equivalence requirement of paragraph (2)(A) is met.

(b) Application of MA waiver authority. The provisions of section 1857(i) [*42 USCS § 1395w-27(i)*] shall apply with respect to prescription drug plans in relation to employment-based retiree health coverage in a manner similar to the manner in which they apply to an MA plan in relation to employers, including authorizing the establishment of separate premium amounts for enrollees in a prescription drug plan by reason of such coverage and limitations on enrollment to part D eligible individuals enrolled under such coverage.

(c) Definitions. For purposes of this section:

(1) Employment-based retiree health coverage. The term "employment-based retiree health coverage" means health insurance or other coverage of health care costs (whether provided by voluntary insurance coverage or pursuant to statutory or contractual obligation) for part D eligible individuals (or for such individuals and their spouses and dependents) under a group health plan based on their status as retired participants in such plan.

(2) Sponsor. The term "sponsor" means a plan sponsor, as defined in section 3(16)(B) of the Employee Retirement Income Security Act of 1974 [*29 USCS § 1002(16)(B)*], in relation to a group health plan, except that, in the case of a plan maintained jointly by one employer and an employee organization and with respect to which the employer is the primary source of financing, such term means such employer.

(3) Group health plan. The term "group health plan" includes such a plan as defined in section 607(1) of the Employee Retirement Income Security Act of 1974 [*29 USCS § 1167(1)*] and also includes the following:

(A) Federal and State governmental plans. Such a plan established or maintained for its employees by the Government of the United States, by the government of any State or political subdivision thereof, or by any agency or instrumentality of any of the foregoing, including a health benefits plan offered under chapter 89 of title 5, United States Code [*5 USCS §§ 8901* et seq.].

(B) Collectively bargained plans. Such a plan established or maintained under or pursuant to one or more collective bargaining agreements.

(C) Church plans. Such a plan established and maintained for its employees (or their beneficiaries) by a church or by a convention or association of churches which is exempt from tax under *section 501 of the Internal Revenue Code of 1986* [*26 USCS § 501*].

HISTORY:

(Aug. 4, 1935, ch 531, Title XVIII, Part D, Subpart 3, § 1860D-22, as added Dec. 8, 2003, P.L. 108-173, Title I, § 101(a)(2), 117 Stat. 2125.)

§ 1395w-133. State pharmaceutical assistance programs

(a) Requirements for benefit coordination.

(1) In general. Before July 1, 2005, the Secretary shall establish consistent with this section requirements for prescription drug plans to ensure the effective coordination between a part D plan (as defined in paragraph (5)) and a State Pharmaceutical Assistance Program (as defined in subsection (b)) with respect to--

(A) payment of premiums and coverage; and

(B) payment for supplemental prescription drug benefits,

for part D eligible individuals enrolled under both types of plans.

(2) Coordination elements. The requirements under paragraph (1) shall include requirements relating to coordination of each of the following:

(A) Enrollment file sharing.

(B) The processing of claims, including electronic processing.

(C) Claims payment.

(D) Claims reconciliation reports.

(E) Application of the protection against high out-of-pocket expenditures under section 1860D-2(b)(4) [*42 USCS § 1395w-102(b)(4)*].

(F) Other administrative processes specified by the Secretary.

Such requirements shall be consistent with applicable law to safeguard the privacy of any individually identifiable beneficiary information.

(3) Use of lump sum per capita method. Such requirements shall include a method for the application by a part D plan of specified funding amounts from a State Pharmaceutical Assistance Program for enrolled individuals for supplemental prescription drug benefits.

(4) Consultation. In establishing requirements under this subsection, the Secretary shall consult with State Pharmaceutical Assistance Programs, MA organizations, States, pharmaceutical benefit managers, employers, representatives of part D eligible individuals, the data processing experts, pharmacists, pharmaceutical manufacturers, and other experts.

(5) Part D plan defined. For purposes of this section and section 1860D-24 [*42 USCS § 1395w-134*], the term "part D plan" means a prescription drug plan and an MA-PD plan.

(b) State Pharmaceutical Assistance Program. For purposes of this part [*42 USCS §§ 1395w-101* et seq.], the term "State Pharmaceutical Assistance Program" means a State program--

(1) which provides financial assistance for the purchase or provision of supplemental prescription drug coverage or benefits on behalf of part D eligible individuals;

(2) which, in determining eligibility and the amount of assistance to part D eligible individuals under the Program, provides assistance to such individuals in all part D plans and does not discriminate based upon the part D plan in which the individual is enrolled; and

(3) which satisfies the requirements of subsections (a) and (c).

(c) Relation to other provisions.

(1) Medicare as primary payor. The requirements of this section shall not change or affect the primary payor status of a part D plan.

(2) Use of a single card. A card that is issued under section 1860D-4(b)(2)(A) [*42 USCS § 1395w-104(b)(2)(A)*] for use under a part D plan may also be used in connection with coverage of benefits provided under a State Pharmaceutical Assistance Program and, in such case, may contain an emblem or symbol indicating such connection.

(3) Other provisions. The provisions of section 1860D-24(c) [*42 USCS § 1395w-134(c)*] shall apply to the requirements under this section.

(4) Special treatment under out-of-pocket rule. In applying section 1860D-2(b)(4)(C)(ii) [*42 USCS § 1395w-102(b)(4)(C)(ii)*], expenses incurred under a State Pharmaceutical Assistance Program may be counted toward the annual out-of-pocket threshold.

(5) Construction. Nothing in this section shall be construed as requiring a State Pharmaceutical Assistance Program to coordinate or provide financial assistance with respect to any part D plan.

(d) Facilitation of transition and coordination with State Pharmaceutical Assistance Programs.

(1) Transitional grant program. The Secretary shall provide payments to State Pharmaceutical Assistance Programs with an application approved under this subsection.

(2) Use of funds. Payments under this section may be used by a Program for any of the following:

(A) Educating part D eligible individuals enrolled in the Program about the prescription drug coverage available through part D plans under this part [*42 USCS §§ 1395w-101* et seq.].

(B) Providing technical assistance, phone support, and counseling for such enrollees to facilitate selection and enrollment in such plans.

(C) Other activities designed to promote the effective coordination of enrollment, coverage, and payment between such Program and such plans.

(3) Allocation of funds. Of the amount appropriated to carry out this subsection for a fiscal year, the Secretary shall allocate payments among Programs that have applications approved under paragraph (4) for such fiscal year in proportion to the number of enrollees enrolled in each such Program as of October 1, 2003.

(4) Application. No payments may be made under this subsection except pursuant to an application that is submitted and approved in a time, manner, and form specified by the Secretary.

(5) Funding. Out of any funds in the Treasury not otherwise appropriated, there are appropriated for each of fiscal years 2005 and 2006, $ 62,500,000 to carry out this subsection.

HISTORY:

(Aug. 4, 1935, ch 531, Title XVIII, Part D, Subpart 3, § 1860D-23, as added Dec. 8, 2003, P.L. 108-173, Title I, § 101(a)(2), 117 Stat. 2128.)

§ 1395w-134. Coordination requirements for plans providing prescription drug coverage

(a) Application of benefit coordination requirements to additional plans.

(1) In general. The Secretary shall apply the coordination requirements established under section 1860D-23(a) [*42 USCS § 1395w-133(a)*] to Rx plans described in subsection (b) in the same manner as such requirements apply to a State Pharmaceutical Assistance Program.

(2) Application to treatment of certain out-of-pocket expenditures. To the extent specified by the Secretary, the requirements referred to in paragraph (1) shall apply to procedures established under section 1860D-2(b)(4)(D) [*42 USCS § 1395w-102(b)(4)(D)*].

(3) User fees.

(A) In general. The Secretary may impose user fees for the transmittal of information necessary for benefit coordination under section 1860D-2(b)(4)(D) [*42 USCS § 1395w-102(b)(4)(D)*] in a manner similar to the manner in which user fees are imposed under section 1842(h)(3)(B) [*42 USCS § 1395u(h)(3)(B)*], except that the Secretary may retain a portion of such fees to defray the Secretary's costs in carrying out procedures under section 1860D-2(b)(4)(D) [*42 USCS § 1395w-102(b)(4)(D)*].

(B) Application. A user fee may not be imposed under subparagraph (A) with respect to a State Pharmaceutical Assistance Program.

(b) Rx plan. An Rx plan described in this subsection is any of the following:

(1) Medicaid programs. A State plan under title XIX [*42 USCS §§ 1396* et seq.], including such a plan operating under a waiver under section 1115 [*42 USCS § 1315*], if it meets the requirements of section 1860D-23(b)(2) [*42 USCS § 1395w-133(b)(2)*].

(2) Group health plans. An employer group health plan.

(3) FEHBP. The Federal employees health benefits plan under chapter 89 of title 5, United States Code [*5 USCS §§ 8901* et seq.].

(4) Military coverage (including TRICARE). Coverage under chapter 55 of title 10, United States Code [*10 USCS §§ 1071* et seq.].

(5) Other prescription drug coverage. Such other health benefit plans or programs that provide coverage or financial assistance for the purchase or provision of prescription drug coverage on behalf of part D eligible individuals as the Secretary may specify.

(c) Relation to other provisions.

(1) Use of cost management tools. The requirements of this section shall not impair or prevent a PDP sponsor or MA organization from applying cost management tools (including differential payments) under all methods of operation.

(2) No affect [effect] on treatment of certain out-of-pocket expenditures. The requirements of this section shall not affect the application of the procedures established under section 1860D-2(b)(4)(D) [*42 USCS § 1395w-102(b)(4)(D)*].

HISTORY:

(Aug. 4, 1935, ch 531, Title XVIII, Part D, Subpart 3, § 1860D-24, as added Dec. 8, 2003, P.L. 108-173, Title I, § 101(a)(2), 117 Stat. 2130.)

§ 1395w-141. Medicare prescription drug discount card and transitional assistance program

(a) Establishment of program.

(1) In general. The Secretary shall establish a program under this section--

(A) to endorse prescription drug discount card programs that meet the requirements of this section in order to provide access to prescription drug discounts through prescription drug card sponsors for discount card eligible individuals throughout the United States; and

(B) to provide for transitional assistance for transitional assistance eligible individuals enrolled in such endorsed programs.

(2) Period of operation.

(A) Implementation deadline. The Secretary shall implement the program under this section so that discount cards and transitional assistance are first available by not later than 6 months after the date of the enactment of this section [enacted Dec. 8, 2003].

(B) Expediting implementation. The Secretary shall promulgate regulations to carry out the program under this section which may be effective and final immediately on an interim basis as of the date of publication of the interim final regulation. If the Secretary provides for an interim final regulation, the Secretary shall provide for a period of public comments on such regulation after the date of publication. The Secretary may change or revise such regulation after completion of the period of public comment.

(C) Termination and transition.

(i) In general. Subject to clause (ii)--

(I) the program under this section shall not apply to covered discount card drugs dispensed after December 31, 2005; and

(II) transitional assistance shall be available after such date to the extent the assistance relates to drugs dispensed on or before such date.

(ii) Transition. In the case of an individual who is enrolled in an endorsed discount card program as of December 31, 2005, during the individual's transition period (if any) under clause (iii), in accordance with transition rules specified by the Secretary--

(I) such endorsed program may continue to apply to covered discount card drugs dispensed to the individual under the program during such transition period;

(II) no annual enrollment fee shall be applicable during the transition period;

(III) during such period the individual may not change the endorsed program plan in which the individual is enrolled; and

(IV) the balance of any transitional assistance remaining on January 1, 2006, shall remain available for drugs dispensed during the individual's transition period.

(iii) Transition period. The transition period under this clause for an individual is the period beginning on January 1, 2006, and ending in the case of an individual who--

(I) is enrolled in a prescription drug plan or an MA-PD plan before the last date of the initial enrollment period under section 1860D-1(b)(2)(A) [*42 USCS § 1395w-101(b)(2)(A)*], on the effective date of the individual's coverage under such part; or

(II) is not so enrolled, on the last day of such initial period.

(3) Voluntary nature of program. Nothing in this section shall be construed as requiring a discount card eligible individual to enroll in an endorsed discount card program under this section.

(4) Glossary and definitions of terms. For purposes of this section:

(A) Covered discount card drug. The term "covered discount card drug" has the meaning given the term "covered part D drug" in section 1860D-2(e) [*42 USCS § 1395w-102(e)*].

(B) Discount card eligible individual. The term "discount card eligible individual" is defined in subsection (b)(1)(A).

(C) Endorsed discount card program; endorsed program. The terms "endorsed discount card program" and "endorsed program" mean a prescription drug discount card program that is endorsed (and for which the sponsor has a contract with the Secretary) under this section.

(D) Negotiated price. Negotiated prices are described in subsection (e)(1)(A)(ii).

(E) Prescription drug card sponsor; sponsor. The terms "prescription drug card sponsor" and "sponsor" are defined in subsection (h)(1)(A).

(F) State. The term "State" has the meaning given such term for purposes of title XIX [*42 USCS §§ 1396* et seq.].

(G) Transitional assistance eligible individual. The term "transitional assistance eligible individual" is defined in subsection (b)(2).

(b) Eligibility for discount card and for transitional assistance. For purposes of this section:

(1) Discount card eligible individual.

(A) In general. The term "discount card eligible individual" means an individual who--

(i) is entitled to benefits, or enrolled, under part A [*42 USCS §§ 1395c* et seq.] or enrolled under part B [*42 USCS §§ 1395j* et seq.]; and

(ii) subject to paragraph (4), is not an individual described in subparagraph (B).

(B) Individual described. An individual described in this subparagraph is an individual described in subparagraph (A)(i) who is enrolled under title XIX [*42 USCS §§ 1396* et seq.] (or under a waiver under section 1115 [*42 USCS § 1315*] of the requirements of such title) and is entitled to any medical assistance for outpatient prescribed drugs described in section 1905(a)(12) [*42 USCS § 1396d(a)(12)*].

(2) Transitional assistance eligible individual.

(A) In general. Subject to subparagraph (B), the term "transitional assistance eligible individual" means a discount card eligible individual who resides in one of the 50 States or the District of Columbia and whose income (as determined under subsection (f)(1)(B)) is not more than 135 percent of the poverty line (as defined in section 673(2) of the Community Services Block Grant Act, *42 U.S.C. 9902(2)*, including any revision required by such section) applicable to the family size involved (as determined under subsection (f)(1)(B)).

(B) Exclusion of individuals with certain prescription drug coverage. Such term does not include an individual who has coverage of, or assistance for, covered discount card drugs under any of the following:

(i) A group health plan or health insurance coverage (as such terms are defined in section 2791 of the Public Health Service Act [*42 USCS § 300gg-91*]), other than coverage under a plan under part C [*42 USCS §§ 1395w-21* et seq.] and other than coverage consisting only of excepted benefits (as defined in such section).

(ii) Chapter 55 of title 10, United States Code [*10 USCS §§ 1071* et seq.] (relating to medical and dental care for members of the uniformed services).

(iii) A plan under chapter 89 of title 5, United States Code [*5 USCS §§ 8901* et seq.] (relating to the Federal employees' health benefits program).

(3) Special transitional assistance eligible individual. The term "special transitional assistance eligible individual" means a transitional assistance eligible individual whose income (as determined under subsection (f)(1)(B)) is not more than 100 percent of the poverty line (as defined in section 673(2) of the Community Services Block Grant Act, *42 U.S.C. 9902(2)*, including any revision required by such section) applicable to the family size involved (as determined under subsection (f)(1)(B)).

(4) Treatment of medicaid medically needy. For purposes of this section, the Secretary shall provide for appropriate rules for the treatment of medically needy individuals described in section 1902(a)(10)(C) [*42 USCS § 1396a(a)(10)(C)*] as discount card eligible individuals and as transitional assistance eligible individuals.

(c) Enrollment and enrollment fees.

(1) Enrollment process. The Secretary shall establish a process through which a discount card eligible individual is enrolled and disenrolled in an endorsed discount card program under this section consistent with the following:

(A) Continuous open enrollment. Subject to the succeeding provisions of this paragraph and subsection (h)(9), a discount card eligible individual who is not enrolled in an endorsed discount card program and is residing in a State may enroll in any such endorsed program--

(i) that serves residents of the State; and

(ii) at any time beginning on the initial enrollment date, specified by the Secretary, and before January 1, 2006.

(B) Use of standard enrollment form. An enrollment in an endorsed program shall only be effected through completion of a standard enrollment form specified by the Secretary. Each sponsor of an endorsed program shall transmit to the Secretary (in a form and manner specified by the Secretary) information on individuals who complete such enrollment forms and, to the extent provided under subsection (f), information regarding certification as a transitional assistance eligible individual.

(C) Enrollment only in one program.

(i) In general. Subject to clauses (ii) and (iii), a discount card eligible individual may be enrolled in only one endorsed discount card program under this section.

(ii) Change in endorsed program permitted for 2005. The Secretary shall establish a process, similar to (and coordinated with) the process for annual, coordinated elections under section 1851(e)(3) [*42 USCS § 1395w-21(e)(3)*] during 2004, under which an individual enrolled in an endorsed discount card program may change the endorsed program in which the individual is enrolled for 2005.

(iii) Additional exceptions. The Secretary shall permit an individual to change the endorsed discount card program in which the individual is enrolled in the case of an individual who changes residence to be outside the service area of such program and in such other exceptional cases as the Secretary may provide (taking into account the circumstances for special election periods under section 1851(e)(4) [*42 USCS § 1395w-21(e)(4)*]). Under the previous sentence, the Secretary may consider a change in residential setting (such as placement in a nursing facility) or enrollment in or disenrollment from a plan under part C [*42 USCS §§ 1395w-21* et seq.] through which the individual was enrolled in an endorsed program to be an exceptional circumstance.

(D) Disenrollment.

(i) Voluntary. An individual may voluntarily disenroll from an endorsed discount card program at any time. In the case of such a voluntary disenrollment, the individual may not enroll in another endorsed program, except under such exceptional circumstances as the Secretary may recognize under subparagraph (C)(iii) or during the annual coordinated enrollment period provided under subparagraph (C)(ii).

(ii) Involuntary. An individual who is enrolled in an endorsed discount card program and not a transitional assistance eligible individual may be disenrolled by the sponsor of the program if the individual fails to pay any annual enrollment fee required under the program.

(E) Application to certain enrollees. In the case of a discount card eligible individual who is enrolled in a plan described in section 1851(a)(2)(A) [*42 USCS § 1395w-21(a)(2)(A)*] or under a reasonable cost reimbursement contract under section 1876(h) [*42 USCS § 1395mm(h)*] that is offered by an organization that also is a prescription discount card sponsor that offers an endorsed discount card program under which the individual may be enrolled and that has made an election to apply the special rules under subsection (h)(9)(B) for such an endorsed program, the individual may only enroll in such an endorsed discount card program offered by that sponsor.

(2) Enrollment fees.

(A) In general. Subject to the succeeding provisions of this paragraph, a prescription drug card sponsor may charge an annual enrollment fee for each discount card eligible individual enrolled in an endorsed discount card program offered by such sponsor. The annual enrollment fee for either 2004 or 2005 shall not be prorated for portions of a year. There shall be no annual enrollment fee for a year after 2005.

(B) Amount. No annual enrollment fee charged under subparagraph (A) may exceed $ 30.

(C) Uniform enrollment fee. A prescription drug card sponsor shall ensure that the annual enrollment fee (if any) for an endorsed discount card program is the same for all discount card eligible individuals enrolled in the program and residing in the State.

(D) Collection. The annual enrollment fee (if any) charged for enrollment in an endorsed program shall be collected by the sponsor of the program.

(E) Payment of fee for transitional assistance eligible individuals. Under subsection (g)(1)(A), the annual enrollment fee (if any) otherwise charged under this paragraph with respect to a transitional assistance eligible individual shall be paid by the Secretary on behalf of such individual.

(F) Optional payment of fee by State.

(i) In general. The Secretary shall establish an arrangement under which a State may provide for payment of some or all of the enrollment fee for some or all enrollees who are not transitional assistance eligible individuals in the State, as specified by the State under the arrangement. Insofar as such a payment arrangement is made with respect to an enrollee, the amount of the enrollment fee shall be paid directly by the State to the sponsor.

(ii) No Federal matching available under medicaid or SCHIP. Expenditures made by a State for enrollment fees described in clause (i) shall not be treated as State expenditures for purposes of Federal matching payments under title XIX or XXI [*42 USCS §§ 1396* et seq. or *1397aa* et seq.].

(G) Rules in case of changes in program enrollment during a year. The Secretary shall provide special rules in the case of payment of an annual enrollment fee for a discount card eligible individual who changes the endorsed program in which the individual is enrolled during a year.

(3) Issuance of discount card. Each prescription drug card sponsor of an endorsed discount card program shall issue, in a standard format specified by the Secretary, to each discount card eligible individual enrolled in such program a card that establishes proof of enrollment and that can be used in a coordinated manner to identify the sponsor, program, and individual for purposes of the program under this section.

(4) Period of access. In the case of a discount card eligible individual who enrolls in an endorsed program, access to negotiated prices and transitional assistance, if any, under such endorsed program shall take effect on such date as the Secretary shall specify.

(d) Provision of information on enrollment and program features.

(1) Secretarial responsibilities.

(A) In general. The Secretary shall provide for activities under this subsection to broadly disseminate information to discount card eligible individuals (and prospective eligible individuals) regarding--

(i) enrollment in endorsed discount card programs; and

(ii) the features of the program under this section, including the availability of transitional assistance.

(B) Promotion of informed choice. In order to promote informed choice among endorsed prescription drug discount card programs, the Secretary shall provide for the dissemination of information which--

(i) compares the annual enrollment fee and other features of such programs, which may include comparative prices for covered discount card drugs; and

(ii) includes educational materials on the variability of discounts on prices of covered discount card drugs under an endorsed program.

The dissemination of information under clause (i) shall, to the extent practicable, be coordinated with the dissemination of educational information on other medicare options.

(C) Special rule for initial enrollment date under the program. To the extent practicable, the Secretary shall ensure, through the activities described in subparagraphs (A) and (B), that discount card eligible individuals are provided with such information at least 30 days prior to the initial enrollment date specified under subsection (c)(1)(A)(ii).

(D) Use of medicare toll-free number. The Secretary shall provide through the toll-free telephone number 1-800-MEDICARE for the receipt and response to inquiries and complaints concerning the program under this section and endorsed programs.

(2) Prescription drug card sponsor responsibilities.

(A) In general. Each prescription drug card sponsor that offers an endorsed discount card program shall make available to discount card eligible individuals (through the Internet and otherwise) information that the Secretary identifies as being necessary to promote informed choice among endorsed discount card programs by such individuals, including information on enrollment fees and negotiated prices for covered discount card drugs charged to such individuals.

(B) Response to enrollee questions. Each sponsor offering an endorsed discount card program shall have a mechanism (including a toll-free telephone number) for providing upon request specific information (such as negotiated prices and the amount of transitional assistance remaining available through the program) to discount card eligible individuals enrolled in the program. The sponsor shall inform transitional assistance eligible individuals enrolled in the program of the availability of such toll-free telephone number to provide information on the amount of available transitional assistance.

(C) Information on balance of transitional assistance available at point-of-sale. Each sponsor offering an endorsed discount card program shall have a mechanism so that information on the amount of transitional assistance remaining under subsection (g)(1)(B) is available (electronically or by telephone) at the point-of-sale of covered discount card drugs.

(3) Public disclosure of pharmaceutical prices for equivalent drugs.

(A) In general. A prescription drug card sponsor offering an endorsed discount card program shall provide that each pharmacy that dispenses a covered discount card drug shall inform a discount card eligible individual enrolled in the program of any differential between the price of the drug to the enrollee and the price of the lowest priced generic covered discount card drug under the program that is therapeutically equivalent and bioequivalent and available at such pharmacy.

(B) Timing of notice.

(i) In general. Subject to clause (ii), the information under subparagraph (A) shall be provided at the time of purchase of the drug involved, or, in the case of dispensing by mail order, at the time of delivery of such drug.

(ii) Waiver. The Secretary may waive clause (i) in such circumstances as the Secretary may specify.

(e) Discount card features.

(1) Savings to enrollees through negotiated prices.

(A) Access to negotiated prices.

(i) In general. Each prescription drug card sponsor that offers an endorsed discount card program shall provide each discount card eligible individual enrolled in the program with access to negotiated prices.

(ii) Negotiated prices. For purposes of this section, negotiated prices shall take into account negotiated price concessions, such as discounts, direct or indirect subsidies, rebates, and direct or indirect remunerations, for covered discount card drugs, and include any dispensing fees for such drugs.

(B) Ensuring pharmacy access. Each prescription drug card sponsor offering an endorsed discount card program shall secure the participation in its network of a sufficient number of pharmacies that dispense (other than solely by mail order) drugs directly to enrollees to ensure convenient access to covered discount card drugs at negotiated prices (consistent with rules established by the Secretary). The Secretary shall establish convenient access rules under this clause that are no less favorable to enrollees than the standards for convenient access to pharmacies included in the statement of work of solicitation (#MDA906-03-R-0002) of the Department of Defense under the TRICARE Retail Pharmacy (TRRx) as of March 13, 2003.

(C) Prohibition on charges for required services.

(i) In general. Subject to clause (ii), a prescription drug card sponsor (and any pharmacy contracting with such sponsor for the provision of covered discount card drugs to individuals enrolled in such sponsor's endorsed discount card program) may not charge an enrollee any amount for any items and services required to be provided by the sponsor under this section.

(ii) Construction. Nothing in clause (i) shall be construed to prevent--

(I) the sponsor from charging the annual enrollment fee (except in the case of a transitional assistance eligible individual); and

(II) the pharmacy dispensing the covered discount card drug, from imposing a charge (consistent with the negotiated price) for the covered discount card drug dispensed, reduced by the amount of any transitional assistance made available.

(D) Inapplicability of medicaid best price rules. The prices negotiated from drug manufacturers for covered discount card drugs under an endorsed discount card program under this section shall (notwithstanding any other provision of law) not be taken into account for the purposes of establishing the best price under section 1927(c)(1)(C) [*42 USCS § 1396s(c)(1)(C)*].

(2) Reduction of medication errors and adverse drug interactions. Each endorsed discount card program shall implement a system to reduce the likelihood of medication errors and adverse drug interactions and to improve medication use.

(f) Eligibility procedures for endorsed programs and transitional assistance.

(1) Determinations.

(A) Procedures. The determination of whether an individual is a discount card eligible individual or a transitional assistance eligible individual or a special transitional assistance eligible individual (as defined in subsection (b)) shall be determined under procedures specified by the Secretary consistent with this subsection.

(B) Income and family size determinations. For purposes of this section, the Secretary shall define the terms "income" and "family size" and shall specify the methods and period for which they are determined. If under such methods income or family size is determined based on the income or family size for prior periods of time, the Secretary shall permit (whether through a process of reconsideration or otherwise) an individual whose income or family size has changed to elect to have eligibility for transitional assistance determined based on income or family size for a more recent period.

(2) Use of self-certification for transitional assistance.

(A) In general. Under the procedures specified under paragraph (1)(A) an individual who wishes to be treated as a transitional assistance eligible individual or a special transitional assistance eligible individual under this section (or another qualified person on such individual's behalf) shall certify on the enrollment form under subsection (c)(1)(B) (or similar form specified by the Secretary), through a simplified means specified by the Secretary and under penalty of perjury or similar sanction for false statements, as to the amount of the individual's income, family size, and individual's prescription drug coverage (if any) insofar as they relate to eligibility to be a transitional assistance eligible individual or a special transitional assistance eligible individual. Such certification shall be deemed as consent to verification of respective eligibility under paragraph (3). A certification under this paragraph may be provided before, on, or after the time of enrollment under an endorsed program.

(B) Treatment of self-certification. The Secretary shall treat a certification under subparagraph (A) that is verified under paragraph (3) as a determination that the individual involved is a transitional assistance eligible individual or special transitional assistance eligible individual (as the case may be) for the entire period of the enrollment of the individual in any endorsed program.

(3) Verification.

(A) In general. The Secretary shall establish methods (which may include the use of sampling and the use of information described in subparagraph (B)) to verify eligibility for individuals who seek to enroll in an endorsed program and for individuals who provide a certification under paragraph (2).

(B) Information described. The information described in this subparagraph is as follows:

(i) Medicaid-related information. Information on eligibility under title XIX [*42 USCS §§ 1396* et seq.] and provided to the Secretary under arrangements between the Secretary and States in order to verify the eligibility of individuals who seek to enroll in an endorsed program and of individuals who provide certification under paragraph (2).

(ii) Social security information. Financial information made available to the Secretary under arrangements between the Secretary and the Commissioner of Social Security in order to verify the eligibility of individuals who provide such certification.

(iii) Information from Secretary of the Treasury. Financial information made available to the Secretary under *section 6103(l)(19) of the Internal Revenue Code of 1986* [*26 USCS § 6103(l)(19)*] in order to verify the eligibility of individuals who provide such certification.

(C) Verification in cases of medicaid enrollees.

(i) In general. Nothing in this section shall be construed as preventing the Secretary from finding that a discount card eligible individual meets the income requirements under subsection (b)(2)(A) if the individual is within a category of discount card eligible individuals who are enrolled under title XIX [*42 USCS §§ 1396* et seq.] (such as qualified medicare beneficiaries (QMBs), specified low-income medicare beneficiaries (SLMBs), and certain qualified individuals (QI-1s)).

(ii) Availability of information for verification purposes. As a condition of provision of Federal financial participation to a State that is one of the 50 States or the District of Columbia under title XIX [*42 USCS §§ 1396* et seq.], for purposes of carrying out this section, the State shall provide the information it submits to the Secretary relating to such title in a manner specified by the Secretary that permits the Secretary to identify individuals who are described in subsection (b)(1)(B) or are transitional assistance eligible individuals or special transitional assistance eligible individuals.

(4) Reconsideration.

(A) In general. The Secretary shall establish a process under which a discount card eligible individual, who is determined through the certification and verification methods under paragraphs (2) and (3) not to be a transitional assistance eligible individual or a special transitional assistance eligible individual, may request a reconsideration of the determination.

(B) Contract authority. The Secretary may enter into a contract to perform the reconsiderations requested under subparagraph (A).

(C) Communication of results. Under the process under subparagraph (A) the results of such reconsideration shall be communicated to the individual and the prescription drug card sponsor involved.

(g) Transitional assistance.

(1) Provision of transitional assistance. An individual who is a transitional assistance eligible individual (as determined under this section) and who is enrolled with an endorsed program is entitled--

(A) to have payment made of any annual enrollment fee charged under subsection (c)(2) for enrollment under the program; and

(B) to have payment made, up to the amount specified in paragraph (2), under such endorsed program of 90 percent (or 95 percent in the case of a special transitional assistance eligible individual) of the costs incurred for covered discount card drugs obtained through the program taking into account the negotiated price (if any) for the drug under the program.

(2) Limitation on dollar amount.

(A) In general. Subject to subparagraph (B), the amount specified in this paragraph for a transitional assistance eligible individual--

(i) for costs incurred during 2004, is $ 600; or

(ii) for costs incurred during 2005, is--

(I) $ 600, plus

(II) except as provided in subparagraph (E), the amount by which the amount available under this paragraph for 2004 for that individual exceeds the amount of payment made under paragraph (1)(B) for that individual for costs incurred during 2004.

(B) Proration.

(i) In general. In the case of an individual not described in clause (ii) with respect to a year, the Secretary may prorate the amount specified in subparagraph (A) for the balance of the year involved in a manner specified by the Secretary.

(ii) Individual described. An individual described in this clause is a transitional assistance eligible individual who--

(I) with respect to 2004, enrolls in an endorsed program, and provides a certification under subsection (f)(2), before the initial implementation date of the program under this section; and

(II) with respect to 2005, is enrolled in an endorsed program, and has provided such a certification, before February 1, 2005.

(C) Accounting for available balances in cases of changes in program enrollment. In the case of a transitional assistance eligible individual who changes the endorsed discount card program in which the individual is enrolled under this section, the Secretary shall provide a process under which the Secretary provides to the sponsor of the endorsed program in which the individual enrolls information concerning the balance of amounts available on behalf of the individual under this paragraph.

(D) Limitation on use of funds. Pursuant to subsection (a)(2)(C), no assistance shall be provided under paragraph (1)(B) with respect to covered discount card drugs dispensed after December 31, 2005.

(E) No rollover permitted in case of voluntary disenrollment. Except in such exceptional cases as the Secretary may provide, in the case of a transitional assistance eligible individual who voluntarily disenrolls from an endorsed plan, the provisions of subclause (II) of subparagraph (A)(ii) shall not apply.

(3) Payment. The Secretary shall provide a method for the reimbursement of prescription drug card sponsors for assistance provided under this subsection.

(4) Coverage of coinsurance.

(A) Waiver permitted by pharmacy. Nothing in this section shall be construed as precluding a pharmacy from reducing or waiving the application of coinsurance imposed under paragraph (1)(B) in accordance with section 1128B(b)(3)(G) [*42 USCS § 1320a-7b(b)(3)(G)*].

(B) Optional payment of coinsurance by State.

(i) In general. The Secretary shall establish an arrangement under which a State may provide for payment of some or all of the coinsurance under paragraph (1)(B) for some or all enrollees in the State, as specified by the State under the arrangement. Insofar as such a payment arrangement is made with respect to an enrollee, the amount of the coinsurance shall be paid directly by the State to the pharmacy involved.

(ii) No Federal matching available under medicaid or SCHIP. Expenditures made by a State for coinsurance described in clause (i) shall not be treated as State expenditures for purposes of Federal matching payments under title XIX or XXI [*42 USCS §§ 1396* et seq. or *1397aa* et seq.].

(iii) Not treated as medicare cost-sharing. Coinsurance described in paragraph (1)(B) shall not be treated as coinsurance under this title for purposes of section 1905(p)(3)(B) [*42 USCS § 1396d(p)(3)(B)*].

(C) Treatment of coinsurance. The amount of any coinsurance imposed under paragraph (1)(B), whether paid or waived under this paragraph, shall not be taken into account in applying the limitation in dollar amount under paragraph (2).

(5) Ensuring access to transitional assistance for qualified residents of long-term care facilities and American Indians.

(A) Residents of long-term care facilities. The Secretary shall establish procedures and may waive requirements of this section as necessary to negotiate arrangements with sponsors to provide arrangements with pharmacies that support long-term care facilities in order to ensure access to transitional assistance for transitional assistance eligible individuals who reside in long-term care facilities.

(B) American Indians. The Secretary shall establish procedures and may waive requirements of this section to ensure that, for purposes of providing transitional assistance, pharmacies operated by the Indian Health Service, Indian tribes and tribal organizations, and urban Indian organizations (as defined in section 4 of the Indian Health Care Improvement Act [*25 USCS § 1603*]) have the opportunity to participate in the pharmacy networks of at least two endorsed programs in each of the 50 States and the District of Columbia where such a pharmacy operates.

(6) No impact on benefits under other programs. The availability of negotiated prices or transitional assistance under this section shall not be treated as benefits or otherwise taken into account in determining an individual's eligibility for, or the amount of benefits under, any other Federal program.

(7) Disregard for purposes of part C. Nonuniformity of benefits resulting from the implementation of this section (including the provision or nonprovision of transitional assistance and the payment or waiver of any enrollment fee under this section) shall not be taken into account in applying section 1854(f) [*42 USCS § 1395w-24(f)*].

(h) Qualification of prescription drug card sponsors and endorsement of discount card programs; beneficiary protections.

(1) Prescription drug card sponsor and qualifications.

(A) Prescription drug card sponsor and sponsor defined. For purposes of this section, the terms "prescription drug card sponsor" and "sponsor" mean any nongovernmental entity that the Secretary determines to be appropriate to offer an endorsed discount card program under this section, which may include--

(i) a pharmaceutical benefit management company;

(ii) a wholesale or retail pharmacy delivery system;

(iii) an insurer (including an insurer that offers medicare supplemental policies under section 1882 [*42 USCS § 1395ss*]);

(iv) an organization offering a plan under part C [*42 USCS §§ 1395w-21* et seq.]; or

(v) any combination of the entities described in clauses (i) through (iv).

(B) Administrative qualifications. Each endorsed discount card program shall be operated directly, or through arrangements with an affiliated organization (or organizations), by one or more entities that have demonstrated experience and expertise in operating such a program or a similar program and that meets such business stability and integrity requirements as the Secretary may specify.

(C) Accounting for transitional assistance. The sponsor of an endorsed discount card program shall have arrangements satisfactory to the Secretary to account for the assistance provided under subsection (g) on behalf of transitional assistance eligible individuals.

(2) Applications for program endorsement.

(A) Submission. Each prescription drug card sponsor that seeks endorsement of a prescription drug discount card program under this section shall submit to the Secretary, at such time and in such manner as the Secretary may specify, an application containing such information as the Secretary may require.

(B) Approval; compliance with applicable requirements. The Secretary shall review the application submitted under subparagraph (A) and shall determine whether to endorse the prescription drug discount card program. The Secretary may not endorse such a program unless--

(i) the program and prescription drug card sponsor offering the program comply with the applicable requirements under this section; and

(ii) the sponsor has entered into a contract with the Secretary to carry out such requirements.

(C) Termination of endorsement and contracts. An endorsement of an endorsed program and a contract under subparagraph (B) shall be for the duration of the program under this section (including any transition applicable under subsection (a)(2)(C)(ii)), except that the Secretary may, with notice and for cause (as defined by the Secretary), terminate such endorsement and contract.

(D) Ensuring choice of programs.

(i) In general. The Secretary shall ensure that there is available to each discount card eligible individual a choice of at least 2 endorsed programs (each offered by a different sponsor).

(ii) Limitation on number. The Secretary may limit (but not below 2) the number of sponsors in a State that are awarded contracts under this paragraph.

(3) Service area encompassing entire States. Except as provided in paragraph (9), if a prescription drug card sponsor that offers an endorsed program enrolls in the program individuals residing in any part of a State, the sponsor must permit any discount card eligible individual residing in any portion of the State to enroll in the program.

(4) Savings to medicare beneficiaries. Each prescription drug card sponsor that offers an endorsed discount card program shall pass on to discount card eligible individuals enrolled in the program negotiated prices on covered discount card drugs, including discounts negotiated with pharmacies and manufacturers, to the extent disclosed under subsection (i)(1).

(5) Grievance mechanism. Each prescription drug card sponsor shall provide meaningful procedures for hearing and resolving grievances between the sponsor (including any entity or individual through which the sponsor carries out the endorsed discount card program) and enrollees in endorsed discount card programs of the sponsor under this section in a manner similar to that required under section 1852(f) [*42 USCS § 1395w-22(f)*].

(6) Confidentiality of enrollee records.

(A) In general. For purposes of the program under this section, the operations of an endorsed program are covered functions and a prescription drug card sponsor is a covered entity for purposes of applying part C of title XI [*42 USCS §§ 1320d* et seq.] and all regulatory provisions promulgated thereunder, including regulations (relating to privacy) adopted pursuant to the authority of the Secretary under section 264(c) of the Health Insurance Portability and Accountability Act of 1996 (*42 U.S.C. 1320d-2* note).

(B) Waiver authority. In order to promote participation of sponsors in the program under this section, the Secretary may waive such relevant portions of regulations relating to privacy referred to in subparagraph (A), for such appropriate, limited period of time, as the Secretary specifies.

(7) Limitation on provision and marketing of products and services. The sponsor of an endorsed discount card program--

(A) may provide under the program--

(i) a product or service only if the product or service is directly related to a covered discount card drug; or

(ii) a discount price for nonprescription drugs; and

(B) may, to the extent otherwise permitted under paragraph (6) (relating to application of HIPAA requirements), market a product or service under the program only if the product or service is directly related to--

(i) a covered discount card drug; or

(ii) a drug described in subparagraph (A)(ii) and the marketing consists of information on the discounted price made available for the drug involved.

(8) Additional protections. Each endorsed discount card program shall meet such additional requirements as the Secretary identifies to protect and promote the interest of discount card eligible individuals, including requirements that ensure that discount card eligible individuals enrolled in endorsed discount card programs are not charged more than the lower of the price based on negotiated prices or the usual and customary price.

(9) Special rules for certain organizations.

(A) In general. In the case of an organization that is offering a plan under part C [*42 USCS §§ 1395w-21* et seq.] or enrollment under a reasonable cost reimbursement contract under section 1876(h) [*42 USCS § 1395mm(h)*] that is seeking to be a prescription drug card sponsor under this section, the organization may elect to apply the special rules under subparagraph (B) with respect to enrollees in any plan described in section 1851(a)(2)(A) [*42 USCS § 1395w-21(a)(2)(A)*] that it offers or under such contract and an endorsed discount card program it offers, but only if it limits enrollment under such program to individuals enrolled in such plan or under such contract.

(B) Special rules. The special rules under this subparagraph are as follows:

(i) Limitation on enrollment. The sponsor limits enrollment under this section under the endorsed discount card program to discount card eligible individuals who are enrolled in the part C [*42 USCS §§ 1395w-21* et seq.] plan involved or under the reasonable cost reimbursement contract involved and is not required nor permitted to enroll other individuals under such program.

(ii) Pharmacy access. Pharmacy access requirements under subsection (e)(1)(B) are deemed to be met if the access is made available through a pharmacy network (and not only through mail order) and the network used by the sponsor is approved by the Secretary.

(iii) Sponsor requirements. The Secretary may waive the application of such requirements for a sponsor as the Secretary determines to be duplicative or to conflict with a requirement of the organization under part C [*42 USCS §§ 1395w-21* et seq.] or *section 1876* [*42 USCS § 1395mm*] (as the case may be) or to be necessary in order to improve coordination of this section with the benefits under such part or section.

(i) Disclosure and oversight.

(1) Disclosure. Each prescription drug card sponsor offering an endorsed discount card program shall disclose to the Secretary (in a manner specified by the Secretary) information relating to program performance, use of prescription drugs by discount card eligible individuals enrolled in the program, the extent to which negotiated price concessions described in subsection (e)(1)(A)(ii) made available to the entity by a manufacturer are passed through to enrollees through pharmacies or otherwise, and such other information as the Secretary may specify. The provisions of section 1927(b)(3)(D) [*42 USCS § 1396r-8(b)(3)(D)*] shall apply to drug pricing data reported under the previous sentence (other than data in aggregate form).

(2) Oversight; audit and inspection authority. The Secretary shall provide appropriate oversight to ensure compliance of endorsed discount card programs and their sponsors with the requirements of this section. The Secretary shall have the right to audit and inspect any books and records of a prescription discount card sponsor (and of any affiliated organization referred to in subsection (h)(1)(B)) that pertain to the endorsed discount card program under this section, including amounts payable to the sponsor under this section.

(3) Sanctions for abusive practices. The Secretary may implement intermediate sanctions or may revoke the endorsement of a program offered by a sponsor under this section if the Secretary determines that the sponsor or the program no longer meets the applicable requirements of this section or that the sponsor has engaged in false or misleading marketing practices. The Secretary may impose a civil money penalty in an amount not to exceed $ 10,000 for conduct that a party knows or should know is a violation of this section. The provisions of section 1128A [*42 USCS § 1320a-7a*] (other than subsections (a) and (b) and the second sentence of subsection (f)) shall apply to a civil money penalty under the previous sentence in the same manner as such provisions apply to a penalty or proceeding under section 1128A(a) [*42 USCS § 1320a-7a(a)*].

(j) Treatment of territories.

(1) In general. The Secretary may waive any provision of this section (including subsection (h)(2)(D)) in the case of a resident of a State (other than the 50 States and the District of Columbia) insofar as the Secretary determines it is necessary to secure access to negotiated prices for discount card eligible individuals (or, at the option of the Secretary, individuals described in subsection (b)(1)(A)(i)).

(2) Transitional assistance.

(A) In general. In the case of a State, other than the 50 States and the District of Columbia, if the State establishes a plan described in subparagraph (B) (for providing transitional assistance with respect to the provision of prescription drugs to some or all individuals residing in the State who are described in subparagraph (B)(i)), the Secretary shall pay to the State for the entire period of the operation of this section an amount equal to the amount allotted to the State under subparagraph (C).

(B) Plan. The plan described in this subparagraph is a plan that--

(i) provides transitional assistance with respect to the provision of covered discount card drugs to some or all individuals who are entitled to benefits under part A [*42 USCS §§ 1395c* et seq.] or enrolled under part B [*42 USCS §§ 1395j* et seq.], who reside in the State, and who have income below 135 percent of the poverty line; and

(ii) assures that amounts received by the State under this paragraph are used only for such assistance.

(C) Allotment limit. The amount described in this subparagraph for a State is equal to $ 35,000,000 multiplied by the ratio (as estimated by the Secretary) of--

(i) the number of individuals who are entitled to benefits under part A [*42 USCS §§ 1395c* et seq.] or enrolled under part B [*42 USCS §§ 1395j* et seq.] and who reside in the State (as determined by the Secretary as of July 1, 2003), to

(ii) the sum of such numbers for all States to which this paragraph applies.

(D) Continued availability of funds. Amounts made available to a State under this paragraph which are not used under this paragraph shall be added to the amount available to that State for purposes of carrying out section 1935(e) [*42 USCS § 1396u-5(e)*].

(k) Funding.

(1) Establishment of Transitional Assistance Account.

(A) In general. There is created within the Federal Supplementary Medical Insurance Trust Fund established by section 1841 [*42 USCS § 1395t*] an account to be known as the "Transitional Assistance Account" (in this subsection referred to as the "Account").

(B) Funds. The Account shall consist of such gifts and bequests as may be made as provided in section 201(i)(1) [*42 USCS § 401(i)(1)*], accrued interest on balances in the Account, and such amounts as may be deposited in, or appropriated to, the Account as provided in this subsection.

(C) Separate from rest of Trust Fund. Funds provided under this subsection to the Account shall be kept separate from all other funds within the Federal Supplementary Medical Insurance Trust Fund, but shall be invested, and such investments redeemed, in the same manner as all other funds and investments within such Trust Fund.

(2) Payments from account.

(A) In general. The Managing Trustee shall pay from time to time from the Account such amounts as the Secretary certifies are necessary to make payments for transitional assistance provided under subsections (g) and (j)(2).

(B) Treatment in relation to part B premium. Amounts payable from the Account shall not be taken into account in computing actuarial rates or premium amounts under section 1839 [*42 USCS § 1395r*].

(3) Appropriations to cover benefits. There are appropriated to the Account in a fiscal year, out of any moneys in the Treasury not otherwise appropriated, an amount equal to the payments made from the Account in the year.

(4) For administrative expenses. There are authorized to be appropriated to the Secretary such sums as may be necessary to carry out the Secretary's responsibilities under this section.

(5) Transfer of any remaining balance to medicare prescription drug account. Any balance remaining in the Account after the Secretary determines that funds in the Account are no longer necessary to carry out the program under this section shall be transferred and deposited into the Medicare Prescription Drug Account under section 1860D-16 [*42 USCS § 1395w-116*].

(6) Construction. Nothing in this section shall be construed as authorizing the Secretary to provide for payment (other than payment of an enrollment fee on behalf of a transitional assistance eligible individual under subsection (g)(1)(A)) to a sponsor for administrative expenses incurred by the sponsor in carrying out this section (including in administering the transitional assistance provisions of subsections (f) and (g)).

HISTORY:

(Aug. 4, 1935, ch 531, Title XVIII, Part D, Subpart 4, § 1860D-31, as added Dec. 8, 2003, P.L. 108-173, Title I, § 101(a)(2), 117 Stat. 2131.)

§ 1395w-151. Definitions; treatment of references to provisions in part C

(a) Definitions. For purposes of this part [*42 USCS §§ 1395w-101* et seq.]:

(1) Basic prescription drug coverage. The term "basic prescription drug coverage" is defined in section 1860D-2(a)(3) [*42 USCS § 1395w-102(a)(3)*].

(2) Covered part D drug. The term "covered part D drug" is defined in section 1860D-2(e) [*42 USCS § 1395w-102(e)*].

(3) Creditable prescription drug coverage. The term "creditable prescription drug coverage" has the meaning given such term in section 1860D-13(b)(4) [*42 USCS § 1395w-113(b)(4)*].

(4) Part D eligible individual. The term "part D eligible individual" has the meaning given such term in section 1860D-1(a)(4)(A) [*42 USCS § 1395w-101(a)(4)(A)*].

(5) Fallback prescription drug plan. The term "fallback prescription drug plan" has the meaning given such term in section 1860D-11(g)(4) [*42 USCS § 1395w-111(g)(4)*].

(6) Initial coverage limit. The term "initial coverage limit" means such limit as established under section 1860D-2(b)(3) [*42 USCS § 1395w-102(b)(3)*], or, in the case of coverage that is not standard prescription drug coverage, the comparable limit (if any) established under the coverage.

(7) Insurance risk. The term "insurance risk" means, with respect to a participating pharmacy, risk of the type commonly assumed only by insurers licensed by a State and does not include payment variations designed to reflect performance-based measures of activities within the control of the pharmacy, such as formulary compliance and generic drug substitution.

(8) MA plan. The term "MA plan" has the meaning given such term in section 1860D-1(a)(4)(B) [*42 USCS § 1395w-101(a)(4)(B)*].

(9) MA-PD plan. The term "MA-PD plan" has the meaning given such term in section 1860D-1(a)(4)(C) [*42 USCS § 1395w-101(a)(4)(C)*].

(10) Medicare Prescription Drug Account. The term "Medicare Prescription Drug Account" means the Account created under section 1860D-16(a) [*42 USCS § 1395w-116(a)*].

(11) PDP approved bid. The term "PDP approved bid" has the meaning given such term in section 1860D-13(a)(6) [*42 USCS § 1395w-113(a)(6)*].

(12) PDP region. The term "PDP region" means such a region as provided under section 1860D-11(a)(2) [*42 USCS § 1395w-111(a)(2)*].

(13) PDP sponsor. The term "PDP sponsor" means a nongovernmental entity that is certified under this part [*42 USCS §§ 1395w-101* et seq.] as meeting the requirements and standards of this part [*42 USCS §§ 1395w-101* et seq.] for such a sponsor.

(14) Prescription drug plan. The term "prescription drug plan" means prescription drug coverage that is offered--

(A) under a policy, contract, or plan that has been approved under section 1860D-11(e) [*42 USCS § 1395w-111(e)*]; and

(B) by a PDP sponsor pursuant to, and in accordance with, a contract between the Secretary and the sponsor under section 1860D-12(b) [*42 USCS § 1395w-112(b)*].

(15) Qualified prescription drug coverage. The term "qualified prescription drug coverage" is defined in section 1860D-2(a)(1) [*42 USCS § 1395w-102(a)(1)*].

(16) Standard prescription drug coverage. The term "standard prescription drug coverage" is defined in section 1860D-2(b) [*42 USCS § 1395w-102(b)*].

(17) State pharmaceutical assistance program. The term "State Pharmaceutical Assistance Program" has the meaning given such term in section 1860D-23(b) [*42 USCS § 1395w-133(b)*].

(18) Subsidy eligible individual. The term "subsidy eligible individual" has the meaning given such term in section 1860D-14(a)(3)(A) [*42 USCS § 1395w-114(a)(3)(A)*].

(b) Application of part C provisions under this part. For purposes of applying provisions of part C [*42 USCS §§ 1395w-21* et seq.] under this part [*42 USCS §§ 1395w-101* et seq.] with respect to a prescription drug plan and a PDP sponsor, unless otherwise provided in this part [*42 USCS §§ 1395w-101* et seq.] such provisions shall be applied as if--

(1) any reference to an MA plan included a reference to a prescription drug plan;

(2) any reference to an MA organization or a provider-sponsored organization included a reference to a PDP sponsor;

(3) any reference to a contract under section 1857 [*42 USCS § 1395w-27*] included a reference to a contract under section 1860D-12(b) [*42 USCS § 1395w-112(b)*];

(4) any reference to part C [*42 USCS §§ 1395w-21* et seq.] included a reference to this part [*42 USCS §§ 1395w-101* et seq.]; and

(5) any reference to an election period under section 1851 [*42 USCS § 1395w-21*] were a reference to an enrollment period under section 1860D-1 [*42 USCS § 1395w-101*].

HISTORY:

(Aug. 4, 1935, ch 531, Title XVIII, Part D, Subpart 5, § 1860D-41, as added Dec. 8, 2003, P.L. 108-173, Title I, § 101(a)(2), 117 Stat. 2148.)

§ 1395w-152. Miscellaneous provisions

(a) Access to coverage in territories. The Secretary may waive such requirements of this part [*42 USCS §§ 1395w-101* et seq.], including section 1860D-3(a)(1) [*42 USCS § 1395w-103(a)(1)*], insofar as the Secretary determines it is necessary to secure access to qualified prescription drug coverage for part D eligible individuals residing in a State (other than the 50 States and the District of Columbia).

(b) Application of demonstration authority. The provisions of section 402 of the Social Security Amendments of 1967 (Public Law 90-248) shall apply with respect to this part and part C [*42 USCS §§ 1395w-101* et seq. and *1395w-21* et seq.] in the same manner it applies with respect to parts A and B [*42 USCS §§ 1395c* et seq. and *1395j* et seq.], except that any reference with respect to a Trust Fund in relation to an experiment or demonstration project relating to prescription drug coverage under this part [*42 USCS §§ 1395w-101* et seq.] shall be deemed a reference to the Medicare Prescription Drug Account within the Federal Supplementary Medical Insurance Trust Fund.

HISTORY:

(Aug. 4, 1935, ch 531, Title XVIII, Part D, Subpart 5, § 1860D-42, as added Dec. 8, 2003, P.L. 108-173, Title I, § 101(a)(2), 117 Stat. 2149.)

§ 1395x. Definitions

For purpose of this *title [42 USCS §§ 1395* et seq.]--

(a) Spell of illness. The term "spell of illness" with respect to any individual means a period of consecutive days--

(1) beginning with the first day (not included in a previous spell of illness) (A) on which such individual is furnished inpatient hospital services, inpatient critical access hospital services or extended care services, and (B) which occurs in a month for which he is entitled to benefits under part A [*42 USCS §§ 1395c* et seq.], and

(2) ending with the close of the first period of 60 consecutive days thereafter on each of which he is neither an inpatient of a hospital or critical access hospital nor an inpatient of a facility described in section 1819(a)(2) [*42 USCS § 1395i-3 (a)(2)*] or subsection (y)(1).

(b) Inpatient hospital services. The term "inpatient hospital services" means the following items and services furnished to an inpatient of a hospital and (except as provided in paragraph (3)) by the hospital--

(1) bed and board;

(2) such nursing services and other related services, such use of hospital facilities, and such medical social services as are ordinarily furnished by the hospital for the care and treatment of inpatients, and such drugs, biologicals, supplies, appliances, and equipment, for use in the hospital, as are ordinarily furnished by such hospital for the care and treatment of inpatients; and

(3) such other diagnostic or therapeutic items or services, furnished by the hospital or by others under arrangements with them made by the hospital, as are ordinarily furnished to inpatients either by such hospital or by others under such arrangements;

excluding, however--

(4) medical or surgical services provided by a physician, resident, or, services described by subsection (s)(2)(K), certified nurse-midwife services, qualified psychologist services, and services of a certified registered nurse anesthetist; and

(5) the services of a private-duty nurse or other private-duty attendant.

Paragraph (4) shall not apply to services provided in a hospital by--

(6) an intern or a resident-in-training under a teaching program approved by the Council on Medical Education of the American Medical Association or, in the case of an osteopathic hospital, approved by the Committee on Hospitals of the Bureau of Professional Education of the American Osteopathic Association, or, in the case of services in a hospital or osteopathic hospital by an intern or resident-in-training in the field of dentistry, approved by the Council on Dental Education of the American Dental Association, or in the case of services in a hospital or osteopathic hospital by an intern or resident-in-training in the field of podiatry, approved by the Council on Podiatric Medical Education of the American Podiatric Medical Association; or

(7) a physician where the hospital has a teaching program approved as specified in paragraph (6), if (A) the hospital elects to receive any payment due under this *title [42 USCS §§ 1395* et seq.] for reasonable costs of such services, and (B) all physicians in such hospital agree not to bill charges for professional services rendered in such hospital to individuals covered under the insurance program established by this *title [42 USCS §§ 1395* et seq.].

(c) Inpatient psychiatric hospital services. The term "inpatient psychiatric hospital services" means inpatient hospital services furnished to an inpatient of a psychiatric hospital.

(d) Supplier. The term "supplier" means, unless the context otherwise requires, a physician or other practitioner, a facility, or other entity (other than a provider of services) that furnishes items or services under this *title [42 USCS §§ 1395* et seq.].

(e) Hospital [Caution: For provisions applicable to accreditions of hospitals granted before July 15, 2010, see 2008 amendment note below.]. The term "hospital" (except for purposes of sections 1814(d), 1814(f), and 1835(b) [*42 USCS §§ 1395f(d)*, (f), and 1395n(b)], subsection (a)(2) of this section, paragraph (7) of this subsection, and subsection (i) of this section) means an institution which--

(1) is primarily engaged in providing, by or under the supervision of physicians, to inpatients (A) diagnostic services and therapeutic services for medical diagnosis, treatment, and care of injured, disabled, or sick persons, or (B) rehabilitation services for the rehabilitation of injured, disabled, or sick persons;

(2) maintains clinical records on all patients;

(3) has bylaws in effect with respect to its staff of physicians;

(4) has a requirement that every patient with respect to whom payment may be made under this *title [42 USCS §§ 1395* et seq.] must be under the care of a physician, except that a patient receiving qualified psychologist services (as defined in subsection (ii)) may be under the care of a clinical psychologist with respect to such services to the extent permitted under State law;

(5) provides 24-hour nursing service rendered or supervised by a registered professional nurse, and has a licensed practical nurse or registered professional nurse on duty at all times; except that until January 1, 1979, the Secretary is authorized to waive the requirement of this paragraph for any one-year period with respect to any institution, insofar as such requirement relates to the provision of twenty-four-hour nursing service rendered or supervised by a registered professional nurse (except that in any event a registered professional nurse must be present on the premises to render or supervise the nursing service provided, during at least the regular daytime shift), where immediately preceding such one-year period he finds that--

(A) such institution is located in a rural area and the supply of hospital services in such area is not sufficient to meet the needs of individuals residing therein,

(B) the failure of such institution to qualify as a hospital would seriously reduce the availability of such services to such individuals, and

(C) such institution has made and continues to make a good faith effort to comply with this paragraph, but such compliance is impeded by the lack of qualified nursing personnel in such area;

(6) (A) has in effect a hospital utilization review plan which meets the requirements of subsection (k) and (B) has in place a discharge planning process that meets the requirements of subsection (ee);

(7) in the case of an institution in any State in which State or applicable local law provides for the licensing of hospitals, (A) is licensed pursuant to such law or (B) is approved, by the agency of such State or locality responsible for licensing hospitals, as meeting the standards established for such licensing;

(8) has in effect an overall plan and budget that meets the requirements of subsection (z); and

(9) meets such other requirements as the Secretary finds necessary in the interest of the health and safety of individuals who are furnished services in the institution.

For purposes of subsection (a)(2), such term includes any institution which meets the requirements of paragraph (1) of this subsection. For purposes of sections 1814(d) [*42 USCS § 1395f(d)*] and 1835(b) [*42 USCS § 1395n(b)*] (including determination of whether an individual received inpatient hospital services or diagnostic services for purposes of such sections), section 1814(f)(2) [*42 USCS § 1395f(f)(2)*], and subsection (i) of this section, such term includes any institution which (i) meets the requirements of paragraphs (5) and (7) of this subsection, (ii) is not primarily engaged in providing the services described in section 1861(j)(1)(A) [subsec. (j)(1)(A) of this section] and (iii) is primarily engaged in providing, by or under the supervision of individuals referred to in paragraph (1) of section 1861(r) [subsec. (r)(1) of this section], to inpatients diagnostic services and therapeutic services for medical diagnosis, treatment, and care of injured, disabled, or sick persons, or rehabilitation services for the rehabilitation of injured, disabled, or sick persons. For purposes of section 1814(f)(1) [*42 USCS § 1395f(f)(1)*], such term includes an institution which (i) is a hospital for purposes of sections 1814(d), 1814(f)(2), and 1835(b) [*42 USCS §§ 1395f(d)*, (f)(2), and 1395n(b)] and (ii) is accredited by a national accreditation body recognized by the Secretary under section 1865(a), or is accredited by or approved by a program of the country in which such institution is located if the Secretary finds the accreditation or comparable approval standards of such program to be essentially equivalent to those of such a national accreditation body.[.] Notwithstanding the preceding provisions of this subsection, such term shall not, except for purposes of subsection (a)(2) include any institution which is primarily for the care and treatment of mental diseases unless it is a psychiatric hospital (as defined in subsection (f)). The term "hospital" also includes a religious nonmedical health care institution (as defined in subsection (ss)(1)), but only with respect to items and services ordinarily furnished by such institution to inpatients, and payment may be made with respect to services provided by or in such an institution only to such extent and under such conditions, limitations, and requirements (in addition to or in lieu of the conditions, limitations, and requirements otherwise applicable) as may be provided in regulations consistent with section 1821 [*42 USCS § 1395i-5*]. For provisions deeming certain requirements of this subsection to be met in the case of accredited institutions, see section 1865 [*42 USCS § 1395bb*]. The term "hospital" also includes a facility of fifty beds or less which is located in an area determined by the Secretary to meet the definition relating to a rural area described in subparagraph (A) of paragraph (5) of this subsection and which meets the other requirements of this subsection, except that--

(A) with respect to the requirements for nursing services applicable after December 31, 1978, such requirements shall provide for temporary waiver of the requirements, for such period as the Secretary deems appropriate, where (i) the facility's failure to fully comply with the requirements is attributable to a temporary shortage of qualified nursing personnel in the area in which the facility is located, (ii) a registered professional nurse is present on the premises to render or supervise the nursing service provided during at least the regular daytime shift, and (iii) the Secretary determines that the employment of such nursing personnel as are available to the facility during such temporary period will not adversely affect the health and safety of patients;

(B) with respect to the health and safety requirements promulgated under paragraph (9), such requirements shall be applied by the Secretary to a facility herein defined in such manner as to assure that personnel requirements take into account the availability of technical personnel and the educational opportunities for technical personnel in the area in which such facility is located, and the scope of services rendered by such facility; and the Secretary, by regulations, shall provide for the continued participation of such a facility where such personnel requirements are not fully met, for such period as the Secretary determines that (i) the facility is making good faith efforts to fully comply with the personnel requirements, (ii) the employment by the facility of such personnel as are available to the facility will not adversely affect the health and safety of patients, and (iii) if the Secretary has determined that because of the facility's waiver under this subparagraph the facility should limit its scope of services in order not to adversely affect the health and safety of the facility's patients, the facility is so limiting the scope of services it provides; and

(C) with respect to the fire and safety requirements promulgated under paragraph (9), the Secretary (i) may, waive, for such period as he deems appropriate, specific provisions of such requirements which if rigidly applied would result in unreasonable hardship for such a facility and which, if not applied, would not jeopardize the health and safety of patients, and (ii) may accept a facility's compliance with all applicable State codes relating to fire and safety in lieu of compliance with the fire and safety requirements promulgated under paragraph (9), if he determines that such State has in effect fire and safety codes, imposed by State law, which adequately protect patients.

The term "hospital" does not include, unless the context otherwise requires, a critical access hospital (as defined in section 1861(mm)(1) [subsec. (mm)(1) of this section]).

(f) Psychiatric hospital. The term "psychiatric hospital" means an institution which--

(1) is primarily engaged in providing, by or under the supervision of a physician, psychiatric services for the diagnosis and treatment of mentally ill persons;

(2) satisfies the requirements of paragraphs (3) through (9) of subsection (e);

(3) maintains clinical records on all patients and maintains such records as the Secretary finds to be necessary to determine the degree and intensity of the treatment provided to individuals entitled to hospital insurance benefits under part A [*42 USCS §§ 1395c* et seq.] and

(4) meets such staffing requirements as the Secretary finds necessary for the institution to carry out an active program of treatment for individuals who are furnished services in the institution.

In the case of an institution which satisfies paragraphs (1) and (2) of the preceding sentence and which contains a distinct part which also satisfies paragraphs (3) and (4) of such sentence, such distinct part shall be considered to be a "psychiatric hospital".

(g) Outpatient occupational therapy services. The term "outpatient occupational therapy services" has the meaning given the term "outpatient physical therapy services" in subsection (p), except that "occupational" shall be substituted for "physical" each place it appears therein.

(h) Extended care services. The term "extended care services" means the following items and services furnished to an inpatient of a skilled nursing facility and (except as provided in paragraphs (3), (6), and (7)) by such skilled nursing facility--

(1) nursing care provided by or under the supervision of a registered professional nurse;

(2) bed and board in connection with the furnishing of such nursing care;

(3) physical or occupational therapy or speech-language pathology services furnished by the skilled nursing facility or by others under arrangements with them made by the facility;

(4) medical social services;

(5) such drugs, biologicals, supplies, appliances, and equipment, furnished for use in the skilled nursing facility, as are ordinarily furnished by such facility for the care and treatment of inpatients;

(6) medical services provided by an intern or resident-in-training of a hospital with which the facility has in effect a transfer agreement (meeting the requirements of subsection (l)), under a teaching program of such hospital approved as

provided in the last sentence of subsection (b), and other diagnostic or therapeutic services provided by a hospital with which the facility has such an agreement in effect; and

(7) such other services necessary to the health of the patients as are generally provided by skilled nursing facilities, or by others under arrangements with them made by the facility;

excluding, however, any item or service if it would not be included under subsection (b) if furnished to an inpatient of a hospital.

(i) Post-hospital extended care services. The term "post-hospital extended care services" means extended care services furnished an individual after transfer from a hospital in which he was an inpatient for not less than 3 consecutive days before his discharge from the hospital in connection with such transfer. For purposes of the preceding sentence, items and services shall be deemed to have been furnished to an individual after transfer from a hospital, and he shall be deemed to have been an inpatient in the hospital immediately before transfer therefrom, if he is admitted to the skilled nursing facility (A) within 30 days after discharge from such hospital, or (B) within such time as it would be medically appropriate to begin an active course of treatment, in the case of an individual whose condition is such that skilled nursing facility care would not be medically appropriate within 30 days after discharge from a hospital; and an individual shall be deemed not to have been discharged from a skilled nursing facility if, within 30 days after discharge therefrom, he is admitted to such facility or any other skilled nursing facility.

(j) Skilled nursing facility. The term "skilled nursing facility" has the meaning given such term in section 1819(a) [*42 USCS § 1395i-3(a)*].

(k) Utilization review. A utilization review plan of a hospital or skilled nursing facility shall be considered sufficient if it is applicable to services furnished by the institution to individuals entitled to insurance benefits under this *title [42 USCS §§ 1395* et seq.] and if it provides--

(1) for the review, on a sample or other basis, of admissions to the institution, the duration of stays therein, and the professional services (including drugs and biologicals) furnished, (A) with respect to the medical necessity of the services, and (B) for the purpose of promoting the most efficient use of available health facilities and services;

(2) for such review to be made by either (A) a staff committee of the institution composed of two or more physicians (of which at least two must be physicians described in subsection (r)(1) of this section), with or without participation of other professional personnel, or (B) a group outside the institution which is similarly composed and (i) which is established by the local medical society and some or all of the hospitals and skilled nursing facilities in the locality, or (ii) if (and for as long as) there has not been established such a group which serves such institution, which is established in such other manner as may be approved by the Secretary;

(3) for such review, in each case of inpatient hospital services or extended care services furnished to such an individual during a continuous period of extended duration, as of such days of such period (which may differ for different classes of cases) as may be specified in regulations, with such review to be made as promptly as possible, after each day so specified, and in no event later than one week following such day; and

(4) for prompt notification to the institution, the individual, and his attending physician of any finding (made after opportunity for consultation to such attending physician) by the physician members of such committee or group that any further stay in the institution is not medically necessary.

The review committee must be composed as provided in clause (B) of paragraph (2) rather than as provided in clause (A) of such paragraph in the case of any hospital or skilled nursing facility where, because of the small size of the institution, or (in the case of a skilled nursing facility) because of lack of an organized medical staff, or for such other reason or reasons as may be included in regulations, it is impracticable for the institution to have a properly functioning staff committee for the purposes of this subsection. If the Secretary determines that the utilization review procedures established pursuant to title XIX [*42 USCS §§ 1396* et seq.] are superior in their effectiveness to the procedures required under this section, he may, to the extent that he deems it appropriate, require for purposes of this *title [42 USCS §§ 1395* et seq.] that the procedures established pursuant to title XIX [*42 USCS §§ 1396* et seq.] be utilized instead of the procedures required by this section.

(l) Agreements for transfer between skilled nursing facilities and hospitals. A hospital and a skilled nursing facility shall be considered to have a transfer agreement in effect if, by reason of a written agreement between them or (in case the two institutions are under common control) by reason of a written undertaking by the person or body which controls them, there is reasonable assurance that--

(1) transfer of patients will be effected between the hospital and the skilled nursing facility whenever such transfer is medically appropriate as determined by the attending physician; and

(2) there will be interchange of medical and other information necessary or useful in the care and treatment of individuals transferred between the institutions, or in determining whether such individuals can be adequately cared for otherwise than in either of such institutions.

Any skilled nursing facility which does not have such an agreement in effect, but which is found by a State agency (of the State in which such facility is situated) with which an agreement under section 1864 [*42 USCS § 1395aa*] is in effect (or, in the case of a State in which no such agency has an agreement under section 1864 [*42 USCS § 1395aa*], by the Secretary) to have attempted in good faith to enter into such an agreement with a hospital sufficiently close to the facility to make feasible the transfer between them of patients and the information referred to in paragraph (2), shall be considered to have such an agreement in effect if and for so long as such agency (or the Secretary, as the case may be) finds that to do so is in the public interest and essential to assuring extended care services for persons in the community who are eligible for payments with respect to such services under this *title [42 USCS §§ 1395* et seq.].

(m) Home health services. The term "home health services" means the following items and services furnished to an individual, who is under the care of a physician, by a home health agency or by others under arrangements with them made by such agency, under a plan (for furnishing such items and services to such individual) established and periodically reviewed by a physician, which items and services are, except as provided in paragraph (7), provided on a visiting basis in a place of residence used as such individual's home--

(1) part-time or intermittent nursing care provided by or under the supervision of a registered professional nurse;

(2) physical or occupational therapy or speech-language pathology services;

(3) medical social services under the direction of a physician;

(4) to the extent permitted in regulations, part-time or intermittent services of a home health aide who has successfully completed a training program approved by the Secretary;

(5) medical supplies (including catheters, catheter supplies, ostomy bags, and supplies related to ostomy care, and a covered osteoporosis drug (as defined in subsection (kk)), but excluding other drugs and biologicals) and durable medical equipment while under such a plan;

(6) in the case of a home health agency which is affiliated or under common control with a hospital, medical services provided by an intern or resident-in-training of such hospital, under a teaching program of such hospital approved as provided in the last sentence of subsection (b); and

(7) any of the foregoing items and services which are provided on an out-patient basis, under arrangements made by the home health agency, at a hospital or skilled nursing facility, or at a rehabilitation center which meets such standards as may be prescribed in regulations, and--

(A) the furnishing of which involves the use of equipment of such a nature that the items and services cannot readily be made available to the individual in such place of residence, or

(B) which are furnished at such facility while he is there to receive any such item or service described in clause (A), but not including transportation of the individual in connection with any such item or service;

excluding, however, any item or service if it would not be included under subsection (b) if furnished to an inpatient of a hospital. For purposes of paragraphs (1) and (4), the term "part-time or intermittent services" means skilled nursing and home health aide services furnished any number of days per week as long as they are furnished (combined) less than 8 hours each day and 28 or fewer hours each week (or, subject to review on a case-by-case basis as to the need for care, less than 8 hours each day and 35 or fewer hours per week). For purposes of sections 1814(a)(2)(C) and 1835(a)(2)(A) [*42 USCS §§ 1395f(a)(2)(C)* and *1395n(a)(2)(A)*], "intermittent" means skilled nursing care that is either provided or needed on fewer than 7 days each week, or less than 8 hours of each day for periods of 21 days or less (with extensions in exceptional circumstances when the need for additional care is finite and predictable).

(n) Durable medical equipment. The term "durable medical equipment" includes iron lungs, oxygen tents, hospital beds, and wheelchairs (which may include a power-operated vehicle that may be appropriately used as a wheelchair, but only where the use of such a vehicle is determined to be necessary on the basis of the individual's medical and physical condition and the vehicle meets such safety requirements as the Secretary may prescribe) used in the patient's home (including an institution used as his home other than an institution that meets the requirements of subsection (e)(1) of this section or of section 1819(a)(1) [*42 USCS § 1395i-3(a)(1)*]), whether furnished on a rental basis or purchased, and includes blood-testing strips and blood glucose monitors for individuals with diabetes without regard to whether the individual has Type I or Type II diabetes or to the individual's use of insulin (as determined under standards established by the Secretary in consultation with the appropriate organizations); except that such term does not include such

equipment furnished by a supplier who has used, for the demonstration and use of specific equipment, an individual who has not met such minimum training standards as the Secretary may establish with respect to the demonstration and use of such specific equipment. With respect to a seat-lift chair, such term includes only the seat-lift mechanism and does not include the chair.

(o) Home health agency. The term "home health agency" means a public agency or private organization, or a subdivision of such an agency or organization, which--

(1) is primarily engaged in providing skilled nursing services and other therapeutic services;

(2) has policies, established by a group of professional personnel (associated with the agency or organization), including one or more physicians and one or more registered professional nurses, to govern the services (referred to in paragraph (1)) which it provides, and provides for supervision of such services by a physician or registered professional nurse;

(3) maintains clinical records on all patients;

(4) in the case of an agency or organization in any State in which State or applicable local law provides for the licensing of agencies or organizations of this nature, (A) is licensed pursuant to such law, or (B) is approved, by the agency of such State or locality responsible for licensing agencies or organizations of this nature, as meeting the standards established for such licensing;

(5) has in effect an overall plan and budget that meets the requirements of subsection (z);

(6) meets the conditions of participation specified in section 1891(a) [*42 USCS §§ 1395bbb(a)*] such other conditions of participation as the Secretary may find necessary in the interest of the health and safety of individuals who are furnished services by such agency or organization;

(7) provides the Secretary with a surety bond--

(A) effective for a period of 4 years (as specified by the Secretary) or in the case of a change in the ownership or control of the agency (as determined by the Secretary) during or after such 4-year period, an additional period of time that the Secretary determines appropriate, such additional period not to exceed 4 years from the date of such change in ownership or control;

(B) in a form specified by the Secretary; and

(C) for a year in the period described in subparagraph (A) in an amount that is equal to the lesser of $ 50,000 or 10 percent of the aggregate amount of payments to the agency under this title and title XIX [*42 USCS §§ 1395* et seq. and *1396* et seq.] for that year, as estimated by the Secretary; and

(8) meets such additional requirements (including conditions relating to bonding or establishing of escrow accounts as the Secretary finds necessary for the financial security of the program) as the Secretary finds necessary for the effective and efficient operation of the program;

except that for purposes of part A [*42 USCS §§ 1395c* et seq.] such term shall not include any agency or organization which is primarily for the care and treatment of mental diseases. The Secretary may waive the requirement of a surety bond under paragraph (7) in the case of an agency or organization that provides a comparable surety bond under State law.

(p) Outpatient physical therapy services [Caution: For provisions applicable to serviced furnished before July 1, 2009, see 2008 amendment note below.]. The term "outpatient physical therapy services" means physical therapy services furnished by a provider of services, a clinic, rehabilitation agency, or a public health agency, or by others under an arrangement with, and under the supervision of, such provider, clinic, rehabilitation agency, or public health agency to an individual as an outpatient--

(1) who is under the care of a physician (as defined in paragraph (1), (3), or (4) of section 1861(r) [subsec. (r) of this section]), and

(2) with respect to whom a plan prescribing the type, amount, and duration of physical therapy services that are to be furnished such individual has been established by a physician (as so defined) or by a qualified physical therapist and is periodically reviewed by a physician (as so defined);

excluding, however--

(3) any item or service if it would not be included under subsection (b) if furnished to an inpatient of a hospital; and

(4) any such service--

(A) if furnished by a clinic or rehabilitation agency, or by others under arrangements with such clinic or agency, unless such clinic or rehabilitation agency--

(i) provides an adequate program of physical therapy services for outpatients and has the facilities and personnel required for such program or required for the supervision of such a program, in accordance with such requirements as the Secretary may specify,

(ii) has policies, established by a group of professional personnel, including one or more physicians (associated with the clinic or rehabilitation agency) and one or more qualified physical therapists, to govern the services (referred to in clause (i)) it provides,

(iii) maintains clinical records on all patients,

(iv) if such clinic or agency is situated in a State in which State or applicable local law provides for the licensing of institutions of this nature, (I) is licensed pursuant to such law, or (II) is approved by the agency of such State or locality responsible for licensing institutions of this nature, as meeting the standards established for such licensing; and

(v) meets such other conditions relating to the health and safety of individuals who are furnished services by such clinic or agency on an outpatient basis, as the Secretary may find necessary, and provides the Secretary on a continuing basis with a surety bond in a form specified by the Secretary and in an amount that is not less than $ 50,000,or

(B) if furnished by a public health agency, unless such agency meets such other conditions relating to health and safety of individuals who are furnished services by such agency on an outpatient basis, as the Secretary may find necessary.

The term "outpatient physical therapy services" also includes physical therapy services furnished an individual by a physical therapist (in his office or in such individual's home) who meets licensing and other standards prescribed by the Secretary in regulations, otherwise than under an arrangement with and under the supervision of a provider of services, clinic, rehabilitation agency, or public health agency, if the furnishing of such services meets such conditions relating to health and safety as the Secretary may find necessary. In addition, such term includes physical therapy services which meet the requirements of the first sentence of this subsection except that they are furnished to an individual as an inpatient of a hospital or extended care facility. Nothing in this subsection shall be construed as requiring, with respect to outpatients who are not entitled to benefits under this *title [42 USCS §§ 1395* et seq.], a physical therapist to provide outpatient physical therapy services only to outpatients who are under the care of a physician or pursuant to a plan of care established by a physician. The Secretary may waive the requirement of a surety bond under paragraph (4)(A)(v) in the case of a clinic or agency that provides a comparable surety bond under State law.

(q) Physicians' services. The term "physicians' services" means professional services performed by physicians, including surgery, consultation, and home, office, and institutional calls (but not including services described in subsection (b)(6)).

(r) Physician. The term "physician", when used in connection with the performance of any function or action, means (1) a doctor of medicine or osteopathy legally authorized to practice medicine and surgery by the State in which he performs such function or action (including a physician within the meaning of section 1101(a)(7) [*42 USCS § 1301(a)(7)*]), (2) a doctor of dental surgery or of dental medicine who is legally authorized to practice dentistry by the State in which he performs such function and who is acting within the scope of his license when he performs such functions, (3) a doctor of podiatric medicine for the purposes of subsections (k), (m), (p)(1), and (s) of this section and sections 1814(a), 1832(a)(2)(F)(ii), and 1835 [*42 USCS §§ 1395f(a), 1395k(a)(2)(F)(ii)*, and *1395n*] but only with respect to functions which he is legally authorized to perform as such by the State in which he performs them, (4) a doctor of optometry, but only for purposes of subsection (p)(1) and with respect to the provision of items or services described in subsection (s) which he is legally authorized to perform as a doctor of optometry by the State in which he performs them, or (5) a chiropractor who is licensed as such by the State (or in a State which does not license chiropractors as such, is legally authorized to perform the services of a chiropractor in the jurisdiction in which he performs such services), and who meets uniform minimum standards promulgated by the Secretary, but only for the purpose of sections 1861(s)(1) and 1861(s)(2)(A) [subsecs. (s)(1) and (s)(2)(A) of this section] and only with respect to treatment by means of manual manipulation of the spine (to correct a subluxation which he is legally authorized to perform by the State or jurisdiction in which such treatment is provided. For the purposes of section 1862(a)(4) [*42 USCS § 1395y(a)(4)*] and subject to the limitations and conditions provided in the previous sentence, such term includes a doctor of one of the arts, specified in such previous sentence, legally authorized to practice such art in the country in which the inpatient hospital services (referred to in such section 1862(a)(4) [*42 USCS § 1395y(a)(4)*] are furnished.

(s) Medical and other health services. The term "medical and other health services" means any of the following items or services:

(1) physicians' services;

(2)

(A) services and supplies (including drugs and biologicals which are not usually self-administered by the patient) furnished as an incident to a physician's professional service, or kinds which are commonly furnished in physicians' offices and are commonly either rendered without charge or included in the physicians' bills (or would have been so included but for the application of section 1847B [*42 USCS § 1395w-3b*]);

(B) hospital services (including drugs and biologicals which are not usually self-administered by the patient) incident to physicians' services rendered to outpatients and partial hospitalization services incident to such services;

(C) diagnostic services which are--

(i) furnished to an individual as an outpatient by a hospital or by others under arrangements with them made by a hospital, and

(ii) ordinarily furnished by such hospital (or by others under such arrangements) to its outpatients for the purpose of diagnostic study;

(D) **[Caution: For provisions applicable to serviced furnished before July 1, 2009, see 2008 amendment note below.]** outpatient physical therapy services, outpatient speech-language pathology services, and outpatient occupational therapy services;

(E) rural health clinic services and Federally qualified health center services;

(F) home dialysis supplies and equipment, self-care home dialysis support services, and institutional dialysis services and supplies, and, for items and services furnished on or after January 1, 2011, renal dialysis services (as defined in section 1881(b)(14)(B) [*42 USCS § 1395rr(b)(14)(B)*]);

(G) antigens (subject to quantity limitations prescribed in regulations by the Secretary) prepared by a physician, as defined in section 1861(r)(1) [subsec. (r)(1) of this section], for a particular patient, including antigens so prepared which are forwarded to another qualified person (including a rural health clinic) for administration to such patient, from time to time, by or under the supervision of another such physician;

(H) (i) services furnished pursuant to a contract under section 1876 [*42 USCS § 1395mm*] to a member of an eligible organization by a physician assistant or by a nurse practitioner (as defined in subsection (aa)(5)) and such services and supplies furnished as an incident to his service to such a member as would otherwise be covered under this part [*42 USCS §§ 1395x* et seq.] if furnished by a physician or as an incident to a physician's service; and

(ii) services furnished pursuant to a risk-sharing contract under section 1876(g) [*42 USCS § 1395mm(g)*] to a member of an eligible organization by a clinical psychologist (as defined by the Secretary) or by a clinical social worker (as defined in subsection (hh)(2)), and such services and supplies furnished as an incident to such clinical psychologist's services or clinical social worker's services to such a member as would otherwise be covered under this part [*42 USCS §§ 1395x* et seq.] if furnished by a physician or as an incident to a physician's service;

(I) blood clotting factors, for hemophilia patients competent to use such factors to control bleeding without medical or other supervision, and items related to the administration of such factors, subject to utilization controls deemed necessary by the Secretary for the efficient use of such factors;

(J) prescription drugs used in immunosuppressive therapy furnished, to an individual who receives an organ transplant for which payment is made under this *title [42 USCS §§ 1395* et seq.];

(K) (i) services which would be physicians' services and services described in subsection (ww)(1) if furnished by a physician (as defined in subsection (r)(1)) and which are performed by a physician assistant (as defined in subsection (aa)(5)) under the supervision of a physician (as so defined) and which the physician assistant is legally authorized to perform by the State in which the services are performed, and such services and supplies furnished as incident to such services as would be covered under subparagraph (A) if furnished incident to a physician's professional service, but only if no facility or other provider charges or is paid any amounts with respect to the furnishing of such services, [and]

(ii) services which would be physicians' services and services described in subsection (ww)(1) if furnished by a physician (as defined in subsection (r)(1)) and which are performed by a nurse practitioner or clinical nurse specialist (as defined in subsection (aa)(5)) working in collaboration (as defined in subsection (aa)(6)) with a physician (as defined in subsection (r)(1)) which the nurse practitioner or clinical nurse specialist is legally authorized to perform by the State in which the services are performed, and such services and supplies furnished as an incident to such services as would be covered under subparagraph (A) if furnished incident to a physician's professional service, but only if no facility or other provider charges or is paid any amounts with respect to the furnishing of such services;

(L) certified nurse-midwife services;

(M) qualified psychologist services;

(N) clinical social worker services (as defined in subsection (hh)(2));

(O) erythropoietin for dialysis patients competent to use such drug without medical or other supervision with respect to the administration of such drug, subject to methods and standards established by the Secretary by regulation for the safe and effective use of such drug, and items related to the administration of such drug;

(P) prostate cancer screening tests (as defined in subsection (oo));

(Q) an oral drug (which is approved by the Federal Food and Drug Administration) prescribed for use as an anticancer chemotherapeutic agent for a given indication, and containing an active ingredient (or ingredients), which is the same indication and active ingredient (or ingredients) as a drug which the carrier determines would be covered pursuant to subparagraph (A) or (B) if the drug could not be self-administered;

(R) colorectal cancer screening tests (as defined in subsection (pp));

(S) diabetes outpatient self-management training services (as defined in subsection (qq));

(T) an oral drug (which is approved by the Federal Food and Drug Administration) prescribed for use as an acute anti-emetic used as part of an anticancer chemotherapeutic regimen if the drug is administered by a physician (or as prescribed by a physician)--

(i) for use immediately before, at, or within 48 hours after the time of the administration of the anticancer chemotherapeutic agent; and

(ii) as a full replacement for the anti-emetic therapy which would otherwise be administered intravenously;

(U) screening for glaucoma (as defined in subsection (uu)) for individuals determined to be at high risk for glaucoma, individuals with a family history of glaucoma and individuals with diabetes;

(V) medical nutrition therapy services (as defined in subsection (vv)(1)) in the case of a beneficiary with diabetes or a renal disease who--

(i) has not received diabetes outpatient self-management training services within a time period determined by the Secretary;

(ii) is not receiving maintenance dialysis for which payment is made under section 1881 [*42 USCS § 1395rr*]; and

(iii) meets such other criteria determined by the Secretary after consideration of protocols established by dietitian or nutrition professional organizations;

(W) an initial preventive physical examination (as defined in subsection (ww));

(X) cardiovascular screening blood tests (as defined in subsection (xx)(1));

(Y) diabetes screening tests (as defined in subsection (yy));

(Z) intravenous immune globulin for the treatment of primary immune deficiency diseases in the home (as defined in subsection (zz));

(AA) ultrasound screening for abdominal aortic aneurysm (as defined in subsection (bbb)) for an individual--

(i) who receives a referral for such an ultrasound screening as a result of an initial preventive physical examination (as defined in section 1861(ww)(1) [subsec. (ww)(1) of this section]);

(ii) who has not been previously furnished such an ultrasound screening under this *title [42 USCS §§ 1395* et seq.]; and

(iii) who--

(I) has a family history of abdominal aortic aneurysm; or

(II) manifests risk factors included in a beneficiary category recommended for screening by the United States Preventive Services Task Force regarding abdominal aortic aneurysms;

(BB) additional preventive services (described in subsection (ddd)(1));

(CC) **[Caution: This subparagraph applies to items and services furnished on or after January 1, 2010, as provided by § 144(a)(3) of Act July 15, 2008, P.L. 110-275, which appears as *42 USCS § 1395w-4* note.]** items and services furnished under a cardiac rehabilitation program (as defined in subsection (eee)(1)) or under a pulmonary rehabilitation program (as defined in subsection (fff)(1));

(DD) **[Caution: This subparagraph applies to items and services furnished on or after January 1, 2010, as provided by § 144(a)(3) of Act July 15, 2008, P.L. 110-275, which appears as *42 USCS § 1395w-4* note.]** items and services furnished under an intensive cardiac rehabilitation program (as defined in subsection (eee)(4)); and

(EE) **[Caution: This subparagraph applies to services furnished on or after January 1, 2010, as provided by § 152(b)(2) of Act July 15, 2008, P.L. 110-275, which appears as *42 USCS § 1395w-4* note.]** kidney disease education services (as defined in subsection (ggg));

(3) diagnostic X-ray tests (including tests under the supervision of a physician, furnished in a place of residence used as the patient's home, if the performance of such tests meets such conditions relating to health and safety as the Secretary may find necessary and including diagnostic mammography if conducted by a facility that has a certificate (or provisional certificate) issued under section 354 of the Public Health Service Act [*42 USCS § 263b*], diagnostic laboratory tests, and other diagnostic tests;

(4) X-ray, radium, and radioactive isotope therapy, including materials and services of technicians;

(5) surgical dressings, and splints, casts, and other devices used for reduction of fractures and dislocations;

(6) durable medical equipment;

(7) ambulance service where the use of other methods of transportation is contraindicated by the individual's condition, but, subject to section 1834(l)(14) [*42 USCS § 1395m(l)(14)*], only to the extent provided in regulations;

(8) prosthetic devices (other than dental) which replace all or part of an internal body organ (including colostomy bags and supplies directly related to colostomy care), including replacement of such devices, and including one pair of conventional eyeglasses or contact lenses furnished subsequent to each cataract surgery with insertion of an intraocular lens

(9) leg, arm, back, and neck braces, and artificial legs, arms, and eyes, including replacements if required because of a change in the patient's physical condition;

(10) (A) pneumococcal vaccine and its administration and subject to section 4071(b) of the Omnibus Budget Reconciliation Act of 1987 [note to this section], influenza vaccine and its administration; and

(B) hepatitis B vaccine and its administration, furnished to an individual who is at high or intermediate risk of contracting hepatitis B (as determined by the Secretary under regulations); and

(11) services of a certified registered nurse anesthetist (as defined in subsection (bb));

(12) subject to section 4072(e) of the Omnibus Budget Reconciliation Act of 1987 [note to this section], extra-depth shoes with inserts or custom molded shoes with inserts for an individual with diabetes, if--

(A) the physician who is managing the individual's diabetic condition (i) documents that the individual has peripheral neuropathy with evidence of callus formation, a history of preulcerative calluses, a history of previous ulceration, foot deformity, or previous amputation, or poor circulation, and (ii) certifies that the individual needs such shoes under a comprehensive plan of care related to the individual's diabetic condition;

(B) the particular type of shoes are prescribed by a podiatrist or other qualified physician (as established by the Secretary); and

(C) the shoes are fitted and furnished by a podiatrist or other qualified individual (such as a pedorthist or orthotist, as established by the Secretary) who is not the physician described in subparagraph (A) (unless the Secretary finds that the physician is the only such qualified individual in the area);

(13) screening mammography (as defined in subsection (jj);

(14) screening pap smear and screening pelvic exam; and

(15) bone mass measurement (as defined in subsection (rr)).

No diagnostic tests performed in any laboratory, including a laboratory that is part of a rural health clinic, or a hospital (which, for purposes of this sentence, means an institution considered a hospital for purposes of section 1814(d) [*42 USCS § 1395f(d)*]) shall be included within paragraph (3) unless such laboratory--

(16) if situated in any State in which State or applicable local law provides for licensing of establishments of this nature, (A) is licensed pursuant to such law, or (B) is approved, by the agency of such State or locality responsible for licensing establishments of this nature, as meeting the standards established for such licensing; and

(17) (A) meets the certification requirements under section 353 of the Public Health Service Act [*42 USCS § 263a*]; and

(B) meets such other conditions relating to the health and safety of individuals with respect to whom such tests are performed as the Secretary may find necessary.

There shall be excluded from the diagnostic services specified in paragraph (2)(C) any item or service (except services referred to in paragraph (1)) which would not be included under subsection (b) if it were furnished to an inpatient of a hospital. None of the items and services referred to in the preceding paragraphs (other than paragraphs (1) and (2)(A)) of this subsection which are furnished to a patient of an institution which meets the definition of a hospital for purposes of section 1814(d) [*42 USCS § 1395f(d)*] shall be included unless such other conditions are met as the Secretary may find necessary relating to health and safety of individuals with respect to whom such items and services are furnished.

(t) Drugs and biologicals.

(1) The term "drugs" and the term "biologicals", except for purposes of subsection (m)(5) and paragraph (2) of this section, include only such drugs (including contrast agents) and biologicals, respectively, as are included (or approved for inclusion) in the United States Pharmacopoeia, the National Formulary, or the United States Homeopathic Pharmacopoeia, or in New Drugs or Accepted Dental Remedies (except for any drugs and biologicals unfavorably evaluated therein), or as are approved by the pharmacy and drug therapeutics committee (or equivalent committee) of the medical staff of the hospital furnishing such drugs and biologicals for use in such hospital.

(2)

(A) For purposes of paragraph (1), the term "drugs" also includes any drugs or biologicals used in an anticancer chemotherapeutic regimen for a medically accepted indication (as described in subparagraph (B)).

(B) In subparagraph (A), the term "medically accepted indication", with respect to the use of a drug, includes any use which has been approved by the Food and Drug Administration for the drug, and includes another use of the drug if--

(i) the drug has been approved by the Food and Drug Administration; and

(ii) (I) such use is supported by one or more citations which are included (or approved for inclusion) in one or more of the following compendia: the American Hospital Formulary Service-Drug Information, the American Medical Association Drug Evaluations, the United States Pharmacopoeia-Drug Information (or its successor publications), and other authoritative compendia as identified by the Secretary, unless the Secretary has determined that the use is not medically appropriate or the use is identified as not indicated in one or more such compendia, or

(II) the carrier involved determines, based upon guidance provided by the Secretary to carriers for determining accepted uses of drugs, that such use is medically accepted based on supportive clinical evidence in peer reviewed medical literature appearing in publications which have been identified for purposes of this subclause by the Secretary.

The Secretary may revise the list of compendia in clause (ii)(I) as is appropriate for identifying medically accepted indications for drugs. On and after January 1, 2010, no compendia may be included on the list of compendia under this subparagraph unless the compendia has a publicly transparent process for evaluating therapies and for identifying potential conflicts of interests.

(u) Provider of services. The term "provider of services" means a hospital, critical access hospital, skilled nursing facility, comprehensive outpatient rehabilitation facility, home health agency, hospice program, or, for purposes of section 1814(g) [*42 USCS § 1395f(g)*] and section 1835(e) [*42 USCS § 1395n(e)*], a fund.

(v) Reasonable costs.

(1)

(A) The reasonable cost of any services shall be the cost actually incurred, excluding therefrom any part of incurred cost found to be unnecessary in the efficient delivery of needed health services, and shall be determined in accordance with regulations establishing the method or methods to be used, and the items to be included, in determining such costs for various types or classes of institutions, agencies, and services; except that in any case to which paragraph (2) or (3) applies, the amount of the payment determined under such paragraph with respect to the services involved shall be considered the reasonable cost of such services. In prescribing the regulations referred to in the preceding sentence, the Secretary shall consider, among other things, the principles generally applied by national organizations or established prepayment organizations (which have developed such principles) in computing the amount of payment, to be made by persons other than the recipients of services, to providers of services on account of services furnished to such recipients by such providers. Such regulations may provide for determination of the costs of services on a per diem, per unit, per capita, or other basis, may provide for using different methods in different circumstances, may provide for the use of estimates of costs of particular items or services[,] may provide for the establishment of limits on the direct or indirect overall incurred costs or incurred costs of specific items or services or groups of items or services to be recognized as reasonable based on estimates of the costs necessary in the efficient delivery of needed health services to individuals covered by the insurance programs established under this *title [42 USCS §§ 1395* et seq.], and may provide for the use of charges or a percentage of charges where this method reasonably reflects the costs. Such regulations shall (i) take into account both direct and indirect costs of providers of services (excluding therefrom any such costs, including standby costs, which are determined in accordance with regulations to be unnecessary in the efficient delivery of services covered by the insurance programs established under this *title [42 USCS §§ 1395* et seq.]) in order that, under the methods of determining costs, the necessary costs of efficiently delivering covered services to individuals covered by the insurance programs established by this *title [42 USCS §§ 1395* et seq.] will not be borne by individuals not so covered, and the costs with respect to individuals not so covered will not be borne by such insurance programs, and (ii) provide for the making of suitable retroactive corrective adjustments where, for a provider of services for any fiscal period, the aggregate reimbursement produced by the methods of determining costs proves to be either inadequate or excessive.

(B) In the case of extended care services, the regulations under subparagraph (A) shall not include provision for specific recognition of a return on equity capital.

(C) Where a hospital has an arrangement with a medical school under which the faculty of such school provides services at such hospital, an amount not in excess of the reasonable cost of such services to the medical school shall be included in determining the reasonable cost to the hospital of furnishing services--

(i) for which payment may be made under part A [*42 USCS §§ 1395c* et seq.], but only if--

(I) payment for such services as furnished under such arrangement would be made under part A [*42 USCS §§ 1395c* et seq.] to the hospital had such services been furnished by the hospital, and

(II) such hospital pays to the medical school at least the reasonable cost of such services to the medical school, or

(ii) for which payment may be made under part B, [*42 USCS §§ 1395j* et seq.] but only if such hospital pays to the medical school at least the reasonable cost of such services to the medical school.

(D) Where (i) physicians furnish services which are either inpatient hospital services (including services in conjunction with the teaching programs of such hospital) by reason of paragraph (7) of subsection (b) or for which entitlement exists by reason of clause (II) of section 1832(a)(2)(B)(i) [*42 USCS § 1395k(a)(2)(B)(i)(II)*], and (ii) such hospital (or medical school under arrangement with such hospital) incurs no actual cost in the furnishing of such services, the reasonable cost of such services shall (under regulations of the Secretary) be deemed to be the cost such hospital or medical school would have incurred had it paid a salary to such physicians rendering such services approximately equivalent to the average salary paid to all physicians employed by such hospital (or if such employment does not exist, or is minimal in such hospital, by similar hospitals in a geographic area of sufficient size to assure reasonable inclusion of sufficient physicians in development of such average salary).

(E) Such regulations may, in the case of skilled nursing facilities in any State, provide for the use of rates, developed by the State in which such facilities are located, for the payment of the cost of skilled nursing facility services furnished under the State's plan approved under title XIX [*42 USCS §§ 1396* et seq.] (and such rates may be increased by the Secretary on a class or size of institution or on a geographical basis by a percentage factor not in excess of 10 percent to take into account determinable items or services or other requirements under this *title [42 USCS §§ 1395* et seq.] not otherwise included in the computation of such State rates), if the Secretary finds that such rates are reasonably related to (but not necessarily limited to) analyses undertaken by such State of costs of care in comparable facilities in such State. Notwithstanding the previous sentence, such regulations with respect to skilled nursing facilities shall take into account (in a manner consistent with subparagraph (A) and based on patient-days of services furnished) the costs (including the costs of services required to attain or maintain the highest practicable physical, mental, and psychosocial well-being of each resident eligible for benefits under this *title [42 USCS §§ 1395* et seq.]) of such facilities complying with the requirements of subsections (b), (c), and (d) of section 1819 [*42 USCS § 1395i-3(b)*, (c), and (d)] (including the costs of conducting nurse aide training and competency evaluation programs and competency evaluation programs).

(F) Such regulations shall require each provider of services (other than a fund) to make reports to the Secretary of information described in section 1121(a) [*42 USCS § 1320a(a)*] in accordance with the uniform reporting system (established under such section) for that type of provider.

(G) (i) In any case in which a hospital provides inpatient services to an individual that would constitute post-hospital extended care services if provided by a skilled nursing facility and a quality control and peer review organization (or, in the absence of such a qualified organization, the Secretary or such agent as the Secretary may designate) determines that inpatient hospital services for the individual are not medically necessary but post-hospital extended care services for the individual are medically necessary and such post-hospital extended care services are not otherwise available to the individual (as determined in accordance with criteria established by the Secretary) at the time of such determination, payment for such services provided to the individual shall continue to be made under this *title [42 USCS §§ 1395* et seq.] at the payment rate described in clause (ii) during the period in which--

(I) such post-hospital extended care services for the individual are medically necessary and not otherwise available to the individual (as so determined),

(II) inpatient hospital services for the individual are not medically necessary, and

(III) the individual is entitled to have payment made for post-hospital extended care services under this *title [42 USCS §§ 1395* et seq.],

except that if the Secretary determines that there is not an excess of hospital beds in such hospital and (subject to clause (iv), there is not an excess of hospital beds in the area of such hospital, such payment shall be made (during such period) on the basis of the amount otherwise payable under part A [*42 USCS §§ 1395c* et seq.] with respect to inpatient hospital services.

(ii) (I) Except as provided in subclause (II), the payment rate referred to in clause (i) is a rate equal to the estimated adjusted Statewide average rate per patient-day paid for services provided in skilled nursing facilities under the State plan approved under title XIX [*42 USCS §§ 1396* et seq.] for the State in which such hospital is located, or, if the State in which the hospital is located does not have a State plan approved under title XIX [*42 USCS §§ 1396* et seq.], the estimated adjusted State-wide average allowable costs per patient-day for extended care services under this *title [42 USCS §§ 1395* et seq.] in that State.

(II) If a hospital has a unit which is a skilled nursing facility, the payment rate referred to in clause (i) for the hospital is a rate equal to the lesser of the rate described in subclause (I) or the allowable costs in effect under this *title [42 USCS §§ 1395* et seq.] for extended care services provided to patients of such unit.

(iii) Any day on which an individual receives inpatient services for which payment is made under this subparagraph shall, for purposes of this Act (other than this subparagraph), be deemed to be a day on which the individual received inpatient hospital services.

(iv) In determining under clause (i), in the case of a public hospital, whether or not there is an excess of hospital beds in the area of such hospital, such determination shall be made on the basis of only the public hospitals (including the hospital) which are in the area of the hospital and which are under common ownership with that hospital.

(H) In determining such reasonable cost with respect to home health agencies, the Secretary may not include--

(i) any costs incurred in connection with bonding or establishing an escrow account by any such agency as a result of the surety bond requirement described in subsection (o)(7) and the financial security requirement described in subsection (o)(8);

(ii) in the case of home health agencies to which the surety bond requirement described in subsection (o)(7) and the financial security requirement described in subsection (o)(8) apply, any costs attributed to interest charged such an agency in connection with amounts borrowed by the agency to repay overpayments made under this *title [42 USCS §§ 1395* et seq.] to the agency, except that such costs may be included in reasonable cost if the Secretary determines that the agency was acting in good faith in borrowing the amounts;

(iii) in the case of contracts entered into by a home health agency after the date of the enactment of this subparagraph [enacted Dec. 5, 1980] for the purpose of having services furnished for or on behalf of such agency, any cost incurred by such agency pursuant to any such contract which is entered into for a period exceeding five years; and

(iv) in the case of contracts entered into by a home health agency before the date of the enactment of this subparagraph [enacted Dec. 5, 1980] for the purpose of having services furnished for or on behalf of such agency, any cost incurred by such agency pursuant to any such contract, which determines the amount payable by the home health agency on the basis of a percentage of the agency's reimbursement or claim for reimbursement for services furnished by the agency, to the extent that such cost exceeds the reasonable value of the services furnished on behalf of such agency.

(I) In determining such reasonable cost, the Secretary may not include any costs incurred by a provider with respect to any services furnished in connection with matters for which payment may be made under this *title [42 USCS §§ 1395* et seq.] and furnished pursuant to a contract between the provider and any of its subcontractors which is entered into after the date of the enactment of this subparagraph [enacted Dec. 5, 1980] and the value or cost of which is $ 10,000 or more over a twelve-month period unless the contract contains a clause to the effect that--

(i) until the expiration of four years after the furnishing of such services pursuant to such contract, the subcontractor shall make available, upon written request by the Secretary, or upon request by the Comptroller General, or any of their duly authorized representatives, the contract, and books, documents and records of such subcontractor that are necessary to certify the nature and extent of such costs, and

(ii) if the subcontractor carries out any of the duties of the contract through a subcontract, with a value or cost of $ 10,000 or more over a twelve-month period, with a related organization, such subcontract shall contain a clause to the effect that until the expiration of four years after the furnishing of such services pursuant to such subcontract, the related organization shall make available, upon written request by the Secretary, or upon request by the Comptroller General, or any of their duly authorized representatives, the subcontract, and books, documents and records of such organization that are necessary to verify the nature and extent of such costs.

The Secretary shall prescribe in regulation [regulations] criteria and procedures which the Secretary shall use in obtaining access to books, documents, and records under clauses required in contracts and subcontracts under this subparagraph.

(J) Such regulations may not provide for any inpatient routine salary cost differential as a reimbursable cost for hospitals and skilled nursing facilities.

(K) (i) The Secretary shall issue regulations that provide, to the extent feasible, for the establishment of limitations on the amount of any costs or charges that shall be considered reasonable with respect to services provided on an outpatient basis by hospitals (other than bona fide emergency services as defined in clause (ii), or clinics (other than rural health clinics), which are reimbursed on a cost basis or on the basis of cost related charges, and by physicians utilizing such outpatient facilities. Such limitations shall be reasonably related to the charges in the same area for similar services provided in physicians' offices. Such regulations shall provide for exceptions to such limitations in cases where similar services are not generally available in physicians' offices in the area to individuals entitled to benefits under this *title [42 USCS §§ 1395* et seq.].

(ii) For purposes of clause (i), the term "bona fide emergency services" means services provided in a hospital emergency room after the sudden onset of a medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain) such that the absence of immediate medical attention could reasonably be expected to result in--

(I) placing the patient's health in serious jeopardy;

(II) serious impairment to bodily functions; or

(III) serious dysfunction of any bodily organ or part.

(L) (i) The Secretary, in determining the amount of the payments that may be made under this *title [42 USCS §§ 1395* et seq.] with respect to services furnished by home health agencies, may not recognize as reasonable (in the efficient delivery of such services) costs for the provision of such services by an agency to the extent these costs exceed (on the aggregate for the agency) for cost reporting periods beginning on or after--

(I) July 1, 1985, and before July 1, 1986, 120 percent of the mean of the labor-related and nonlabor per visit costs for freestanding home health agencies,

(II) July 1, 1986, and before July 1, 1987, 115 percent of such mean,

(III) July 1, 1987, and before October 1, 1997, 112 percent of such mean,

(IV) October 1, 1997, and before October 1, 1998, 105 percent of the median of the labor-related and nonlabor per visit costs for freestanding home health agencies, or

(V) October 1, 1998, 106 percent of such median.

(ii) Effective for cost reporting periods beginning on or after July 1, 1986, such limitations shall be applied on an aggregate basis for the agency, rather than on a discipline specific basis. The Secretary may provide for such exemptions and exceptions to such limitation as he deems appropriate.

(iii) Not later than July 1, 1991, and annually thereafter (but not for cost reporting periods beginning on or after July 1, 1994, and before July 1, 1996, or on or after July 1, 1997, and before October 1, 1997), the Secretary shall establish limits under this subparagraph for cost reporting periods beginning on or after such date by utilizing the area wage index applicable under section 1886(d)(3)(E) [*42 USCS § 1395ww(d)(3)(E)*] and determined using the survey of the most recent available wages and wage-related costs of hospitals located in the geographic area in which the home health service is furnished (determined without regard to whether such hospitals have been reclassified to a new geographic area pursuant to section 1886(d)(8)(B) [*42 USCS § 1395ww(d)(8)(B)*], a decision of the Medicare Geographic Classification Review Board under section 1886(d)(10) [*42 USCS § 1395ww(d)(10)*], or a decision of the Secretary).

(iv) In establishing limits under this subparagraph for cost reporting periods beginning after September 30, 1997, the Secretary shall not take into account any changes in the home health market basket, as determined by the Secretary, with respect to cost reporting periods which began on or after July 1, 1994, and before July 1, 1996.

(v) For services furnished by home health agencies for cost reporting periods beginning on or after October 1, 1997, subject to clause (viii)(I), the Secretary shall provide for an interim system of limits. Payment shall not exceed the costs determined under the preceding provisions of this subparagraph or, if lower, the product of--

(I) an agency-specific per beneficiary annual limitation calculated based 75 percent on 98 percent of the reasonable costs (including nonroutine medical supplies) for the agency's 12-month cost reporting period ending during fiscal year 1994, and based 25 percent on 98 percent of the standardized regional average of such costs for the agency's census division, as applied to such agency, for cost reporting periods ending during fiscal year 1994, such costs updated by the home health market basket index; and

(II) the agency's unduplicated census count of patients (entitled to benefits under this *title [42 USCS §§ 1395* et seq.]) for the cost reporting period subject to the limitation.

(vi) For services furnished by home health agencies for cost reporting periods beginning on or after October 1, 1997, the following rules apply:

(I) For new providers and those providers without a 12-month cost reporting period ending in fiscal year 1994 subject to clauses (viii)(II) and (viii)(III), the per beneficiary limitation shall be equal to the median of these limits (or the Secretary's best estimates thereof) applied to other home health agencies as determined by the Secretary. A home health agency that has altered its corporate structure or name shall not be considered a new provider for this purpose.

(II) For beneficiaries who use services furnished by more than one home health agency, the per beneficiary limitations shall be prorated among the agencies.

(vii) (I) Not later than January 1, 1998, the Secretary shall establish per visit limits applicable for fiscal year 1998, and not later than April 1, 1998, the Secretary shall establish per beneficiary limits under clause (v)(I) for fiscal year 1998.

(II) Not later than August 1 of each year (beginning in 1998) the Secretary shall establish the limits applicable under this subparagraph for services furnished during the fiscal year beginning October 1 of the year.

(viii) (I) In the case of a provider with a 12-month cost reporting period ending in fiscal year 1994, if the limit imposed under clause (v) (determined without regard to this subclause) for a cost reporting period beginning during or after fiscal year 1999 is less than the median described in clause (vi)(I) (but determined as if any reference in clause (v) to "98 percent" were a reference to "100 percent"), the limit otherwise imposed under clause (v) for such provider and period shall be increased by 1/3 of such difference.

(II) Subject to subclause (IV), for new providers and those providers without a 12-month cost reporting period ending in fiscal year 1994, but for which the first cost reporting period begins before fiscal year 1999, for cost reporting periods beginning during or after fiscal year 1999, the per beneficiary limitation described in clause (vi)(I) shall be equal to the median described in such clause (determined as if any reference in clause (v) to "98 percent" were a reference to "100 percent").

(III) Subject to subclause (IV), in the case of a new provider for which the first cost reporting period begins during or after fiscal year 1999, the limitation applied under clause (vi)(I) (but only with respect to such provider) shall be equal to 75 percent of the median described in clause (vi)(I).

(IV) In the case of a new provider or a provider without a 12-month cost reporting period ending in fiscal year 1994, subclause (II) shall apply, instead of subclause (III), to a home health agency which filed an application for home health agency provider status under this *title [42 USCS §§ 1395* et seq.] before September 15, 1998, or which was approved as a branch of its parent agency before such date and becomes a subunit of the parent agency or a separate agency on or after such date.

(V) Each of the amounts specified in subclauses (I) through (III) are such amounts as adjusted under clause (iii) to reflect variations in wages among different areas.

(ix) Notwithstanding the per beneficiary limit under clause (viii), if the limit imposed under clause (v) (determined without regard to this clause) for a cost reporting period beginning during or after fiscal year 2000 is less than the median described in clause (vi)(I) (but determined as if any reference in clause (v) to "98 percent" were a reference to "100 percent"), the limit otherwise imposed under clause (v) for such provider and period shall be increased by 2 percent.

(x) Notwithstanding any other provision of this subparagraph, in updating any limit under this subparagraph by a home health market basket index for cost reporting periods beginning during each of fiscal years 2000, 2002, and 2003, the update otherwise provided shall be reduced by 1.1 percentage points. With respect to cost reporting periods beginning during fiscal year 2001, the update to any limit under this subparagraph shall be the home health market basket index.

(M) Such regulations shall provide that costs respecting care provided by a provider of services, pursuant to an assurance under title VI or XVI of the Public Health Service Act [*42 USCS §§ 291* et seq. or *300q* et seq.] that the provider will make available a reasonable volume of services to persons unable to pay therefor, shall not be allowable as reasonable costs.

(N) In determining such reasonable costs, costs incurred for activities directly related to influencing employees respecting unionization may not be included.

(O) (i) In establishing an appropriate allowance for depreciation and for interest on capital indebtedness with respect to an asset of a provider of services which has undergone a change of ownership, such regulations shall provide, except as provided in clause (iii), that the valuation of the asset after such change of ownership shall be the historical cost of the asset, as recognized under this *title [42 USCS §§ 1395* et seq.], less depreciation allowed, to the owner of record as of the date of enactment of the Balanced Budget Act of 1997 [enacted August 5, 1997] (or, in the case of an asset not in existence as of that date, the first owner of record of the asset after that date).

(ii) Such regulations shall not recognize, as reasonable in the provision of health care services, costs (including legal fees, accounting and administrative costs, travel costs, and the costs of feasibility studies) attributable to the negotiation or settlement of the sale or purchase of any capital asset (by acquisition or merger) for which any payment has previously been made under this *title [42 USCS §§ 1395* et seq.].

(iii) In the case of the transfer of a hospital from ownership by a State to ownership by a nonprofit corporation without monetary consideration, the basis for capital allowances to the new owner shall be the book value of the hospital to the State at the time of the transfer.

(P) If such regulations provide for the payment for a return on equity capital (other than with respect to costs of inpatient hospital services), the rate of return to be recognized, for determining the reasonable cost of services furnished in a cost reporting period, shall be equal to the average of the rates of interest, for each of the months any part of which is included in the period, on obligations issued for purchase by the Federal Hospital Insurance Trust Fund.

(Q) Except as otherwise explicitly authorized, the Secretary is not authorized to limit the rate of increase on allowable costs of approved medical educational activities.

(R) In determining such reasonable cost, costs incurred by a provider of services representing a beneficiary in an unsuccessful appeal of a determination described in section 1869(b) [*42 USCS § 1395ff(b)*] shall not be allowable as reasonable costs.

(S) (i) Such regulations shall not include provision for specific recognition of any return on equity capital with respect to hospital outpatient departments.

(ii) (I) Such regulations shall provide that, in determining the amount of the payments that may be made under this *title [42 USCS §§ 1395* et seq.] with respect to all the capital-related costs of outpatient hospital services, the Secretary shall reduce the amounts of such payments otherwise established under this *title [42 USCS §§ 1395* et seq.] by 15 percent for payments attributable to portions of cost reporting periods occurring during fiscal year 1990, by 15 percent for payments attributable to portions of cost reporting periods occurring during fiscal year 1991, and by 10 percent for payments attributable to portions of cost reporting periods occurring during fiscal years 1992 through 1999 and until the first date that the prospective payment system under section 1833(t) [*42 USCS § 1395l(t)*] is implemented.

(II) The Secretary shall reduce the reasonable cost of outpatient hospital services (other than the capital-related costs of such services) otherwise determined pursuant to section 1833(a)(2)(B)(i)(I) [*42 USCS § 1395l(a)(2)(B)(i)(I)*] by 5.8 percent for payments attributable to portions of cost reporting periods occurring during fiscal years 1991 through 1999 and until the first date that the prospective payment system under section 1833(t) [*42 USCS § 1395l(t)*] is implemented.

(III) Subclauses (I) and (II) shall not apply to payments with respect to the costs of hospital out-patient services provided by any hospital that is a sole community hospital (as defined in section 1886(d)(5)(D)(iii) [*42 USCS § 1395ww(d)(5)(D)(iii)*]) or a critical access hospital (as defined in section 1861(mm)(1) [subsec. (mm)(1) of this section]).

(IV) In applying subclauses (I) and (II) to services for which payment is made on the basis of a blend amount under section 1833(i)(3)(A)(ii) or 1833(n)(1)(A)(ii) [*42 USCS § 1395l(i)(3)(A)(ii)* or (n)(1)(A)(ii)], the costs reflected in the amounts described in sections 1833(i)(3)(B)(i)(I) and 1833(n)(1)(B)(i)(I) [*42 USCS § 1395l(i)(3)(B)(i)(I)* and (n)(1)(B)(i)(I)], respectively, shall be reduced in accordance with such subclause [subclauses].

(T) In determining such reasonable costs for hospitals, no reduction in copayments under section 1833(t)(8)(B) [*42 USCS § 1395l(t)(8)(B)*] shall be treated as a bad debt and the amount of bad debts otherwise treated as allowable costs which are attributable to the deductibles and coinsurance amounts under this *title [42 USCS §§ 1395* et seq.] shall be reduced--

(i) for cost reporting periods beginning during fiscal year 1998, by 25 percent of such amount otherwise allowable,

(ii) for cost reporting periods beginning during fiscal year 1999, by 40 percent of such amount otherwise allowable,

(iii) for cost reporting periods beginning during fiscal year 2000, by 45 percent of such amount otherwise allowable, and

(iv) for cost reporting periods beginning during a subsequent fiscal year, by 30 percent of such amount otherwise allowable.

(U) In determining the reasonable cost of ambulance services (as described in subsection (s)(7)) provided during fiscal year 1998, during fiscal year 1999, and during so much of fiscal year 2000 as precedes January 1, 2000, the Secretary shall not recognize the costs per trip in excess of costs recognized as reasonable for ambulance services provided on a per trip basis during the previous fiscal year (after application of this subparagraph), increased by the percentage increase in the consumer price index for all urban consumers (U.S. city average) as estimated by the Secretary for the 12-month period ending with the midpoint of the fiscal year involved reduced by 1.0 percentage point. For ambulance services provided after June 30, 1998, the Secretary may provide that claims for such services must include a code (or codes) under a uniform coding system specified by the Secretary that identifies the services furnished.

(V) In determining such reasonable costs for skilled nursing facilities with respect to cost reporting periods beginning on or after October 1, 2005, the amount of bad debts otherwise treated as allowed costs which are attributable to the coinsurance amounts under this *title [42 USCS §§ 1395* et seq.] for individuals who are entitled to benefits under part A [*42 USCS §§ 1395c* et seq.] and--

(i) are not described in section 1935(c)(6)(A)(ii) [*42 USCS § 1396u-5(c)(6)(A)(ii)*] shall be reduced by 30 percent of such amount otherwise allowable; and

(ii) are described in such section shall not be reduced.

(2)

(A) If the bed and board furnished as part of inpatient hospital services (including inpatient tuberculosis hospital services and inpatient psychiatric hospital services) or post-hospital extended care services is in accomodations [accommodations] more expensive than semi-private accomodations [accommodations], the amount taken into account for purposes of payment under this *title [42 USCS §§ 1395* et seq.] with respect to such services may not exceed the amount that would be taken into account with respect to such services if furnished in such semi-private accommodations unless the more expensive accomodations [accommodations] were required for medical reasons.

(B) Where a provider of services which has an agreement in effect under this *title [42 USCS §§ 1395* et seq.] furnishes to an individual items or services which are in excess of or more expensive than the items or services with respect to which payment may be made under part A or part B [*42 USCS §§ 1395c* et seq. or *1395j* et seq.], as the case may be, the Secretary shall take into account for purposes of payment to such provider of services only the items or services with respect to which such payment may be made.

(3) If the bed and board furnished as part of inpatient hospital services (including inpatient tuberculosis hospital services and inpatient psychiatric hospital services) or post-hospital extended care services is in accommodations other than, but not more expensive than, semi-private accommodations and the use of such other accommodations rather than semi-private accommodations was neither at the request of the patient nor for a reason which the Secretary determines is consistent with the purposes of this *title [42 USCS §§ 1395* et seq.], the amount of the payment with respect to such bed and board under part A [*42 USCS §§ 1395c* et seq.] shall be the amount otherwise payable under this *title [42 USCS §§*

1395 et seq.] for such bed and board furnished in semi-private accommodations minus the difference between the charge customarily made by the hospital or skilled nursing facility for bed and board in semi-private accommodations and the charge customarily made by it for bed and board in the accommodations furnished.

(4) If a provider of services furnishes items or services to an individual which are in excess of or more expensive than the items or services determined to be necessary in the efficient delivery of needed health services and charges are imposed for such more expensive items or services under the authority granted in section 1866(a)(2)(B)(ii), the amount of payment with respect to such items or services otherwise due such provider in any fiscal period shall be reduced to the extent that such payment plus such charges exceed the cost actually incurred for such items or services in the fiscal period in which such charges are imposed.

(5) (A) Where physical therapy services, occupational therapy services, speech therapy services, or other therapy services or services of other health-related personnel (other than physicians) are furnished under an arrangement with a provider of services or other organization, specified in the first sentence of subsection (p) (including through the operation of subsection (g)) the amount included in any payment to such provider or other organization under this *title [42 USCS §§ 1395* et seq.] as the reasonable cost of such services (as furnished under such arrangements) shall not exceed an amount equal to the salary which would reasonably have been paid for such services (together with any additional costs that would have been incurred by the provider or other organization) to the person performing them if they had been performed in an employment relationship with such provider or other organization (rather than under such arrangement) plus the cost of such other expenses (including a reasonable allowance for traveltime and other reasonable types of expense related to any differences in acceptable methods of organization for the provision of such therapy) incurred by such person, as the Secretary may in regulations determine to be appropriate.

(B) Notwithstanding the provisions of subparagraph (A), if a provider of services or other organization specified in the first sentence of section 1861(p) [subsec. (p) of this section] requires the services of a therapist on a limited part-time basis, or only to perform intermittent services, the Secretary may make payment on the basis of a reasonable rate per unit of service, even though such rate is greater per unit of time than salary related amounts, where he finds that such greater payment is, in the aggregate, less than the amount that would have been paid if such organization had employed a therapist on a full- or part-time salary basis.

(6) For purposes of this subsection, the term "semi-private accommodations" means two-bed, three-bed, or four-bed accommodations.

(7) (A) For limitation on Federal participation for capital expenditures which are out of conformity with a comprehensive plan of a State or areawide planning agency, see section 1122 [*42 USCS § 1320a-1*].

(B) For further limitations on reasonable cost and determination of payment amounts for operating costs of inpatient hospital services and waivers for certain States, see section 1886 [*42 USCS § 1395ww*].

(C) For provisions restricting payment for provider-based physicians' services and for payments under certain percentage arrangements, see section 1887 [*42 USCS § 1395xx*].

(D) For further limitations on reasonable cost and determination of payment amounts for routine service costs of skilled nursing facilities, see subsections (a) through (c) of section 1888 [*42 USCS §§ 1395yy(a)*-(c)].

(8) Items unrelated to patient care. Reasonable costs do not include costs for the following--

(i) entertainment, including tickets to sporting and other entertainment events;

(ii) gifts or donations;

(iii) personal use of motor vehicles;

(iv) costs for fines and penalties resulting from violations of Federal, State, or local laws; and

(v) education expenses for spouses or other dependents of providers of services, their employees or contractors.

(w) Arrangements for certain services; payments pursuant to arrangements for utilization review activities.

(1) The term "arrangements" is limited to arrangements under which receipt of payment by the hospital, critical access hospital, skilled nursing facility, home health agency, or hospice program (whether in its own right or as agent), with respect to services for which an individual is entitled to have payment made under this *title [42 USCS §§ 1395* et seq.], discharges the liability of such individual or any other person to pay for the services.

(2) Utilization review activities conducted, in accordance with the requirements of the program established under part B of title XI of the Social Security Act [*42 USCS §§ 1320c* et seq.] with respect to services furnished by a hospital or critical access hospital to patients insured under part A of this *title [42 USCS §§ 1395c* et seq.] or entitled to have payment made for such services under part B of this *title [42 USCS § 1395j* et seq.] or under a State plan approved under title XIX [*42 USCS §§ 1396* et seq.] by a quality control and peer review organization designated for the area in which such hospital or critical access hospital is located shall be deemed to have been conducted pursuant to arrangements between such hospital or critical access hospital and such organization under which such hospital or critical access hospital is obligated to pay to such organization, as a condition of receiving payment for hospital or critical access hospital services so furnished under this part [*42 USCS §§ 1395x* et seq.] or under such a State plan, such

amount as is reasonably incurred and requested (as determined under regulations of the Secretary) by such organization in conducting such review activities with respect to services furnished by such hospital or critical access hospital to such patients.

(x) State and United States. The terms "State" and "United States" have the meaning given to them by subsections (h) and (i), respectively, of section 210 [*42 USCS § 410(h)* and (i)].

(y) Extended care in religious nonmedical health care institutions.

(1) The term "skilled nursing facility" also includes a religious nonmedical health care institution (as defined in subsection (ss)(1)), but only (except for purposes of subsection (a)(2)) with respect to items and services ordinarily furnished by such an institution to inpatients, and payment may be made with respect to services provided by or in such an institution only to such extent and under such conditions, limitations, and requirements (in addition to or in lieu of the conditions, limitations, and requirements otherwise applicable) as may be provided in regulations consistent with section 1821 [*42 USCS § 1395i-5*].

(2) Notwithstanding any other provision of this *title [42 USCS §§ 1395* et seq.], payment under part A [*42 USCS §§ 1395c* et seq.] may not be made for services furnished an individual in a skilled nursing facility to which paragraph (1) applies unless such individual elects, in accordance with regulations, for a spell of illness to have such services treated as post-hospital extended care services for purposes of such part [*42 USCS §§ 1395c* et seq.]; and payment under part A [*42 USCS §§ 1395c* et seq.] may not be made for extended care services--

(A) furnished an individual during such spell of illness in a skilled nursing facility to which paragraph (1) applies after--

(i) such services have been furnished to him in such a facility for 30 days during such spell, or

(ii) such services have been furnished to him during such spell in a skilled nursing facility to which such paragraph does not apply; or

(B) furnished an individual during such spell of illness in a skilled nursing facility to which paragraph (1) does not apply after such services have been furnished to him during such spell in a skilled nursing facility to which such paragraph applies.

(3) The amount payable under part A [*42 USCS §§ 1395c* et seq.] for post-hospital extended care services furnished an individual during any spell of illness in a skilled nursing facility to which paragraph (1) applies shall be reduced by a coinsurance amount equal to one-eighth of the inpatient hospital deductible for each day before the 31st day on which he is furnished such services in such a facility during such spell (and the reduction under this paragraph shall be in lieu of any reduction under section 1813(a)(3) [*42 USCS § 1395e(a)(3)*]).

(4) For purposes of subsection (i), the determination of whether services furnished by or in an institution described in paragraph (1) constitute post-hospital extended care services shall be made in accordance with and subject to such conditions, limitations, and requirements as may be provided in regulations.

(z) Institutional planning. An overall plan and budget of a hospital, skilled nursing facility, comprehensive outpatient rehabilitation facility, or home health agency shall be considered sufficient if it--

(1) provides for an annual operating budget which includes all anticipated income and expenses related to items which would, under generally accepted accounting principles, be considered income and expense items (except that nothing in this paragraph shall require that there be prepared, in connection with any budget, an item-by-item identification of the components of each type of anticipated expenditure or income);

(2) (A) provides for a capital expenditures plan for at least a 3-year period (including the year to which the operating budget described in paragraph (1) is applicable) which includes and identifies in detail the anticipated sources of financing for, and the objectives of, each anticipated expenditures in excess of $ 600,000 (or such lesser amount as may be established by the State under section 1122(g)(1) [*42 USCS § 1320a-1(g)(1)*] in which the hospital is located) related to the acquisition of land, the improvement of land, buildings, and equipment, and the replacement, modernization, and expansion of the buildings and equipment which would, under generally accepted accounting principles, be considered capital items;

(B) provides that such plan is submitted to the agency designated under section 1122(b) [*42 USCS § 1320a-1(b)*], or if no such agency is designated, to the appropriate health planning agency in the State (but this subparagraph shall not apply in the case of a facility exempt from review under section 1122 [*42 USCS § 1320a-1*] by reason of section 1122(j) [*42 USCS § 1320a-1(j)*]);

(3) provides for review and updating at least annually; and

(4) is prepared, under the direction of the governing body of the institution or agency, by a committee consisting of representatives of the governing body, the administrative staff, and the medical staff (if any) of the institution or agency.

(aa) Rural health clinic services and Federally qualified health center services.

(1) The term "rural health clinic services" means--

(A) physicians' services and such services and supplies as are covered under section 1861(s)(2)(A) [subsec. (s)(2)(A) of this section] if furnished as an incident to a physician's professional service and items and services described in section 1861(s)(10) [subsec. (s)(10) of this section],

(B) such services furnished by a physician assistant or a nurse practitioner (as defined in paragraph (5)), by a clinical psychologist (as defined by the Secretary) or by a clinical social worker (as defined in subsection (hh)(1)), and such services and supplies furnished as an incident to his service as would otherwise be covered if furnished by a physician or as an incident to a physician's service, and

(C) in the case of a rural health clinic located in an area in which there exists a shortage of home health agencies, part-time or intermittent nursing care and related medical supplies (other than drugs and biologicals) furnished by a registered professional nurse or licensed practical nurse to a homebound individual under a written plan of treatment (i) established and periodically reviewed by a physician described in paragraph (2)(B), or (ii) established by a nurse practitioner or physician assistant and periodically reviewed and approved by a physician described in paragraph (2)(B), when furnished to an individual as an outpatient of a rural health clinic.

(2) The term "rural health clinic" means a facility which--

(A) is primarily engaged in furnishing to outpatients services described in subparagraphs (A) and (B) of paragraph (1);

(B) in the case of a facility which is not a physician-directed clinic, has an arrangement (consistent with the provisions of State and local law relative to the practice, performance, and delivery of health services) with one or more physicians (as defined in subsection (r)(1)) under which provision is made for the periodic review by such physicians of covered services furnished by physician assistants and nurse practitioners, the supervision and guidance by such physicians of physician assistants and nurse practitioners, the preparation by such physicians of such medical orders for care and treatment of clinic patients as may be necessary, and the availability of such physicians for such referral of and consultation for patients as is necessary and for advice and assistance in the management of medical emergencies; and, in the case of a physician-directed clinic, has one or more of its staff physicians perform the activities accomplished through such an arrangement;

(C) maintains clinical records on all patients;

(D) has arrangements with one or more hospitals, having agreements in effect under section 1866 [*42 USCS § 1395cc*], for the referral and admission of patients requiring inpatient services or such diagnostic or other specialized services as are not available at the clinic;

(E) has written policies, which are developed with the advice of (and with provision for review of such policies from time to time by) a group of professional personnel, including one or more physicians and one or more physician assistants or nurse practitioners, to govern those services described in paragraph (1) which it furnishes;

(F) has a physician, physician assistant, or nurse practitioner responsible for the execution of policies described in subparagraph (E) and relating to the provision of the clinic's services;

(G) directly provides routine diagnostic services, including clinical laboratory services, as prescribed in regulations by the Secretary, and has prompt access to additional diagnostic services from facilities meeting requirements under this *title [42 USCS §§ 1395* et seq.];

(H) in compliance with State and Federal law, has available for administering to patients of the clinic at least such drugs and biologicals as are determined by the Secretary to be necessary for the treatment of emergency cases (as defined in regulations) and has appropriate procedures or arrangements for storing, administering, and dispensing any drugs and biologicals;

(I) has a quality assessment and performance improvement program, and appropriate procedures for review of utilization of clinic services, as the Secretary may specify;

(J) has a nurse practitioner, a physician assistant, or a certified nurse-midwife (as defined in subsection (gg)) available to furnish patient care services not less than 50 percent of the time the clinic operates; and

(K) meets such other requirements as the Secretary may find necessary in the interest of the health and safety of the individuals who are furnished services by the clinic.

For the purposes of this *title [42 USCS §§ 1395* et seq.], such term includes only a facility which (i) is located in an area that is not an urbanized area (as defined by the Bureau of the Census) and in which there are insufficient numbers of needed health care practitioners (as determined by the Secretary), and that, within the previous 4-year period, has been designated by the chief executive officer of the State and certified by the Secretary as an area with a shortage of personal health services or designated by the Secretary either (I) as an area with a shortage of personal health services under section 330(b)(3) or 1302(7) of the Public Health Service Act, (II) as a health professional shortage area described in section 332(a)(1)(A) of that Act [*42 USCS § 254e(a)(1)(A)*] because of its shortage of primary medical care manpower, (III) as a high impact area described in section 329(a)(5) of that Act [*42 USCS § 254b(a)(5)*], or (IV) as an

area which includes a population group which the Secretary determines has a health manpower shortage under section 332(a)(1)(B) of that Act [*42 USCS § 256(a)(1)(B)*], (ii) has filed an agreement with the Secretary by which it agrees not to charge any individual or other person for items or services for which such individual is entitled to have payment made under this *title [42 USCS §§ 1395* et seq.], except for the amount of any deductible or coinsurance amount imposed with respect to such items or services (not in excess of the amount customarily charged for such items and services by such clinic), pursuant to subsections (a) and (b) of section 1833 [*42 USCS § 1395l(a)* and (b)], (iii) employs a physician assistant or nurse practitioner, and (iv) is not a rehabilitation agency or a facility which is primarily for the care and treatment of mental diseases. A facility that is in operation and qualifies as a rural health clinic under this title or title XIX [*42 USCS §§ 1395* et seq. or *1396* et seq.] and that subsequently fails to satisfy the requirement of clause (i) shall be considered, for purposes of this title and title XIX [*42 USCS §§ 1395* et seq. or *1396* et seq.], as still satisfying the requirement of such clause if it is determined, in accordance with criteria established by the Secretary in regulations, to be essential to the delivery of primary care services that would otherwise be unavailable in the geographic area served by the clinic. If a State agency has determined under section 1864(a) *[42 USCS § 1395laa*(a)] that a facility is a rural health clinic and the facility has applied to the Secretary for approval as such a clinic, the Secretary shall notify the facility of the Secretary's approval or disapproval not later than 60 days after the date of the State agency determination or the application (whichever is later).

(3) The term "Federally qualified health center services" means--

(A) services of the type described in subparagraphs (A) through (C) of paragraph (1) and services described in subsections (qq) and (vv); and

(B) preventive primary health services that a center is required to provide under section 330 of the Public Health Service Act [*42 USCS § 254b*],

when furnished to an individual as an outpatient of a Federally qualified health center by the center or by a health care professional under contract with the center and, for this purpose, any reference to a rural health clinic or a physician described in paragraph (2)(B) is deemed a reference to a Federally qualified health center or a physician at the center, respectively.

(4) The term "Federally qualified health center" means an entity which--

(A) (i) is receiving a grant under section 330 of the Public Health Service Act [*42 USCS § 254b*], or

(ii) (I) is receiving funding from such a grant under a contract with the recipient of such a grant, and (II) meets the requirements to receive a grant under section 330 of such Act [*42 USCS § 254b*];

(B) based on the recommendation of the Health Resources and Services Administration within the Public Health Service, is determined by the Secretary to meet the requirements for receiving such a grant;

(C) was treated by the Secretary, for purposes of part B [*42 USCS §§ 1395j* et seq.], as a comprehensive Federally funded health center as of January 1, 1990; or

(D) is an outpatient health program or facility operated by a tribe or tribal organization under the Indian Self-Determination Act or by an urban Indian organization receiving funds under title V of the Indian Health Care Improvement Act [*25 USCS §§ 1651* et seq.].

(5)

(A) The term "physician assistant" and the term "nurse practitioner" mean, for purposes of this *title [42 USCS §§ 1395* et seq.], a physician assistant or nurse practitioner who performs such services as such individual is legally authorized to perform (in the State in which the individual performs such services) in accordance with State law (or the State regulatory mechanism provided by State law), and who meets such training, education, and experience requirements (or any combination thereof) as the Secretary may prescribe in regulations.

(B) The term "clinical nurse specialist" means, for purposes of this title, an individual who--

(i) is a registered nurse and is licensed to practice nursing in the State in which the clinical nurse specialist services are performed; and

(ii) holds a master's degree in a defined clinical area of nursing from an accredited educational institution.

(6) The term "collaboration" means a process in which a nurse practitioner works with a physician to deliver health care services within the scope of the practitioner's professional expertise, with medical direction and appropriate supervision as provided for in jointly developed guidelines or other mechanisms as defined by the law of the State in which the services are performed.

(7) (A) The Secretary shall waive for a 1-year period the requirements of paragraph (2) that a rural health clinic employ a physician assistant, nurse practitioner or certified nurse midwife or that such clinic require such providers to furnish services at least 50 percent of the time that the clinic operates for any facility that requests such waiver if the facility demonstrates that the facility has been unable, despite reasonable efforts, to hire a physician assistant, nurse practitioner, or certified nurse-midwife in the previous 90-day period.

(B) The Secretary may not grant such a waiver under subparagraph (A) to a facility if the request for the waiver is made less than 6 months after the date of the expiration of any previous such waiver for the facility, or if the facility has

not yet been determined to meet the requirements (including subparagraph (J) of the first sentence of paragraph (2)) of a rural health clinic.

(C) A waiver which is requested under this paragraph shall be deemed granted unless such request is denied by the Secretary within 60 days after the date such request is received.

(bb) Services of a certified registered nurse anesthetist.

(1) The term "services of a certified registered nurse anesthetist" means anesthesia services and related care furnished by a certified registered nurse anesthetist (as defined in paragraph (2)) which the nurse anesthetist is legally authorized to perform as such by the State in which the services are furnished.

(2) The term "certified registered nurse anesthetist" means a certified registered nurse anesthetist licensed by the State who meets such education, training, and other requirements relating to anesthesia services and related care as the Secretary may prescribe. In prescribing such requirements the Secretary may use the same requirements as those established by a national organization for the certification of nurse anesthetists. Such term also includes, as prescribed by the Secretary, an anesthesiologist assistant.

(cc) Comprehensive outpatient rehabilitation facility services.

(1) The term "comprehensive outpatient rehabilitation facility services" means the following items and services furnished by a physician or other qualified professional personnel (as defined in regulations by the Secretary) to an individual who is an outpatient of a comprehensive outpatient rehabilitation facility under a plan (for furnishing such items and services to such individual) established and periodically reviewed by a physician--

(A) physicians' services;

(B) physical therapy, occupational therapy, speech-language pathology services, and respiratory therapy;

(C) prosthetic and orthotic devices, including testing, fitting, or training in the use of prosthetic and orthotic devices;

(D) social and psychological services;

(E) nursing care provided by or under the supervision of a registered professional nurse;

(F) drugs and biologicals which cannot, as determined in accordance with regulations, be self-administered;

(G) supplies and durable medical equipment; and

(H) such other items and services as are medically necessary for the rehabilitation of the patient and are ordinarily furnished by comprehensive inpatient rehabilitation facilities,

excluding, however, any item or service if it would not be included under subsection (b) if furnished to an outpatient of a hospital. In the case of physical therapy, occupational therapy, and speech pathology services, there shall be no requirement that the item or service be furnished at any single fixed location if the item or service is furnished pursuant to such plan and payments are not otherwise made for the item or service under this *title [42 USCS §§ 1395* et seq.].

(2) The term "comprehensive outpatient rehabilitation facility" means a facility which--

(A) is primarily engaged in providing (by or under the supervision of physicians) diagnostic, therapeutic, and restorative services to outpatients for the rehabilitation of injured, disabled, or sick persons;

(B) provides at least the following comprehensive outpatient rehabilitation services: (i) physicians' services (rendered by physicians, as defined in section 1861(r)(1) [subsec. (r)(1) of this section], who are available at the facility on a full- or part-time basis); (ii) physical therapy; and (iii) social or psychological services;

(C) maintains clinical records on all patients;

(D) has policies established by a group of professional personnel (associated with the facility), including one or more physicians defined in subsection (r)(1) to govern the comprehensive outpatient rehabilitation services it furnishes, and provides for the carrying out of such policies by a full- or part-time physician referred to in subparagraph (B)(i);

(E) has a requirement that every patient must be under the care of a physician;

(F) in the case of a facility in any State in which State or applicable local law provides for the licensing of facilities of this nature (i) is licensed pursuant to such law, or (ii) is approved by the agency of such State or locality, responsible for licensing facilities of this nature, as meeting the standards established for such licensing;

(G) has in effect a utilization review plan in accordance with regulations prescribed by the Secretary;

(H) has in effect an overall plan and budget that meets the requirements of subsection (z);

(I) provides the Secretary on a continuing basis with a surety bond in a form specified by the Secretary and in an amount that is not less than $ 50,000; and

(J) meets such other conditions of participation as the Secretary may find necessary in the interest of the health and safety of individuals who are furnished services by such facility, including conditions concerning qualifications of personnel in these facilities.

The Secretary may waive the requirement of a surety bond under subparagraph (I) in the case of a facility that provides a comparable surety bond under State law.

(dd) Hospice care; hospice program; definitions; certification; waiver by Secretary.

(1) The term "hospice care" means the following items and services provided to a terminally ill individual by, or by others under arrangements made by, a hospice program under a written plan (for providing such care to such individual) established and periodically reviewed by the individual's attending physician and by the medical director (and by the interdisciplinary group described in paragraph (2)(B)) of the program--

(A) nursing care provided by or under the supervision of a registered professional nurse,

(B) physical or occupational therapy, or speech-language pathology services,

(C) medical social services under the direction of a physician,

(D) (i) services of a home health aide who has successfully completed a training program approved by the Secretary and (ii) homemaker services,

(E) medical supplies (including drugs and biologicals) and the use of medical appliances, while under such a plan,

(F) physicians' services,

(G) short-term inpatient care (including both respite care and procedures necessary for pain control and acute and chronic symptom management) in an inpatient facility meeting such conditions as the Secretary determines to be appropriate to provide such care, but such respite care may be provided only on an intermittent, nonroutine, and occasional basis and may not be provided consecutively over longer than five days,

(H) counseling (including dietary counseling) with respect to care of the terminally ill individual and adjustment to his death, and

(I) any other item or service which is specified in the plan and for which payment may otherwise be made under this *title [42 USCS §§ 1395* et seq.].

The care and services described in subparagraphs (A) and (D) may be provided on a 24-hour, continuous basis only during periods of crisis (meeting criteria established by the Secretary) and only as necessary to maintain the terminally ill individual at home.

(2) The term "hospice program" means a public agency or private organization (or a subdivision thereof) which--

(A) (i) is primarily engaged in providing the care and services described in paragraph (1) and makes such services available (as needed) on a 24-hour basis and which also provides bereavement counseling for the immediate family of terminally ill individuals and services described in section 1812(a)(5) [*42 USCS § 1395d(a)(5)*],

(ii) provides for such care and services in individuals' homes, on an outpatient basis, and on a short-term inpatient basis, directly or under arrangements made by the agency or organization, except that--

(I) the agency or organization must routinely provide directly substantially all of each of the services described in subparagraphs (A), (C), and (H) of paragraph (1), except as otherwise provided in paragraph (5), and

(II) in the case of other services described in paragraph (1) which are not provided directly by the agency or organization, the agency or organization must maintain professional management responsibility for all such services furnished to an individual, regardless of the location or facility in which such services are furnished; and

(iii) provides assurances satisfactory to the Secretary that the aggregate number of days of inpatient care described in paragraph (1)(G) provided in any 12-month period to individuals who have an election in effect under section 1812(d) [*42 USCS § 1395d(d)*] with respect to that agency or organization does not exceed 20 percent of the aggregate number of days during that period on which such elections for such individuals are in effect;

(B) has an interdisciplinary group of personnel which--

(i) includes at least--

(I) one physician (as defined in subsection (r)(1)),

(II) one registered professional nurse, and

(III) one social worker,

employed by or, in the case of a physician described in subclause (I), under contract with the agency or organization, and also includes at least one pastoral or other counselor,

(ii) provides (or supervises the provision of) the care and services described in paragraph (1), and

(iii) establishes the policies governing the provision of such care and services;

(C) maintains central clinical records on all patients;

(D) does not discontinue the hospice care it provides with respect to a patient because of the inability of the patient to pay for such care;

(E) (i) utilizes volunteers in its provision of care and services in accordance with standards set by the Secretary, which standards shall ensure a continuing level of effort to utilize such volunteers, and (ii) maintains records on the use of these volunteers and the cost savings and expansion of care and services achieved through the use of these volunteers;

(F) in the case of an agency or organization in any State in which State or applicable local law provides for the licensing of agencies or organizations of this nature, is licensed pursuant to such law; and

(G) meets such other requirements as the Secretary may find necessary in the interest of the health and safety of the individuals who are provided care and services by such agency or organization.

(3) (A) An individual is considered to be "terminally ill" if the individual has a medical prognosis that the individual's life expectancy is 6 months or less.

(B) The term "attending physician" means, with respect to an individual, the physician (as defined in subsection (r)(1)) or nurse practitioner (as defined in subsection (aa)(5)), who may be employed by a hospice program, whom the individual identifies as having the most significant role in the determination and delivery of medical care to the individual at the time the individual makes an election to receive hospice care.

(4) (A) An entity which is certified as a provider of services other than a hospice program shall be considered, for purposes of certification as a hospice program, to have met any requirements under paragraph (2) which are also the same requirements for certification as such other type of provider. The Secretary shall coordinate surveys for determining certification under this *title [42 USCS §§ 1395* et seq.] so as to provide, to the extent feasible, for simultaneous surveys of an entity which seeks to be certified as a hospice program and as a provider of services of another type.

(B) Any entity which is certified as a hospice program and as a provider of another type shall have separate provider agreements under section 1866 [*42 USCS § 1395cc*] and shall file separate cost reports with respect to costs incurred in providing hospice care and in providing other services and items under this *title [42 USCS §§ 1395* et seq.].

(5) (A) The Secretary may waive the requirements of paragraph (2)(A)(ii)(I) for an agency or organization with respect to all or part of the nursing care described in paragraph (1)(A) if such agency or organization--

(i) is located in an area which is not an urbanized area (as defined by the Bureau of the Census);

(ii) was in operation on or before January 1, 1983; and

(iii) has demonstrated a good faith effort (as determined by the Secretary) to hire a sufficient number of nurses to provide such nursing care directly.

(B) Any waiver, which is in such form and containing such information as the Secretary may require and which is requested by an agency or organization under subparagraph (A) or (C), shall be deemed to be granted unless such request is denied by the Secretary within 60 days after the date such request is received by the Secretary. The granting of a waiver under subparagraph (A) or (C) shall not preclude the granting of any subsequent waiver request should such a waiver again become necessary.

(C) The Secretary may waive the requirements of paragraph (2)(A)(i) and (2)(A)(ii) for an agency or organization with respect to the services described in paragraph (1)(B) and, with respect to dietary counseling, paragraph (1)(H), if such agency or organization--

(i) is located in an area which is not an urbanized area (as defined by the Bureau of Census), and

(ii) demonstrates to the satisfaction of the Secretary that the agency or organization has been unable, despite diligent efforts, to recruit appropriate personnel.

(D) In extraordinary, exigent, or other non-routine circumstances, such as unanticipated periods of high patient loads, staffing shortages due to illness or other events, or temporary travel of a patient outside a hospice program's service area, a hospice program may enter into arrangements with another hospice program for the provision by that other program of services described in paragraph (2)(A)(ii)(I). The provisions of paragraph (2)(A)(ii)(II) shall apply with respect to the services provided under such arrangements.

(E) A hospice program may provide services described in paragraph (1)(A) other than directly by the program if the services are highly specialized services of a registered professional nurse and are provided non-routinely and so infrequently so that the provision of such services directly would be impracticable and prohibitively expensive.

(ee) Discharge planning process.

(1) A discharge planning process of a hospital shall be considered sufficient if it is applicable to services furnished by the hospital to individuals entitled to benefits under this *title [42 USCS §§ 1395* et seq.] and if it meets the guidelines and standards established by the Secretary under paragraph (2).

(2) The Secretary shall develop guidelines and standards for the discharge planning process in order to ensure a timely and smooth transition to the most appropriate type of and setting for post-hospital or rehabilitative care. The guidelines and standards shall include the following:

(A) The hospital must identify, at an early stage of hospitalization, those patients who are likely to suffer adverse health consequences upon discharge in the absence of adequate discharge planning.

(B) Hospitals must provide a discharge planning evaluation for patients identified under subparagraph (A) and for other patients upon the request of the patient, patient's representative, or patient's physician.

(C) Any discharge planning evaluation must be made on a timely basis to ensure that appropriate arrangements for post-hospital care will be made before discharge and to avoid unnecessary delays in discharge.

(D) A discharge planning evaluation must include an evaluation of a patient's likely need for appropriate post-hospital services, including hospice care and post-hospital extended services, and the availability of those services, including the availability of home health services through individuals and entities that participate in the program under

this *title [42 USCS § 1395* et seq.] and that serve the area in which the patient resides and that request to be listed by the hospital as available and, in the case of individuals who are likely to need post-hospital extended care services, the availability of such services through facilities that participate in the program under this *title [42 USCS § 1395* et seq.] and that serve the area in which the patient resides.

(E) The discharge planning evaluation must be included in the patient's medical record for use in establishing an appropriate discharge plan and the results of the evaluation must be discussed with the patient (or the patient's representative).

(F) Upon the request of a patient's physician, the hospital must arrange for the development and initial implementation of a discharge plan for the patient.

(G) Any discharge planning evaluation or discharge plan required under this paragraph must be developed by, or under the supervision of, a registered professional nurse, social worker, or other appropriately qualified personnel.

(H) Consistent with section 1802 [*42 USCS § 1395a*], the discharge plan shall--

(i) not specify or otherwise limit the qualified provider which may provide post-hospital home health services, and

(ii) identify (in a form and manner specified by the Secretary) any entity to whom the individual is referred in which the hospital has a disclosable financial interest (as specified by the Secretary consistent with section 1866(a)(1)(S) [*42 USCS § 1395cc(a)(1)(S)*]) or which has such an interest in the hospital.

(3) With respect to a discharge plan for an individual who is enrolled with a Medicare + Choice organization under a Medicare + Choice plan and is furnished inpatient hospital services by a hospital under a contract with the organization--

(A) the discharge planning evaluation under paragraph (2)(D) is not required to include information on the availability of home health services through individuals and entities which do not have a contract with the organization; and

(B) notwithstanding subparagraph (H)(i) [(2)(H)(i)], the plan may specify or limit the provider (or providers) of post-hospital home health services or other post-hospital services under the plan.

(ff) Partial hospitalization services.

(1) The term "partial hospitalization services" means the items and services described in paragraph (2) prescribed by a physician and provided under a program described in paragraph (3) under the supervision of a physician pursuant to an individualized, written plan of treatment established and periodically reviewed by a physician (in consultation with appropriate staff participating in such program), which plan sets forth the physician's diagnosis, the type, amount, frequency, and duration of the items and services provided under the plan, and the goals for treatment under the plan.

(2) The items and services described in this paragraph are--

(A) individual and group therapy with physicians or psychologists (or other mental health professionals to the extent authorized under State law),

(B) occupational therapy requiring the skills of a qualified occupational therapist,

(C) services of social workers, trained psychiatric nurses, and other staff trained to work with psychiatric patients,

(D) drugs and biologicals furnished for therapeutic purposes (which cannot, as determined in accordance with regulations, be self-administered),

(E) individualized activity therapies that are not primarily recreational or diversionary,

(F) family counseling (the primary purpose of which is treatment of the individual's condition),

(G) patient training and education (to the extent that training and educational activities are closely and clearly related to individual's care and treatment),

(H) diagnostic services, and

(I) such other items and services as the Secretary may provide (but in no event to include meals and transportation);

that are reasonable and necessary for the diagnosis or active treatment of the individual's condition, reasonably expected to improve or maintain the individual's condition and functional level and to prevent relapse or hospitalization, and furnished pursuant to such guidelines relating to frequency and duration of services as the Secretary shall by regulation establish (taking into account accepted norms of medical practice and the reasonable expectation of patient improvement).

(3)

(A) A program described in this paragraph is a program which is furnished by a hospital to its outpatients or by a community mental health center (as defined in subparagraph (B)), and which is a distinct and organized intensive ambulatory treatment service offering less than 24-hour-daily care.

(B) For purposes of subparagraph (A), the term "community mental health center" means an entity that--

(i) (I) provides the mental health services described in section 1913(c)(1) of the Public Health Service Act [*42 USCS § 300x-2(c)(1)*]; or

(II) in the case of an entity operating in a State that by law precludes the entity from providing itself the service described in subparagraph (E) of such section, provides for such service by contract with an approved organization or entity (as determined by the Secretary);

(ii) meets applicable licensing or certification requirements for community mental health centers in the State in which it is located; and

(iii) meets such additional conditions as the Secretary shall specify to ensure (I) the health and safety of individuals being furnished such services, (II) the effective and efficient furnishing of such services, and (III) the compliance of such entity with the criteria described in section 1931(c)(1) of the Public Health Service Act [*42 USCS § 300x-31(c)(1)*].

(gg) Certified nurse-midwife services.

(1) The term "certified nurse-midwife services" means such services furnished by a certified nurse-midwife (as defined in paragraph (2)) and such services and supplies furnished as an incident to the nurse-midwife's service which the certified nurse-midwife is legally authorized to perform under State law (or the State regulatory mechanism provided by State law) as would otherwise be covered if furnished by a physician or as an incident to a physicians' service.

(2) The term "certified nurse-midwife" means a registered nurse who has successfully completed a program of study and clinical experience meeting guidelines prescribed by the Secretary, or has been certified by an organization recognized by the Secretary.

(hh) Clinical social worker; clinical social worker services.

(1) The term "clinical social worker" means an individual who--

(A) possesses a master's or doctor's degree in social work;

(B) after obtaining such degree has performed at least 2 years of supervised clinical social work; and

(C) (i) is licensed or certified as a clinical social worker by the State in which the services are performed, or

(ii) in the case of an individual in a State which does not provide for licensure or certification--

(I) has completed at least 2 years or 3,000 hours of postmaster's degree supervised clinical social work practice under the supervision of a master's level social worker in an appropriate setting (as determined by the Secretary), and

(II) meets such other criteria as the Secretary establishes.

(2) The term "clinical social worker services" means services performed by a clinical social worker (as defined in paragraph (1)) for the diagnosis and treatment of mental illnesses (other than services furnished to an inpatient of a hospital and other than services furnished to an inpatient of a skilled nursing facility which the facility is required to provide as a requirement for participation) which the clinical social worker is legally authorized to perform under State law (or the State regulatory mechanism provided by State law) of the State in which such services are performed as would otherwise be covered if furnished by a physician or as an incident to a physician's professional service.

(ii) Qualified psychologist services. The term "qualified psychologist services" means such services and such services and supplies furnished as an incident to his service furnished by a clinical psychologist (as defined by the Secretary) which the psychologist is legally authorized to perform under State law (or the State regulatory mechanism provided by State law) as would otherwise be covered if furnished by a physician or as an incident to a physician's service.

(jj) Screening mammography. The term "screening mammography" means a radiologic procedure provided to a woman for the purpose of early detection of breast cancer and includes a physician's interpretation of the results of the procedure.

(kk) Covered osteoporosis drug. The term "covered osteoporosis drug" means an injectable drug approved for the treatment of post-menopausal osteoporosis provided to an individual by a home health agency if, in accordance with regulations promulgated by the Secretary--

(1) the individual's attending physician certifies that the individual has suffered a bone fracture related to post-menopausal osteoporosis and that the individual is unable to learn the skills needed to self-administer such drug or is otherwise physically or mentally incapable of self-administering such drug; and

(2) the individual is confined to the individual's home (except when receiving items and services referred to in subsection (m)(7)).

(ll) Speech-language pathology services; audiology services [Caution: For provisions applicable to serviced furnished before July 1, 2009, see 2008 amendment note below.].

(1) The term "speech-language pathology services" means such speech, language, and related function assessment and rehabilitation services furnished by a qualified speech-language pathologist as the speech-language pathologist is legally

authorized to perform under State law (or the State regulatory mechanism provided by State law) as would otherwise be covered if furnished by a physician.

(2) The term "outpatient speech-language pathology services" has the meaning given the term "outpatient physical therapy services" in subsection (p), except that in applying such subsection--

(A) "speech-language pathology" shall be substituted for "physical therapy" each place it appears; and

(B) "speech-language pathologist" shall be substituted for "physical therapist" each place it appears.

(3) The term "audiology services" means such hearing and balance assessment services furnished by a qualified audiologist as the audiologist is legally authorized to perform under State law (or the State regulatory mechanism provided by State law), as would otherwise be covered if furnished by a physician.

(4) In this subsection:

(A) The term "qualified speech-language pathologist" means an individual with a master's or doctoral degree in speech-language pathology who--

(i) is licensed as a speech-language pathologist by the State in which the individual furnishes such services, or

(ii) in the case of an individual who furnishes services in a State which does not license speech-language pathologists, has successfully completed 350 clock hours of supervised clinical practicum (or is in the process of accumulating such supervised clinical experience), performed not less than 9 months of supervised full-time speech-language pathology services after obtaining a master's or doctoral degree in speech-language pathology or a related field, and successfully completed a national examination in speech-language pathology approved by the Secretary.

(B) The term "qualified audiologist" means an individual with a master's or doctoral degree in audiology who--

(i) is licensed as an audiologist by the State in which the individual furnishes such services, or

(ii) in the case of an individual who furnishes services in a State which does not license audiologists, has successfully completed 350 clock hours of supervised clinical practicum (or is in the process of accumulating such supervised clinical experience), performed not less than 9 months of supervised full-time audiology services after obtaining a master's or doctoral degree in audiology or a related field, and successfully completed a national examination in audiology approved by the Secretary.

(mm) Critical access hospital; critical access hospital services.

(1) The term "critical access hospital" means a facility certified by the Secretary as a critical access hospital under section 1820(e) [*42 USCS § 1395i-4(e)*].

(2) The term "inpatient critical access hospital services" means items and services, furnished to an inpatient of a critical access hospital by such facility, that would be inpatient hospital services if furnished to an inpatient of a hospital by a hospital.

(3) The term "outpatient critical access hospital services" means medical and other health services furnished by a critical access hospital on an outpatient basis.

(nn) Screening pap smear; screening pelvic exam.

(1) The term "screening pap smear" means a diagnostic laboratory test consisting of a routine exfoliative cytology test (Papanicolaou test) provided to a woman for the purpose of early detection of cervical or vaginal cancer and includes a physician's interpretation of the results of the test, if the individual involved has not had such a test during the preceding 2 years, or during the preceding year in the case of a woman described in paragraph (3).

(2) The term "screening pelvic exam" means a pelvic examination provided to a woman if the woman involved has not had such an examination during the preceding 2 years, or during the preceding year in the case of a woman described in paragraph (3), and includes a clinical breast examination.

(3) A woman described in this paragraph is a woman who--

(A) is of childbearing age and has had a test described in this subsection during any of the preceding 3 years that indicated the presence of cervical or vaginal cancer or other abnormality; or

(B) is at high risk of developing cervical or vaginal cancer (as determined pursuant to factors identified by the Secretary).

(oo) Prostate cancer screening tests.

(1) The term "prostate cancer screening test" means a test that consists of any (or all) of the procedures described in paragraph (2) provided for the purpose of early detection of prostate cancer to a man over 50 years of age who has not had such a test during the preceding year.

(2) The procedures described in this paragraph are as follows:

(A) A digital rectal examination.

(B) A prostate-specific antigen blood test.

(C) For years beginning after 2002, such other procedures as the Secretary finds appropriate for the purpose of early detection of prostate cancer, taking into account changes in technology and standards of medical practice, availability, effectiveness, costs, and such other factors as the Secretary considers appropriate.

(pp) Colorectal cancer screening tests.

(1) The term "colorectal cancer screening test" means any of the following procedures furnished to an individual for the purpose of early detection of colorectal cancer:

(A) Screening fecal-occult blood test.

(B) Screening flexible sigmoidoscopy.

(C) Screening colonoscopy.

(D) Such other tests or procedures, and modifications to tests and procedures under this subsection, with such frequency and payment limits, as the Secretary determines appropriate, in consultation with appropriate organizations.

(2) An "individual at high risk for colorectal cancer" is an individual who, because of family history, prior experience of cancer or precursor neoplastic polyps, a history of chronic digestive disease condition (including inflammatory bowel disease, Crohn's Disease, or ulcerative colitis), the presence of any appropriate recognized gene markers for colorectal cancer, or other predisposing factors, faces a high risk for colorectal cancer.

(qq) Diabetes outpatient self-management training services.

(1) The term "diabetes outpatient self-management training services" means educational and training services furnished (at such times as the Secretary determines appropriate) to an individual with diabetes by a certified provider (as described in paragraph (2)(A)) in an outpatient setting by an individual or entity who meets the quality standards described in paragraph (2)(B), but only if the physician who is managing the individual's diabetic condition certifies that such services are needed under a comprehensive plan of care related to the individual's diabetic condition to ensure therapy compliance or to provide the individual with necessary skills and knowledge (including skills related to the self-administration of injectable drugs) to participate in the management of the individual's condition.

(2) In paragraph (1)--

(A) a "certified provider" is a physician, or other individual or entity designated by the Secretary, that, in addition to providing diabetes outpatient self-management training services, provides other items or services for which payment may be made under this *title [42 USCS §§ 1395* et seq.]; and

(B) a physician, or such other individual or entity, meets the quality standards described in this paragraph if the physician, or individual or entity, meets quality standards established by the Secretary, except that the physician or other individual or entity shall be deemed to have met such standards if the physician or other individual or entity meets applicable standards originally established by the National Diabetes Advisory Board and subsequently revised by organizations who participated in the establishment of standards by such Board, or is recognized by an organization that represents individuals (including individuals under this *title [42 USCS §§ 1395* et seq.]) with diabetes as meeting standards for furnishing the services.

(rr) Bone mass measurement.

(1) The term "bone mass measurement" means a radiologic or radioisotopic procedure or other procedure approved by the Food and Drug Administration performed on a qualified individual (as defined in paragraph (2)) for the purpose of identifying bone mass or detecting bone loss or determining bone quality, and includes a physician's interpretation of the results of the procedure.

(2) For purposes of this subsection, the term "qualified individual" means an individual who is (in accordance with regulations prescribed by the Secretary)--

(A) an estrogen-deficient woman at clinical risk for osteoporosis;

(B) an individual with vertebral abnormalities;

(C) an individual receiving long-term glucocorticoid steroid therapy;

(D) an individual with primary hyperparathyroidism; or

(E) an individual being monitored to assess the response to or efficacy of an approved osteoporosis drug therapy.

(3) The Secretary shall establish such standards regarding the frequency with which a qualified individual shall be eligible to be provided benefits for bone mass measurement under this *title [42 USCS §§ 1395* et seq.]. Religious Nonmedical Health Care Institution

(ss) Religious nonmedical health care institution.

(1) The term "religious nonmedical health care institution" means an institution that--

(A) is described in subsection (c)(3) of *section 501 of the Internal Revenue Code of 1986* [*26 USCS § 501(c)(3)*] and is exempt from taxes under subsection (a) of such section;

(B) is lawfully operated under all applicable Federal, State, and local laws and regulations;

(C) provides only nonmedical nursing items and services exclusively to patients who choose to rely solely upon a religious method of healing and for whom the acceptance of medical health services would be inconsistent with their religious beliefs;

(D) provides such nonmedical items and services exclusively through nonmedical nursing personnel who are experienced in caring for the physical needs of such patients;

(E) provides such nonmedical items and services to inpatients on a 24-hour basis;

(F) on the basis of its religious beliefs, does not provide through its personnel or otherwise medical items and services (including any medical screening, examination, diagnosis, prognosis, treatment, or the administration of drugs) for its patients;

(G) (i) is not owned by, under common ownership with, or has an ownership interest in, a provider of medical treatment or services;

(ii) is not affiliated with--

(I) a provider of medical treatment or services, or

(II) an individual who has an ownership interest in a provider of medical treatment or services;

(H) has in effect a utilization review plan which--

(i) provides for the review of admissions to the institution, of the duration of stays therein, of cases of continuous extended duration, and of the items and services furnished by the institution,

(ii) requires that such reviews be made by an appropriate committee of the institution that includes the individuals responsible for overall administration and for supervision of nursing personnel at the institution,

(iii) provides that records be maintained of the meetings, decisions, and actions of such committee, and

(iv) meets such other requirements as the Secretary finds necessary to establish an effective utilization review plan;

(I) provides the Secretary with such information as the Secretary may require to implement section 1821 [*42 USCS § 1395i-5*], including information relating to quality of care and coverage determinations; and

(J) meets such other requirements as the Secretary finds necessary in the interest of the health and safety of individuals who are furnished services in the institution.

(2) To the extent that the Secretary finds that the accreditation of an institution by a State, regional, or national agency or association provides reasonable assurances that any or all of the requirements of paragraph (1) are met or exceeded, the Secretary may treat such institution as meeting the condition or conditions with respect to which the Secretary made such finding.

(3) (A)

(i) In administering this subsection and section 1821 [*42 USCS § 1395i-5*], the Secretary shall not require any patient of a religious nonmedical health care institution to undergo medical screening, examination, diagnosis, prognosis, or treatment or to accept any other medical health care service, if such patient (or legal representative of the patient) objects thereto on religious grounds.

(ii) Clause (i) shall not be construed as preventing the Secretary from requiring under section 1821(a)(2) [*42 USCS § 1395i-5(a)(2)*] the provision of sufficient information regarding an individual's condition as a condition for receipt of benefits under part A [*42 USCS §§ 1395c* et seq.] for services provided in such an institution.

(B) (i) In administering this subsection and section 1821 [*42 USCS § 1395i-5*], the Secretary shall not subject a religious nonmedical health care institution or its personnel to any medical supervision, regulation, or control, insofar as such supervision, regulation, or control would be contrary to the religious beliefs observed by the institution or such personnel.

(ii) Clause (i) shall not be construed as preventing the Secretary from reviewing items and services billed by the institution to the extent the Secretary determines such review to be necessary to determine whether such items and services were not covered under part A [*42 USCS §§ 1395c* et seq.], are excessive, or are fraudulent.

(4) (A) For purposes of paragraph (1)(G)(i), an ownership interest of less than 5 percent shall not be taken into account.

(B) For purposes of paragraph (1)(G)(ii), none of the following shall be considered to create an affiliation:

(i) An individual serving as an uncompensated director, trustee, officer, or other member of the governing body of a religious nonmedical health care institution.

(ii) An individual who is a director, trustee, officer, employee, or staff member of a religious nonmedical health care institution having a family relationship with an individual who is affiliated with (or has an ownership interest in) a provider of medical treatment or services.

(iii) An individual or entity furnishing goods or services as a vendor to both providers of medical treatment or services and religious nonmedical health care institutions.

(tt) Post-institutional home health services; home health spell of illness.

(1) The term "post-institutional home health services" means home health services furnished to an individual--

(A) after discharge from a hospital or critical access hospital in which the individual was an inpatient for not less than 3 consecutive days before such discharge if such home health services were initiated within 14 days after the date of such discharge; or

(B) after discharge from a skilled nursing facility in which the individual was provided post-hospital extended care services if such home health services were initiated within 14 days after the date of such discharge.

(2) The term "home health spell of illness" with respect to any individual means a period of consecutive days--

(A) beginning with the first day (not included in a previous home health spell of illness) (i) on which such individual is furnished post-institutional home health services, and (ii) which occurs in a month for which the individual is entitled to benefits under part A [*42 USCS §§ 1395c* et seq.], and

(B) ending with the close of the first period of 60 consecutive days thereafter on each of which the individual is neither an inpatient of a hospital or critical access hospital nor an inpatient of a facility described in section 1819(a)(1) [*42 USCS § 1395i-3(a)(1)*] or subsection (y)(1) nor provided home health services.

(uu) Screening for glaucoma. The term "screening for glaucoma" means a dilated eye examination with an intraocular pressure measurement, and a direct ophthalmoscopy or a slit-lamp biomicroscopic examination for the early detection of glaucoma which is furnished by or under the direct supervision of an optometrist or ophthalmologist who is legally authorized to furnish such services under State law (or the State regulatory mechanism provided by State law) of the State in which the services are furnished, as would otherwise be covered if furnished by a physician or as an incident to a physician's professional service, if the individual involved has not had such an examination in the preceding year.

(vv) Medical nutrition therapy services; registered dietitian or nutrition professional.

(1) The term "medical nutrition therapy services" means nutritional diagnostic, therapy, and counseling services for the purpose of disease management which are furnished by a registered dietitian or nutrition professional (as defined in paragraph (2)) pursuant to a referral by a physician (as defined in subsection (r)(1)).

(2) Subject to paragraph (3), the term "registered dietitian or nutrition professional" means an individual who--

(A) holds a baccalaureate or higher degree granted by a regionally accredited college or university in the United States (or an equivalent foreign degree) with completion of the academic requirements of a program in nutrition or dietetics, as accredited by an appropriate national accreditation organization recognized by the Secretary for this purpose;

(B) has completed at least 900 hours of supervised dietetics practice under the supervision of a registered dietitian or nutrition professional; and

(C) (i) is licensed or certified as a dietitian or nutrition professional by the State in which the services are performed; or

(ii) in the case of an individual in a State that does not provide for such licensure or certification, meets such other criteria as the Secretary establishes.

(3) Subparagraphs (A) and (B) of paragraph (2) shall not apply in the case of an individual who, as of the date of the enactment of this subsection [enacted Dec. 21, 2000], is licensed or certified as a dietitian or nutrition professional by the State in which medical nutrition therapy services are performed.

(ww) Initial preventive physical examination.

(1) The term "initial preventive physical examination" means physicians' services consisting of a physical examination (including measurement of height, weight[,] body mass index,[,] and blood pressure) with the goal of health promotion and disease detection and includes education, counseling, and referral with respect to screening and other preventive services described in paragraph (2) and end-of-life planning (as defined in paragraph (3)) upon the agreement with the individual, but does not include clinical laboratory tests.

(2) The screening and other preventive services described in this paragraph include the following:

(A) Pneumococcal, influenza, and hepatitis B vaccine and administration under subsection (s)(10).

(B) Screening mammography as defined in subsection (jj).

(C) Screening pap smear and screening pelvic exam as defined in subsection (nn).

(D) Prostate cancer screening tests as defined in subsection (oo).

(E) Colorectal cancer screening tests as defined in subsection (pp).

(F) Diabetes outpatient self-management training services as defined in subsection (qq)(1).

(G) Bone mass measurement as defined in subsection (rr).

(H) Screening for glaucoma as defined in subsection (uu).

(I) Medical nutrition therapy services as defined in subsection (vv).

(J) Cardiovascular screening blood tests as defined in subsection (xx)(1).

(K) Diabetes screening tests as defined in subsection (yy).

(L) Ultrasound screening for abdominal aortic aneurysm as defined in section 1861(bbb) [subsec. (bbb) of this section].

(M) An electrocardiogram.

(N) Additional preventive services (as defined in subsection (ddd)(1)).

(3) For purposes of paragraph (1), the term "end-of-life planning" means verbal or written information regarding--

(A) an individual's ability to prepare an advance directive in the case that an injury or illness causes the individual to be unable to make health care decisions; and

(B) whether or not the physician is willing to follow the individual's wishes as expressed in an advance directive.

(xx) Cardiovascular screening blood test.

(1) The term "cardiovascular screening blood test" means a blood test for the early detection of cardiovascular disease (or abnormalities associated with an elevated risk of cardiovascular disease) that tests for the following:

(A) Cholesterol levels and other lipid or triglyceride levels.

(B) Such other indications associated with the presence of, or an elevated risk for, cardiovascular disease as the Secretary may approve for all individuals (or for some individuals determined by the Secretary to be at risk for cardiovascular disease), including indications measured by noninvasive testing.

The Secretary may not approve an indication under subparagraph (B) for any individual unless a blood test for such is recommended by the United States Preventive Services Task Force.

(2) The Secretary shall establish standards, in consultation with appropriate organizations, regarding the frequency for each type of cardiovascular screening blood tests, except that such frequency may not be more often than once every 2 years.

(yy) Diabetes screening tests.

(1) The term "diabetes screening tests" means testing furnished to an individual at risk for diabetes (as defined in paragraph (2)) for the purpose of early detection of diabetes, including--

(A) a fasting plasma glucose test; and

(B) such other tests, and modifications to tests, as the Secretary determines appropriate, in consultation with appropriate organizations.

(2) For purposes of paragraph (1), the term "individual at risk for diabetes" means an individual who has any of the following risk factors for diabetes:

(A) Hypertension.

(B) Dyslipidemia.

(C) Obesity, defined as a body mass index greater than or equal to 30 kg/m<2>.

(D) Previous identification of an elevated impaired fasting glucose.

(E) Previous identification of impaired glucose tolerance.

(F) A risk factor consisting of at least 2 of the following characteristics:

(i) Overweight, defined as a body mass index greater than 25, but less than 30, kg/m<2>.

(ii) A family history of diabetes.

(iii) A history of gestational diabetes mellitus or delivery of a baby weighing greater than 9 pounds.

(iv) 65 years of age or older.

(3) The Secretary shall establish standards, in consultation with appropriate organizations, regarding the frequency of diabetes screening tests, except that such frequency may not be more often than twice within the 12-month period following the date of the most recent diabetes screening test of that individual.

(zz) Intravenous immune globulin. The term "intravenous immune globulin" means an approved pooled plasma derivative for the treatment in the patient's home of a patient with a diagnosed primary immune deficiency disease, but not including items or services related to the administration of the derivative, if a physician determines administration of the derivative in the patient's home is medically appropriate.

(aaa) Extended care in religious nonmedical health care institutions.

(1) The term "home health agency" also includes a religious nonmedical health care institution (as defined in subsection (ss)(1)), but only with respect to items and services ordinarily furnished by such an institution to individuals in their homes, and that are comparable to items and services furnished to individuals by a home health agency that is not religious nonmedical health care institution.

(2) (A) Subject to subparagraphs (B), payment may be made with respect to services provided by such an institution only to such extent and under such conditions, limitations, and requirements (in addition to or in lieu of the conditions, limitations, and requirements otherwise applicable) as may be provided in regulations consistent with section 1821 [*42 USCS § 1395i-5*].

(B) Notwithstanding any other provision of this *title [42 USCS §§ 1395* et seq.], payment may not be made under subparagraph (A)--

(i) in a year insofar as such payments exceed $ 700,000; and

(ii) after December 31, 2006.

(bbb) Ultrasound screening for abdominal aortic aneurysm. The term "ultrasound screening for abdominal aortic aneurysm" means--

(1) a procedure using sound waves (or such other procedures using alternative technologies, of commensurate accuracy and cost, that the Secretary may specify) provided for the early detection of abdominal aortic aneurysm; and

(2) includes a physician's interpretation of the results of the procedure.

(ccc) Long-term care hospital. The term "long-term care hospital" means a hospital which--

(1) is primarily engaged in providing inpatient services, by or under the supervision of a physician, to Medicare beneficiaries whose medically complex conditions require a long hospital stay and programs of care provided by a long-term care hospital;

(2) has an average inpatient length of stay (as determined by the Secretary) of greater than 25 days, or meets the requirements of clause (II) of section 1886(d)(1)(B)(iv) [*42 USCS § 1395ww(d)(1)(B)(iv)*];

(3) satisfies the requirements of subsection (e); and

(4) meets the following facility criteria:

(A) the institution has a patient review process, documented in the patient medical record, that screens patients prior to admission for appropriateness of admission to a long-term care hospital, validates within 48 hours of admission that patients meet admission criteria for long-term care hospitals, regularly evaluates patients throughout their stay for continuation of care in a long-term care hospital, and assesses the available discharge options when patients no longer meet such continued stay criteria;

(B) the institution has active physician involvement with patients during their treatment through an organized medical staff, physician-directed treatment with physician on-site availability on a daily basis to review patient progress, and consulting physicians on call and capable of being at the patient's side within a moderate period of time, as determined by the Secretary; and

(C) the institution has interdisciplinary team treatment for patients, requiring interdisciplinary teams of health care professionals, including physicians, to prepare and carry out an individualized treatment plan for each patient.

(ddd) Additional preventive services.

(1) The term "additional preventive services" means services not otherwise described in this *title [42 USCS §§ 1395* et seq.] that identify medical conditions or risk factors and that the Secretary determines are--

(A) reasonable and necessary for the prevention or early detection of an illness or disability;

(B) recommended with a grade of A or B by the United States Preventive Services Task Force; and

(C) appropriate for individuals entitled to benefits under part A [*42 USCS §§ 1395c* et seq.] or enrolled under part B [*42 USCS §§ 1395j* et seq.].

(2) In making determinations under paragraph (1) regarding the coverage of a new service, the Secretary shall use the process for making national coverage determinations (as defined in section 1869(f)(1)(B) [*42 USCS § 1395ff(f)(1)(B)*]) under this *title [42 USCS §§ 1395* et seq.]. As part of the use of such process, the Secretary may conduct an assessment of the relation between predicted outcomes and the expenditures for such service and may take into account the results of such assessment in making such determination.

(eee) Cardiac rehabilitation program; intensive cardiac rehabilitation program [Caution: This subsection applies to items and services furnished on or after January 1, 2010, as provided by § 144(a)(3) of Act July 15, 2008, P.L. 110-275, which appears as *42 USCS § 1395w-4* note.].

(1) The term "cardiac rehabilitation program" means a physician-supervised program (as described in paragraph (2)) that furnishes the items and services described in paragraph (3).

(2) A program described in this paragraph is a program under which--

(A) items and services under the program are delivered--

(i) in a physician's office;

(ii) in a hospital on an outpatient basis; or

(iii) in other settings determined appropriate by the Secretary.

(B) a physician is immediately available and accessible for medical consultation and medical emergencies at all times items and services are being furnished under the program, except that, in the case of items and services furnished under such a program in a hospital, such availability shall be presumed; and

(C) individualized treatment is furnished under a written plan established, reviewed, and signed by a physician every 30 days that describes--

(i) the individual's diagnosis;

(ii) the type, amount, frequency, and duration of the items and services furnished under the plan; and

(iii) the goals set for the individual under the plan.

(3) The items and services described in this paragraph are--

(A) physician-prescribed exercise;

(B) cardiac risk factor modification, including education, counseling, and behavioral intervention (to the extent such education, counseling, and behavioral intervention is closely related to the individual's care and treatment and is tailored to the individual's needs);

(C) psychosocial assessment;

(d) outcomes assessment; and

(E) such other items and services as the Secretary may determine, but only if such items and services are--

(i) reasonable and necessary for the diagnosis or active treatment of the individual's condition;

(ii) reasonably expected to improve or maintain the individual's condition and functional level; and

(iii) furnished under such guidelines relating to the frequency and duration of such items and services as the Secretary shall establish, taking into account accepted norms of medical practice and the reasonable expectation of improvement of the individual.

(4)

(A) The term "intensive cardiac rehabilitation program" means a physician-supervised program (as described in paragraph (2)) that furnishes the items and services described in paragraph (3) and has shown, in peer-reviewed published research, that it accomplished--

(i) one or more of the following:

(I) positively affected the progression of coronary heart disease; or

(II) reduced the need for coronary bypass surgery; or

(III) reduced the need for percutaneous coronary interventions; and

(ii) a statistically significant reduction in 5 or more of the following measures from their level before receipt of cardiac rehabilitation services to their level after receipt of such services:

(I) low density lipoprotein;

(II) triglycerides;

(III) body mass index;

(IV) systolic blood pressure;

(V) diastolic blood pressure; or

(VI) the need for cholesterol, blood pressure, and diabetes medications.

(B) To be eligible for an intensive cardiac rehabilitation program, an individual must have--

(i) had an acute myocardial infarction within the preceding 12 months;

(ii) had coronary bypass surgery;

(iii) stable angina pectoris;

(iv) had heart valve repair or replacement;

(v) had percutaneous transluminal coronary angioplasty (PTCA) or coronary stenting; or

(vi) had a heart or heart-lung transplant.

(C) An intensive cardiac rehabilitation program may be provided in a series of 72 one-hour sessions (as defined in section 1848(b)(5) [*42 USCS § 1395w-4(b)(5)*]), up to 6 sessions per day, over a period of up to 18 weeks.

(5) The Secretary shall establish standards to ensure that a physician with expertise in the management of individuals with cardiac pathophysiology who is licensed to practice medicine in the State in which a cardiac rehabilitation program (or the intensive cardiac rehabilitation program, as the case may be) is offered--

(A) is responsible for such program; and

(B) in consultation with appropriate staff, is involved substantially in directing the progress of individual in the program.

(fff) Pulmonary rehabilitation program [Caution: This subsection applies to items and services furnished on or after January 1, 2010, as provided by § 144(a)(3) of Act July 15, 2008, P.L. 110-275, which appears as *42 USCS § 1395w-4* note.].

(1) The term "pulmonary rehabilitation program" means a physician-supervised program (as described in subsection (eee)(2) with respect to a program under this subsection) that furnishes the items and services described in paragraph (2).

(2) The items and services described in this paragraph are--

(A) physician-prescribed exercise;

(B) education or training (to the extent the education or training is closely and clearly related to the individual's care and treatment and is tailored to such individual's needs);

(C) psychosocial assessment;

(D) outcomes assessment; and

(E) such other items and services as the Secretary may determine, but only if such items and services are--

(i) reasonable and necessary for the diagnosis or active treatment of the individual's condition;

(ii) reasonably expected to improve or maintain the individual's condition and functional level; and

(iii) furnished under such guidelines relating to the frequency and duration of such items and services as the Secretary shall establish, taking into account accepted norms of medical practice and the reasonable expectation of improvement of the individual.

(3) The Secretary shall establish standards to ensure that a physician with expertise in the management of individuals with respiratory pathophysiology who is licensed to practice medicine in the State in which a pulmonary rehabilitation program is offered--

(A) is responsible for such program; and

(B) in consultation with appropriate staff, is involved substantially in directing the progress of individual in the program.

(ggg) Kidney disease education services [Caution: This subsection applies to services furnished on or after January 1, 2010, as provided by § 152(b)(2) of Act July 15, 2008, P.L. 110-275, which appears as *42 USCS § 1395w-4* note.].

(1) The term "kidney disease education services" means educational services that are--

(A) furnished to an individual with stage IV chronic kidney disease who, according to accepted clinical guidelines identified by the Secretary, will require dialysis or a kidney transplant;

(B) furnished, upon the referral of the physician managing the individual's kidney condition, by a qualified person (as defined in paragraph (2)); and

(C) designed--

(i) to provide comprehensive information (consistent with the standards set under paragraph (3)) regarding--

(I) the management of comorbidities, including for purposes of delaying the need for dialysis;

(II) the prevention of uremic complications; and

(III) each option for renal replacement therapy (including hemodialysis and peritoneal dialysis at home and in-center as well as vascular access options and transplantation);

(ii) to ensure that the individual has the opportunity to actively participate in the choice of therapy; and

(iii) to be tailored to meet the needs of the individual involved.

(2)

(A) The term "qualified person" means--

(i) a physician (as defined in section 1861(r)(1) [subsec. (r)(1) of this section]) or a physician assistant, nurse practitioner, or clinical nurse specialist (as defined in section 1861(aa)(5) [subsec. (aa)(5) of this section]), who furnishes services for which payment may be made under the fee schedule established under section 1848 [*42 USCS § 1395w-4*]; and

(ii) a provider of services located in a rural area (as defined in section 1886(d)(2)(D) [*42 USCS § 1395ww(d)(2)(D)*]).

(B) Such term does not include a provider of services (other than a provider of services described in subparagraph (A)(ii)) or a renal dialysis facility.

(3) The Secretary shall set standards for the content of such information to be provided under paragraph (1)(C)(i) after consulting with physicians, other health professionals, health educators, professional organizations, accrediting organizations, kidney patient organizations, dialysis facilities, transplant centers, network organizations described in section 1881(c)(2) [*42 USCS § 1395rr(c)(2)*], and other knowledgeable persons. To the extent possible the Secretary shall consult with persons or entities described in the previous sentence, other than a dialysis facility, that has not received industry funding from a drug or biological manufacturer or dialysis facility.

(4) No individual shall be furnished more than 6 sessions of kidney disease education services under this *title [42 USCS §§ 1395* et seq.].

HISTORY:

(Aug. 14, 1935, ch 531, Title XVIII, Part E[D][C], § 1861, as added July 30, 1965, P.L. 89-97, Title I, Part 1, § 102(a), 79 Stat. 313; Nov. 2, 1966, P.L. 89-713, § 7, 80 Stat. 1111; Jan. 2, 1968, P.L. 90-248, Title I, Part 3, §§ 127(a), 129(a), (b), (c)(9)(C)-(11), 132(a), 133(a), (b), 134(a), 143(a), 144(a)-(d), 81 Stat. 846-850, 852, 857, 858; Jan. 12, 1971, P.L. 91-690, 84 Stat. 2074; Oct. 30, 1972, P.L. 92-603, Title II, §§ 211(b), (c)(2), 221(c)(4), 223(a)-(d), (f), 227(a), (c), (d)(1), (f), 234(a)-(f), 237(c), 244(c), 246(b), 248, 249(b), 251(a)(1), (b)(1), (c), 252(a), 256(b), 264(a), 265, 267, 273(a), 276(a), 278(a)(4)-(15), (b)(6), (10), (11), (13), 283(a), 86 Stat. 1383, 1384, 1389, 1393, 1394, 1404-1407, 1412, 1413, 1416, 1423-1426, 1445-1447, 1449-1454, 1456; Dec. 31, 1975, P.L. 94-182, Title I, §§ 102, 106(a), 112(a)(1), 89 Stat. 1051, 1052, 1055; Oct. 25, 1977, P.L. 95-142, §§ 3(a)(2), 5(m), 19(b)(1), 21(a), 91 Stat. 1178, 1191, 1204, 1207; Dec. 13, 1977, P.L. 95-210, § 1(d), (g), (h), 91 Stat. 1485, 1487, 1488; Dec. 20, 1977, P.L. 95-216, Title V, § 501(a), 91 Stat. 1564; June 13, 1978, P.L. 95-292, § 4(d), 92 Stat. 315; Dec. 5, 1980, P.L. 96-499, Title IX, Part A, Subpart I, § 902(a)(1), Subpart II, § 915(a), Part B, Subpart I, §§ 930(k)-(n), (p), 931(c), (d), 933(c)-(e), 936(a), 937(a), 938(a), Subpart II, § 948(a)(1), 949, 950, 951(a), (b), 952(a) [952], 94 Stat. 2612, 2623, 2632, 2633, 2635, 2639, 2640, 2643, 2645, 2646; Dec. 28, 1980, P.L. 96-611, § 1(a)(1), (b)(3), 94 Stat. 3566; Aug. 13, 1981, P.L. 97-35, Title XXI, Subtitle A, Ch 1, § 2102(a), Ch 3, § 2114, Subtitle B, Ch 1, § 2121(c), (d), Ch 3, §§ 2141(a), 2142(a), 2144(a), Subtitle D, § 2193(c)(9), 95 Stat. 787, 796-799, 828; Sept. 3, 1982, P.L. 97-248, Title I, Subtitle A, Part I, Subpart A, §§ 101(a)(2), (d), 102(a), 103(a), 105(a), 106(a), 107(a), 108(a)(2), 109(b), Subpart B, § 114(b), Part II, § 122(d), Part III, §§ 127(l), 128(a)(1), (d)(2), Subtitle C, § 148(b), 96 Stat. 335-339, 350, 359, 366, 367, 394; Jan. 12, 1983, P.L. 97-448, Title III, § 309(a)(4), 96 Stat. 2408; April 20, 1983, P.L. 98-21, Title VI, §§ 602(d), 607(b)(2), (d), 97 Stat. 163, 171, 172; July 18, 1984, P.L. 98-369, Division B, Title III, Subtitle A, Part I, §§ 2314(a), 2318(a), (b), 2319(a), 2321(e), 2322(a), 2323(a), 2324(a), Part II, §§ 2335(b), 2340(a), 2341(a), (c), 2342(a), 2343(a), (b), 2354(b)(18)-(29), 98 Stat. 1079, 1081, 1082, 1085, 1086, 1090, 1093, 1094, 1101; Nov. 8, 1984, P.L. 98-617, § 3(a)(4), (b)(7), 98 Stat. 3295, 3296; April 7, 1986, P.L. 99-272, Title IX, Subtitle A, Part 1, Subpart A, §§ 9107(b), 9110(a), Part 2, Subpart A, § 9202(i)(1), Subpart B, § 9219(b)(1)(B), (3)(A), 100 Stat. 160, 162, 177, 182, 183; Oct. 21, 1986, P.L. 99-509, Title IX, Subtitle D, Part 1, § 9305(c)(1), (2), Part 2, §§ 9313(a)(2), 9315(a), 9320(b), (c), (f), Part 3, §§ 9335(c)(1), 9336(a), 9337(d), (g), 9338(a), 100 Stat. 1989, 2002, 2005, 2013, 2015, 2029, 2032, 2033, 2034; Dec. 22, 1987, P.L. 100-203, Title IV, Subtitle A, Part 1, § 4009(e)(1), (f), Part 2, Subpart B, § 4021(a), 4026(a)(1), Part 2, Subpart C, § 4039(b), Part 3, Subpart B, §§ 4064(e)(1), 4065(a), Part 3, Subpart C, §§ 4070(b)(1), (2), 4071(a), 4072(a), 4073(a), (c), 4074(a), (b), 4075(a), 4076(a), 4077(a)(1), (b)(1), (4) [(5)], 4078, Subpart D, § 4084(c)(1), 4085(i), (9)-(14), Subtitle C, Part 1, § 4201(a)(1), (b), (d), 100 Stat. 1330-58, 1330-67, 1330-74, 1330-81, 1330-111, 1330-112, 1330-114, 1330-116, 1330-118, 1330-119, 1330-120, 1330-121, 1330-132, 1330-160, 1330-174; July 1, 1988, P.L. 100-360, Title I, Subtitle A, § 104(d)(4), Title II, §§ 202(a)(1), (2), 203(e)(1), 204(a)(1), 206(a), Title IV, Subtitle B, § 411(d)(1)(B)(i), (h)(1)(B), (2), (3)(A), (4)(D), (5)-(7)(A), (E), (F), (i)(3), (l)(1)(B), 102 Stat. 689, 702, 725, 731, 773, 785-788, 801; Oct. 13, 1988, P.L. 100-485, Title VI, § 608(d)(6)(A), (23)(B), (27)(B) 102 Stat. 2412, 2421, 2422; Nov. 10, 1988, P.L. 100-647, Title VIII, Subtitle E, Part III, §§ 8423(a), 8424(a), 102 Stat. 3803; Dec. 13, 1989, P.L. 101-234, Title I, §§ 101(a)(1), 201(a)(1), 103 Stat. 1979, 1981; Dec. 19, 1989, P.L. 101-239, Title VI, Subtitle A, Part 1, Subpart A, § 6003(g)(3)(A), (C)(i), (D)(x), Part 2, Subpart A, §§ 6110, 6112(e)(1), 6113(a)-(b)(2), 6114(a), (d), 6115(a), 6116(a)(1), Part 2, Subpart B, §§ 6131(a)(2), 6141(a), Part 3, Subpart B, § 6213(a)-(c), 103 Stat. 2151-2153, 2213, 2215-2217, 2218, 2219, 2221, 2225, 2250; Nov. 5, 1990, P.L. 101-508, Title IV, Subtitle A, Part 1, § 4008(h)(2)(A)(i), Part 2, Subpart B, §§ 4151(a), (b)(1), 4153(b)(2)(A), 4155(a), (d), 4156(a), 4157(a), 4161(a)(1), (2), (5), 4162(a), 4163(a), Part 3, §§ 4201(d)(1), 4207(d)(1), 104 Stat. 1388-48, 1388-71, 1388-72, 1388-74, 1388-84, 1388-87, 1388-88, 1388-93, 1388-94, 1388-96, 1388-104, 1388-120; Nov. 16, 1990, P.L. 101-597, Title IV, § 401(c)(2), 104 Stat. 3035; Nov. 5, 1990, P.L. 101-508, Title IV, Subtitle A, Part 1, § 4008(h)(2)(A)(i), Part 2, Subpart B, §§ 4151(a), (b)(1), 4153(b)(2)(A), 4155(a), (d), 4156(a), 4157(a), 4161(a)(1), (2), (5), 4162(a), 4163(a), Part 3, §§ 4201(d)(1), 4207(d)(1), 104 Stat. 1388-48, 1388-71, 1388-72, 1388-74, 1388-84, 1388-87, 1388-88, 1388-93, 1388-94, 1388-96, 1388-104, 1388-120; Nov. 16, 1990, P.L. 101-597, Title IV, § 401(c)(2), 104 Stat. 3035; Aug. 10, 1993, P.L. 103-66, Title XIII, Ch 2, Subch A, Part I, § 13503(c)(1), Part II, Subpart B, § 13521, Subpart E, §§ 13553(a), (b), 13554(a), 13556(a), Part III, §§ 13564(a)(2), (b)(1), 13565, 13566(b), 107 Stat. 579, 586, 591, 592, 607; Oct. 31, 1994, P.L. 103-432, Title I, Subtitle A, §§ 102(g)(4), 104, 107(a), Subtitle B, Part III, § 145(b), 146(a), (b), 147(e)(1), (4), (5), (f)(3), (4), (6)(A), (B), (E), Subtitle C, §§ 158(a)(1), 160(d)(4), 108 Stat. 4404, 4405, 4407, 4427, 4428, 4430-4432, 4442, 4444; Oct. 11, 1996, P.L. 104-299, § 4(b)(1), 110 Stat. 3645; Aug. 5, 1997, P.L. 105-33, Title IV, Subtitle A, Ch 1, Subch A, § 4001, Subtitle B, §§ 4102(a), (c), 4103(a), 4104(a)(1), 4105(a)(1), (b)(1), 4106(a), Subtitle C, § 4201(c), 4205(b)(1), (c)(1), (d)(1), (2), (3)(A), Subtitle D, Ch 2, §§ 4312(b)(1), (2), (d), (e), 4320, 4321(a), Subtitle E, Ch 1, § 4404(a), Ch 3, § 4432(b)(5)(D), (E), Ch 4, 4444(a), 4445, 4446, Ch 5, 4451, 4454(a)(1), Subtitle F, Ch 1, Subch B, 4511(a)(1)-(2)(B), (d), 4512(a), 4513(a), Ch 2, § 4522, Ch 3, § 4531(a)(1), Ch 5, § 4557(a), Subtitle G, Ch 1, Subch A, §§ 4601(a), 4602(a)-(c), 4604(b), Subch B, §§ 4611(b), 4612(a), 111 Stat. 275, 360, 361, 362, 366, 367, 373, 376, 386, 394, 400, 421, 423-426, 442-444, 450, 463, 466, 472, 474; Oct. 21, 1998, P.L. 105-277, Div J, Title V, Subtitle A, § 5101(a), (b), (d)(1), 112 Stat. 2681-913, 2681-914; Nov. 29, 1999, P.L. 106-113, Div B, § 1000(a)(6), 113 Stat. 1536; Dec. 21, 2000, P.L. 106-554, § 1(a)(6), 114 Stat. 2763; Dec. 8, 2003, P.L. 108-173, Title I, §

101(a)(1), Title III, § 303(i)(2), Title IV, Subtitle A, § 408(a), Subtitle B, §§ 414(g)(2), 415(b), Title V, Subtitle B, § 512(c), Title VI, Subtitle B, §§ 611(a), (b), (d)(2), 612(a), (b), 613(a), (b), Subtitle D, § 642(a), Title VII, Subtitle A, § 706(b), Subtitle D, § 736(a)(10), (11), (b)(3), (11), (12), (c)(4), Title IX, Subtitle A, § 901(b), Subtitle C, § 926(b)(1), Subtitle E, § 946(a), 117 Stat. 2071, 2254, 2270, 2281, 2282, 2299, 2303, 2304, 2305, 2322, 2339, 2355, 2356, 2374, 2396, 2424.)

(As amended Feb. 8, 2006, P.L. 109-171, Title V, Subtitle A, § 5004, Ch. 2, §§ 5112(a), (b), 5114(a)(1), (b), Title VI, Subtitle A, Ch. 1, § 6001(f)(1), 120 Stat. 32, 43, 45, 58; Dec. 29, 2007, P.L. 110-173, Title I, § 114(a), 121 Stat. 2501; July 15, 2008, P.L. 110-275, Title I, Subtitle A, Part I, § 101(a)(1), (b)(1), Subtitle B, § 125(b)(2), Subtitle C, Part II, §§ 143(a), (b)(5), (6), 144(a)(1), 152(b)(1)(A), (B), 153(b)(3)(B), Subtitle F, § 182(b), 122 Stat. 2496, 2497, 2519, 2542, 2543, 2544, 2551, 2556, 2583; Oct. 8, 2008, P.L. 110-355, § 7(a), 122 Stat. 3995.)

§ 1395y. Exclusions from coverage and medicare as secondary payer

(a) Items or services specifically excluded. Notwithstanding any other provision of this *title [42 USCS §§ 1395* et seq.], no payment may be made under part A or part B [*42 USCS §§ 1395c* et seq. or *1395j* et seq.] for any expenses incurred for items or services--

(1) (A) which, except for items and services described in a succeeding subparagraph or additional preventive services (as described in section 1861(ddd)(1) [*42 USCS § 1395x(ddd)(1)*]), are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member,

(B) in the case of items and services described in section 1861(s)(10) [*42 USCS § 1395x(s)(10)*], which are not reasonable and necessary for the prevention of illness,

(C) in the case of hospice care, which are not reasonable and necessary for the palliation or management of terminal illness,

(D) in the case of clinical care items and services provided with the concurrence of the Secretary and with respect to research and experimentation conducted by, or under contract with, the Medicare Payment Advisory Commission or the Secretary, which are not reasonable and necessary to carry out the purposes of section 1886(e)(6),

(E) in the case of research conducted pursuant to section 1142 [*42 USCS § 1320b-12*], which is not reasonable and necessary to carry out the purposes of that section,

(F) in the case of screening mammography, which is performed more frequently than is covered under section 1834(c)(2) [*42 USCS § 1395m(c)(2)*] or which is not conducted by a facility described in section 1834(c)(1)(B) [*42 USCS § 1395m(c)(1)(B)*], in the case of screening pap smear and screening pelvic exam, which is performed more frequently than is provided under section 1861(nn) [*42 USCS § 1395x(nn)*], and, in the case of screening for glaucoma, which is performed more frequently than is provided under section 1861(uu) [*42 USCS § 1395x(uu)*],

(G) in the case of prostate cancer screening tests (as defined in section 1861(oo)), which are performed more frequently than is covered under such section,

(H) in the case of colorectal cancer screening tests, which are performed more frequently than is covered under section 1834(d) [*42 USCS § 1395m(d)*],

(I) the frequency and duration of home health services which are in excess of normative guidelines that the Secretary shall establish by regulation,

(J) in the case of a drug or biological specified in section 1847A(c)(6)(C) [*42 USCS § 1395w-3a(c)(6)(C)*] for which payment is made under part B [*42 USCS §§ 1395j* et seq.] that is furnished in a competitive area under section 1847B [*42 USCS § 1395w-3b*], that is not furnished by an entity under a contract under such section,

(K) in the case of an initial preventive physical examination, which is performed more than 1 year after the date the individual's first coverage period begins under part B [*42 USCS §§ 1395j* et seq.],

(L) in the case of cardiovascular screening blood tests (as defined in section 1861(xx)(1) [*42 USCS § 1395x(xx)(1)*]), which are performed more frequently than is covered under section 1861(xx)(2) [*42 USCS § 1395x(xx)(2)*],

(M) in the case of a diabetes screening test (as defined in section 1861(yy)(1) [*42 USCS § 1395x(yy)(1)*]), which is performed more frequently than is covered under section 1861(yy)(3) [*42 USCS § 1395x(yy)(3)*],

(N) in the case of ultrasound screening for abdominal aortic aneurysm which is performed more frequently than is provided for under section 1861(s)(2)(AA) [*42 USCS § 1395x(s)(2)(AA)*], and

(O) **[Caution: This subparagraph is applicable to services furnished on or after January 1, 2010, as provided by § 152(b)(2) of Act July 15, 2008, P.L. 110-275, which appears as *42 USCS § 1395w-4* note]** in the case of kidney disease education services (as defined in paragraph (1) of section 1861(ggg) [*42 USCS § 1395x(ggg)*]), which are furnished in excess of the number of sessions covered under paragraph (4) of such section;

(2) for which the individual furnished such items or services has no legal obligation to pay, and which no other person (by reason of such individual's membership in a prepayment plan or otherwise) has a legal obligation to provide or pay for, except in the case of Federally qualified health center services;

(3) which are paid for directly or indirectly by a governmental entity (other than under this Act and other than under a health benefits or insurance plan established for employees of such an entity), except in the case of rural health clinic services, as defined in section 1861(aa)(1) [*42 USCS § 1395x(aa)(1)*], in the case of Federally qualified health center services, as defined in section 1861(aa)(3) [*42 USCS § 1395x(aa)(3)*], in the case of services for which payment may be made under section 1880(e) [*42 USCS § 1395qq(e)*], and in such other cases as the Secretary may specify;

(4) which are not provided within the United States (except for inpatient hospital services furnished outside the United States under the conditions described in section 1814(f) [*42 USCS § 1395(f)*] and, subject to such conditions, limitations, and requirements as are provided under or pursuant to this *title [42 USCS §§ 1395* et seq.], physicians' services and ambulance services furnished an individual in conjunction with such inpatient hospital services but only for the period during which such inpatient hospital services were furnished);

(5) which are required as a result of war, or of an act of war, occurring after the effective date of such individual's current coverage under such part [*42 USCS §§ 1395c* et seq. or *1395j* et seq.];

(6) which constitute personal comfort items (except, in the case of hospice care, as is otherwise permitted under paragraph (1)(C));

(7) where such expenses are for routine physical checkups, eyeglasses (other than eyewear described in section 1861(s)(8) [*42 USCS § 1395x(s)(8)*]) or eye examinations for the purpose of prescribing, fitting, or changing eyeglasses, procedures performed (during the course of any eye examination) to determine the refractive state of the eyes, hearing aids or examinations therefor, or immunizations (except as otherwise allowed under section 1861(s)(10) [*42 USCS § 1395x(s)(10)*] and subparagraph (B), (F), (G), (H), or (K) of paragraph (1));

(8) where such expenses are for orthopedic shoes or other supportive devices for the feet, other than shoes furnished pursuant to section 1861(s)(12) [*42 USCS § 1395x(s)(12)*];

(9) where such expenses are for custodial care (except, in the case of hospice care, as is otherwise permitted under paragraph (1)(C));

(10) where such expenses are for cosmetic surgery or are incurred in connection therewith, except as required for the prompt repair of accidental injury or for improvement of the functioning of a malformed body member;

(11) where such expenses constitute charges imposed by immediate relatives of such individual or members of his household;

(12) where such expenses are for services in connection with the care, treatment, filling, removal, or replacement of teeth or structures directly supporting teeth, except that payment may be made under part A [*42 USCS §§ 1395c* et seq.] in the case of inpatient hospital services in connection with the provision of such dental services if the individual, because of his underlying medical condition and clinical status or because of the severity of the dental procedure, requires hospitalization in connection with the provision of such services;

(13) where such expenses are for--

(A) the treatment of flat foot conditions and the prescription of supportive devices therefor,

(B) the treatment of subluxations of the foot, or

(C) routine foot care (including the cutting or removal of corns or calluses, the trimming of nails, and other routine hygienic care);

(14) which are other than physicians' services (as defined in regulations promulgated specifically for purposes of this paragraph), services described by section 1861(s)(2)(K) [*42 USCS § 1395x(s)(2)(K)*], certified nurse-midwife services, qualified psychologist services, and services of a certified registered nurse anesthetist, and which are furnished to an individual who is a patient of a hospital or critical access hospital by an entity other than the hospital or critical access hospital, unless the services are furnished under arrangements (as defined in section 1861(w)(1) [*42 USCS § 1395x(w)(1)*]) with the entity made by the hospital or critical access hospital;

(15) (A) which are for services of an assistant at surgery in a cataract operation (including subsequent insertion of an intraocular lens) unless, before the surgery is performed, the appropriate utilization and quality control peer review organization (under part B of title XI [*42 USCS §§ 1320c* et seq.]) or a carrier under section 1842 [*42 USCS § 1395u*] has approved of the use of such an assistant in the surgical procedure based on the existence of a complicating medical condition, or

(B) which are for services of an assistant at surgery to which section 1848(i)(2)(B) [*42 USCS § 1395w-4(i)(2)(B)*] applies;

(16) in the case in which funds may not be used for such items and services under the Assisted Suicide Funding Restriction Act of 1997;

(17) where the expenses are for an item or service furnished in a competitive acquisition area (as established by the Secretary under section 1847(a) [*42 USCS § 1395w-3(a)*]) by an entity other than an entity with which the Secretary has entered into a contract under section 1847(b) [*42 USCS § 1395w-3(b)*] for the furnishing of such an item or service in that area, unless the Secretary finds that the expenses were incurred in a case of urgent need, or in other circumstances specified by the Secretary;

(18) which are covered skilled nursing facility services described in section 1888(e)(2)(A)(i) [*42 USCS § 1395yy(e)(2)(A)(i)*] and which are furnished to an individual who is a resident of a skilled nursing facility during a period in which the resident is provided covered post-hospital extended care services (or, for services described in section 1861(s)(2)(D) [*42 USCS § 1395x(s)(2)(D)*], which are furnished to such an individual without regard to such period), by an entity other than the skilled nursing facility, unless the services are furnished under arrangements (as defined in section 1861(w)(1) [*42 USCS § 1395x(w)(1)*]) with the entity made by the skilled nursing facility;

(19) which are for items or services which are furnished pursuant to a private contract described in section 1802(b) [*42 USCS § 1395a(b)*];

(20) **[Caution: For provisions applicable to services furnished before July 1, 2009, see 2008 amendment note below.]** in the case of outpatient physical therapy services, outpatient speech-language pathology services, or outpatient occupational therapy services furnished as an incident to a physician's professional services (as described in section 1861(s)(2)(A) [*42 USCS § 1395x(s)(2)(A)*]), that do not meet the standards and conditions (other than any licensing requirement specified by the Secretary) under the second sentence of section 1861(p) [*42 USCS § 1395x(p)*] (or under such sentence through the operation of subsection (g) or (ll)(2) of section 1861 [*42 USCS § 1395x*]) as such standards and conditions would apply to such therapy services if furnished by a therapist;

(21) where such expenses are for home health services (including medical supplies described in section 1861(m)(5) [*42 USCS § 1395x(m)(5)*], but excluding durable medical equipment to the extent provided for in such section) furnished to an individual who is under a plan of care of the home health agency if the claim for payment for such services is not submitted by the agency;

(22) subject to subsection (h), for which a claim is submitted other than in an electronic form specified by the Secretary;

(23) **[Caution: This paragraph applies to advanced diagnostic imaging services furnished on or after January 1, 2012, as provided by § 135(a)(2)(B) of Act July 15, 2008, P.L. 110-275, which appears as a note to this section.]** which are the technical component of advanced diagnostic imaging services described in section 1834(e)(1)(B) [*42 USCS § 1395m(e)(1)(B)*] for which payment is made under the fee schedule established under section 1848(b) [*42 USCS § 1395w-4(b)*] and that are furnished by a supplier (as defined in section 1861(d) [*42 USCS § 1395x(d)*]), if such supplier is not accredited by an accreditation organization designated by the Secretary under section 1834(e)(2)(B) [*42 USCS § 1395m(e)(2)(B)*]; or

(24) where such expenses are for renal dialysis services (as defined in subparagraph (B) of section 1881(b)(14) [*42 USCS § 1395rr(b)(14)*]) for which payment is made under such section unless such payment is made under such section to a provider of services or a renal dialysis facility for such services.

Paragraph (7) shall not apply to Federally qualified health center services described in section 1861(aa)(3)(B) [*42 USCS § 1395x(aa)(3)(B)*]. In making a national coverage determination (as defined in paragraph (1)(B) of section 1869(f) [*42 USCS § 1395ff(f)*]) the Secretary shall ensure consistent with subsection (l) that the public is afforded notice and opportunity to comment prior to implementation by the Secretary of the determination; meetings of advisory committees with respect to the determination are made on the record; in making the determination, the Secretary has considered applicable information (including clinical experience and medical, technical, and scientific evidence) with respect to the subject matter of the determination; and in the determination, provide a clear statement of the basis for the determination (including responses to comments received from the public), the assumptions underlying that basis, and make available to the public the data (other than proprietary data) considered in making the determination.

(b) Medicare as secondary payer.

(1) Requirements of group health plans.

(A) Working aged under group health plans.

(i) In general. A group health plan--

(I) may not take into account that an individual (or the individual's spouse) who is covered under the plan by virtue of the individual's current employment status with an employer is entitled to benefits under this title under section 226(a) [*42 USCS § 426(a)*], and

(II) shall provide that any individual age 65 or older (and the spouse age 65 or older of any individual) who has current employment status with an employer shall be entitled to the same benefits under the plan under the same conditions as any such individual (or spouse) under age 65.

(ii) Exclusion of group health plan of a small employer. Clause (i) shall not apply to a group health plan unless the plan is a plan of, or contributed to by, an employer that has 20 or more employees for each working day in each of 20 or more calendar weeks in the current calendar year or the preceding calendar year.

(iii) Exception for small employers in multiemployer or multiple employer group health plans. Clause (i) also shall not apply with respect to individuals enrolled in a multiemployer or multiple employer group health plan if the coverage

of the individuals under the plan is by virtue of current employment status with an employer that does not have 20 or more individuals in current employment status for each working day in each of 20 or more calendar weeks in the current calendar year and the preceding calendar year; except that the exception provided in this clause shall only apply if the plan elects treatment under this clause.

(iv) Exception for individuals with end stage renal disease. Subparagraph (C) shall apply instead of clause (i) to an item or service furnished in a month to an individual if for the month the individual is, or (without regard to entitlement under section 226 [*42 USCS § 426*]) would upon application be, entitled to benefits under section 226A [*42 USCS § 426-1*].

(v) "Group health plan" defined. In this subparagraph, and subparagraph (C), the term "group health plan" has the meaning given such term in *section 5000(b)(1) of the Internal Revenue Code of 1986* [*26 USCS § 5000(b)(1)*], without regard to section 5000(d) of such Code [*26 USCS § 5000(d)*].

(B) Disabled individuals in large group health plans.

(i) In general. A large group health plan (as defined in clause (iii)) may not take into account that an individual (or a member of the individual's family) who is covered under the plan by virtue of the individual's current employment status with an employer is entitled to benefits under this *title [42 USCS §§ 1395* et seq.] under section 226(b) [*42 USCS § 426(b)*].

(ii) Exception for individuals with end stage renal disease. Subparagraph (C) shall apply instead of clause (i) to an item or service furnished in a month to an individual if for the month the individual is, or (without regard to entitlement under section 226 [*42 USCS § 426*]) would upon application be, entitled to benefits under section 226A [*42 USCS § 426-1*].

(iii) Large group health plan defined. In this subparagraph, the term "large group health plan" has the meaning given such term in *section 5000(b)(2) of the Internal Revenue Code of 1986* [*26 USCS § 5000(b)(2)*], without regard to section 5000(d) of such Code [*26 USCS § 5000(d)*].

(C) Individuals with end stage renal disease. A group health plan (as defined in subparagraph (A)(v))--

(i) may not take into account that an individual is entitled to or eligible for benefits under this *title [42 USCS §§ 1395* et seq.] under section 226A [*42 USCS § 426-1*] during the 12-month period which begins with the first month in which the individual becomes entitled to benefits under part A [*42 USCS §§ 1395c* et seq.] under the provisions of section 226A [*42 USCS § 426-1*], or, if earlier, the first month in which the individual would have been entitled to benefits under such part under the provisions of section 226A [*42 USCS § 426-1*] if the individual had filed an application for such benefits; and

(ii) may not differentiate in the benefits it provides between individuals having end stage renal disease and other individuals covered by such plan on the basis of the existence of end stage renal disease, the need for renal dialysis, or in any other manner;

except that clause (ii) shall not prohibit a plan from paying benefits secondary to this *title [42 USCS §§ 1395* et seq.] when an individual is entitled to or eligible for benefits under this *title [42 USCS §§ 1395* et seq.] under section 226A [*42 USCS § 426-1*] after the end of the 12-month period described in clause (i). Effective for items and services furnished on or after February 1, 1991, and before the date of enactment of the Balanced Budget Act of 1997 [enacted Aug. 5, 1997], (with respect to periods beginning on or after February 1, 1990), this subparagraph shall be applied by substituting "18-month" for "12-month" each place it appears. Effective for items and services furnished on or after the date of enactment of the Balanced Budget Act of 1997 [enacted Aug. 5, 1997][,] (with respect to periods beginning on or after the date that is 18 months prior to such date), clauses (i) and (ii) shall be applied by substituting "30-month" for "12-month" each place it appears.

(D) Treatment of certain members of religious orders. In this subsection, an individual shall not be considered to be employed, or an employee, with respect to the performance of services as a member of a religious order which are considered employment only by virtue of an election made by the religious order under *section 3121(r) of the Internal Revenue Code of 1986* [*26 USCS § 3121(r)*].

(E) General provisions. For purposes of this subsection:

(i) Aggregation rules.

(I) All employers treated as a single employer under subsection (a) or (b) of *section 52 of the Internal Revenue Code of 1986* [*26 USCS § 52(a)* or (b)] shall be treated as a single employer.

(II) All employees of the members of an affiliated service group (as defined in section 414(m) of such Code [*26 USCS § 414(m)*]) shall be treated as employed by a single employer.

(III) Leased employees (as defined in section 414(n)(2) of such Code [*26 USCS § 414(n)(2)*]) shall be treated as employees of the person for whom they perform services to the extent they are so treated under section 414(n) of such Code [*26 USCS § 414(n)*].

In applying sections of the Internal Revenue Code of 1986 [*26 USCS §§ 1* et seq.] under this clause, the Secretary shall rely upon regulations and decisions of the Secretary of the Treasury respecting such sections.

(ii) Current employment status defined. An individual has "current employment status" with an employer if the individual is an employee, is the employer, or is associated with the employer in a business relationship.

(iii) Treatment of self-employed persons as employers. The term "employer" includes a self-employed person.

(F) Limitation on beneficiary liability. An individual who is entitled to benefits under this *title [42 USCS §§ 1395* et seq.] and is furnished an item or service for which such benefits are incorrectly paid is not liable for repayment of such benefits under this paragraph unless payment of such benefits was made to the individual.

(2) Medicare secondary payer.

(A) In general. Payment under this *title [42 USCS §§ 1395* et seq.] may not be made, except as provided in subparagraph (B), with respect to any item or service to the extent that--

(i) payment has been made, or can reasonably be expected to be made, with respect to the item or service as required under paragraph (1), or

(ii) payment has been made or can reasonably be expected to be made under a workmen's compensation law or plan of the United States or a State or under an automobile or liability insurance policy or plan (including a self-insured plan) or under no fault insurance.

In this subsection, the term "primary plan" means a group health plan or large group health plan, to the extent that clause (i) applies, and a workmen's compensation law or plan, an automobile or liability insurance policy or plan (including a self-insured plan) or no fault insurance, to the extent that clause (ii) applies. An entity that engages in a business, trade, or profession shall be deemed to have a self-insured plan if it carries its own risk (whether by a failure to obtain insurance, or otherwise) in whole or in part.

(B) Conditional payment.

(i) Authority to make conditional payment. The Secretary may make payment under this title with respect to an item or service if a primary plan described in subparagraph (A)(ii) has not made or cannot reasonably be expected to make payment with respect to such item or service promptly (as determined in accordance with regulations). Any such payment by the Secretary shall be conditioned on reimbursement to the appropriate Trust Fund in accordance with the succeeding provisions of this subsection.

(ii) Repayment required. A primary plan, and an entity that receives payment from a primary plan, shall reimburse the appropriate Trust Fund for any payment made by the Secretary under this *title [42 USCS §§ 1395* et seq.] with respect to an item or service if it is demonstrated that such primary plan has or had a responsibility to make payment with respect to such item or service. A primary plan's responsibility for such payment may be demonstrated by a judgment, a payment conditioned upon the recipient's compromise, waiver, or release (whether or not there is a determination or admission of liability) of payment for items or services included in a claim against the primary plan or the primary plan's insured, or by other means. If reimbursement is not made to the appropriate Trust Fund before the expiration of the 60-day period that begins on the date notice of, or information related to, a primary plan's responsibility for such payment or other information is received, the Secretary may charge interest (beginning with the date on which the notice or other information is received) on the amount of the reimbursement until reimbursement is made (at a rate determined by the Secretary in accordance with regulations of the Secretary of the Treasury applicable to charges for late payments).

(iii) Action by United States. In order to recover payment made under this *title [42 USCS §§ 1395* et seq.] for an item or service, the United States may bring an action against any or all entities that are or were required or responsible (directly, as an insurer or self-insurer, as a third-party administrator, as an employer that sponsors or contributes to a group health plan, or large group health plan, or otherwise) to make payment with respect to the same item or service (or any portion thereof) under a primary plan. The United States may, in accordance with paragraph (3)(A) collect double damages against any such entity. In addition, the United States may recover under this clause from any entity that has received payment from a primary plan or from the proceeds of a primary plan's payment to any entity. The United States may not recover from a third-party administrator under this clause in cases where the third-party administrator would not be able to recover the amount at issue from the employer or group health plan and is not employed by or under contract with the employer or group health plan at the time the action for recovery is initiated by the United States or for whom it provides administrative services due to the insolvency or bankruptcy of the employer or plan.

(iv) Subrogation rights. The United States shall be subrogated (to the extent of payment made under this *title [42 USCS §§ 1395* et seq.] for such an item or service) to any right under this subsection of an individual or any other entity to payment with respect to such item or service under a primary plan.

(v) Waiver of rights. The Secretary may waive (in whole or in part) the provisions of this subparagraph in the case of an individual claim if the Secretary determines that the waiver is in the best interests of the program established under this *title [42 USCS §§ 1395* et seq.].

(vi) Claims-filing period. Notwithstanding any other time limits that may exist for filing a claim under an employer group health plan, the United States may seek to recover conditional payments in accordance with this subparagraph where the request for payment is submitted to the entity required or responsible under this subsection to

pay with respect to the item or service (or any portion thereof) under a primary plan within the 3-year period beginning on the date on which the item or service was furnished.

(C) Treatment of questionnaires. The Secretary may not fail to make payment under subparagraph (A) solely on the ground that an individual failed to complete a questionnaire concerning the existence of a primary plan.

(3) Enforcement.

(A) Private cause of action. There is established a private cause of action for damages (which shall be in an amount double the amount otherwise provided) in the case of a primary plan which fails to provide for primary payment (or appropriate reimbursement) in accordance with paragraphs (1) and (2)(A).

(B) Reference to excise tax with respect to nonconforming group health plans. For provision imposing an excise tax with respect to nonconforming group health plans, see *section 5000 of the Internal Revenue Code of 1986* [*26 USCS § 5000*].

(C) Prohibition of financial incentives not to enroll in a group health plan or a large group health plan. It is unlawful for an employer or other entity to offer any financial or other incentive for an individual entitled to benefits under this *title [42 USCS §§ 1395* et seq.] not to enroll (or to terminate enrollment) under a group health plan or a large group health plan which would (in the case of such enrollment) be a primary plan (as defined in paragraph (2)(A)). Any entity that violates the previous sentence is subject to a civil money penalty of not to exceed $ 5,000 for each such violation. The provisions of section 1128A [*42 USCS § 1320a-7a*] (other than subsections (a) and (b)) shall apply to a civil money penalty under the previous sentence in the same manner as such provisions apply to a penalty or proceeding under section 1128A(a) [*42 USCS § 1320a-7a(a)*].

(4) Coordination of benefits. Where payment for an item or service by a primary plan is less than the amount of the charge for such item or service and is not payment in full, payment may be made under this *title [42 USCS §§ 1395* et seq.] (without regard to deductibles and coinsurance under this *title [42 USCS §§ 1395* et seq.]) for the remainder of such charge, but--

(A) payment under this *title [42 USCS §§ 1395* et seq.] may not exceed an amount which would be payable under this *title [42 USCS §§ 1395* et seq.] for such item or service if paragraph (2)(A) did not apply; and

(B) payment under this *title [42 USCS §§ 1395* et seq.], when combined with the amount payable under the primary plan, may not exceed--

(i) in the case of an item or service payment for which is determined under this *title [42 USCS §§ 1395* et seq.] on the basis of reasonable cost (or other cost-related basis) or under section 1886 [*42 USCS § 1395ww*], the amount which would be payable under this *title [42 USCS §§ 1395* et seq.] on such basis, and

(ii) in the case of an item or service for which payment is authorized under this *title [42 USCS §§ 1395* et seq.] on another basis--

(I) the amount which would be payable under the primary plan (without regard to deductibles and coinsurance under such plan), or

(II) the reasonable charge or other amount which would be payable under this *title [42 USCS §§ 1395* et seq.] (without regard to deductibles and coinsurance under this *title [42 USCS §§ 1395* et seq.]),

whichever is greater.

(5) Identification of secondary payer situations.

(A) Requesting matching information.

(i) Commissioner of Social Security. The Commissioner of Social Security shall, not less often than annually, transmit to the Secretary of the Treasury a list of the names and TINs of medicare beneficiaries (as defined in *section 6103(l)(12) of the Internal Revenue Code of 1986* [*26 USCS § 6103(l)(12)*]) and request that the Secretary disclose to the Commissioner the information described in subparagraph (A) of such section.

(ii) Administrator. The Administrator of the Centers for Medicare & Medicaid Services shall request, not less often than annually, the Commissioner of the Social Security Administration to disclose to the Administrator the information described in subparagraph (B) of *section 6103(l)(12) of the Internal Revenue Code of 1986* [*26 USCS § 6103(l)(12)(B)*].

(B) Disclosure to fiscal intermediaries and carriers. In addition to any other information provided under this *title [42 USCS §§ 1395* et seq.] to fiscal intermediaries and carriers, the Administrator shall disclose to such intermediaries and carriers (or to such a single intermediary or carrier as the Secretary may designate) the information received under subparagraph (A) for purposes of carrying out this subsection.

(C) Contacting employers.

(i) In general. With respect to each individual (in this subparagraph referred to as an "employee") who was furnished a written statement under *section 6051 of the Internal Revenue Code of 1986* [*26 USCS § 6051*] by a qualified employer (as defined in section 6103(l)(12)(E)(iii) of such Code [*26 USCS § 6103(l)(12)(E)(iii)*]), as disclosed under subparagraph (B), the appropriate fiscal intermediary or carrier shall contact the employer in order to determine during what period the employee or employee's spouse may be (or have been) covered under a group health plan of the

employer and the nature of the coverage that is or was provided under the plan (including the name, address, and identifying number of the plan).

(ii) Employer response. Within 30 days of the date of receipt of the inquiry, the employer shall notify the intermediary or carrier making the inquiry as to the determinations described in clause (i). An employer (other than a Federal or other governmental entity) who willfully or repeatedly fails to provide timely and accurate notice in accordance with the previous sentence shall be subject to a civil money penalty of not to exceed $ 1,000 for each individual with respect to which such an inquiry is made. The provisions of section 1128A [*42 USCS § 1320a-7a*] (other than subsections (a) and (b)) shall apply to a civil money penalty under the previous sentence in the same manner as such provisions apply to a penalty or proceeding under section 1128A(a) [*42 USCS § 1320a-7a(a)*].

(D) Obtaining information from beneficiaries. Before an individual applies for benefits under part A [*42 USCS §§ 1395c* et seq.] or enrolls under part B [*42 USCS §§ 1395j* et seq.], the Administrator shall mail the individual a questionnaire to obtain information on whether the individual is covered under a primary plan and the nature of the coverage provided under the plan, including the name, address, and identifying number of the plan.

(6) Screening requirements for providers and suppliers.

(A) In general. Notwithstanding any other provision of this *title [42 USCS §§ 1395* et seq.], no payment may be made for any item or service furnished under part B [*42 USCS §§ 1395j* et seq.] unless the entity furnishing such item or service completes (to the best of its knowledge and on the basis of information obtained from the individual to whom the item or service is furnished) the portion of the claim form relating to the availability of other health benefit plans.

(B) Penalties. An entity that knowingly, willfully, and repeatedly fails to complete a claim form in accordance with subparagraph (A) or provides inaccurate information relating to the availability of other health benefit plans on a claim form under such subparagraph shall be subject to a civil money penalty of not to exceed $ 2,000 for each such incident. The provisions of section 1128A [*42 USCS § 1320a-7a*] (other than subsections (a) and (b)) shall apply to a civil money penalty under the previous sentence in the same manner as such provisions apply to a penalty or proceeding under section 1128A(a) [*42 USCS § 1320a-7a(a)*].

(7) Required submission of information by group health plans.

(A) Requirement. On and after the first day of the first calendar quarter beginning after the date that is 1 year after the date of the enactment of this paragraph [enacted Dec. 29, 2007], an entity serving as an insurer or third party administrator for a group health plan, as defined in paragraph (1)(A)(v), and, in the case of a group health plan that is self-insured and self-administered, a plan administrator or fiduciary, shall--

(i) secure from the plan sponsor and plan participants such information as the Secretary shall specify for the purpose of identifying situations where the group health plan is or has been a primary plan to the program under this *title [42 USCS §§ 1395* et seq.]; and

(ii) submit such information to the Secretary in a form and manner (including frequency) specified by the Secretary.

(B) Enforcement.

(i) In general. An entity, a plan administrator, or a fiduciary described in subparagraph (A) that fails to comply with the requirements under such subparagraph shall be subject to a civil money penalty of $ 1,000 for each day of noncompliance for each individual for which the information under such subparagraph should have been submitted. The provisions of subsections (e) and (k) of section 1128A [*42 USCS § 1320a-7a*] shall apply to a civil money penalty under the previous sentence in the same manner as such provisions apply to a penalty or proceeding under section 1128A(a) [*42 USCS § 1320a-7a(a)*]. A civil money penalty under this clause shall be in addition to any other penalties prescribed by law and in addition to any Medicare secondary payer claim under this title with respect to an individual.

(ii) Deposit of amounts collected. Any amounts collected pursuant to clause (i) shall be deposited in the Federal Hospital Insurance Trust Fund under section 1817 [*42 USCS § 1395i*].

(C) Sharing of information. Notwithstanding any other provision of law, under terms and conditions established by the Secretary, the Secretary--

(i) shall share information on entitlement under Part A [*42 USCS §§ 1395c* et seq.] and enrollment under Part B under this *title [42 USCS §§ 1395j* et seq.] with entities, plan administrators, and fiduciaries described in subparagraph (A);

(ii) may share the entitlement and enrollment information described in clause (i) with entities and persons not described in such clause; and

(iii) may share information collected under this paragraph as necessary for purposes of the proper coordination of benefits.

(D) Implementation. Notwithstanding any other provision of law, the Secretary may implement this paragraph by program instruction or otherwise.

(8) Required submission of information by or on behalf of liability insurance (including self-insurance), no fault insurance, and workers' compensation laws and plans.

(A) Requirement. On and after the first day of the first calendar quarter beginning after the date that is 18 months after the date of the enactment of this paragraph [enacted Dec. 29, 2007], an applicable plan shall--

(i) determine whether a claimant (including an individual whose claim is unresolved) is entitled to benefits under the program under this *title [42 USCS §§ 1395* et seq.] on any basis; and

(ii) if the claimant is determined to be so entitled, submit the information described in subparagraph (B) with respect to the claimant to the Secretary in a form and manner (including frequency) specified by the Secretary.

(B) Required information. The information described in this subparagraph is--

(i) the identity of the claimant for which the determination under subparagraph (A) was made; and

(ii) such other information as the Secretary shall specify in order to enable the Secretary to make an appropriate determination concerning coordination of benefits, including any applicable recovery claim.

(C) Timing. Information shall be submitted under subparagraph (A)(ii) within a time specified by the Secretary after the claim is resolved through a settlement, judgment, award, or other payment (regardless of whether or not there is a determination or admission of liability).

(D) Claimant. For purposes of subparagraph (A), the term "claimant" includes--

(i) an individual filing a claim directly against the applicable plan; and

(ii) an individual filing a claim against an individual or entity insured or covered by the applicable plan.

(E) Enforcement.

(i) In general. An applicable plan that fails to comply with the requirements under subparagraph (A) with respect to any claimant shall be subject to a civil money penalty of $ 1,000 for each day of noncompliance with respect to each claimant. The provisions of subsections (e) and (k) of section 1128A [*42 USCS § 1320a-7a*] shall apply to a civil money penalty under the previous sentence in the same manner as such provisions apply to a penalty or proceeding under section 1128A(a) [*42 USCS § 1320a-7a(a)*]. A civil money penalty under this clause shall be in addition to any other penalties prescribed by law and in addition to any Medicare secondary payer claim under this *title [42 USCS §§ 1395* et seq.] with respect to an individual.

(ii) Deposit of amounts collected. Any amounts collected pursuant to clause (i) shall be deposited in the Federal Hospital Insurance Trust Fund.

(F) Applicable plan. In this paragraph, the term "applicable plan" means the following laws, plans, or other arrangements, including the fiduciary or administrator for such law, plan, or arrangement:

(i) Liability insurance (including self-insurance).

(ii) No fault insurance.

(iii) Workers' compensation laws or plans.

(G) Sharing of information. The Secretary may share information collected under this paragraph as necessary for purposes of the proper coordination of benefits.

(H) Implementation. Notwithstanding any other provision of law, the Secretary may implement this paragraph by program instruction or otherwise.

(c) Drug products. No payment may be made under part B [*42 USCS §§ 1395j* et seq.] for any expenses incurred for--

(1) a drug product--

(A) which is described in section 107(c)(3) of the Drug Amendments of 1962 [*21 USCS § 321* note],

(B) which may be dispensed only upon prescription,

(C) for which the Secretary has issued a notice of an opportunity for a hearing under subsection (e) of section 505 of the Federal Food, Drug, and Cosmetic Act [*21 USCS § 355(e)*] on a proposed order of the Secretary to withdraw approval of an application for such drug product under such section because the Secretary has determined that the drug is less than effective for all conditions of use prescribed, recommended, or suggested in its labeling, and

(D) for which the Secretary has not determined there is a compelling justification for its medical need; and

(2) any other drug product--

(A) which is identical, related, or similar (as determined in accordance with *section 310.6 of title 21 of the Code of Federal R*egulations) to a drug product described in paragraph (1), and

(B) for which the Secretary has not determined there is a compelling justification for its medical need,

until such time as the Secretary withdraws such proposed order.

(d) Payment for EMTALA-mandated screening and stabilization services. For purposes of subsection (a)(1)(A), in the case of any item or service that is required to be provided pursuant to section 1867 [*42 USCS § 1395dd*] to an individual who is entitled to benefits under this *title [42 USCS §§ 1395* et seq.], determinations as to whether the item or service is reasonable and necessary shall be made on the basis of the information available to the treating physician or practitioner (including the patient's presenting symptoms or complaint) at the time the item or service was ordered or furnished by the physician or practitioner (and not on the patient's principal diagnosis). When making such determinations with

respect to such an item or service, the Secretary shall not consider the frequency with which the item or service was provided to the patient before or after the time of the admission or visit.

(e) Item or service by excluded individual or entity or at direction of excluded physician; limitation of liability of beneficiaries with respect to services furnished by excluded individuals and entities.

(1) No payment may be made under this *title [42 USCS §§ 1395* et seq.] with respect to any item or service (other than an emergency item or service, not including items or services furnished in an emergency room of a hospital) furnished--

(A) by an individual or entity during the period when such individual or entity is excluded pursuant to section 1128, 1128A, 1156 or 1842(j)(2) [*42 USCS § 1320a-7, 1320a-7a, 1320c-5,* or *1395u(j)(2)*] from participation in the program under this *title [42 USCS §§ 1395* et seq.]; or

(B) at the medical direction or on the prescription of a physician during the period when he is excluded pursuant to section 1128, 1128A, 1156 or 1842(j)(2) [*42 USCS § 1320a-7, 1320a-7a, 1320c-5,* or *1395u(j)(2)*] from participation in the program under this *title [42 USCS §§ 1395* et seq.] and when the person furnishing such item or service knew or had reason to know of the exclusion (after a reasonable time period after reasonable notice has been furnished to the person).

(2) Where an individual eligible for benefits under this *title [42 USCS §§ 1395* et seq.] submits a claim for payment for items or services furnished by an individual or entity excluded from participation in the programs under this *title [42 USCS §§ 1395* et seq.], pursuant to section 1128, 1128A, 1156, 1160 [*42 USCS § 1320a-7, 1320a-7a, 1320c-5, 1320c-9*] (as in effect on September 2, 1982), 1842(j)(2), 1862(d) [*42 USCS § 1395u(j)(2), 1395y(d)*] (as in effect on the date of the enactment of the Medicare and Medicaid Patient and Program Protection Act of 1987 [enacted Aug. 18, 1987]), or 1866 [*42 USCS § 1395cc*], and such beneficiary did not know or have reason to know that such individual or entity was so excluded, then, to the extent permitted by this *title [42 USCS §§ 1395* et seq.], and notwithstanding such exclusion, payment shall be made for such items or services. In each such case the Secretary shall notify the beneficiary of the exclusion of the individual or entity furnishing the items or services. Payment shall not be made for items or services furnished by an excluded individual or entity to a beneficiary after a reasonable time (as determined by the Secretary in regulations) after the Secretary has notified the beneficiary of the exclusion of that individual or entity.

(f) Utilization guidelines for provision of home health services. The Secretary shall establish utilization guidelines for the determination of whether or not payment may be made, consistent with paragraph (1)(A) of subsection (a), under part A or part B [*42 USCS §§ 1395c* et seq. or *1395j* et seq.] for expenses incurred with respect to the provision of home health services, and shall provide for the implementation of such guidelines through a process of selective postpayment coverage review by intermediaries or otherwise.

(g) Contracts with utilization and quality control peer review organizations. The Secretary shall, in making the determinations under paragraphs (1) and (9) of subsection (a), and for the purposes of promoting the effective, efficient, and economical delivery of health care services, and of promoting the quality of services of the type for which payment may be made under this *title [42 USCS §§ 1395* et seq.], enter into contracts with utilization and quality control peer review organizations pursuant to part B of title XI of this Act [*42 USCS §§ 1320c* et seq.].

(h) Waiver of electronic submission of claims.

(1) The Secretary--

(A) shall waive the application of subsection (a)(22) in cases in which--

(i) there is no method available for the submission of claims in an electronic form; or

(ii) the entity submitting the claim is a small provider of services or supplier; and

(B) may waive the application of such subsection in such unusual cases as the Secretary finds appropriate.

(2) For purposes of this subsection, the term "small provider of services or supplier" means--

(A) a provider of services with fewer than 25 full-time equivalent employees; or

(B) a physician, practitioner, facility, or supplier (other than provider of services) with fewer than 10 full-time equivalent employees.

(i) Awards and contracts for original research and experimentation of new and existing medical procedures; conditions. In order to supplement the activities of the Medicare Payment Advisory Commission under section 1886(e) [*42 USCS § 1395ww(e)*] in assessing the safety, efficacy, and cost-effectiveness of new and existing medical procedures, the Secretary may carry out, or award grants or contracts for, original research and experimentation of the type described in clause (ii) of section 1886(e)(6)(E) [*42 USCS § 1395ww(e)(6)(E)(ii)*] with respect to such a procedure if the Secretary finds that--

(1) such procedure is not of sufficient commercial value to justify research and experimentation by a commercial organization;

(2) research and experimentation with respect to such procedure is not of a type that may appropriately be carried out by an institute, division, or bureau of the National Institutes of Health; and

(3) such procedure has the potential to be more cost-effective in the treatment of a condition than procedures currently in use with respect to such condition.

(j) Advisory committees with respect to exclusions from medicare coverage.

(1) Any advisory committee appointed to advise the Secretary on matters relating to the interpretation, application, or implementation of subsection (a)(1) shall assure the full participation of a nonvoting member in the deliberations of the advisory committee, and shall provide such nonvoting member access to all information and data made available to voting members of the advisory committee, other than information that--

(A) is exempt from disclosure pursuant to subsection (a) of *section 552 of title 5, United States Code*, by reason of subsection (b)(4) of such section (relating to trade secrets); or

(B) the Secretary determines would present a conflict of interest relating to such nonvoting member.

(2) If an advisory committee described in paragraph (1) organizes into panels of experts according to types of items or services considered by the advisory committee, any such panel of experts may report any recommendation with respect to such items or services directly to the Secretary without the prior approval of the advisory committee or an executive committee thereof.

(k) Treatment of certain dental claims.

(1) Subject to paragraph (2), a group health plan (as defined in subsection (a)(1)(A)(v)) providing supplemental or secondary coverage to individuals also entitled to services under this title shall not require a medicare claims determination under this title for dental benefits specifically excluded under subsection (a)(12) as a condition of making a claims determination for such benefits under the group health plan.

(2) A group health plan may require a claims determination under this title in cases involving or appearing to involve inpatient dental hospital services or dental services expressly covered under this title pursuant to actions taken by the Secretary.

(l) National and local coverage determination process.

(1) Factors and evidence used in making national coverage determinations. The Secretary shall make available to the public the factors considered in making national coverage determinations of whether an item or service is reasonable and necessary. The Secretary shall develop guidance documents to carry out this paragraph in a manner similar to the development of guidance documents under section 701(h) of the Federal Food, Drug, and Cosmetic Act (*21 U.S.C. 371(h)*).

(2) Timeframe for decisions on requests for national coverage determinations. In the case of a request for a national coverage determination that--

(A) does not require a technology assessment from an outside entity or deliberation from the Medicare Coverage Advisory Committee, the decision on the request shall be made not later than 6 months after the date of the request; or

(B) requires such an assessment or deliberation and in which a clinical trial is not requested, the decision on the request shall be made not later than 9 months after the date of the request.

(3) Process for public comment in national coverage determinations.

(A) Period for proposed decision. Not later than the end of the 6-month period (or 9-month period for requests described in paragraph (2)(B)) that begins on the date a request for a national coverage determination is made, the Secretary shall make a draft of proposed decision on the request available to the public through the Internet website of the Centers for Medicare & Medicaid Services or other appropriate means.

(B) 30-day period for public comment. Beginning on the date the Secretary makes a draft of the proposed decision available under subparagraph (A), the Secretary shall provide a 30-day period for public comment on such draft.

(C) 60-day period for final decision. Not later than 60 days after the conclusion of the 30-day period referred to under subparagraph (B), the Secretary shall--

(i) make a final decision on the request;

(ii) include in such final decision summaries of the public comments received and responses to such comments;

(iii) make available to the public the clinical evidence and other data used in making such a decision when the decision differs from the recommendations of the Medicare Coverage Advisory Committee; and

(iv) in the case of a final decision under clause (i) to grant the request for the national coverage determination, the Secretary shall assign a temporary or permanent code (whether existing or unclassified) and implement the coding change.

(4) Consultation with outside experts in certain national coverage determinations. With respect to a request for a national coverage determination for which there is not a review by the Medicare Coverage Advisory Committee, the Secretary shall consult with appropriate outside clinical experts.

(5) Local coverage determination process.

(A) Plan to promote consistency of coverage determinations. The Secretary shall develop a plan to evaluate new local coverage determinations to determine which determinations should be adopted nationally and to what extent greater consistency can be achieved among local coverage determinations.

(B) Consultation. The Secretary shall require the fiscal intermediaries or carriers providing services within the same area to consult on all new local coverage determinations within the area.

(C) Dissemination of information. The Secretary should serve as a center to disseminate information on local coverage determinations among fiscal intermediaries and carriers to reduce duplication of effort.

(6) National and local coverage determination defined. For purposes of this subsection--

(A) National coverage determination. The term "national coverage determination" means a determination by the Secretary with respect to whether or not a particular item or service is covered nationally under this title.

(B) Local coverage determination. The term "local coverage determination" has the meaning given that in section 1869(f)(2)(B) [*42 USCS § 1395ff(f)(2)(B)*].

(m) Coverage of routine costs associated with certain clinical trials of category A devices.

(1) In general. In the case of an individual entitled to benefits under part A [*42 USCS §§ 1395c* et seq.], or enrolled under part B [*42 USCS §§ 1395j* et seq.], or both who participates in a category A clinical trial, the Secretary shall not exclude under subsection (a)(1) payment for coverage of routine costs of care (as defined by the Secretary) furnished to such individual in the trial.

(2) Category A clinical trial. For purposes of paragraph (1), a "category A clinical trial" means a trial of a medical device if--

(A) the trial is of an experimental/investigational (category A) medical device (as defined in regulations under *section 405.201(b) of title 42, Code of Federal R*egulations (as in effect as of September 1, 2003));

(B) the trial meets criteria established by the Secretary to ensure that the trial conforms to appropriate scientific and ethical standards; and

(C) in the case of a trial initiated before January 1, 2010, the device involved in the trial has been determined by the Secretary to be intended for use in the diagnosis, monitoring, or treatment of an immediately life-threatening disease or condition.

HISTORY:

(Aug. 14, 1935, ch 531, Title XVIII, Part E[D][C], § 1862, as added July 30, 1965, P.L. 89-97 Title I, Part 1, § 102(a), 79 Stat. 325; Jan. 2, 1968, P.L. 90-248, Title I, Part 3, §§ 127(b), 128, 81 Stat. 846, 847; Oct. 30, 1972, P.L. 92-603, Title II, §§ 210, 211(c)(1), 229(a), 256(c), 86 Stat. 1382, 1384, 1408, 1447; Dec. 31, 1973, P.L. 93-233, § 18(k)(3), 87 Stat. 970; Oct. 26, 1974, P.L. 93-480, § 4(a), 88 Stat. 1454; Dec. 31, 1975, P.L. 94-182, Title I, § 103, 89 Stat. 1051; Oct. 25, 1977, P.L. 95-142, §§ 7(a), 13(a), (b)(1), (2), 91 Stat. 1192, 1197, 1198; Dec. 13, 1977, P.L. 95-210, § 1(f), 91 Stat. 1487; June 17, 1980, P.L. 96-272, Title III, § 308(a), 94 Stat. 531; Dec. 5, 1980, P.L. 96-499, Title IX, Part A, Subpart II, § 913(b), Part B, Subpart I, §§ 936(c), 939(a), Subpart II, § 953, 94 Stat. 2620, 2640, 2647; Dec. 28, 1980, P.L. 96-611, § 1(a)(3), 94 Stat. 3566; Aug. 13, 1981, P.L. 97-35, Title XXI, Subtitle A, Ch 1, § 2103(a)(1) Subtitle B, Ch 3, § 2146(a), Ch 4, 2152(a), 95 Stat. 787, 800, 802; Sept. 3, 1982, P.L. 97-248, Title I, Subtitle A, Part I, Subpart C, § 116(b), Part II, § 122(f), (g)(1), Part III, § 128(a)(2)-(4), Subtitle C, §§ 142, 148(a), 96 Stat. 353, 362, 366, 381, 394; Jan. 12, 1983, P.L. 97-448, Title III, § 309(b)(10), 96 Stat. 2409; April 20, 1983, P.L. 98-21, Title VI, §§ 601(f), 602(e), 97 Stat. 162; July 18, 1984, P.L. 98-369, Division B, Title III, Subtitle A, Part I, §§ 2301(a), 2304(c), 2313(c), Part II, §§ 2344(a)-(c), 2354(b)(30), (31), 98 Stat. 1063, 1068, 1078, 1095, 1101; April 7, 1986, P.L. 99-272, Title IX, Subtitle A, Part 2, Subpart A, § 9201(a), Part 3, Subpart A, § 9307(a), Part 4, § 9401(c), 100 Stat. 170, 193, 199; Oct. 21, 1986, P.L. 99-509, Title IX, Subtitle D, Part 2, §§ 9316(b), 9319(a), (b), 9320(h)(1), Part 3, 9343(c)(1), 100 Stat. 2007, 2010, 2015, 2039; Aug. 18, 1987, P.L. 100-93, § 8(c)(1), (3), 101 Stat. 692, 693; Dec. 22, 1987, P.L. 100-203, Title IV, Subtitle A, Part 1, § 4009(j)(6)(C), Part 2, Subpart C, §§ 4034(a), 4036(a)(1), 4039(c)(1), Part 3, Subpart D, §§ 4072(c), 4085(i)(15), (16), 101 Stat. 1330-77, 1330-79, 1330-82, 1330-117, 1330-133; July 1, 1988, P.L. 100-360, Title II, Subtitle A, §§ 202(d), 204(d)(2), 205(e)(1), Title IV, Subtitle B, § 411(f)(4)(D)(i), (ii)(iv)(i)(4)(D), 102 Stat. 715, 729, 731, 778, 790; Oct. 13, 1988, P.L. 100-485, Title VI, § 608(d)(24)(C)(i), (ii)(III), 102 Stat. 2421; Dec. 13, 1989, P.L. 101-234, Title II, § 201(a)(1), 103 Stat. 1981; Dec. 19, 1989, P.L. 101-239, Title VI, Subtitle A, Part 1, Subpart A, § 6003(g)(3)(D)(xi), Part 2, Subpart A, §§ 6103(b)(3)(B), 6115(b), Part 3, Subpart A, § 6202(a)(2)(A), (b)(1), (e)(1), Subtitle B, Part 2, § 6411(d)(2), 103 Stat 2154, 2199, 2219, 2228, 2229, 2234, 2271; Nov. 5, 1990, P.L. 101-508, Title IV, Subtitle A, Part 2, Subpart A, § 4107(b), Subpart B, §§ 4153(b)(2)(B), 4157(c)(1), 4161(a)(3)(C), 4163(d)(2),

4203(a)(1), (b), (c), 4204(g)(1), 104 Stat. 1388-62, 1388-84, 1388-89, 1388-94, 1388-100, 1388-107, 1388-112; Aug. 10, 1993, P.L. 103-66, Title XIII, Ch 2, Subch A, Part III, §§ 13561(a)(1), (b), (c), (d)(1), (e)(1), Part V, 13581(b), 107 Stat. 593-595, 611; Oct. 31, 1994, P.L. 103-432, Title I, Subtitle B, Part III, §§ 145(c)(1), 147(e)(6), Subtitle C, §§ 151(a)(1)(A), (C), (2)(A), (b)(3)(A), (B), (c)(1), (4)-(6), (9), 156(a)(2)(D), 157(b)(7), 108 Stat. 4427, 4430, 4432-4436, 4441, 4442; Oct. 2, 1996, P.L. 104-224, § 1, 110 Stat. 3031; Oct. 2, 1996, P.L. 104-226, § 1(b)(1), 110 Stat. 3033; April 30, 1997, P.L. 105-12, § 9(a)(1), 111 Stat. 26; Aug. 5, 1997, P.L. 105-33, Title IV, Subtitle A, Ch 1, Subch A, § 4001, Ch 3, § 4022(b)(1)(B), Subtitle B, §§ 4102(c), 4103(c), 4104(c)(3), Subtitle C, § 4201(c)(1), Subtitle D, Ch 2, § 4319(b), Subtitle E, Ch 3, § 4432(b)(1), Subtitle F, Ch 1, Subch A, § 4507(a)(2)(B), Subch B, § 4511(a)(2)(C), Ch 4, § 4541(b), Subtitle G, Ch 1, Subch A, § 4603(c)(2)(C), Subch B, § 4614(a), Ch 3, §§ 4631(a)(1), (b), (c)(1), 4632(a), 4633(a), (b), 111 Stat. 275, 354, 361, 362, 365, 373, 394, 420, 440, 442, 456, 471, 474, 486, 487; Nov. 29, 1999, P.L. 106-113, Div B, § 1000(a)(6), 113 Stat. 1536; Dec. 21, 2000, P.L. 106-554, § 1(a)(6), 114 Stat. 2763; Dec. 27, 2001, P.L. 107-105, § 3(a), 115 Stat. 1006; Dec. 8, 2003, P.L. 108-173, Title I, § 101(a)(1), Title III, §§ 301(a)-(c), 303(i)(3)(B), Title VI, Subtitle B, §§ 611(d)(1), 612(c), 613(c), Title VII, Subtitle D, § 731(a)(1), (b)(1), Title IX, § 900(e)(1)(J), Subtitle E, §§ 944(a)(1), 948(a), 950(a), 117 Stat. 2071, 2221, 2254, 2304, 2305, 2306, 2349, 2351, 2372, 2422, 2425, 2426.)

(As amended Feb. 8, 2006, P.L. 109-171, Title V, Subtitle B, Ch. 2, § 5112(d), 120 Stat. 44; Dec. 29, 2007, P.L. 110-173, Title I, § 111(a), 121 Stat. 2497; July 15, 2008, P.L. 110-275, Title I, Subtitle A, Part I, § 101(a)(3), (b)(3), (4), Subtitle C, Part I, § 135(a)(2)(A), Part II, §§ 143(b)(7), 152(b)(1)(D), 153(b)(2), 122 Stat. 2497, 2498, 2535, 2543, 2552, 2555.)

§ 1395z. Consultation with State agencies and other organizations to develop conditions of participation for providers of services

In carrying out his functions, relating to determination of conditions of participation by providers of services, under subsections (e)(9), (f)(4), (j)(15), (o)(6), (cc)(2)(I), [and] (dd)(2) and (mm)(1) of section 1861 [*42 USCS § 1395x(e)(9)*, (f)(4), (o)(6), (cc)(2)(I), (dd)(2), and (mm)(1)], or by ambulatory surgical centers under section 1832(a)(2)(F)(i) [*42 USCS § 1395k(a)(2)(F)(i)*], the Secretary shall consult with appropriate State agencies and recognized national listing or accrediting bodies, and may consult with appropriate local agencies. Such conditions prescribed under any of such subsections may be varied for different areas or different classes of institutions or agencies and may, at the request of a State, provide higher requirements for such State than for other States; except that, in the case of any State or political subdivision of a State which imposes higher requirements on institutions as a condition to the purchase of services (or of certain specified services) in such institutions under a State plan approved under title I, XVI, or XIX, [*42 USCS §§ 301* et seq., *1381* et seq. or *1396* et seq.] the Secretary shall impose like requirements as a condition to the payment for services (or for the services specified by the State or subdivision) in such institutions in such State or subdivision.

HISTORY:

(Aug. 14, 1935, ch 581, Title XVIII, Part E[D][C], § 1863, as added July 30, 1965, P.L. 89-97, Title I, Part 1, § 102(a), 79 Stat. 325; Oct. 30, 1972, P.L. 92-603, Title II, § 234(g)(2), 86 Stat. 1413; Dec. 5, 1980, P.L. 96-499, Title IX, Part B, Subpart I, §§ 933(f), 934(c)(1), 94 Stat. 2636, 2639; Sept. 3, 1982, P.L. 97-248, Title I, Subtitle A, Part II, § 122(g)(2), 96 Stat. 362; July 18, 1984, P.L. 98-369, Division B, Title III, Subtitle A, Part II, §§ 2335(c), 2349(b)(1), 2354(b)(32), 98 Stat. 1090, 1097, 1102; July 1, 1988, P.L. 100-360, Title II, Subtitle A, §§ 203(e)(2), 204(c)(1), 102 Stat. 725, 728; Dec. 13, 1989, P.L. 101-234, Title II, § 201(a)(1), 103 Stat. 1981; Dec. 19, 1989, P.L. 101-239, Title VI, Subtitle A, Part 1, Subpart A, § 6003(g)(3)(C)(ii), 103 Stat. 2152; Nov. 5, 1990, P.L. 101-508, Title IV, Subtitle A, Part 2, Subpart B, § 4163(c)(1), 104 Stat. 1388-99; Oct. 31, 1994, P.L. 103-432, Title I, Subtitle B, Part III, § 145(c)(2), 108 Stat. 4427; Aug. 5, 1997, P.L. 105-33, Title IV, Subtitle A, Chapter 1, Subchapter A, § 4001, 111 Stat. 275; Dec. 8, 2003, P.L. 108-173, Title I, § 101(a)(1), 117 Stat. 2071.)

§ 1395aa. Agreements with States

(a) Use of State agencies to determine compliance by providers of services with conditions of participation. The Secretary shall make an agreement with any State which is able and willing to do so under which the services of the State health agency or other appropriate State agency (or the appropriate local agencies) will be utilized by him for the purpose of determining whether an institution therein is a hospital or skilled nursing facility, or whether an agency therein is a home health agency, or whether an agency is a hospice program or whether a facility therein is a rural health clinic as defined in section 1861(aa)(2) [*42 USCS § 1395x(aa)(2)*], a critical access hospital, as defined in section 1861(mm)(1) [*42 USCS § 1395x(mm)(1)*], or a comprehensive outpatient rehabilitation facility as defined in section 1861(cc)(2) [*42 USCS § 1395x(cc)(2)*], or whether a laboratory meets the requirements of paragraphs (16) and (17) of section 1861(s) [*42 USCS § 1395x(s)(16)* and (17)], or whether a clinic, rehabilitation agency or public health agency

meets the requirements of subparagraph (A) or (B), as the case may be, of section 1861(p)(4) [*42 USCS § 1395x(p)(4)(A)* or (B)], or whether an ambulatory surgical center meets the standards specified under section 1832(a)(2)(F)(i) [*42 USCS § 1395k(a)(2)(F)(i)*]. To the extent that the Secretary finds it appropriate, an institution or agency which such a State (or local) agency certifies is a hospital, skilled nursing facility, rural health clinic, comprehensive outpatient rehabilitation facility, home health agency, or hospice program (as those terms are defined in section 1861 [*42 USCS § 1395x*]) may be treated as such by the Secretary. Any State agency which has such an agreement may (subject to approval of the Secretary) furnish to a skilled nursing facility, after proper request by such facility, such specialized consultative services (which such agency is able and willing to furnish in a manner satisfactory to the Secretary) as such facility may need to meet one or more of the conditions specified in section 1819(a) [*42 USCS § 1395i-3(a)*]. Any such services furnished by a State agency shall be deemed to have been furnished pursuant to such agreement. Within 90 days following the completion of each survey of any health care facility, ambulatory surgical center, rural health clinic, comprehensive outpatient rehabilitation facility, laboratory, clinic, agency, or organization by the appropriate State or local agency described in the first sentence of this subsection, the Secretary shall make public in readily available form and place, and require (in the case of skilled nursing facilities) the posting in a place readily accessible to patients (and patients' representatives), the pertinent findings of each such survey relating to the compliance of each such health care facility, ambulatory surgical center, rural health clinic, comprehensive outpatient rehabilitation facility, laboratory, clinic, agency, or organization with (1) the statutory conditions of participation imposed under this *title [42 USCS §§ 1395* et seq.] and (2) the major additional conditions which the Secretary finds necessary in the interest of health and safety of individuals who are furnished care or services by any such health care facility, laboratory, clinic, agency, or organization. Any agreement under this subsection shall provide for the appropriate State or local agency to maintain a toll-free hotline (1) to collect, maintain, and continually update information on home health agencies located in the State or locality that are certified to participate in the program established under this *title [42 USCS §§ 1395* et seq.] (which information shall include any significant deficiencies found with respect to patient care in the most recent certification survey conducted by a State agency or accreditation survey conducted by a private accreditation agency under section 1865 [*42 USCS § 1395bb*] with respect to the home health agency, when that survey was completed, whether corrective actions have been taken or are planned, and the sanctions, if any, imposed under this *title [42 USCS §§ 1395* et seq.] with respect to the agency) and (2) to receive complaints (and answer questions) with respect to home health agencies in the State or locality. Any such agreement shall provide for such State or local agency to maintain a unit for investigating such complaints that possesses enforcement authority and has access to survey and certification reports, information gathered by any private accreditation agency utilized by the Secretary under section 1865 [*42 USCS § 1395bb*], and consumer medical records (but only with the consent of the consumer or his or her legal representative).

(b) Payment in advance or by way of reimbursement to State for performance of functions of subsection (a). The Secretary shall pay any such State, in advance or by way of reimbursement, as may be provided in the agreement with it (and may make adjustments in such payments on account of overpayments or underpayments previously made), for the reasonable cost of performing the functions specified in subsection (a), and for the Federal Hospital Insurance Trust Fund's fair share of the costs attributable to the planning and other efforts directed toward coordination of activities in carrying out its agreement and other activities related to the provision of services similar to those for which payment may be made under part A [*42 USCS §§ 1395c* et seq.], or related to the facilities and personnel required for the provision of such services, or related to improving the quality of such services.

(c) Use of State or local agencies to survey hospitals [Caution: For provisions applicable to accreditations of hospitals granted before July 15, 2010, see 2008 amendment note below.]. The Secretary is authorized to enter into an agreement with any State under which the appropriate State or local agency which performs the certification function described in subsection (a) will survey, on a selective sample basis (or where the Secretary finds that a survey is appropriate because of substantial allegations of the existence of a significant deficiency or deficiencies which would, if found to be present, adversely affect health and safety of patients), provider entities that, pursuant to section 1865(a)(1) [*42 USCS § 1395bb(a)(1)*], are treated as meeting the conditions or requirements of this *title [42 USCS §§ 1395* et seq.]. The Secretary shall pay for such services in the manner prescribed in subsection (b).

(d) Fulfillment of requirements by State. The Secretary may not enter an agreement under this section with a State with respect to determining whether an institution therein is a skilled nursing facility unless the State meets the requirements specified in section 1819(e) and section 1819(g) [*42 USCS § 1395i-3(e)* and (g)] and the establishment of remedies under sections 1819(h)(2)(B) and 1819(h)(2)(C) [*42 USCS § 1395i-3(h)(2)(B)* and (h)(2)(C)] (relating to establishment and application of remedies).

(e) Prohibition of user fees for survey and certification. Notwithstanding any other provision of law, the Secretary may not impose, or require a State to impose, any fee on any facility or entity subject to a determination under subsection (a), or any renal dialysis facility subject to the requirements of section 1881(b)(1) [*42 USCS § 1395rr(b)(1)*], for any such determination or any survey relating to determining the compliance of such facility or entity with any requirement of this *title [42 USCS §§ 1395* et seq.] (other than any fee relating to section 353 of the Public Health Service Act [*42 USCS § 263a*]).

HISTORY:

(Aug. 14, 1935, ch 531, Title XVIII, Part E[D][C], § 1864, as added July 30, 1965, P.L. 89-97, Title I, Part 1, § 102(a), 79 Stat. 326; Jan. 2, 1968, P.L. 90-248, Title I, Part 3, § 133(f), Title II, Part 2, § 228(b), 81 Stat. 852, 904; Oct. 30, 1972, P.L. 92-603, Title II, §§ 244(a), 277, 278(a)(16), (b)(15), 299D(a), 86 Stat. 1422, 1452-1454, 1461; Dec. 13, 1977, P.L. 95-210, § 1(i), 91 Stat. 1488; Dec. 5, 1980, P.L. 96-499, Title IX, Part B, Subpart I, §§ 933(g), 934(c)(2), 94 Stat. 2637, 2639; Dec. 28, 1980, P.L. 96-611, § 1(a)(2), 94 Stat. 3566; Sept. 3, 1982, P.L. 97-248, Title I, Subtitle A, Part II, § 122(g)(3), 96 Stat. 362; July 18, 1984, P.L. 98-369, Division B, Title III, Subtitle A, Part II, § 2354(b)(17), 98 Stat. 1101; Oct. 21, 1986, P.L. 99-509, Title IX, Subtitle D, Part 2, § 9320(h)(3), 100 Stat. 2105; Dec. 22, 1987, P.L. 100-203, Title IV, Subtitle A, Part 2, Subpart B, § 4025(a), Subtitle C, Part 1, §§ 4201(a)(2), (d)(4), 4202(a)(1), (c)(1), 4203(a)(1), 4212(b), 101 Stat. 1330-160, 1330-74, 1330-179, 1330-212; July 1, 1988, P.L. 100-360, Title II, Subtitle A, §§ 203(e)(3) 204(c)(2), (d)(3), Title IV, Subtitle B, § 411(d)(4)(A), (l)(1)(C), 102 Stat. 725, 728, 729, 774; Oct. 13, 1988, P.L. 100-485, Title VI, § 608(d)(20)(B), (C), (27)(B), 102 Stat. 2419, 2422; Dec. 13, 1989, P.L. 101-234, Title II, § 201(a)(1), 103 Stat. 1981; Dec. 19, 1989, P.L. 101-239, Title VI, Subtitle A, Part 1, Subpart A, § 6003(g)(3)(C)(iii), Part 2, Subpart A, § 6115(c), 103 Stat. 2152, 2219; Nov. 5, 1990, P.L. 101-508, Title IV, Subtitle A, Part 2, Subpart B, §§ 4154(d)(1), 4163(c)(2), 4207(g), 104 Stat. 1388-85, 1388-100, 1388-123; Nov. 5, 1990, P.L. 101-508, Title IV, Subtitle A, Part 2, Subpart B, §§ 4154(d)(1), 4163(c)(2), 4207(g), 104 Stat. 1388-85, 1388-100, 1388-123; Oct. 31, 1994, P.L. 103-432, Title I, Subtitle B, Part III, § 145(c)(3), Subtitle C, § 160(a)(1), (d)(4), 108 Stat. 4427, 4443, 4444; April 26, 1996, P.L. 104-134, Title I [Title V, § 516(c)(1)], 110 Stat. 1321-247; May 2, 1996, P.L. 104-140, § 1(a), 110 Stat. 1327; Aug. 5, 1997, P.L. 105-33, Title IV, Subtitle A, Chapter 1, Subchapter A, § 4001, Subtitle B, § 4106(c), Subtitle C, § 4201(c)(1), 111 Stat. 275, 368, 373; Dec. 8, 2003, P.L. 108-173, Title I, § 101(a)(1), 117 Stat. 2071; July 15, 2008, P.L. 110-275, Title I, Subtitle B, § 125(b)(3), 122 Stat. 2519.)

§ 1395bb. Effect of accreditation [Caution: For provisions applicable to accreditations of hospitals granted before July 15, 2010, see 2008 amendment note below.]

(a) Accreditation by American Osteopathic Association or other national accreditation body.

(1) If the Secretary finds that accreditation of a provider entity (as defined in paragraph (4)) by the American Osteopathic Association or any other national accreditation body demonstrates that all of the applicable conditions or requirements of this *title [42 USCS §§ 1395* et seq.] (other than the requirements of section 1834(j) [*42 USCS § 1395m(j)*] or the conditions and requirements under section 1881(b) [*42 USCS § 1395rr(b)*]) are met or exceeded--

(A) in the case of a provider entity not described in paragraph (3)(B), the Secretary shall treat such entity as meeting those conditions or requirements with respect to which the Secretary made such finding; or

(B) in the case of a provider entity described in paragraph (3)(B), the Secretary may treat such entity as meeting those conditions or requirements with respect to which the Secretary made such finding.

(2) In making such a finding, the Secretary shall consider, among other factors with respect to a national accreditation body, its requirements for accreditation, its survey procedures, its ability to provide adequate resources for conducting required surveys and supplying information for use in enforcement activities, its monitoring procedures for provider entities found out of compliance with the conditions or requirements, and its ability to provide the Secretary with necessary data for validation.

(3) (A) Except as provided in subparagraph (B), not later than 60 days after the date of receipt of a written request for a finding under paragraph (1) (with any documentation necessary to make a determination on the request), the Secretary shall publish a notice identifying the national accreditation body making the request, describing the nature of the request, and providing a period of at least 30 days for the public to comment on the request. The Secretary shall approve or deny a request for such a finding, and shall publish notice of such approval or denial, not later than 210 days after the date of receipt of the request (with such documentation). Such an approval shall be effective with respect to accreditation determinations made on or after such effective date (which may not be later than the date of publication of the approval) as the Secretary specifies in the publication notice.

(B) The 210-day and 60-day deadlines specified in subparagraph (A) shall not apply in the case of any request for a finding with respect to accreditation of a provider entity to which the conditions and requirements of sections 1819 and 1861(j) [*42 USCS §§ 1395i-3, 1395x(j)*] apply.

(4) For purposes of this section, the term "provider entity" means a provider of services, supplier, facility, clinic, agency, or laboratory.

(b) Disclosure of accreditation survey. The Secretary may not disclose any accreditation survey (other than a survey with respect to a home health agency) made and released to the Secretary by the American Osteopathic Association or any other national accreditation body, of an entity accredited by such body, except that the Secretary may disclose such a survey and information related to such a survey to the extent such survey and information relate to an enforcement action taken by the Secretary.

(c) Deficiencies. Notwithstanding any other provision of this *title [42 USCS §§ 1395* et seq.], if the Secretary finds that a provider entity has significant deficiencies (as defined in regulations pertaining to health and safety), the entity shall, after the date of notice of such finding to the entity and for such period as may be prescribed in regulations, be deemed not to meet the conditions or requirements the entity has been treated as meeting pursuant to subsection (a)(1).

(d) State or local accreditation. For provisions relating to validation surveys of entities that are treated as meeting applicable conditions or requirements of this *title [42 USCS §§ 1395* et seq.] pursuant to subsection (a)(1), see section 1864(c) [*42 USCS § 1395aa(c)*].

(e) [Redesignated]

HISTORY:

(Aug. 14, 1935, ch 531, Title XVIII, Part E[D][C], § 1865, as added July 30, 1965, P.L. 89-97, Title I, Part 1, § 102(a), 79 Stat. 326; Oct. 30, 1972, P.L. 92-603, Title II, §§ 234(h), 244(b), 86 Stat. 1413, 1423; Sept. 3, 1982, P.L. 97-248, Title I, Subtitle A, Part II, § 122(g)(4), Part III, § 128(d)(3), 96 Stat. 362, 367; July 18, 1984, P.L. 98-369, Division B, Title III, Subtitle A, Part II, §§ 2345(a), 2346(a), 98 Stat. 1096; Oct. 21, 1986, P.L. 99-509, Title IX, Subtitle D, Part 1, § 9305(c)(3), Part 2, § 9320(h)(3), 100 Stat. 1989, 1990; Dec. 22, 1987, P.L. 100-203, Title IV, Subtitle A, Part 3, Subpart C, § 4072(d), 101 Stat. 1330-117; July 1, 1988, P.L. 100-360, Title II, Subtitle A, § 204(c)(3), (d)(3), Title IV, Subtitle B, § 411(d)(B)(ii), 102 Stat. 728, 774; Oct. 13, 1988, P.L. 100-485, Title VI, § 608(d)(20)(D), 102 Stat. 2420; Dec. 13, 1989, P.L. 101-234, Title II, § 201(a)(1), 103 Stat. 1981; Dec. 19, 1989, P.L. 101-239, Title VI, Subtitle A, Part 1, Subpart A, § 6003(g)(3)(C)(iv), Subpart B, § 6019(a)-(c), Part 2, Subpart A, § 6115(c), 103 Stat. 2153, 2165, 2219; Nov. 5, 1990, P.L. 101-508, Title IV, Subtitle A, Part 2, Subpart B, § 4163(c)(3), 104 Stat. 1388-100; Oct. 31, 1994, P.L. 103-432, Title I, Subtitle B, Part III, § 145(c)(4), 108 Stat. 4427; April 26, 1996, P.L. 104-134, Title I [Title V, § 516(b), (c)(2)], 110 Stat. 1321-246, 247; May 2, 1996, P.L. 104-140, § 1(a), 110 Stat. 1327; Aug. 5, 1997, P.L. 105-33, Title IV, Subtitle A, Chapter 1, Subchapter A, § 4001, 111 Stat. 275; Dec. 8, 2003, P.L. 108-173, Title I, § 101(a)(1), Title VII, Subtitle D, § 736(a)(12), 117 Stat. 2071, 2355; July 15, 2008, P.L. 110-275, Title I, Subtitle B, § 125(a), (b)(1), 122 Stat. 2519.)

§ 1395cc. Agreements with providers of services; enrollment processes

(a) Filing of agreements; eligibility for payment; charges with respect to items and services.

(1) Any provider of services (except a fund designated for purposes of section 1814(g) and section 1835(e) [*42 USCS §§ 1395f(g)* and *1395n(e)*]) shall be qualified to participate under this *title [42 USCS §§ 1395* et seq.] and shall be eligible for payments under this *title [42 USCS §§ 1395* et seq.] if it files with the Secretary an agreement--

(A) (i) not to charge, except as provided in paragraph (2), any individual or any other person for items or services for which such individual is entitled to have payment made under this *title [42 USCS §§ 1395* et seq.] (or for which he would be so entitled if such provider of services had complied with the procedural and other requirements under or pursuant to this *title [42 USCS §§ 1395* et seq.] or for which such provider is paid pursuant to the provisions of section 1814(e) [*42 USCS § 1395f(e)*]), and (ii) not to impose any charge that is prohibited under section 1902(n)(3) [*42 USCS § 1396a(n)(3)*],

(B) not to charge any individual or any other person for items or services for which such individual is not entitled to have payment made under this *title [42 USCS §§ 1395* et seq.] because payment for expenses incurred for such items or services may not be made by reason of the provisions of paragraph (1) or (9) of section 1862(a) [*42 USCS § 1395y(a)(1)* or (9)] but only if (i) such individual was without fault in incurring such expenses and (ii) the Secretary's determination that such payment may not be made for such items and services was made after the third year following the year in which notice of such payment was sent to such individual; except that the Secretary may reduce such three-year period to not less than one year if he finds such reduction is consistent with the objectives of this *title [42 USCS §§ 1395* et seq.],

(C) to make adequate provision for return (or other disposition, in accordance with regulations) of any moneys incorrectly collected from such individual or other person,

(D) to promptly notify the Secretary of its employment of an individual who, at any time during the year preceding such employment, was employed in a managerial, accounting, auditing, or similar capacity (as determined by the Secretary by regulation) by an agency or organization which serves as a fiscal intermediary or carrier (for purposes of part A or part B, or both, of this *title [42 USCS §§ 1395c* et seq. or *1395j* et seq.]) with respect to the provider,

(E) to release data with respect to patients of such provider upon request to an organization having a contract with the Secretary under part B of title XI [*42 USCS §§ 1320c* et seq.] as may be necessary (i) to allow such organization to carry out its functions under such contract, or (ii) to allow such organization to carry out similar review functions under any contract the organization may have with a private or public agency paying for health care in the same area with respect to patients who authorize release of such data for such purposes,

(F) (i) in the case of hospitals which provide hospital services for which payment may be made under subsection (b), (c), or (d) of section 1886 [*42 USCS § 1395ww(b)*, (c), or (d)], to maintain an agreement with a professional standards review organization (if there is such an organization in existence in the area in which the hospital is located) or with a utilization and quality control peer review organization which has a contract with the Secretary under part B of title XI [*42 USCS §§ 1320c* et seq.] for the area in which the hospital is located, under which the organization will perform functions under that part [*42 USCS §§ 1320c* et seq.] with respect to the review of the validity of diagnostic information provided by such hospital, the completeness, adequacy, and quality of care provided, the appropriateness of admissions and discharges, and the appropriateness of care provided for which additional payments are sought under section 1886(d)(5) [*42 USCS § 1395ww(d)(5)*], with respect to inpatient hospital services for which payment may be made under part A of this *title [42 USCS §§ 1395c* et seq.] (and for purposes of payment under this *title [42 USCS §§ 1395* et seq.], the cost of such agreement to the hospital shall be considered a cost incurred by such hospital in providing inpatient services under part A [*42 USCS §§ 1395c* et seq.], and (I) shall be paid directly by the Secretary to such organization on behalf of such hospital in accordance with a rate per review established by the Secretary, (II) shall be transferred from the Federal Hospital Insurance Trust Fund, without regard to amounts appropriated in advance in appropriation Acts, in the same manner as transfers are made for payment for services provided directly to beneficiaries, and (III) shall not be less in the aggregate for a fiscal year than the aggregate amount expended in fiscal year 1988 for direct and administrative costs (adjusted for inflation and for any direct or administrative costs incurred as a result of review functions added with respect to a subsequent fiscal year) of such reviews),

(ii) in the case of hospitals, critical access hospitals, skilled nursing facilities, and home health agencies, to maintain an agreement with a utilization and quality control peer review organization (which has a contract with the Secretary under part B of title XI [*42 USCS §§ 1320c* et seq.] for the area in which the hospital, facility, or agency is located) to perform the functions described in paragraph (3)(A),

(G) in the case of hospitals which provide inpatient hospital services for which payment may be made under subsection (b) or (d) of section 1886 [*42 USCS § 1395ww(b)* or (d)], not to charge any individual or any other person for inpatient hospital services for which such individual would be entitled to have payment made under part A [*42 USCS §§ 1395c* et seq.] but for a denial or reduction of payments under section 1886(f)(2) [*42 USCS § 1395ww(f)(2)*],

(H) (i) in the case of hospitals which provide services for which payment may be made under this *title [42 USCS §§ 1395* et seq.] and in the case of critical access hospitals which provide critical access hospital services, to have all items and services (other than physicians' services as defined in regulations for purposes of section 1862(a)(14) [*42 USCS § 1395y(a)(14)*], and other than services described by section 1861(s)(2)(K) [*42 USCS § 1395x(s)(2)(K)*], certified nurse-midwife services, qualified psychologist services, and services of a certified registered nurse anesthetist) (I) that are furnished to an individual who is a patient of the hospital, and (II) for which the individual is entitled to have payment made under this *title [42 USCS §§ 1395* et seq.], furnished by the hospital or otherwise under arrangements (as defined in section 1861(w)(1) [*42 USCS § 1395x(w)(1)*]) made by the hospital,

(ii) in the case of skilled nursing facilities which provide covered skilled nursing facility services--

(I) that are furnished to an individual who is a resident of the skilled nursing facility during a period in which the resident is provided covered post-hospital extended care services (or, for services described in section 1861(s)(2)(D) [*42 USCS § 1395x(s)(2)(D)*], that are furnished to such an individual without regard to such period), and

(II) for which the individual is entitled to have payment made under this *title [42 USCS §§ 1395* et seq.],

to have items and services (other than services described in section 1888(e)(2)(A)(ii) [*42 USCS § 1395yy(e)(2)(A)(ii)*]) furnished by the skilled nursing facility or otherwise under arrangements (as defined in section 1861(w)(1) [*42 USCS § 1395x(w)(1)*]) made by the skilled nursing facility,

(I) in the case of a hospital or critical access hospital--

(i) to adopt and enforce a policy to ensure compliance with the requirements of section 1867 [*42 USCS § 1395dd*] and to meet the requirements of such section,

(ii) to maintain medical and other records related to individuals transferred to or from the hospital for a period of five years from the date of the transfer, and

(iii) to maintain a list of physicians who are on call for duty after the initial examination to provide treatment necessary to stabilize an individual with an emergency medical condition,

(J) in the case of hospitals which provide inpatient hospital services for which payment may be made under this *title [42 USCS §§ 1395* et seq.], to be a participating provider of medical care under any health plan contracted for under section 1079 or 1086 of title 10, or under section 613 [1713] of title 38, United States Code, in accordance with admission practices, payment methodology, and amounts as prescribed under joint regulations issued by the Secretary and by the Secretaries of Defense and Transportation, in implementation of sections 1079 and 1086 of title 10, United States Code,

(K) not to charge any individual or any other person for items or services for which payment under this *title [42 USCS §§ 1395* et seq.] is denied under section 1154(a)(2) [*42 USCS § 1320c-3(a)(2)*] by reason of a determination under section 1154(a)(1)(B) [*42 USCS § 1320c-3(a)(1)(B)*],

(L) in the case of hospitals which provide inpatient hospital services for which payment may be made under this *title [42 USCS §§ 1395* et seq.], to be a participating provider of medical care under section 603 [1703] of title 38, United States Code, in accordance with such admission practices, and such payment methodology and amounts, as are prescribed under joint regulations issued by the Secretary and by the Secretary of Veterans Affairs in implementation of such section,

(M) in the case of hospitals, to provide to each individual who is entitled to benefits under part A [*42 USCS §§ 1395c* et seq.] (or to a person acting on the individual's behalf), at or about the time of the individual's admission as an inpatient to the hospital, a written statement (containing such language as the Secretary prescribes consistent with this paragraph) which explains--

(i) the individual's rights to benefits for inpatient hospital services and for post-hospital services under this *title [42 USCS §§ 1395* et seq.],

(ii) the circumstances under which such an individual will and will not be liable for charges for continued stay in the hospital,

(iii) the individual's right to appeal denials of benefits for continued inpatient hospital services, including the practical steps to initiate such an appeal, and

(iv) the individual's liability for payment for services if such a denial of benefits is upheld on appeal,

and which provides such additional information as the Secretary may specify,

(N) in the case of hospitals and critical access hospitals--

(i) to make available to its patients the directory or directories of participating physicians (published under section 1842(h)(4) [*42 USCS § 1395u(h)(4)*]) for the area served by the hospital or critical access hospital,

(ii) if hospital personnel (including staff of any emergency or outpatient department) refer a patient to a nonparticipating physician for further medical care on an outpatient basis, the personnel must inform the patient that the physician is a nonparticipating physician and, whenever practicable, must identify at least one qualified participating physician who is listed in such a directory and from whom the patient may receive the necessary services,

(iii) to post conspicuously in any emergency department a sign (in a form specified by the Secretary) specifying rights of individuals under section 1867 [*42 USCS § 1395dd*] with respect to examination and treatment for emergency medical conditions and women in labor, and

(iv) to post conspicuously (in a form specified by the Secretary) information indicating whether or not the hospital participates in the medicaid program under a State plan approved under title XIX [*42 USCS §§ 1396* et seq.],

(O) to accept as payment in full for services that are covered under this *title [42 USCS §§ 1395* et seq.] and are furnished to any individual enrolled with a Medicare + Choice organization under part C [*42 USCS §§ 1395w-21* et seq.], with a PACE provider under section 1894 or 1934 [*42 USCS § 1395eee* or *1396u-4*], or with an eligible organization with a risk-sharing contract under section 1876 [*42 USCS § 1395mm*], under section 1876(i)(2)(A) [*42 USCS § 1395mm(i)(2)(A)*] (as in effect before February 1, 1985), under section 402(a) of the Social Security Amendments of 1967 [*42 USCS § 1395b-1*], or under section 222(a) of the Social Security Amendments of 1972, which does not have a contract (or, in the case of a PACE provider, contract or other agreement) establishing payment amounts for services furnished to members of the organization or PACE program eligible individuals enrolled with the PACE provider, the amounts that would be made as a payment in full under this *title [42 USCS §§ 1395* et seq.] (less any payments under sections 1886(d)(11) and 1886(h)(3)(D) [*42 USCS §§ 1395ww(d)(11)* and (h)(3)(D)]) if the individuals were not so enrolled,

(P) in the case of home health agencies which provide home health services to individuals entitled to benefits under this *title [42 USCS §§ 1395* et seq.] who require catheters, catheter supplies, ostomy bags, and supplies related to ostomy care (described in section 1861(m)(5) [*42 USCS § 1395x(m)(5)*]), to offer to furnish such supplies to such an individual as part of their furnishing of home health services,

(Q) in the case of hospitals, skilled nursing facilities, home health agencies, and hospice programs, to comply with the requirement of subsection (f) (relating to maintaining written policies and procedures respecting advance directives),

(R) to contract only with a health care clearinghouse (as defined in section 1171 [*42 USCS § 1320d*]) that meets each standard and implementation specification adopted or established under part C of title XI [*42 USCS §§ 1320d* et seq.] on or after the date on which the health care clearinghouse is required to comply with the standard or specification,

(S) **[Caution: This subparagraph takes effect on such date, on or after issuance of implementing regulations, as the Secretary specifies in such regulations, as provided by § 4321(d)(2) of Act Aug. 5, 1997, P.L. 105-33, which appears as a note to *42 USCS § 1320b-16*.]** in the case of a hospital that has a financial interest (as specified by the Secretary in regulations) in an entity to which individuals are referred as described in section 1861(ee)(2)(H)(ii) [*42 USCS § 1395x(ee)(2)*], or in which such an entity has such a financial interest, or in which another entity has such a financial interest (directly or indirectly) with such hospital and such an entity, to maintain and disclose to the Secretary (in a form and manner specified by the Secretary) information on--

(i) the nature of such financial interest,

(ii) the number of individuals who were discharged from the hospital and who were identified as requiring home health services, and

(iii) the percentage of such individuals who received such services from such provider (or another such provider),

(T) in the case of hospitals and critical access hospitals, to furnish to the Secretary such data as the Secretary determines appropriate pursuant to subparagraph (E) of section 1886(d)(12) [*42 USCS § 1395ww(d)(12)*] to carry out such section,

(U) in the case of hospitals which furnish inpatient hospital services for which payment may be made under this *title [42 USCS §§ 1395* et seq.], to be a participating provider of medical care both--

(i) under the contract health services program funded by the Indian Health Service and operated by the Indian Health Service, an Indian tribe, or tribal organization (as those terms are defined in section 4 of the Indian Health Care Improvement Act [*25 USCS § 1603*]), with respect to items and services that are covered under such program and furnished to an individual eligible for such items and services under such program; and

(ii) under any program funded by the Indian Health Service and operated by an urban Indian organization with respect to the purchase of items and services for an eligible urban Indian (as those terms are defined in such section 4),

in accordance with regulations promulgated by the Secretary regarding admission practices, payment methodology, and rates of payment (including the acceptance of no more than such payment rate as payment in full for such items and services, and

(V) in the case of hospitals that are not otherwise subject to the Occupational Safety and Health Act of 1970 (or a State occupational safety and health plan that is approved under 18(b) of such Act [*29 USCS § 667(b)*]), to comply with the Bloodborne Pathogens standard under *section 1910.1030 of title 29 of the Code of Federal R*egulations (or as subsequently redesignated).

In the case of a hospital which has an agreement in effect with an organization described in subparagraph (F), which organization's contract with the Secretary under part B of title XI [*42 USCS §§ 1320c* et seq.] is terminated on or after October 1, 1984, the hospital shall not be determined to be out of compliance with the requirement of such subparagraph during the six month period beginning on the date of the termination of that contract.

(2)

(A) A provider of services may charge such individual or other person (i) the amount of any deduction or coinsurance amount imposed pursuant to section 1813(a)(1), (a)(3), or (a)(4), section 1833(b), or section 1861(y)(3) [*42 USCS §§ 1395e(a)(1)*, (3), or (4), 1395l(b), or 1395x(y)(3)] with respect to such items and services (not in excess of the amount customarily charged for such items and services by such provider), and (ii) an amount equal to 20 per centum of the reasonable charges for such items and services (not in excess of 20 per centum of the amount customarily charged for such items and services by such provider) for which payment is made under part B [*42 USCS §§ 1395j* et seq.] or which are durable medical equipment furnished as home health services (but in the case of items and services furnished to individuals with end-stage renal disease, an amount equal to 20 percent of the estimated amounts for such items and services calculated on the basis established by the Secretary). In the case of items and services described in section 1833(c) [*42 USCS § 1395l(c)*], clause (ii) of the preceding sentence shall be applied by substituting for 20 percent the proportion which is appropriate under such section [*42 USCS § 1395l*]. A provider of services may not impose a charge under clause (ii) of the first sentence of this subparagraph with respect to items and services described in section 1861(s)(10)(A) [*42 USCS § 1395x(s)(10)(A)*] and with respect to clinical diagnostic laboratory tests for which payment is made under part B [*42 USCS §§ 1395j* et seq.]. Notwithstanding the first sentence of this subparagraph, a home health agency may charge such an individual or person, with respect to covered items subject to payment under section 1834(a) [*42 USCS § 1395m(a)*], the amount of any deduction imposed under section 1833(b) [*42 USCS § 1395l(b)*] and 20 percent of the payment basis described in section 1834(a)(1)(B) [*42 USCS § 1395m(a)(1)(B)*]. In the case of items and services for which payment is made under part B [*42 USCS §§ 1395j* et seq.] under the prospective payment system

established under section 1833(t) [*42 USCS § 1395l(t)*], clause (ii) of the first sentence shall be applied by substituting for 20 percent of the reasonable charge, the applicable copayment amount established under section 1833(t)(5) [*42 USCS § 1395l(t)(5)*]. In the case of services described in section 1833(a)(8) or section 1833(a)(9) [*42 USCS § 1395l(a)(8)* or (9)] for which payment is made under part B [*42 USCS §§ 1395j* et seq.] under section 1834(k) [*42 USCS § 1395m(k)*], clause (ii) of the first sentence shall be applied by substituting for 20 percent of the reasonable charge for such services 20 percent of the lesser of the actual charge or the applicable fee schedule amount (as defined in such section) for such services.

(B) Where a provider of services has furnished, at the request of such individual, items or services which are in excess of or more expensive than the items or services with respect to which payment may be made under this *title [42 USCS §§ 1395* et seq.], such provider of services may also charge such individual or other person for such more expensive items or services to the extent that the amount customarily charged by it for the items or services furnished at such request exceeds the amount customarily charged by it for the items or services with respect to which payment may be made under this *title [42 USCS §§ 1395* et seq.].

(C) A provider of services may in accordance with its customary practice also appropriately charge any such individual for any whole blood (or equivalent quantities of packed red blood cells, as defined under regulations) furnished him with respect to which a deductible is imposed under section 1813(a)(2) [*42 USCS § 1395e(a)(2)*], except that (i) any excess of such charge over the cost to such provider for the blood (or equivalent quantities of packed red blood cells, as so defined) shall be deducted from any payment to such provider under this *title [42 USCS §§ 1395* et seq.], (ii) no such charge may be imposed for the cost of administration of such blood (or equivalent quantities of packed red blood cells, as so defined), and (iii) such charge may not be made to the extent such blood (or equivalent quantities of packed red blood cells, as so defined) has been replaced on behalf of such individual or arrangements have been made for its replacement on his behalf. For purposes of subparagraph (C), whole blood (or equivalent quantities of packed red blood cells, as so defined) furnished an individual shall be deemed replaced when the provider of services is given one pint of blood for each pint of blood (or equivalent quantities of packed red blood cells, as so defined) furnished such individual with respect to which a deduction is imposed under section 1813(a)(2) [*42 USCS § 1395e(a)(2)*].

(D) Where a provider of services customarily furnishes items or services which are in excess of or more expensive than the items or services with respect to which payment may be made under this *title [42 USCS §§ 1395* et seq.], such provider, notwithstanding the preceding provisions of this paragraph, may not, under the authority of section 1866(a)(2)(B)(ii) [subsec. (a)(2)(B)(ii) of this section], charge any individual or other person any amount for such items or services in excess of the amount of the payment which may otherwise be made for such items or services under this *title [42 USCS §§ 1395* et seq.] if the admitting physician has a direct or indirect financial interest in such provider.

(3) (A) Under the agreement required under paragraph (1)(F)(ii), the peer review organization must perform functions (other than those covered under an agreement under paragraph (1)(F)(i)) under the third sentence of section 1154(a)(4)(A) [*42 USCS § 1320c-3(a)(4)(A)*] and under section 1154(a)(14) [*42 USCS § 1320c-3(a)(14)*] with respect to services, furnished by the hospital, critical access hospital, facility, or agency involved, for which payment may be made under this *title [42 USCS §§ 1395* et seq.].

(B) For purposes of payment under this *title [42 USCS §§ 1395* et seq.], the cost of such an agreement to the hospital, critical access hospital, facility, or agency shall be considered a cost incurred by such hospital, critical access hospital, facility, or agency in providing covered services under this *title [42 USCS §§ 1395* et seq.] and shall be paid directly by the Secretary to the peer review organization on behalf of such hospital, facility, or agency in accordance with a schedule established by the Secretary.

(C) Such payments--

(i) shall be transferred in appropriate proportions from the Federal Hospital Insurance Trust Fund and from the Federal Supplementary Medical Insurance Trust Fund, without regard to amounts appropriated in advance in appropriation Acts, in the same manner as transfers are made for payment for services provided directly to beneficiaries, and

(ii) shall not be less in the aggregate for a fiscal year--

(I) in the case of hospitals, than the amount specified in paragraph (1)(F)(i)(III), and

(II) in the case of facilities, critical access hospitals, and agencies, than the amounts the Secretary determines to be sufficient to cover the costs of such organizations' conducting the activities described in subparagraph (A) with respect to such facilities, critical access hospitals, or agencies under part B of title XI [*42 USCS § 1320c* et seq.].

(b) Termination or nonrenewal of agreements.

(1) A provider of services may terminate an agreement with the Secretary under this section at such time and upon such notice to the Secretary and the public as may be provided in regulations, except that notice of more than six months shall not be required.

(2) The Secretary may refuse to enter into an agreement under this section or, upon such reasonable notice to the provider and the public as may be specified in regulations, may refuse to renew or may terminate such an agreement after the Secretary--

(A) has determined that the provider fails to comply substantially with the provisions of the agreement, with the provisions of this *title [42 USCS §§ 1395* et seq.] and regulations thereunder, or with a corrective action required under section 1886(f)(2)(B) [*42 USCS § 1395ww(f)(2)(B)*],

(B) has determined that the provider fails substantially to meet the applicable provisions of section 1861 [*42 USCS § 1395x*],

(C) has excluded the provider from participation in a program under this *title [42 USCS §§ 1395* et seq.] pursuant to section 1128 or section 1128A [*42 USCS § 1320a-7* or *1320a-7a*], or

(D) has ascertained that the provider has been convicted of a felony under Federal or State law for an offense which the Secretary determines is detrimental to the best interests of the program or program beneficiaries.

(3) A termination of an agreement or a refusal to renew an agreement under this subsection shall become effective on the same date and in the same manner as an exclusion from participation under the programs under this *title [42 USCS §§ 1395* et seq.] becomes effective under section 1128(c) [*42 USCS § 1320a-7(c)*].

(4) (A) A hospital that fails to comply with the requirement of subsection (a)(1)(V) (relating to the Bloodborne Pathogens standard) is subject to a civil money penalty in an amount described in subparagraph (B), but is not subject to termination of an agreement under this section.

(B) The amount referred to in subparagraph (A) is an amount that is similar to the amount of civil penalties that may be imposed under section 17 of the Occupational Safety and Health Act of 1970 [*29 USCS § 666*] for a violation of the Bloodborne Pathogens standard referred to in subsection (a)(1)(U) by a hospital that is subject to the provisions of such Act.

(C) A civil money penalty under this paragraph shall be imposed and collected in the same manner as civil money penalties under subsection (a) of section 1128A [*42 USCS § 1320a-7a*] are imposed and collected under that section.

(c) Refiling after termination or nonrenewal; agreements with skilled nursing facilities.

(1) Where the Secretary has terminated or has refused to renew an agreement under this *title [42 USCS §§ 1395* et seq.] with a provider of services, such provider may not file another agreement under this *title [42 USCS §§ 1395* et seq.] unless the Secretary finds that the reason for the termination or nonrenewal has been removed and that there is reasonable assurance that it will not recur.

(2) Where an agreement filed under this *title [42 USCS §§ 1395* et seq.] by a provider of services has been terminated by the Secretary, the Secretary shall promptly notify each State agency which administers or supervises the administration of a State plan approved under title XIX [*42 USCS §§ 1396* et seq.] of such termination.

(d) Decision to withhold payment for failure to review long-stay cases. If the Secretary finds that there is a substantial failure to make timely review in accordance with section 1861(k) [*42 USCS § 1395x(k)*] of long-stay cases in a hospital, he may, in lieu of terminating his agreement with such hospital, decide that, with respect to any individual admitted to such hospital after a subsequent date specified by him, no payment shall be made under this *title [42 USCS §§ 1395* et seq.] for inpatient hospital services (including inpatient psychiatric hospital services) after the 20th day of a continuous period of such services. Such decision may be made effective only after such notice to the hospital and to the public, as may be prescribed by regulations, and its effectiveness shall terminate when the Secretary finds that the reason therefor has been removed and that there is reasonable assurance that it will not recur. The Secretary shall not make any such decision except after reasonable notice and opportunity for hearing to the institution or agency affected thereby.

(e) "Provider of services" defined. For purposes of this section, the term "provider of services" shall include--

(1) **[Caution: For provisions applicable to services furnished before July 1, 2009, see 2008 amendment note below.]** a clinic, rehabilitation agency, or public health agency if, in the case of a clinic or rehabilitation agency, such clinic or agency meets the requirements of section 1861(p)(4)(A) [*42 USCS § 1395x(p)(4)(A)*] (or meets the requirements of such section through the operation of subsection (g) or (ll)(2) of section 1861 [*42 USCS § 1395x*]), or if, in the case of a public health agency, such agency meets the requirements of section 1861(p)(4)(B) [*42 USCS § 1395x(p)(4)(B)*] (or meets the requirements of such section through the operation of subsection (g) or (ll)(2) of section 1861 [*42 USCS § 1395x*]), but only with respect to the furnishing of outpatient physical therapy services (as therein defined), (through the operation of section 1861(g) [*42 USCS § 1395x(g)*]) with respect to the furnishing of outpatient occupational therapy services, or (through the operation of section 1861(ll)(2) [*42 USCS § 1395x(ll)(2)*]) with respect to the furnishing of outpatient speech-language pathology; and

(2) a community mental health center (as defined in section 1861(ff)(3)(B) [*42 USCS § 1395x(ff)(3)(B)*]), but only with respect to the furnishing of partial hospitalization services (as described in section 1861(ff)(1) [*42 USCS § 1395x(ff)(1)*]).

(f) Maintenance of written policies and procedures.

(1) For purposes of subsection (a)(1)(Q) and sections 1819(c)(2)(E), 1833(s), 1855(i), 1876(c)(8), and 1891(a)(6) [*42 USCS §§ 1395i-3(c)(2)(E), 1395l(s), 1395w-25(i), 1395mm(c)(8)*, and *1395bbb(a)(6)*], the requirement of this subsection is that a provider of services, Medicare + Choice organization, or prepaid or eligible organization (as the case may be) maintain written policies and procedures with respect to all adult individuals receiving medical care by or through the provider or organization--

(A) to provide written information to each such individual concerning--

(i) an individual's rights under State law (whether statutory or as recognized by the courts of the State) to make decisions concerning such medical care, including the right to accept or refuse medical or surgical treatment and the right to formulate advance directives (as defined in paragraph (3)), and

(ii) the written policies of the provider or organization respecting the implementation of such rights;

(B) to document in a prominent part of the individual's current medical record whether or not the individual has executed an advance directive;

(C) not to condition the provision of care or otherwise discriminate against an individual based on whether or not the individual has executed an advance directive;

(D) to ensure compliance with requirements of State law (whether statutory or as recognized by the courts of the State) respecting advance directives at facilities of the provider or organization; and

(E) to provide (individually or with others) for education for staff and the community on issues concerning advance directives.

Subparagraph (C) shall not be construed as requiring the provision of care which conflicts with an advance directive.

(2) The written information described in paragraph (1)(A) shall be provided to an adult individual--

(A) in the case of a hospital, at the time of the individual's admission as an inpatient,

(B) in the case of a skilled nursing facility, at the time of the individual's admission as a resident,

(C) in the case of a home health agency, in advance of the individual coming under the care of the agency,

(D) in the case of a hospice program, at the time of initial receipt of hospice care by the individual from the program, and

(E) in the case of an eligible organization (as defined in section 1876(b) [*42 USCS § 1395mm(b)*]) or an organization provided payments under section 1833(a)(1)(A) [*42 USCS § 1395l(a)(1)(A)*] or a Medicare + Choice organization, at the time of enrollment of the individual with the organization.

(3) In this subsection, the term "advance directive" means a written instruction, such as a living will or durable power of attorney for health care, recognized under State law (whether statutory or as recognized by the courts of the State) and relating to the provision of such care when the individual is incapacitated.

(4) For construction relating to this subsection, see section 7 of the Assisted Suicide Funding Restriction Act of 1997 [*42 USCS § 14406*] (relating to clarification respecting assisted suicide, euthanasia, and mercy killing).

(g) Penalties for improper billing. Except as permitted under subsection (a)(2), any person who knowingly and willfully presents, or causes to be presented, a bill or request for payment inconsistent with an arrangement under subsection (a)(1)(H) or in violation of the requirement for such an arrangement, is subject to a civil money penalty of not to exceed $ 2,000. The provisions of section 1128A [*42 USCS § 1320a-7a*] (other than subsections (a) and (b)) shall apply to a civil money penalty under the previous sentence in the same manner as such provisions apply to a penalty or proceeding under section 1128A(a) [*42 USCS § 1320a-7a(a)*].

(h) Dissatisfaction with determination of Secretary; appeal by institutions or agencies; single notice and hearing.

(1) (A) Except as provided in paragraph (2), an institution or agency dissatisfied with a determination by the Secretary that it is not a provider of services or with a determination described in subsection (b)(2) shall be entitled to a hearing thereon by the Secretary (after reasonable notice) to the same extent as is provided in section 205(b) [*42 USCS § 405(b)*], and to judicial review of the Secretary's final decision after such hearing as is provided in section 205(g) [*42 USCS § 405(g)*], except that, in so applying such sections and in applying section 205(l) [*42 USCS § 405(l)*] thereto, any reference therein to the Commissioner of Social Security or the Social Security Administration shall be considered a reference to the Secretary or the Department of Health and Human Services, respectively.

(B) An institution or agency described in subparagraph (A) that has filed for a hearing under subparagraph (A) shall have expedited access to judicial review under this subparagraph in the same manner as providers of services, suppliers, and individuals entitled to benefits under part A [*42 USCS §§ 1395c* et seq.] or enrolled under part B [*42 USCS §§ 1395j*

et seq.], or both, may obtain expedited access to judicial review under the process established under section 1869(b)(2) [*42 USCS § 1395r(b)(2)*]. Nothing in this subparagraph shall be construed to affect the application of any remedy imposed under section 1819 [*42 USCS § 1395i-3*] during the pendency of an appeal under this subparagraph.

(C) (i) The Secretary shall develop and implement a process to expedite proceedings under this subsection in which--

(I) the remedy of termination of participation has been imposed;

(II) a remedy described in clause (i) or (iii) of section 1819(h)(2)(B) [*42 USCS § 1395i-3(h)(2)(B)*] has been imposed, but only if such remedy has been imposed on an immediate basis; or

(III) a determination has been made as to a finding of substandard quality of care that results in the loss of approval of a skilled nursing facility's nurse aide training program.

(ii) Under such process under clause (i), priority shall be provided in cases of termination described in clause (i)(I).

(iii) Nothing in this subparagraph shall be construed to affect the application of any remedy imposed under section 1819 [*42 USCS § 1395i-3*] during the pendency of an appeal under this subparagraph.

(2) An institution or agency is not entitled to separate notice and opportunity for a hearing under both section 1128 [*42 USCS § 1320a-7*] and this section with respect to a determination or determinations based on the same underlying facts and issues.

(i) Intermediate sanctions for psychiatric hospitals.

(1) If the Secretary determines that a psychiatric hospital which has an agreement in effect under this section no longer meets the requirements for a psychiatric hospital under this *title [42 USCS §§ 1395* et seq.] and further finds that the hospital's deficiencies--

(A) immediately jeopardize the health and safety of its patients, the Secretary shall terminate such agreement; or

(B) do not immediately jeopardize the health and safety of its patients, the Secretary may terminate such agreement, or provide that no payment will be made under this *title [42 USCS §§ 1395* et seq.] with respect to any individual admitted to such hospital after the effective date of the finding, or both.

(2) If a psychiatric hospital, found to have deficiencies described in paragraph (1)(B), has not complied with the requirements of this title--

(A) within 3 months after the date the hospital is found to be out of compliance with such requirements, the Secretary shall provide that no payment will be made under this *title [42 USCS §§ 1395* et seq.] with respect to any individual admitted to such hospital after the end of such 3-month period, or

(B) within 6 months after the date the hospital is found to be out of compliance with such requirements, no payment may be made under this title with respect to any individual in the hospital until the Secretary finds that the hospital is in compliance with the requirements of this *title [42 USCS §§ 1395* et seq.].

(j) Enrollment process for providers of services and suppliers.

(1) Enrollment process.

(A) In general. The Secretary shall establish by regulation a process for the enrollment of providers of services and suppliers under this *title [42 USCS §§ 1395* et seq..

(B) Deadlines. The Secretary shall establish by regulation procedures under which there are deadlines for actions on applications for enrollment (and, if applicable, renewal of enrollment). The Secretary shall monitor the performance of medicare administrative contractors in meeting the deadlines established under this subparagraph.

(C) Consultation before changing provider enrollment forms. The Secretary shall consult with providers of services and suppliers before making changes in the provider enrollment forms required of such providers and suppliers to be eligible to submit claims for which payment may be made under this *title [42 USCS §§ 1395* et seq..

(2) Hearing rights in cases of denial or non-renewal. A provider of services or supplier whose application to enroll (or, if applicable, to renew enrollment) under this title is denied may have a hearing and judicial review of such denial under the procedures that apply under subsection (h)(1)(A) to a provider of services that is dissatisfied with a determination by the Secretary.

HISTORY:

(Aug. 14, 1935, ch 531, Title XVIII, Part E[D][C], § 1866, as added July 30, 1965, P.L. 89-97, Title I, Part 1, § 102(a), 79 Stat. 327; Jan. 2, 1968, P.L. 90-248, Title I, Part 3, §§ 129(c)(12), 133(c), 135(b), 81 Stat. 849, 851, 852; Oct. 30, 1972, P.L. 92-603, Title II, §§ 223(e), (g), 227(d)(2), 229(b), 249A(b)-(d), 278(a)(17), (b)(18), 281(c), 86 Stat. 1394, 1406, 1409, 1427, 1453-1455; Oct. 25, 1977, P.L. 95-142, §§ 3(b), 8(b), 13(b)(3), 15(a), 91 Stat. 1178, 1194, 1198, 1200; Dec. 13, 1977, P.L. 95-210, § 2(e), 91 Stat. 1489; June 13, 1978, P.L. 95-292, § 4(e), 92 Stat. 315; June 17, 1980, P.L. 96-272, Title III, § 308(b), 94 Stat. 531; Dec. 5, 1980, P.L. 96-499, Title IX, Part A, Subpart II, § 916(a), 94 Stat. 2623; Dec. 28, 1980, P.L. 96-611, § 1(b)(4), 94 Stat. 3566; Aug. 13, 1981, P.L. 97-35, Title XXI, Subtitle B, Ch 4, §

2153, 95 Stat. 802; Sept. 3, 1982, P.L. 97-248, Title I, Subtitle A, Part II, § 122(g)(5), (6), Part II, § 128(a)(5), (d)(4), Subtitle C, § 144, 96 Stat. 362, 366, 367, 393; Jan. 12, 1983, P.L. 97-448, Title III, § 309(a)(5), (b)(11), 96 Stat. 2408, 2409; April 20, 1983, P.L. 98-21, Title VI, § 602(f), (l)(2), 97 Stat. 163, 166; July 18, 1984, P.L. 98-369, Division B, Title III, Subtitle A, Part I, §§ 2303(f), 2315(d), 2321(c), 2323(b)(3), Part II, §§ 2335(d), 2347(a), 2348(a), 2354(b)(33), (34), 98 Stat. 1066, 1080, 1084, 1086, 1090, 1096, 1097, 1102; April 7, 1986, P.L. 99-272, Title IX, Subtitle A, Part 1, Subpart B, §§ 9121(a), 9122(a), Part 4, §§ 9401(b)(2)(F), 9402(a), 9403(b), 100 Stat. 164, 167, 199, 200; Oct. 21, 1986, P.L. 99-509, Title IX, Subtitle D, Part 1, § 9305(b)(1), Part 2, § 9320(h)(2), Part 3, §§ 9332(e)(1), 9337(c)(2) in part, 9343(c)(2), (3), Part 4, § 9353(e)(1), 100 Stat. 1989, 2015, 2024, 2033, 2039, 2046; Oct. 22, 1986, P.L. 99-514, Title XVIII, Subtitle C, Ch 1, § 1855(b)(5), 100 Stat. 2933; Oct. 28, 1986, P.L. 99-576, Title II, Part D, § 233(a), 100 Stat. 3265; Aug. 18, 1987, P.L. 100-93, § 8(d), 101 Stat. 693; Dec. 22, 1987, P.L. 100-203, Title IV, Subtitle A, Part 2, Subpart A, § 4012(a), Part 3, Subpart B, § 4062(d)(4), Subpart D, § 4085(i)(17), Part 4, § 4097(a), (b), Title IV, Subtitle C, Part 2, § 4212(e)(4), 101 Stat. 1330-60, 1330-109, 1330-133, 1330-140, 1330-213; July 1 1988, P.L. 100-360, Title I, Subtitle A, § 104(d)(5), Title II, §§ 201(b), 202(h)(1), Title IV, Subtitle B, § 411(c)(2)(A)(i), (C), (g)(1)(D), (i)(4)(C)(vi), (j)(5), 102 Stat. 689, 702, 718, 772, 782, 790, 791; Oct. 13, 1988, P.L. 100-485, Title VI, § 608(d)(3)(F), (19)(A), (f)(1), 102 Stat. 2414, 2419, 2424; Dec. 13, 1989, P.L. 101-234, Title I, § 101(a)(1), Title II, § 201(a)(1), Title III, § 301(b)(4), (1), 103 Stat. 1979, 1981, 1985, 1986; Dec. 19, 1989, P.L. 101-239, Title VI, Subtitle A, Part 1, Subpart A, § 6003(g)(3)(D)(xii), (xiii), Subpart B, §§ 6017, 6018(a), 6020, Part 2, Subpart A, § 6112(e)(3), 103 Stat. 2154, 2165, 2166, 2216; Nov. 5, 1990, P.L. 101-508, Title IV, Subtitle A, Part 1, § 4008(b)(3)(B), (m)(3) [(F)](G), Part 2, Subpart B, §§ 4153(d)(1), 4157(c)(2), 4162(b)(2), Part 3, § 4206(a), 104 Stat. 1388-44, 1388-54, 1388-84, 1388-89, 1388-96, 1388-115; June 13, 1991, P.L. 102-54, § 13(q)(3)(F), 105 Stat. 280; Aug. 15, 1994, P.L. 103-296, Title I, § 108(c)(5), 108 Stat. 1485; Oct. 31, 1994, P.L. 103-432, Title I, Subtitle A, § 106(b)(1)(B), Subtitle B, § 147(e)(7), Subtitle C, § 156(a)(2)(E), 160(d)(2), 108 Stat. 4406, 4430, 4441, 4443; Aug. 21, 1996, P.L. 104-191, Title II, Subtitle F, § 262(b)(1), 110 Stat. 2031; April 30, 1997, P.L. 105-12, § 9(a)(2), 111 Stat. 26; Aug. 5, 1997, P.L. 105-33, Title IV, Subtitle A, Ch 1, Subch A, §§ 4001, 4002(d), (e), Subtitle C, § 4201(c)(1), Subtitle D, Ch 1, § 4302(a), Ch 2, § 4321(b), Subtitle E, Ch 3, § 4432(b)(5)(F), Ch 4, § 4541(a)(3), Subtitle F, Ch 1, Subch B, § 4511(a)(2)(D), Ch 2, § 4523(b), Subtitle G, Ch 4, § 4641(a), Subtitle H, Ch 2, § 4714(b)(1), 111 Stat. 275, 329, 373, 382, 395, 422, 442, 449, 456, 487, 510; Nov. 29, 1999, P.L. 106-113, Div B, § 1000(a)(6), 113 Stat. 1536; Dec. 21, 2000, P.L. 106-554, § 1(a)(6), 114 Stat. 2763; Dec. 8, 2003, P.L. 108-173, Title I, § 101(a)(1), Title II, Subtitle D, § 236(a)(1), Title V, Subtitle A, § 505(b), 506(a), Title VII, Subtitle D, § 736(a)(13), Title IX, Subtitle D, §§ 932(b), (c)(1), 936(a), 947(a), 117 Stat. 2071, 2210, 2294, 2355, 2400, 2411, 2425; July 15, 2008, P.L. 110-275, Title I, Subtitle C, Part II, § 143(b)(8), 122 Stat. 2543.)

§ 1395cc-1. Demonstration of application of physician volume increases to group practices

(a) Demonstration program authorized.

(1) In general. The Secretary shall conduct demonstration projects to test and, if proven effective, expand the use of incentives to health care groups participating in the program under this *title [42 USCS §§ 1395* et seq.] that--

(A) encourage coordination of the care furnished to individuals under the programs under parts A and B [*42 USCS §§ 1395c* et seq. and *1395j* et seq.] by institutional and other providers, practitioners, and suppliers of health care items and services;

(B) encourage investment in administrative structures and processes to ensure efficient service delivery; and

(C) reward physicians for improving health outcomes.

Such projects shall focus on the efficiencies of furnishing health care in a group-practice setting as compared to the efficiencies of furnishing health care in other health care delivery systems.

(2) Administration by contract. Except as otherwise specifically provided, the Secretary may administer the program under this section in accordance with section 1866B [*42 USCS § 1395cc-2*].

(3) Definitions. For purposes of this section, terms have the following meanings:

(A) Physician. Except as the Secretary may otherwise provide, the term "physician" means any individual who furnishes services which may be paid for as physicians' services under this *title [42 USCS §§ 1395* et seq.].

(B) Health care group. The term "health care group" means a group of physicians (as defined in subparagraph (A)) organized at least in part for the purpose of providing physicians' services under this *title [42 USCS §§ 1395* et seq.]. As the Secretary finds appropriate, a health care group may include a hospital and any other individual or entity furnishing items or services for which payment may be made under this *title [42 USCS §§ 1395* et seq.] that is affiliated with the health care group under an arrangement structured so that such individual or entity participates in a demonstration under this section and will share in any bonus earned under subsection (d).

(b) Eligibility criteria.

(1) In general. The Secretary is authorized to establish criteria for health care groups eligible to participate in a demonstration under this section, including criteria relating to numbers of health care professionals in, and of patients served by, the group, scope of services provided, and quality of care.

(2) Payment method. A health care group participating in the demonstration under this section shall agree with respect to services furnished to beneficiaries within the scope of the demonstration (as determined under subsection (c))--

(A) to be paid on a fee-for-service basis; and

(B) that payment with respect to all such services furnished by members of the health care group to such beneficiaries shall (where determined appropriate by the Secretary) be made to a single entity.

(3) Data reporting. A health care group participating in a demonstration under this section shall report to the Secretary such data, at such times and in such format as the Secretary requires, for purposes of monitoring and evaluation of the demonstration under this section.

(c) Patients within scope of demonstration.

(1) In general. The Secretary shall specify, in accordance with this subsection, the criteria for identifying those patients of a health care group who shall be considered within the scope of the demonstration under this section for purposes of application of subsection (d) and for assessment of the effectiveness of the group in achieving the objectives of this section.

(2) Other criteria. The Secretary may establish additional criteria for inclusion of beneficiaries within a demonstration under this section, which may include frequency of contact with physicians in the group or other factors or criteria that the Secretary finds to be appropriate.

(3) Notice requirements. In the case of each beneficiary determined to be within the scope of a demonstration under this section with respect to a specific health care group, the Secretary shall ensure that such beneficiary is notified of the incentives, and of any waivers of coverage or payment rules, applicable to such group under such demonstration.

(d) Incentives.

(1) Performance target. The Secretary shall establish for each health care group participating in a demonstration under this section--

(A) a base expenditure amount, equal to the average total payments under parts A and B [*42 USCS §§ 1395c* et seq. and *1395j* et seq.] for patients served by the health care group on a fee-for-service basis in a base period determined by the Secretary; and

(B) an annual per capita expenditure target for patients determined to be within the scope of the demonstration, reflecting the base expenditure amount adjusted for risk and expected growth rates.

(2) Incentive bonus. The Secretary shall pay to each participating health care group (subject to paragraph (4)) a bonus for each year under the demonstration equal to a portion of the medicare savings realized for such year relative to the performance target.

(3) Additional bonus for process and outcome improvements. At such time as the Secretary has established appropriate criteria based on evidence the Secretary determines to be sufficient, the Secretary shall also pay to a participating health care group (subject to paragraph (4)) an additional bonus for a year, equal to such portion as the Secretary may designate of the saving to the program under this *title [42 USCS §§ 1395* et seq.] resulting from process improvements made by and patient outcome improvements attributable to activities of the group.

(4) Limitation. The Secretary shall limit bonus payments under this section as necessary to ensure that the aggregate expenditures under this *title [42 USCS §§ 1395* et seq.] (inclusive of bonus payments) with respect to patients within the scope of the demonstration do not exceed the amount which the Secretary estimates would be expended if the demonstration projects under this section were not implemented.

HISTORY:

(Aug. 14, 1935, ch 531, Title XVIII, Part E[D], § 1866A, as added Dec. 21, 2000, P.L. 106-554, § 1(a)(6), 114 Stat. 2763; Dec. 8, 2003, P.L. 108-173, Title I, § 101(a)(1), 117 Stat. 2071.)

§ 1395cc-2. Provisions for administration of demonstration program

(a) General administrative authority.

(1) Beneficiary eligibility. Except as otherwise provided by the Secretary, an individual shall only be eligible to receive benefits under the program under section 1866A [*42 USCS § 1395cc-1*] (in this section referred to as the "demonstration program") if such individual--

(A) is enrolled under the program under part B [*42 USCS §§ 1395j* et seq.] and entitled to benefits under part A [*42 USCS §§ 1395c* et seq.]; and

(B) is not enrolled in a Medicare + Choice plan under part C [*42 USCS §§ 1395w-21* et seq.], an eligible organization under a contract under section 1876 [*42 USCS § 1395mm*] (or a similar organization operating under a demonstration project authority), an organization with an agreement under section 1833(a)(1)(A) [*42 USCS § 1395l(a)(1)(A)*], or a PACE program under section 1894 [*42 USCS § 1395eee*].

(2) Secretary's discretion as to scope of program. The Secretary may limit the implementation of the demonstration program to--

(A) a geographic area (or areas) that the Secretary designates for purposes of the program, based upon such criteria as the Secretary finds appropriate;

(B) a subgroup (or subgroups) of beneficiaries or individuals and entities furnishing items or services (otherwise eligible to participate in the program), selected on the basis of the number of such participants that the Secretary finds consistent with the effective and efficient implementation of the program;

(C) an element (or elements) of the program that the Secretary determines to be suitable for implementation; or

(D) any combination of any of the limits described in subparagraphs (A) through (C).

(3) Voluntary receipt of items and services. Items and services shall be furnished to an individual under the demonstration program only at the individual's election.

(4) Agreements. The Secretary is authorized to enter into agreements with individuals and entities to furnish health care items and services to beneficiaries under the demonstration program.

(5) Program standards and criteria. The Secretary shall establish performance standards for the demonstration program including, as applicable, standards for quality of health care items and services, cost-effectiveness, beneficiary satisfaction, and such other factors as the Secretary finds appropriate. The eligibility of individuals or entities for the initial award, continuation, and renewal of agreements to provide health care items and services under the program shall be conditioned, at a minimum, on performance that meets or exceeds such standards.

(6) Administrative review of decisions affecting individuals and entities furnishing services. An individual or entity furnishing services under the demonstration program shall be entitled to a review by the program administrator (or, if the Secretary has not contracted with a program administrator, by the Secretary) of a decision not to enter into, or to terminate, or not to renew, an agreement with the entity to provide health care items or services under the program.

(7) Secretary's review of marketing materials. An agreement with an individual or entity furnishing services under the demonstration program shall require the individual or entity to guarantee that it will not distribute materials that market items or services under the program without the Secretary's prior review and approval.

(8) Payment in full.

(A) In general. Except as provided in subparagraph (B), an individual or entity receiving payment from the Secretary under a contract or agreement under the demonstration program shall agree to accept such payment as payment in full, and such payment shall be in lieu of any payments to which the individual or entity would otherwise be entitled under this *title [42 USCS §§ 1395* et seq.].

(B) Collection of deductibles and coinsurance. Such individual or entity may collect any applicable deductible or coinsurance amount from a beneficiary.

(b) Contracts for program administration.

(1) In general. The Secretary may administer the demonstration program through a contract with a program administrator in accordance with the provisions of this subsection.

(2) Scope of program administrator contracts. The Secretary may enter into such contracts for a limited geographic area, or on a regional or national basis.

(3) Eligible contractors. The Secretary may contract for the administration of the program with--

(A) an entity that, under a contract under section 1816 or 1842 [*42 USCS § 1395h* or *1395u*], determines the amount of and makes payments for health care items and services furnished under this *title [42 USCS §§ 1395* et seq.]; or

(B) any other entity with substantial experience in managing the type of program concerned.

(4) Contract award, duration, and renewal.

(A) In general. A contract under this subsection shall be for an initial term of up to three years, renewable for additional terms of up to three years.

(B) Noncompetitive award and renewal for entities administering part A or part B [*42 USCS §§ 1395c* et seq. or *1395j* et seq.] payments. The Secretary may enter or renew a contract under this subsection with an entity described in paragraph (3)(A) without regard to the requirements of *section 5 of title 41, United States Code.*

(5) Applicability of Federal Acquisition Regulation. The Federal Acquisition Regulation shall apply to program administration contracts under this subsection.

(6) Performance standards. The Secretary shall establish performance standards for the program administrator including, as applicable, standards for the quality and cost-effectiveness of the program administered, and such other factors as the Secretary finds appropriate. The eligibility of entities for the initial award, continuation, and renewal of

program administration contracts shall be conditioned, at a minimum, on performance that meets or exceeds such standards.

(7) Functions of program administrator. A program administrator shall perform any or all of the following functions, as specified by the Secretary:

(A) Agreements with entities furnishing health care items and services. Determine the qualifications of entities seeking to enter or renew agreements to provide services under the demonstration program, and as appropriate enter or renew (or refuse to enter or renew) such agreements on behalf of the Secretary.

(B) Establishment of payment rates. Negotiate or otherwise establish, subject to the Secretary's approval, payment rates for covered health care items and services.

(C) Payment of claims or fees. Administer payments for health care items or services furnished under the program.

(D) Payment of bonuses. Using such guidelines as the Secretary shall establish, and subject to the approval of the Secretary, make bonus payments as described in subsection (c)(2)(B) to entities furnishing items or services for which payment may be made under the program.

(E) Oversight. Monitor the compliance of individuals and entities with agreements under the program with the conditions of participation.

(F) Administrative review. Conduct reviews of adverse determinations specified in subsection (a)(6).

(G) Review of marketing materials. Conduct a review of marketing materials proposed by an entity furnishing services under the program.

(H) Additional functions. Perform such other functions as the Secretary may specify.

(8) Limitation of liability. The provisions of section 1157(b) [*42 USCS § 1320c-6(b)*] shall apply with respect to activities of contractors and their officers, employees, and agents under a contract under this subsection.

(9) Information sharing. Notwithstanding section 1106 [*42 USCS § 1306*] and *section 552a of title 5, United States Code*, the Secretary is authorized to disclose to an entity with a program administration contract under this subsection such information (including medical information) on individuals receiving health care items and services under the program as the entity may require to carry out its responsibilities under the contract.

(c) Rules applicable to both program agreements and program administration contracts.

(1) Records, reports, and audits. The Secretary is authorized to require entities with agreements to provide health care items or services under the demonstration program, and entities with program administration contracts under subsection (b), to maintain adequate records, to afford the Secretary access to such records (including for audit purposes), and to furnish such reports and other materials (including audited financial statements and performance data) as the Secretary may require for purposes of implementation, oversight, and evaluation of the program and of individuals' and entities' effectiveness in performance of such agreements or contracts.

(2) Bonuses. Notwithstanding any other provision of law, but subject to subparagraph (B)(ii), the Secretary may make bonus payments under the demonstration program from the Federal Health Insurance Trust Fund and the Federal Supplementary Medical Insurance Trust Fund in amounts that do not exceed the amounts authorized under the program in accordance with the following:

(A) Payments to program administrators. The Secretary may make bonus payments under the program to program administrators.

(B) Payments to entities furnishing services.

(i) In general. Subject to clause (ii), the Secretary may make bonus payments to individuals or entities furnishing items or services for which payment may be made under the demonstration program, or may authorize the program administrator to make such bonus payments in accordance with such guidelines as the Secretary shall establish and subject to the Secretary's approval.

(ii) Limitations. The Secretary may condition such payments on the achievement of such standards related to efficiency, improvement in processes or outcomes of care, or such other factors as the Secretary determines to be appropriate.

(3) Antidiscrimination limitation. The Secretary shall not enter into an agreement with an entity to provide health care items or services under the demonstration program, or with an entity to administer the program, unless such entity guarantees that it will not deny, limit, or condition the coverage or provision of benefits under the program, for individuals eligible to be enrolled under such program, based on any health status-related factor described in section 2702(a)(1) of the Public Health Service Act [*42 USCS § 300gg-1(a)(1)*].

(d) Limitations on judicial review. The following actions and determinations with respect to the demonstration program shall not be subject to review by a judicial or administrative tribunal:

(1) Limiting the implementation of the program under subsection (a)(2).

(2) Establishment of program participation standards under subsection (a)(5) or the denial or termination of, or refusal to renew, an agreement with an entity to provide health care items and services under the program.

(3) Establishment of program administration contract performance standards under subsection (b)(6), the refusal to renew a program administration contract, or the noncompetitive award or renewal of a program administration contract under subsection (b)(4)(B).

(4) Establishment of payment rates, through negotiation or otherwise, under a program agreement or a program administration contract.

(5) A determination with respect to the program (where specifically authorized by the program authority or by subsection (c)(2))--

(A) as to whether cost savings have been achieved, and the amount of savings; or

(B) as to whether, to whom, and in what amounts bonuses will be paid.

(e) Application limited to parts A and B. None of the provisions of this section or of the demonstration program shall apply to the programs under part C [*42 USCS §§ 1395w-21* et seq.] [Medicare Advantage program].

(f) Reports to Congress. Not later than two years after the date of the enactment of this section [enacted Dec. 21, 2000], and biennially thereafter for six years, the Secretary shall report to Congress on the use of authorities under the demonstration program. Each report shall address the impact of the use of those authorities on expenditures, access, and quality under the programs under this *title [42 USCS §§ 1395* et seq.].

HISTORY:

(Aug. 14, 1935, ch 531, Title XVIII, Part E[D], § 1866B, as added Dec. 21, 2000, P.L. 106-554, § 1(a)(6), 114 Stat. 2763; Dec. 8, 2003, P.L. 108-173, Title I, § 101(a)(1), Title VII, Subtitle D, § 736(c)(5), 117 Stat. 2071, 2356.)

§ 1395cc-3. Health care quality demonstration program

(a) Definitions. In this section:

(1) Beneficiary. The term "beneficiary" means an individual who is entitled to benefits under part A [*42 USCS §§ 1395c* et seq.] and enrolled under part B [*42 USCS §§ 1395j* et seq.], including any individual who is enrolled in a Medicare Advantage plan under part C [*42 USCS §§ 1395w-21* et seq.].

(2) Health care group.

(A) In general. The term "health care group" means--

(i) a group of physicians that is organized at least in part for the purpose of providing physician's services under this *title [42 USCS §§ 1395* et seq.];

(ii) an integrated health care delivery system that delivers care through coordinated hospitals, clinics, home health agencies, ambulatory surgery centers, skilled nursing facilities, rehabilitation facilities and clinics, and employed, independent, or contracted physicians; or

(iii) an organization representing regional coalitions of groups or systems described in clause (i) or (ii).

(B) Inclusion. As the Secretary determines appropriate, a health care group may include a hospital or any other individual or entity furnishing items or services for which payment may be made under this *title [42 USCS §§ 1395* et seq.] that is affiliated with the health care group under an arrangement structured so that such hospital, individual, or entity participates in a demonstration project under this section.

(3) Physician. Except as otherwise provided for by the Secretary, the term "physician" means any individual who furnishes services that may be paid for as physicians' services under this *title [42 USCS §§ 1395* et seq.].

(b) Demonstration projects. The Secretary shall establish a 5-year demonstration program under which the Secretary shall approve demonstration projects that examine health delivery factors that encourage the delivery of improved quality in patient care, including--

(1) the provision of incentives to improve the safety of care provided to beneficiaries;

(2) the appropriate use of best practice guidelines by providers and services by beneficiaries;

(3) reduced scientific uncertainty in the delivery of care through the examination of variations in the utilization and allocation of services, and outcomes measurement and research;

(4) encourage shared decision making between providers and patients;

(5) the provision of incentives for improving the quality and safety of care and achieving the efficient allocation of resources;

(6) the appropriate use of culturally and ethnically sensitive health care delivery; and

(7) the financial effects on the health care marketplace of altering the incentives for care delivery and changing the allocation of resources.

(c) Administration by contract.

(1) In general. Except as otherwise provided in this section, the Secretary may administer the demonstration program established under this section in a manner that is similar to the manner in which the demonstration program established under section 1866A [*42 USCS § 1395cc-1*] is administered in accordance with section 1866B [*42 USCS § 1395cc-2*].

(2) Alternative payment systems. A health care group that receives assistance under this section may, with respect to the demonstration project to be carried out with such assistance, include proposals for the use of alternative payment systems for items and services provided to beneficiaries by the group that are designed to--

(A) encourage the delivery of high quality care while accomplishing the objectives described in subsection (b); and

(B) streamline documentation and reporting requirements otherwise required under this *title [42 USCS §§ 1395* et seq.].

(3) Benefits. A health care group that receives assistance under this section may, with respect to the demonstration project to be carried out with such assistance, include modifications to the package of benefits available under the original medicare fee-for-service program under parts A and B [*42 USCS §§ 1395c* et seq. and *1395j* et seq.] or the package of benefits available through a Medicare Advantage plan under part C [*42 USCS §§ 1395w-21* et seq.]. The criteria employed under the demonstration program under this section to evaluate outcomes and determine best practice guidelines and incentives shall not be used as a basis for the denial of medicare benefits under the demonstration program to patients against their wishes (or if the patient is incompetent, against the wishes of the patient's surrogate) on the basis of the patient's age or expected length of life or of the patient's present or predicted disability, degree of medical dependency, or quality of life.

(d) Eligibility criteria. To be eligible to receive assistance under this section, an entity shall--

(1) be a health care group;

(2) meet quality standards established by the Secretary, including--

(A) the implementation of continuous quality improvement mechanisms that are aimed at integrating community-based support services, primary care, and referral care;

(B) the implementation of activities to increase the delivery of effective care to beneficiaries;

(C) encouraging patient participation in preference-based decisions;

(D) the implementation of activities to encourage the coordination and integration of medical service delivery; and

(E) the implementation of activities to measure and document the financial impact on the health care marketplace of altering the incentives of health care delivery and changing the allocation of resources; and

(3) meet such other requirements as the Secretary may establish.

(e) Waiver authority. The Secretary may waive such requirements of titles XI and XVIII [*42 USCS §§ 1301* et seq. and *1395* et seq.] as may be necessary to carry out the purposes of the demonstration program established under this section.

(f) Budget neutrality. With respect to the 5-year period of the demonstration program under subsection (b), the aggregate expenditures under this *title [42 USCS §§ 1395* et seq.] for such period shall not exceed the aggregate expenditures that would have been expended under this *title [42 USCS §§ 1395* et seq.] if the program established under this section had not been implemented.

(g) Notice requirements. In the case of an individual that receives health care items or services under a demonstration program carried out under this section, the Secretary shall ensure that such individual is notified of any waivers of coverage or payment rules that are applicable to such individual under this *title [42 USCS §§ 1395* et seq.] as a result of the participation of the individual in such program.

(h) Participation and support by Federal agencies. In carrying out the demonstration program under this section, the Secretary may direct--

(1) the Director of the National Institutes of Health to expand the efforts of the Institutes to evaluate current medical technologies and improve the foundation for evidence-based practice;

(2) the Administrator of the Agency for Healthcare Research and Quality to, where possible and appropriate, use the program under this section as a laboratory for the study of quality improvement strategies and to evaluate, monitor, and disseminate information relevant to such program; and

(3) the Administrator of the Centers for Medicare & Medicaid Services and the Administrator of the Center for Medicare Choices to support linkages of relevant medicare data to registry information from participating health care

groups for the beneficiary populations served by the participating groups, for analysis supporting the purposes of the demonstration program, consistent with the applicable provisions of the Health Insurance Portability and Accountability Act of 1996.

HISTORY:

(Aug. 14, 1935, ch 531, Title XVIII, Part E, § 1866C, as added Dec. 8, 2003, P.L. 108-173, Title VI, Subtitle D, § 646, 117 Stat. 2324.)

§ 1395dd. Examination and treatment for emergency medical conditions and women in labor

(a) Medical screening requirement. In the case of a hospital that has a hospital emergency department, if any individual (whether or not eligible for benefits under this *title [42 USCS §§ 1395* et seq.]) comes to the emergency department and a request is made on the individual's behalf for examination or treatment for a medical condition, the hospital must provide for an appropriate medical screening examination within the capability of the hospital's emergency department, including ancillary services routinely available to the emergency department, to determine whether or not an emergency medical condition (within the meaning of subsection (e)(1)) exists.

(b) Necessary stabilizing treatment for emergency medical conditions and labor.

(1) In general. If any individual (whether or not eligible for benefits under this *title [42 USCS §§ 1395* et seq.]) comes to a hospital and the hospital determines that the individual has an emergency medical condition, the hospital must provide either--

(A) within the staff and facilities available at the hospital, for such further medical examination and such treatment as may be required to stabilize the medical condition, or

(B) for transfer of the individual to another medical facility in accordance with subsection (c).

(2) Refusal to consent to treatment. A hospital is deemed to meet the requirement of paragraph (1)(A) with respect to an individual if the hospital offers the individual the further medical examination and treatment described in that paragraph and informs the individual (or a person acting on the individual's behalf) of the risks and benefits to the individual of such examination and treatment, but the individual (or a person acting on the individual's behalf) refuses to consent to the examination and treatment. The hospital shall take all reasonable steps to secure the individual's (or person's) written informed consent to refuse such examination and treatment.

(3) Refusal to consent to transfer. A hospital is deemed to meet the requirement of paragraph (1) with respect to an individual if the hospital offers to transfer the individual to another medical facility in accordance with subsection (c) and informs the individual (or a person acting on the individual's behalf) of the risks and benefits to the individual of such transfer, but the individual (or a person acting on the individual's behalf) refuses to consent to the transfer. The hospital shall take all reasonable steps to secure the individual's (or person's) written informed consent to refuse such transfer.

(c) Restricting transfers until individual stabilized.

(1) Rule. If an individual at a hospital has an emergency medical condition which has not been stabilized (within the meaning of subsection (e)(3)(B)), the hospital may not transfer the individual unless--

(A) (i) the individual (or a legally responsible person acting on the individual's behalf) after being informed of the hospital's obligations under this section and of the risk of transfer, in writing requests transfer to another medical facility,

(ii) a physician (within the meaning of section 1861(r)(1) [*42 USCS § 1395x(r)(1)*]) has signed a certification that[,] based upon the information available at the time of transfer, the medical benefits reasonably expected from the provision of appropriate medical treatment at another medical facility outweigh the increased risks to the individual and, in the case of labor, to the unborn child from effecting the transfer, or

(iii) if a physician is not physically present in the emergency department at the time an individual is transferred, a qualified medical person (as defined by the Secretary in regulations) has signed a certification described in clause (ii) after a physician (as defined in section 1861(r)(1) [*42 USCS § 1395x(r)(1)*]), in consultation with the person, has made the determination described in such clause, and subsequently countersigns the certification; and

(B) the transfer is an appropriate transfer (within the meaning of paragraph (2)) to that facility.

A certification described in clause (ii) or (iii) of subparagraph (A) shall include a summary of the risks and benefits upon which the certification is based.

(2) Appropriate transfer. An appropriate transfer to a medical facility is a transfer--

(A) in which the transferring hospital provides the medical treatment within its capacity which minimizes the risks to the individual's health and, in the case of a woman in labor, the health of the unborn child;

(B) in which the receiving facility--

(i) has available space and qualified personnel for the treatment of the individual, and

(ii) has agreed to accept transfer of the individual and to provide appropriate medical treatment;

(C) in which the transferring hospital sends to the receiving facility with all medical records (or copies thereof), related to the emergency condition for which the individual has presented, available at the time of the transfer, including records related to the individual's emergency medical condition, observations of signs or symptoms, preliminary diagnosis, treatment provided, results of any tests and the informed written consent or certification (or copy thereof) provided under paragraph (1)(A), and the name and address of any on-call physician (described in subsection (d)(1)(C)) who has refused or failed to appear within a reasonable time to provide necessary stabilizing treatment;

(D) in which the transfer is effected through qualified personnel and transportation equipment, as required including the use of necessary and medically appropriate life support measures during the transfer; and

(E) which meets such other requirements as the Secretary may find necessary in the interest of the health and safety of individuals transferred.

(d) Enforcement.

(1) Civil monetary penalties.

(A) A participating hospital that negligently violates a requirement of this section is subject to a civil money penalty of not more than $ 50,000 (or not more than $ 25,000 in the case of a hospital with less than 100 beds) for each such violation. The provisions of section 1128A [*42 USCS § 1320a-7a*] (other than subsections (a) and (b)) shall apply to a civil money penalty under this subparagraph in the same manner as such provisions apply with respect to a penalty or proceeding under section 1128A(a) [*42 USCS § 1320a-7a(a)*].

(B) Subject to subparagraph (C), any physician who is responsible for the examination, treatment, or transfer of an individual in a participating hospital, including a physician on-call for the care of such an individual, and who negligently violates a requirement of this section, including a physician who--

(i) signs a certification under subsection (c)(1)(A) that the medical benefits reasonably to be expected from a transfer to another facility outweigh the risks associated with the transfer, if the physician knew or should have known that the benefits did not outweigh the risks, or

(ii) misrepresents an individual's condition or other information, including a hospital's obligations under this section,

is subject to a civil money penalty of not more than $ 50,000 for each such violation and, if the violation is gross and flagrant or is repeated, to exclusion from participation in this *title [42 USCS §§ 1395* et seq.] and State health care programs. The provisions of section 1128A [*42 USCS § 1320a-7a*] (other than the first and second sentences of subsection (a) and subsection (b)) shall apply to a civil money penalty and exclusion under this subparagraph in the same manner as such provisions apply with respect to a penalty, exclusion, or proceeding under section 1128A(a) [*42 USCS § 1320a-7a(a)*].

(C) If, after an initial examination, a physician determines that the individual requires the services of a physician listed by the hospital on its list of on-call physicians (required to be maintained under section 1866(a)(1)(I) [*42 USCS § 1395cc(a)(1)(I)*]) and notifies the on-call physician and the on-call physician fails or refuses to appear within a reasonable period of time, and the physician orders the transfer of the individual because the physician determines that without the services of the on-call physician the benefits of transfer outweigh the risks of transfer, the physician authorizing the transfer shall not be subject to a penalty under subparagraph (B). However, the previous sentence shall not apply to the hospital or to the on-call physician who failed or refused to appear.

(2) Civil enforcement.

(A) Personal harm. Any individual who suffers personal harm as a direct result of a participating hospital's violation of a requirement of this section may, in a civil action against the participating hospital, obtain those damages available for personal injury under the law of the State in which the hospital is located, and such equitable relief as is appropriate.

(B) Financial loss to other medical facility. Any medical facility that suffers a financial loss as a direct result of a participating hospital's violation of a requirement of this section may, in a civil action against the participating hospital, obtain those damages available for financial loss, under the law of the State in which the hospital is located, and such equitable relief as is appropriate.

(C) Limitations on actions. No action may be brought under this paragraph more than two years after the date of the violation with respect to which the action is brought.

(3) Consultation with peer review organizations. In considering allegations of violations of the requirements of this section in imposing sanctions under paragraph (1) or in terminating a hospital's participation under this *title [42 USCS §§ 1395* et seq.], the Secretary shall request the appropriate utilization and quality control peer review organization (with a contract under part B of title XI [*42 USCS §§ 1320c* et seq.]) to assess whether the individual involved had an emergency medical condition which had not been stabilized, and provide a report on its findings. Except in the case in

which a delay would jeopardize the health or safety of individuals, the Secretary shall request such a review before effecting a sanction under paragraph (1) and shall provide a period of at least 60 days for such review. Except in the case in which a delay would jeopardize the health or safety of individuals, the Secretary shall also request such a review before making a compliance determination as part of the process of terminating a hospital's participation under this *title [42 USCS §§ 1395* et seq.] for violations related to the appropriateness of a medical screening examination, stabilizing treatment, or an appropriate transfer as required by this section, and shall provide a period of 5 days for such review. The Secretary shall provide a copy of the organization's report to the hospital or physician consistent with confidentiality requirements imposed on the organization under such part B [*42 USCS §§ 1320c* et seq.].

(4) Notice upon closing an investigation. The Secretary shall establish a procedure to notify hospitals and physicians when an investigation under this section is closed.

(e) Definitions. In this section:

(1) The term "emergency medical condition" means--

(A) a medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain) such that the absence of immediate medical attention could reasonably be expected to result in--

(i) placing the health of the individual (or, with respect to a pregnant woman, the health of the woman or her unborn child) in serious jeopardy,

(ii) serious impairment to bodily functions, or

(iii) serious dysfunction of any bodily organ or part; or

(B) with respect to a pregnant woman who is having contractions--

(i) that there is inadequate time to effect a safe transfer to another hospital before delivery, or

(ii) that transfer may pose a threat to the health or safety of the woman or the unborn child.

(2) The term "participating hospital" means a hospital that has entered into a provider agreement under section 1866 [*42 USCS § 1395cc*].

(3) (A) The term "to stabilize" means, with respect to an emergency medical condition described in paragraph (1)(A), to provide such medical treatment of the condition as may be necessary to assure, within reasonable medical probability, that no material deterioration of the condition is likely to result from or occur during the transfer of the individual from a facility, or, with respect to an emergency medical condition described in paragraph (1)(B), to deliver (including the placenta).

(B) The term "stabilized" means, with respect to an emergency medical condition described in paragraph (1)(A), that no material deterioration of the condition is likely, within reasonable medical probability, to result from or occur during the transfer of the individual from a facility, or, with respect to an emergency medical condition described in paragraph (1)(B), that the woman has delivered (including the placenta).

(4) The term "transfer" means the movement (including the discharge) of an individual outside a hospital's facilities at the direction of any person employed by (or affiliated or associated, directly or indirectly, with) the hospital, but does not include such a movement of an individual who (A) has been declared dead, or (B) leaves the facility without the permission of any such person.

(5) The term "hospital" includes a critical access hospital (as defined in section 1861(mm)(1) [*42 USCS § 1395x(mm)(1)*]).

(f) Preemption. The provisions of this section do not preempt any State or local law requirement, except to the extent that the requirement directly conflicts with a requirement of this section.

(g) Nondiscrimination. A participating hospital that has specialized capabilities or facilities (such as burn units, shock-trauma units, neonatal intensive care units, or (with respect to rural areas) regional referral centers as identified by the Secretary in regulation) shall not refuse to accept an appropriate transfer of an individual who requires such specialized capabilities or facilities if the hospital has the capacity to treat the individual.

(h) No delay in examination or treatment. A participating hospital may not delay provision of an appropriate medical screening examination required under subsection (a) or further medical examination and treatment required under subsection (b) in order to inquire about the individual's method of payment or insurance status.

(i) Whistleblower protections. A participating hospital may not penalize or take adverse action against a qualified medical person described in subsection (c)(1)(A)(iii) or a physician because the person or physician refuses to authorize the transfer of an individual with an emergency medical condition that has not been stabilized or against any hospital employee because the employee reports a violation of a requirement of this section.

HISTORY:

(Aug. 14, 1935, ch 531, Title XVIII, Part E[D][C], § 1867, as added April 7, 1986, P.L. 99-272, Title IX, Subtitle A, Part 1, Subpart B, § 9121(b), 100 Stat. 164; Oct. 21, 1986, P.L. 99-509, Title IX, Subtitle D, Part 1, § 9307(c)(4), 100 Stat. 1996; Oct. 22, 1986, P.L. 99-514, Title XVIII, Subtitle C, Ch 1, § 1895(b)(4), 100 Stat. 2933; Dec. 22, 1987, P.L. 100-203, Title IV, Subtitle A, Part 1, § 4009(a)(1), (2), 101 Stat. 1330-56; July 1, 1988, P.L. 100-360, Title IV, Subtitle B, § 411(b)(8)(A)(i), 102 Stat. 772); Oct. 13, 1988, P.L. 100-485, Title VI, § 608(d)(18)(E), 102 Stat. 2419; Dec. 19, 1989, P.L. 101-239, Title VI, Subtitle A, Part 1, Subpart A, § 6003(g)(3)(D)(xiv), Part 3, Subpart B, § 6211(a)-(h), 103 Stat. 2154, 2245; Nov. 5, 1990, P.L. 101-508, Title IV, Subtitle A, Part 1, § 4008(b)(1)-(3)(A), Part 3, § 4207(a)(1)(A), (2), (3), (k)(3), 104 Stat. 1388-44, 1388-117, 1388-124; Oct. 31, 1994, P.L. 103-432, Title I, Subtitle C, § 160(d)(4), (5)(A), 108 Stat. 4444; Aug. 5, 1997, P.L. 105-33, Title IV, Subtitle A, Chapter 1, Subchapter A, § 4001, Subtitle C, § 4201(c)(1), 111 Stat. 275, 373; Dec. 8, 2003, P.L. 108-173, Title I, § 101(a)(1), Title VII, Subtitle D, § 736(a)(14), Title IX, Subtitle E, § 944(b), (c)(1), 117 Stat. 2071, 2355, 2423.)

§ 1395ee. Practicing Physicians Advisory Council; Council for Technology and Innovation

(a) Practicing Physicians Advisory Council.

(1) Appointment. The Secretary shall appoint, based upon nominations submitted by medical organizations representing physicians, a Practicing Physicians Advisory Council (in this subsection referred to as the "Council") to be composed of 15 physicians, each of whom has submitted at least 250 claims for physicians' services under this *title [42 USCS §§ 1395* et seq.] in the previous year. At least 11 of the members of the Council shall be physicians described in section 1861(r)(1) [*42 USCS § 1395x(r)(1)*] and the members of the Council shall include both participating and nonparticipating physicians and physicians practicing in rural areas and underserved urban areas.

(2) Meetings. The Council shall meet once during each calendar quarter to discuss certain proposed changes in regulations and carrier manual instructions related to physician services identified by the Secretary. To the extent feasible and consistent with statutory deadlines, such consultation shall occur before the publication of such proposed changes.

(3) Reimbursement of expenses. Members of the Council shall be entitled to receive reimbursement of expenses and per diem in lieu of subsistence in the same manner as other members of advisory councils appointed by the Secretary are provided such reimbursement and per diem under this *title [42 USCS §§ 1395* et seq.].

(b) Council for Technology and Innovation.

(1) Establishment. The Secretary shall establish a Council for Technology and Innovation within the Centers for Medicare & Medicaid Services (in this section referred to as "CMS").

(2) Composition. The Council shall be composed of senior CMS staff and clinicians and shall be chaired by the Executive Coordinator for Technology and Innovation (appointed or designated under paragraph (4)).

(3) Duties. The Council shall coordinate the activities of coverage, coding, and payment processes under this *title [42 USCS §§ 1395* et seq.] with respect to new technologies and procedures, including new drug therapies, and shall coordinate the exchange of information on new technologies between CMS and other entities that make similar decisions.

(4) Executive Coordinator for Technology and Innovation. The Secretary shall appoint (or designate) a noncareer appointee (as defined in *section 3132(a)(7) of title 5, United States Code*) who shall serve as the Executive Coordinator for Technology and Innovation. Such executive coordinator shall report to the Administrator of CMS, shall chair the Council, shall oversee the execution of its duties, and shall serve as a single point of contact for outside groups and entities regarding the coverage, coding, and payment processes under this *title [42 USCS §§ 1395* et seq.].

HISTORY:

(Aug. 14, 1935, ch 531, Title XVIII, Part E[D][C], § 1868, as added Nov. 5, 1990, P.L. 101-508, Title IV, Subtitle A, Part 2, Subpart A, § 4112, 104 Stat. 1388-64; Aug. 5, 1997, P.L. 105-33, Title IV, Subtitle A, Chapter 1, Subchapter A, § 4001, 111 Stat. 275; Dec. 8, 2003, P.L. 108-173, Title I, § 101(a)(1), Title IX, Subtitle E, § 942(a), 117 Stat. 2071, 2420.)

§ 1395ff. Determinations; appeals

(a) Initial determinations.

(1) Promulgations of regulations. The Secretary shall promulgate regulations and make initial determinations with respect to benefits under part A or part B [*42 USCS §§ 1395c* et seq. or *1395j* et seq.] in accordance with those regulations for the following:

(A) The initial determination of whether an individual is entitled to benefits under such parts.

(B) The initial determination of the amount of benefits available to the individual under such parts.

(C) Any other initial determination with respect to a claim for benefits under such parts, including an initial determination by the Secretary that payment may not be made, or may no longer be made, for an item or service under such parts, an initial determination made by a utilization and quality control peer review organization under section 1154(a)(2) [*42 USCS § 1320c-3(a)(2)*], and an initial determination made by an entity pursuant to a contract (other than a contract under section 1852 [*42 USCS § 1395w-22*]) with the Secretary to administer provisions of this title or title XI [*42 USCS §§ 1395* et seq. or *1301* et seq.].

(2) Deadlines for making initial determinations.

(A) In general. Subject to subparagraph (B), in promulgating regulations under paragraph (1), initial determinations shall be concluded by not later than the 45-day period beginning on the date the fiscal intermediary or the carrier, as the case may be, receives a claim for benefits from an individual as described in paragraph (1). Notice of such determination shall be mailed to the individual filing the claim before the conclusion of such 45-day period.

(B) Clean claims. Subparagraph (A) shall not apply with respect to any claim that is subject to the requirements of section 1816(c)(2) or 1842(c)(2) [*42 USCS § 1395h(c)(2)* or *1395u(c)(2)*].

(3) Redeterminations.

(A) In general. In promulgating regulations under paragraph (1) with respect to initial determinations, such regulations shall provide for a fiscal intermediary or a carrier to make a redetermination with respect to a claim for benefits that is denied in whole or in part.

(B) Limitations.

(i) Appeal rights. No initial determination may be reconsidered or appealed under subsection (b) unless the fiscal intermediary or carrier has made a redetermination of that initial determination under this paragraph.

(ii) Decisionmaker. No redetermination may be made by any individual involved in the initial determination.

(C) Deadlines.

(i) Filing for redetermination. A redetermination under subparagraph (A) shall be available only if notice is filed with the Secretary to request the redetermination by not later than the end of the 120-day period beginning on the date the individual receives notice of the initial determination under paragraph (2).

(ii) Concluding redeterminations. Redeterminations shall be concluded by not later than the 60-day period beginning on the date the fiscal intermediary or the carrier, as the case may be, receives a request for a redetermination. Notice of such determination shall be mailed to the individual filing the claim before the conclusion of such 60-day period.

(D) Construction. For purposes of the succeeding provisions of this section a redetermination under this paragraph shall be considered to be part of the initial determination.

(4) Requirements of notice of determinations. With respect to an initial determination insofar as it results in a denial of a claim for benefits--

(A) the written notice on the determination shall include--

(i) the reasons for the determination, including whether a local medical review policy or a local coverage determination was used;

(ii) the procedures for obtaining additional information concerning the determination, including the information described in subparagraph (B); and

(iii) notification of the right to seek a redetermination or otherwise appeal the determination and instructions on how to initiate such a redetermination under this section;

(B) such written notice shall be provided in printed form and written in a manner calculated to be understood by the individual entitled to benefits under part A [*42 USCS §§ 1395c* et seq.] or enrolled under part B [*42 USCS §§ 1395j* et seq.], or both; and

(C) the individual provided such written notice may obtain, upon request, information on the specific provision of the policy, manual, or regulation used in making the redetermination.

(5) Requirements of notice of redeterminations. With respect to a redetermination insofar as it results in a denial of a claim for benefits--

(A) the written notice on the redetermination shall include--

(i) the specific reasons for the redetermination;

(ii) as appropriate, a summary of the clinical or scientific evidence used in making the redetermination;

(iii) a description of the procedures for obtaining additional information concerning the redetermination; and

(iv) notification of the right to appeal the redetermination and instructions on how to initiate such an appeal under this section;

(B) such written notice shall be provided in printed form and written in a manner calculated to be understood by the individual entitled to benefits under part A [*42 USCS §§ 1395c* et seq.] or enrolled under part B [*42 USCS §§ 1395j* et seq.], or both; and

(C) the individual provided such written notice may obtain, upon request, information on the specific provision of the policy, manual, or regulation used in making the redetermination.

(b) Appeal rights.

(1) In general.

(A) Reconsideration of initial determination. Subject to subparagraph (D), any individual dissatisfied with any initial determination under subsection (a)(1) shall be entitled to reconsideration of the determination, and, subject to subparagraphs (D) and (E), a hearing thereon by the Secretary to the same extent as is provided in section 205(b) [*42 USCS § 405(b)*] and, subject to paragraph (2), to judicial review of the Secretary's final decision after such hearing as is provided in section 205(g) [*42 USCS § 405(g)*]. For purposes of the preceding sentence, any reference to the "Commissioner of Social Security" or the "Social Security Administration" in subsection (g) or (l) of section 205 [*42 USCS § 405*] shall be considered a reference to the "Secretary" or the "Department of Health and Human Services", respectively.

(B) Representation by provider or supplier.

(i) In general. Sections 206(a), 1102, and 1871 [*42 USCS §§ 406(a), 1302*, and *1395hh*] shall not be construed as authorizing the Secretary to prohibit an individual from being represented under this section by a person that furnishes or supplies the individual, directly or indirectly, with services or items, solely on the basis that the person furnishes or supplies the individual with such a service or item.

(ii) Mandatory waiver of right to payment from beneficiary. Any person that furnishes services or items to an individual may not represent an individual under this section with respect to the issue described in section 1879(a)(2) [*42 USCS § 1395pp(a)(2)*] unless the person has waived any rights for payment from the beneficiary with respect to the services or items involved in the appeal.

(iii) Prohibition on payment for representation. If a person furnishes services or items to an individual and represents the individual under this section, the person may not impose any financial liability on such individual in connection with such representation.

(iv) Requirements for representatives of a beneficiary. The provisions of section 205(j) [*42 USCS § 405(j)*] and of section 206 [*42 USCS § 406*] (other than subsection (a)(4) of such section) regarding representation of claimants shall apply to representation of an individual with respect to appeals under this section in the same manner as they apply to representation of an individual under those sections.

(C) Succession of rights in cases of assignment. The right of an individual to an appeal under this section with respect to an item or service may be assigned to the provider of services or supplier of the item or service upon the written consent of such individual using a standard form established by the Secretary for such an assignment.

(D) Time limits for filing appeals.

(i) Reconsiderations. Reconsideration under subparagraph (A) shall be available only if the individual described in subparagraph (A) files notice with the Secretary to request reconsideration by not later than the end of the 180-day period beginning on the date the individual receives notice of the redetermination under subsection (a)(3), or within such additional time as the Secretary may allow.

(ii) Hearings conducted by the Secretary. The Secretary shall establish in regulations time limits for the filing of a request for a hearing by the Secretary in accordance with provisions in sections 205 and 206 [*42 USCS §§ 405* and *406*].

(E) Amounts in controversy.

(i) In general. A hearing (by the Secretary) shall not be available to an individual under this section if the amount in controversy is less than $ 100, and judicial review shall not be available to the individual if the amount in controversy is less than $ 1,000.

(ii) Aggregation of claims. In determining the amount in controversy, the Secretary, under regulations, shall allow two or more appeals to be aggregated if the appeals involve--

(I) the delivery of similar or related services to the same individual by one or more providers of services or suppliers, or

(II) common issues of law and fact arising from services furnished to two or more individuals by one or more providers of services or suppliers.

(iii) Adjustment of dollar amounts. For requests for hearings or judicial review made in a year after 2004, the dollar amounts specified in clause (i) shall be equal to such dollar amounts increased by the percentage increase in the medical care component of the consumer price index for all urban consumers (U.S. city average) for July 2003 to the July preceding the year involved. Any amount determined under the previous sentence that is not a multiple of $ 10 shall be rounded to the nearest multiple of $ 10.

(F) Expedited proceedings.

(i) Expedited determination. In the case of an individual who has received notice from a provider of services that such provider plans--

(I) to terminate services provided to an individual and a physician certifies that failure to continue the provision of such services is likely to place the individual's health at significant risk, or

(II) to discharge the individual from the provider of services,

the individual may request, in writing or orally, an expedited determination or an expedited reconsideration of an initial determination made under subsection (a)(1), as the case may be, and the Secretary shall provide such expedited determination or expedited reconsideration.

(ii) Reference to expedited access to judicial review. For the provision relating to expedited access to judicial review, see paragraph (2).

(G) Reopening and revision of determinations. The Secretary may reopen or revise any initial determination or reconsidered determination described in this subsection under guidelines established by the Secretary in regulations.

(2) Expedited access to judicial review.

(A) In general. The Secretary shall establish a process under which a provider of services or supplier that furnishes an item or service or an individual entitled to benefits under part A [*42 USCS §§ 1395c* et seq.] or enrolled under part B [*42 USCS §§ 1395j* et seq.], or both, who has filed an appeal under paragraph (1) (other than an appeal filed under paragraph (1)(F)(i)) may obtain access to judicial review when a review entity (described in subparagraph (D)), on its own motion or at the request of the appellant, determines that the Departmental Appeals Board does not have the authority to decide the question of law or regulation relevant to the matters in controversy and that there is no material issue of fact in dispute. The appellant may make such request only once with respect to a question of law or regulation for a specific matter in dispute in a case of an appeal.

(B) Prompt determinations. If, after or coincident with appropriately filing a request for an administrative hearing, the appellant requests a determination by the appropriate review entity that the Departmental Appeals Board does not have the authority to decide the question of law or regulations relevant to the matters in controversy and that there is no material issue of fact in dispute, and if such request is accompanied by the documents and materials as the appropriate review entity shall require for purposes of making such determination, such review entity shall make a determination on the request in writing within 60 days after the date such review entity receives the request and such accompanying documents and materials. Such a determination by such review entity shall be considered a final decision and not subject to review by the Secretary.

(C) Access to judicial review.

(i) In general. If the appropriate review entity--

(I) determines that there are no material issues of fact in dispute and that the only issues to be adjudicated are ones of law or regulation that the Departmental Appeals Board does not have authority to decide; or

(II) fails to make such determination within the period provided under subparagraph (B), then the appellant may bring a civil action as described in this subparagraph.

(ii) Deadline for filing. Such action shall be filed, in the case described in--

(I) clause (i)(I), within 60 days of the date of the determination described in such clause; or

(II) clause (i)(II), within 60 days of the end of the period provided under subparagraph (B) for the determination.

(iii) Venue. Such action shall be brought in the district court of the United States for the judicial district in which the appellant is located (or, in the case of an action brought jointly by more than one applicant, the judicial district in which the greatest number of applicants are located) or in the District Court for the District of Columbia.

(iv) Interest on any amounts in controversy. Where a provider of services or supplier is granted judicial review pursuant to this paragraph, the amount in controversy (if any) shall be subject to annual interest beginning on the first day of the first month beginning after the 60-day period as determined pursuant to clause (ii) and equal to the rate of interest on obligations issued for purchase by the Federal Supplementary Medical Insurance Trust Fund for the month in which the civil action authorized under this paragraph is commenced, to be awarded by the reviewing court in favor of the prevailing party. No interest awarded pursuant to the preceding sentence shall be deemed income or cost for the purposes of determining reimbursement due providers of services or suppliers under this *title [42 USCS §§ 1395* et seq.].

(D) Review entity defined. For purposes of this subsection, the term "review entity" means an entity of up to three reviewers who are administrative law judges or members of the Departmental Appeals Board selected for purposes of making determinations under this paragraph.

(3) Requiring full and early presentation of evidence by providers. A provider of services or supplier may not introduce evidence in any appeal under this section that was not presented at the reconsideration conducted by the qualified independent contractor under subsection (c), unless there is good cause which precluded the introduction of such evidence at or before that reconsideration.

(c) Conduct of reconsiderations by independent contractors.

(1) In general. The Secretary shall enter into contracts with qualified independent contractors to conduct reconsiderations of initial determinations made under subparagraphs (B) and (C) of subsection (a)(1). Contracts shall be for an initial term of three years and shall be renewable on a triennial basis thereafter.

(2) Qualified independent contractor. For purposes of this subsection, the term "qualified independent contractor" means an entity or organization that is independent of any organization under contract with the Secretary that makes initial determinations under subsection (a)(1), and that meets the requirements established by the Secretary consistent with paragraph (3).

(3) Requirements. Any qualified independent contractor entering into a contract with the Secretary under this subsection shall meet all of the following requirements:

(A) In general. The qualified independent contractor shall perform such duties and functions and assume such responsibilities as may be required by the Secretary to carry out the provisions of this subsection, and shall have sufficient medical, legal, and other expertise (including knowledge of the program under this *title [42 USCS §§ 1395* et seq.]) and sufficient staffing to make reconsiderations under this subsection.

(B) Reconsiderations.

(i) In general. The qualified independent contractor shall review initial determinations. Where an initial determination is made with respect to whether an item or service is reasonable and necessary for the diagnosis or treatment of illness or injury (under section 1862(a)(1)(A) [*42 USCS § 1395y(a)(1)(A)*]), such review shall include consideration of the facts and circumstances of the initial determination by a panel of physicians or other appropriate health care professionals and any decisions with respect to the reconsideration shall be based on applicable information, including clinical experience (including the medical records of the individual involved) and medical, technical, and scientific evidence.

(ii) Effect of national and local coverage determinations.

(I) National coverage determinations. If the Secretary has made a national coverage determination pursuant to the requirements established under the third sentence of section 1862(a) [*42 USCS § 1395y(a)*], such determination shall be binding on the qualified independent contractor in making a decision with respect to a reconsideration under this section.

(II) Local coverage determinations. If the Secretary has made a local coverage determination, such determination shall not be binding on the qualified independent contractor in making a decision with respect to a reconsideration under this section. Notwithstanding the previous sentence, the qualified independent contractor shall consider the local coverage determination in making such decision.

(III) Absence of national or local coverage determination. In the absence of such a national coverage determination or local coverage determination, the qualified independent contractor shall make a decision with respect to the reconsideration based on applicable information, including clinical experience and medical, technical, and scientific evidence.

(C) Deadlines for decisions.

(i) Reconsiderations. Except as provided in clauses (iii) and (iv), the qualified independent contractor shall conduct and conclude a reconsideration under subparagraph (B), and mail the notice of the decision with respect to the reconsideration by not later than the end of the 60-day period beginning on the date a request for reconsideration has been timely filed.

(ii) Consequences of failure to meet deadline. In the case of a failure by the qualified independent contractor to mail the notice of the decision by the end of the period described in clause (i) or to provide notice by the end of the period described in clause (iii), as the case may be, the party requesting the reconsideration or appeal may request a hearing before the Secretary, notwithstanding any requirements for a reconsidered determination for purposes of the party's right to such hearing.

(iii) Expedited reconsiderations. The qualified independent contractor shall perform an expedited reconsideration under subsection (b)(1)(F) as follows:

(I) Deadline for decision. Notwithstanding section 216(j) [*42 USCS § 416(j)*] and subject to clause (iv), not later than the end of the 72-hour period beginning on the date the qualified independent contractor has received a request for such reconsideration and has received such medical or other records needed for such reconsideration, the qualified independent contractor shall provide notice (by telephone and in writing) to the individual and the provider of services and attending physician of the individual of the results of the reconsideration. Such reconsideration shall be conducted regardless of whether the provider of services or supplier will charge the individual for continued services or whether the individual will be liable for payment for such continued services.

(II) Consultation with beneficiary. In such reconsideration, the qualified independent contractor shall solicit the views of the individual involved.

(III) Special rule for hospital discharges. A reconsideration of a discharge from a hospital shall be conducted under this clause in accordance with the provisions of paragraphs (2), (3), and (4) of section 1154(e) [*42 USCS § 1320c-3(e)*] as in effect on the date that precedes the date of the enactment of this subparagraph [enacted Dec. 21, 2000].

(iv) Extension. An individual requesting a reconsideration under this subparagraph may be granted such additional time as the individual specifies (not to exceed 14 days) for the qualified independent contractor to conclude the reconsideration. The individual may request such additional time orally or in writing.

(D) Qualifications for reviewers. The requirements of subsection (g) shall be met (relating to qualifications of reviewing professionals).

(E) Explanation of decision. Any decision with respect to a reconsideration of a qualified independent contractor shall be in writing, be written in a manner calculated to be understood by the individual entitled to benefits under part A [*42 USCS §§ 1395c* et seq.] or enrolled under part B [*42 USCS §§ 1395j* et seq.], or both, and shall include (to the extent appropriate) [and shall include] a detailed explanation of the decision as well as a discussion of the pertinent facts and applicable regulations applied in making such decision, and a notification of the right to appeal such determination and instructions on how to initiate such appeal under this section and in the case of a determination of whether an item or service is reasonable and necessary for the diagnosis or treatment of illness or injury (under section 1862(a)(1)(A) [*42 USCS § 1395y(a)(1)(A)*]) an explanation of the medical and scientific rationale for the decision.

(F) Notice requirements. Whenever a qualified independent contractor makes a decision with respect to a reconsideration under this subsection, the qualified independent contractor shall promptly notify the entity responsible for the payment of claims under part A or part B [*42 USCS §§ 1395c* et seq. or *1395j* et seq.] of such decision.

(G) Dissemination of decisions on reconsiderations. Each qualified independent contractor shall make available all decisions with respect to reconsiderations of such qualified independent contractors to fiscal intermediaries (under section 1816 [*42 USCS § 1395h*]), carriers (under section 1842 [*42 USCS § 1395u*]), peer review organizations (under part B of title XI [*42 USCS §§ 1320c* et seq.]), Medicare + Choice organizations offering Medicare + Choice plans under part C [*42 USCS §§ 1395w-21* et seq.], other entities under contract with the Secretary to make initial determinations under part A or part B or title XI [*42 USCS §§ 1395c* et seq. or *1395j* et seq. or *1301* et seq.], and to the public. The Secretary shall establish a methodology under which qualified independent contractors shall carry out this subparagraph.

(H) Ensuring consistency in decisions. Each qualified independent contractor shall monitor its decisions with respect to reconsiderations to ensure the consistency of such decisions with respect to requests for reconsideration of similar or related matters.

(I) Data collection.

(i) In general. Consistent with the requirements of clause (ii), a qualified independent contractor shall collect such information relevant to its functions, and keep and maintain such records in such form and manner as the Secretary may require to carry out the purposes of this section and shall permit access to and use of any such information and records as the Secretary may require for such purposes.

(ii) Type of data collected. Each qualified independent contractor shall keep accurate records of each decision made, consistent with standards established by the Secretary for such purpose. Such records shall be maintained in an electronic database in a manner that provides for identification of the following:

(I) Specific claims that give rise to appeals.

(II) Situations suggesting the need for increased education for providers of services, physicians, or suppliers.

(III) Situations suggesting the need for changes in national or local coverage determination.

(IV) Situations suggesting the need for changes in local coverage determinations.

(iii) Annual reporting. Each qualified independent contractor shall submit annually to the Secretary (or otherwise as the Secretary may request) records maintained under this paragraph for the previous year.

(J) Hearings by the Secretary. The qualified independent contractor shall (i) submit such information as is required for an appeal of a decision of the contractor, and (ii) participate in such hearings as required by the Secretary.

(K) Independence requirements.

(i) In general. Subject to clause (ii), a qualified independent contractor shall not conduct any activities in a case unless the entity--

(I) is not a related party (as defined in subsection (g)(5));

(II) does not have a material familial, financial, or professional relationship with such a party in relation to such case; and

(III) does not otherwise have a conflict of interest with such a party.

(ii) Exception for reasonable compensation. Nothing in clause (i) shall be construed to prohibit receipt by a qualified independent contractor of compensation from the Secretary for the conduct of activities under this section if the compensation is provided consistent with clause (iii).

(iii) Limitations on entity compensation. Compensation provided by the Secretary to a qualified independent contractor in connection with reviews under this section shall not be contingent on any decision rendered by the contractor or by any reviewing professional.

(4) Number of qualified independent contractors. The Secretary shall enter into contracts with a sufficient number of qualified independent contractors (but not fewer than 4 such contractors) to conduct reconsiderations consistent with the timeframes applicable under this subsection.

(5) Limitation on qualified independent contractor liability. No qualified independent contractor having a contract with the Secretary under this subsection and no person who is employed by, or who has a fiduciary relationship with, any such qualified independent contractor or who furnishes professional services to such qualified independent contractor, shall be held by reason of the performance of any duty, function, or activity required or authorized pursuant to this subsection or to a valid contract entered into under this subsection, to have violated any criminal law, or to be civilly liable under any law of the United States or of any State (or political subdivision thereof) provided due care was exercised in the performance of such duty, function, or activity.

(d) Deadlines for hearings by the Secretary; notice.

(1) Hearing by administrative law judge.

(A) In general. Except as provided in subparagraph (B), an administrative law judge shall conduct and conclude a hearing on a decision of a qualified independent contractor under subsection (c) and render a decision on such hearing by not later than the end of the 90-day period beginning on the date a request for hearing has been timely filed.

(B) Waiver of deadline by party seeking hearing. The 90-day period under subparagraph (A) shall not apply in the case of a motion or stipulation by the party requesting the hearing to waive such period.

(2) Departmental Appeals Board review.

(A) In general. The Departmental Appeals Board of the Department of Health and Human Services shall conduct and conclude a review of the decision on a hearing described in paragraph (1) and make a decision or remand the case to the administrative law judge for reconsideration by not later than the end of the 90-day period beginning on the date a request for review has been timely filed.

(B) DAB hearing procedure. In reviewing a decision on a hearing under this paragraph, the Departmental Appeals Board shall review the case de novo.

(3) Consequences of failure to meet deadlines.

(A) Hearing by administrative law judge. In the case of a failure by an administrative law judge to render a decision by the end of the period described in paragraph (1), the party requesting the hearing may request a review by the Departmental Appeals Board of the Department of Health and Human Services, notwithstanding any requirements for a hearing for purposes of the party's right to such a review.

(B) Departmental Appeals Board review. In the case of a failure by the Departmental Appeals Board to render a decision by the end of the period described in paragraph (2), the party requesting the hearing may seek judicial review, notwithstanding any requirements for a hearing for purposes of the party's right to such judicial review.

(4) Notice. Notice of the decision of an administrative law judge shall be in writing in a manner calculated to be understood by the individual entitled to benefits under part A [*42 USCS §§ 1395c* et seq.] or enrolled under part B [*42 USCS §§ 1395j* et seq.], or both, and shall include--

(A) the specific reasons for the determination (including, to the extent appropriate, a summary of the clinical or scientific evidence used in making the determination);

(B) the procedures for obtaining additional information concerning the decision; and

(C) notification of the right to appeal the decision and instructions on how to initiate such an appeal under this section.

(e) Administrative provisions.

(1) Limitation on review of certain regulations. A regulation or instruction that relates to a method for determining the amount of payment under part B [*42 USCS §§ 1395j* et seq.] and that was initially issued before January 1, 1981, shall not be subject to judicial review.

(2) Outreach. The Secretary shall perform such outreach activities as are necessary to inform individuals entitled to benefits under this title and providers of services and suppliers with respect to their rights of, and the process for, appeals made under this section. The Secretary shall use the toll-free telephone number maintained by the Secretary under section 1804(b) [*42 USCS § 1395b-2(b)*] to provide information regarding appeal rights and respond to inquiries regarding the status of appeals.

(3) Continuing education requirement for qualified independent contractors and administrative law judges. The Secretary shall provide to each qualified independent contractor, and, in consultation with the Commissioner of Social Security, to administrative law judges that decide appeals of reconsiderations of initial determinations or other decisions

or determinations under this section, such continuing education with respect to coverage of items and services under this title or policies of the Secretary with respect to part B of title XI [*42 USCS §§ 1320c* et seq.] as is necessary for such qualified independent contractors and administrative law judges to make informed decisions with respect to appeals.

(4) Reports.

(A) Annual report to Congress. The Secretary shall submit to Congress an annual report describing the number of appeals for the previous year, identifying issues that require administrative or legislative actions, and including any recommendations of the Secretary with respect to such actions. The Secretary shall include in such report an analysis of determinations by qualified independent contractors with respect to inconsistent decisions and an analysis of the causes of any such inconsistencies.

(B) Survey. Not less frequently than every 5 years, the Secretary shall conduct a survey of a valid sample of individuals entitled to benefits under this title who have filed appeals of determinations under this section, providers of services, and suppliers to determine the satisfaction of such individuals or entities with the process for appeals of determinations provided for under this section and education and training provided by the Secretary with respect to that process. The Secretary shall submit to Congress a report describing the results of the survey, and shall include any recommendations for administrative or legislative actions that the Secretary determines appropriate.

(f) Review of coverage determinations.

(1) National coverage determinations.

(A) In general. Review of any national coverage determination shall be subject to the following limitations:

(i) Such a determination shall not be reviewed by any administrative law judge.

(ii) Such a determination shall not be held unlawful or set aside on the ground that a requirement of *section 553 of title 5, United States Code*, or section 1871(b) of this *title [42 USCS § 1395hh(b)]*, relating to publication in the Federal Register or opportunity for public comment, was not satisfied.

(iii) Upon the filing of a complaint by an aggrieved party, such a determination shall be reviewed by the Departmental Appeals Board of the Department of Health and Human Services. In conducting such a review, the Departmental Appeals Board--

(I) shall review the record and shall permit discovery and the taking of evidence to evaluate the reasonableness of the determination, if the Board determines that the record is incomplete or lacks adequate information to support the validity of the determination;

(II) may, as appropriate, consult with appropriate scientific and clinical experts; and

(III) shall defer only to the reasonable findings of fact, reasonable interpretations of law, and reasonable applications of fact to law by the Secretary.

(iv) The Secretary shall implement a decision of the Departmental Appeals Board within 30 days of receipt of such decision.

(v) A decision of the Departmental Appeals Board constitutes a final agency action and is subject to judicial review.

(B) Definition of national coverage determination. For purposes of this section, the term "national coverage determination" means a determination by the Secretary with respect to whether or not a particular item or service is covered nationally under this *title [42 USCS §§ 1395* et seq.], but does not include a determination of what code, if any, is assigned to a particular item or service covered under this title or a determination with respect to the amount of payment made for a particular item or service so covered.

(2) Local coverage determination.

(A) In general. Review of any local coverage determination shall be subject to the following limitations:

(i) Upon the filing of a complaint by an aggrieved party, such a determination shall be reviewed by an administrative law judge. The administrative law judge--

(I) shall review the record and shall permit discovery and the taking of evidence to evaluate the reasonableness of the determination, if the administrative law judge determines that the record is incomplete or lacks adequate information to support the validity of the determination;

(II) may, as appropriate, consult with appropriate scientific and clinical experts; and

(III) shall defer only to the reasonable findings of fact, reasonable interpretations of law, and reasonable applications of fact to law by the Secretary.

(ii) Upon the filing of a complaint by an aggrieved party, a decision of an administrative law judge under clause (i) shall be reviewed by the Departmental Appeals Board of the Department of Health and Human Services.

(iii) The Secretary shall implement a decision of the administrative law judge or the Departmental Appeals Board within 30 days of receipt of such decision.

(iv) A decision of the Departmental Appeals Board constitutes a final agency action and is subject to judicial review.

(B) Definition of local coverage determination. For purposes of this section, the term "local coverage determination" means a determination by a fiscal intermediary or a carrier under part A or part B [*42 USCS §§ 1395c* et seq. or *1395j* et seq.], as applicable, respecting whether or not a particular item or service is covered on an intermediary- or carrier-wide basis under such parts, in accordance with section 1862(a)(1)(A) [*42 USCS § 1395y(a)(1)(A)*].

(3) No material issues of fact in dispute. In the case of a determination that may otherwise be subject to review under paragraph (1)(A)(iii) or paragraph (2)(A)(i), where the moving party alleges that--

(A) there are no material issues of fact in dispute, and

(B) the only issue of law is the constitutionality of a provision of this title, or that a regulation, determination, or ruling by the Secretary is invalid,

the moving party may seek review by a court of competent jurisdiction without filing a complaint under such paragraph and without otherwise exhausting other administrative remedies.

(4) Pending national coverage determinations.

(A) In general. In the event the Secretary has not issued a national coverage or noncoverage determination with respect to a particular type or class of items or services, an aggrieved person (as described in paragraph (5)) may submit to the Secretary a request to make such a determination with respect to such items or services. By not later than the end of the 90-day period beginning on the date the Secretary receives such a request (notwithstanding the receipt by the Secretary of new evidence (if any) during such 90-day period), the Secretary shall take one of the following actions:

(i) Issue a national coverage determination, with or without limitations.

(ii) Issue a national noncoverage determination.

(iii) Issue a determination that no national coverage or noncoverage determination is appropriate as of the end of such 90-day period with respect to national coverage of such items or services.

(iv) Issue a notice that states that the Secretary has not completed a review of the request for a national coverage determination and that includes an identification of the remaining steps in the Secretary's review process and a deadline by which the Secretary will complete the review and take an action described in clause (i), (ii), or (iii).

(B) Deemed action by the Secretary. In the case of an action described in subparagraph (A)(iv), if the Secretary fails to take an action referred to in such clause by the deadline specified by the Secretary under such clause, then the Secretary is deemed to have taken an action described in subparagraph (A)(iii) as of the deadline.

(C) Explanation of determination. When issuing a determination under subparagraph (A), the Secretary shall include an explanation of the basis for the determination. An action taken under subparagraph (A) (other than clause (iv)) is deemed to be a national coverage determination for purposes of review under paragraph (1)(A).

(5) Standing. An action under this subsection seeking review of a national coverage determination or local coverage determination may be initiated only by individuals entitled to benefits under part A [*42 USCS §§ 1395c* et seq.], or enrolled under part B [*42 USCS §§ 1395j* et seq.], or both, who are in need of the items or services that are the subject of the coverage determination.

(6) Publication on the Internet of decisions of hearings of the Secretary. Each decision of a hearing by the Secretary with respect to a national coverage determination shall be made public, and the Secretary shall publish each decision on the Medicare Internet site of the Department of Health and Human Services. The Secretary shall remove from such decision any information that would identify any individual, provider of services, or supplier.

(7) Annual report on national coverage determinations.

(A) In general. Not later than December 1 of each year, beginning in 2001, the Secretary shall submit to Congress a report that sets forth a detailed compilation of the actual time periods that were necessary to complete and fully implement national coverage determinations that were made in the previous fiscal year for items, services, or medical devices not previously covered as a benefit under this title, including, with respect to each new item, service, or medical device, a statement of the time taken by the Secretary to make and implement the necessary coverage, coding, and payment determinations, including the time taken to complete each significant step in the process of making and implementing such determinations.

(B) Publication of reports on the Internet. The Secretary shall publish each report submitted under clause (i) on the medicare Internet site of the Department of Health and Human Services.

(8) Construction. Nothing in this subsection shall be construed as permitting administrative or judicial review pursuant to this section insofar as such review is explicitly prohibited or restricted under another provision of law.

(g) Qualifications of reviewers.

(1) In general. In reviewing determinations under this section, a qualified independent contractor shall assure that--

(A) each individual conducting a review shall meet the qualifications of paragraph (2);

(B) compensation provided by the contractor to each such reviewer is consistent with paragraph (3); and

(C) in the case of a review by a panel described in subsection (c)(3)(B) composed of physicians or other health care professionals (each in this subsection referred to as a "reviewing professional"), a reviewing professional meets the

qualifications described in paragraph (4) and, where a claim is regarding the furnishing of treatment by a physician (allopathic or osteopathic) or the provision of items or services by a physician (allopathic or osteopathic), a reviewing professional shall be a physician (allopathic or osteopathic).

(2) Independence.

(A) In general. Subject to subparagraph (B), each individual conducting a review in a case shall--

(i) not be a related party (as defined in paragraph (5));

(ii) not have a material familial, financial, or professional relationship with such a party in the case under review; and

(iii) not otherwise have a conflict of interest with such a party.

(B) Exception. Nothing in subparagraph (A) shall be construed to--

(i) prohibit an individual, solely on the basis of a participation agreement with a fiscal intermediary, carrier, or other contractor, from serving as a reviewing professional if--

(I) the individual is not involved in the provision of items or services in the case under review;

(II) the fact of such an agreement is disclosed to the Secretary and the individual entitled to benefits under part A [*42 USCS §§ 1395c* et seq.] or enrolled under part B [*42 USCS §§ 1395j* et seq.], or both, or such individual's authorized representative, and neither party objects; and

(III) the individual is not an employee of the intermediary, carrier, or contractor and does not provide services exclusively or primarily to or on behalf of such intermediary, carrier, or contractor;

(ii) prohibit an individual who has staff privileges at the institution where the treatment involved takes place from serving as a reviewer merely on the basis of having such staff privileges if the existence of such privileges is disclosed to the Secretary and such individual (or authorized representative), and neither party objects; or

(iii) prohibit receipt of compensation by a reviewing professional from a contractor if the compensation is provided consistent with paragraph (3).

For purposes of this paragraph, the term "participation agreement" means an agreement relating to the provision of health care services by the individual and does not include the provision of services as a reviewer under this subsection.

(3) Limitations on reviewer compensation. Compensation provided by a qualified independent contractor to a reviewer in connection with a review under this section shall not be contingent on the decision rendered by the reviewer.

(4) Licensure and expertise. Each reviewing professional shall be--

(A) a physician (allopathic or osteopathic) who is appropriately credentialed or licensed in one or more States to deliver health care services and has medical expertise in the field of practice that is appropriate for the items or services at issue; or

(B) a health care professional who is legally authorized in one or more States (in accordance with State law or the State regulatory mechanism provided by State law) to furnish the health care items or services at issue and has medical expertise in the field of practice that is appropriate for such items or services.

(5) Related party defined. For purposes of this section, the term "related party" means, with respect to a case under this title involving a specific individual entitled to benefits under part A [*42 USCS §§ 1395c* et seq.] or enrolled under part B [*42 USCS §§ 1395j* et seq.], or both, any of the following:

(A) The Secretary, the medicare administrative contractor involved, or any fiduciary, officer, director, or employee of the Department of Health and Human Services, or of such contractor.

(B) The individual (or authorized representative).

(C) The health care professional that provides the items or services involved in the case.

(D) The institution at which the items or services (or treatment) involved in the case are provided.

(E) The manufacturer of any drug or other item that is included in the items or services involved in the case.

(F) Any other party determined under any regulations to have a substantial interest in the case involved.

(h) Prior determination process for certain items and services.

(1) Establishment of process.

(A) In general. With respect to a medicare administrative contractor that has a contract under section 1874A [*42 USCS § 1395kk-1*] that provides for making payments under this *title [42 USCS §§ 1395* et seq.] with respect to physicians' services (as defined in section 1848(j)(3) [*42 USCS § 1395w-4(j)(3)*]), the Secretary shall establish a prior determination process that meets the requirements of this subsection and that shall be applied by such contractor in the case of eligible requesters.

(B) Eligible requester. For purposes of this subsection, each of the following shall be an eligible requester:

(i) A participating physician, but only with respect to physicians' services to be furnished to an individual who is entitled to benefits under this *title [42 USCS §§ 1395* et seq.] and who has consented to the physician making the request under this subsection for those physicians' services.

(ii) An individual entitled to benefits under this *title [42 USCS §§ 1395* et seq.], but only with respect to a physicians' service for which the individual receives, from a physician, an advance beneficiary notice under section 1879(a) [*42 USCS § 1395pp(a)*].

(2) Secretarial flexibility. The Secretary shall establish by regulation reasonable limits on the physicians' services for which a prior determination of coverage may be requested under this subsection. In establishing such limits, the Secretary may consider the dollar amount involved with respect to the physicians' service, administrative costs and burdens, and other relevant factors.

(3) Request for prior determination.

(A) In general. Subject to paragraph (2), under the process established under this subsection an eligible requester may submit to the contractor a request for a determination, before the furnishing of a physicians' service, as to whether the physicians' service is covered under this *title [42 USCS §§ 1395* et seq.] consistent with the applicable requirements of section 1862(a)(1)(A) [*42 USCS § 1395y(a)(1)(A)*] (relating to medical necessity).

(B) Accompanying documentation. The Secretary may require that the request be accompanied by a description of the physicians' service, supporting documentation relating to the medical necessity for the physicians' service, and any other appropriate documentation. In the case of a request submitted by an eligible requester who is described in paragraph (1)(B)(ii), the Secretary may require that the request also be accompanied by a copy of the advance beneficiary notice involved.

(4) Response to request.

(A) In general. Under such process, the contractor shall provide the eligible requester with written notice of a determination as to whether--

(i) the physicians' service is so covered;

(ii) the physicians' service is not so covered; or

(iii) the contractor lacks sufficient information to make a coverage determination with respect to the physicians' service.

(B) Contents of notice for certain determinations.

(i) Noncoverage. If the contractor makes the determination described in subparagraph (A)(ii), the contractor shall include in the notice a brief explanation of the basis for the determination, including on what national or local coverage or noncoverage determination (if any) the determination is based, and a description of any applicable rights under subsection (a).

(ii) Insufficient information. If the contractor makes the determination described in subparagraph (A)(iii), the contractor shall include in the notice a description of the additional information required to make the coverage determination.

(C) Deadline to respond. Such notice shall be provided within the same time period as the time period applicable to the contractor providing notice of initial determinations on a claim for benefits under subsection (a)(2)(A).

(D) Informing beneficiary in case of physician request. In the case of a request by a participating physician under paragraph (1)(B)(i), the process shall provide that the individual to whom the physicians' service is proposed to be furnished shall be informed of any determination described in subparagraph (A)(ii) (relating to a determination of non-coverage) and the right (referred to in paragraph (6)(B)) to obtain the physicians' service and have a claim submitted for the physicians' service.

(5) Binding nature of positive determination. If the contractor makes the determination described in paragraph (4)(A)(i), such determination shall be binding on the contractor in the absence of fraud or evidence of misrepresentation of facts presented to the contractor.

(6) Limitation on further review.

(A) In general. Contractor determinations described in paragraph (4)(A)(ii) or (4)(A)(iii) (relating to pre-service claims) are not subject to further administrative appeal or judicial review under this section or otherwise.

(B) Decision not to seek prior determination or negative determination does not impact right to obtain services, seek reimbursement, or appeal rights. Nothing in this subsection shall be construed as affecting the right of an individual who--

(i) decides not to seek a prior determination under this subsection with respect to physicians' services; or

(ii) seeks such a determination and has received a determination described in paragraph (4)(A)(ii),

from receiving (and submitting a claim for) such physicians' services and from obtaining administrative or judicial review respecting such claim under the other applicable provisions of this section. Failure to seek a prior determination under this subsection with respect to physicians' service shall not be taken into account in such administrative or judicial review.

(C) No prior determination after receipt of services. Once an individual is provided physicians' services, there shall be no prior determination under this subsection with respect to such physicians' services.

(i) Mediation process for local coverage determinations.

(1) Establishment of process. The Secretary shall establish a mediation process under this subsection through the use of a physician trained in mediation and employed by the Centers for Medicare & Medicaid Services.

(2) Responsibility of mediator. Under the process established in paragraph (1), such a mediator shall mediate in disputes between groups representing providers of services, suppliers (as defined in section 1861(d) [*42 USCS § 1395x(d)*]), and the medical director for a medicare administrative contractor whenever the regional administrator (as defined by the Secretary) involved determines that there was a systematic pattern and a large volume of complaints from such groups regarding decisions of such director or there is a complaint from the co-chair of the advisory committee for that contractor to such regional administrator regarding such dispute.

HISTORY:

(Aug. 14, 1935, ch 531, Title XVIII, Part E[D][C], § 1869, as added July 30, 1965, P.L. 89-97, Title I, Part 1, § 102(a), 79 Stat. 330; Oct. 30, 1972, P.L. 92-603, Title II, § 299o(a), 86 Stat. 1464; July 18, 1984, P.L. 98-369, Division B, Title III, Subtitle A, Part II, § 2354(b)(35), 98 Stat. 1102; Oct. 21, 1986, P.L. 99-509, Title IX, Subtitle D, Part 2, § 9313(a)(1), (b)(1), Part 3, § 9341(a)(1), 100 Stat. 2002, 2036; Aug. 18, 1987, P.L. 100-93, § 8(e), 101 Stat. 694; Dec. 22, 1987, P.L. 100-203, Title IV, Subtitle A, Part 3, Subpart D, §§ 4082(a), (b), 4085(i)(18), (19), 101 Stat. 1330-128, 1330-133; Aug. 15, 1994, P.L. 103-296, Title I, § 108(c)(5) 108 Stat. 1485; Aug. 5, 1997, P.L. 105-33, Title IV, Subtitle A, Chapter 1, Subchapter A, § 4001, Subtitle G, Ch 1, Subch B, § 4611(c), 111 Stat. 275, 473; Dec. 21, 2000, P.L. 106-554, § 1(a)(6), 114 Stat. 2763; Dec. 8, 2003, P.L. 108-173, Title I, § 101(a)(1), Title IX, Subtitle D, §§ 931(d), 932(a), 933(a)(1), (b), (c), (d)(1)-(3), 938(a), 940(a), (b)(1), 940A(a), 948(b)(1), (c), 117 Stat. 2071, 2399, 2402, 2413, 2416, 2417, 2426.)

§ 1395gg. Overpayment on behalf of individuals and settlement of claims for benefits on behalf of deceased individuals

(a) Payments to providers of services or other person regarded as payment to individuals. Any payment under this *title [42 USCS §§ 1395* et seq.] to any provider of services or other person with respect to any items or services furnished any individual shall be regarded as a payment to such individual.

(b) Incorrect payments on behalf of individuals; payment adjustment. Where--

(1) more than the correct amount is paid under this *title [42 USCS §§ 1395* et seq.] to a provider of services or other person for items or services furnished an individual and the Secretary determines (A) that, within such period as he may specify, the excess over the correct amount cannot be recouped from such provider of services or other person, or (B) that such provider of services or other person was without fault with respect to the payment of such excess over the correct amount, or

(2) any payment has been made under section 1814(e) [*42 USCS § 1395(e)*] to a provider of services or other person for items or services furnished an individual,

proper adjustments shall be made, under regulations prescribed (after consultation with the Railroad Retirement Board) by the Secretary, by decreasing subsequent payments--

(3) to which such individual is entitled under title II of this Act [*42 USCS §§ 401* et seq.] or under the Railroad Retirement Act of 1974, as the case may be, or

(4) if such individual dies before such adjustment has been completed, to which any other individual is entitled under title II of this Act [*42 USCS §§ 401* et seq.] or under the Railroad Retirement Act of 1974, as the case may be, with respect to the wages and self-employment income or the compensation constituting the basis of the benefits of such deceased individual under title II of such Act [*42 USCS §§ 401* et seq.].

As soon as practicable after any adjustment under paragraph (3) or (4) is determined to be necessary, the Secretary, for purposes of this section, section 1817(g), and section 1841(f) [*42 USCS §§ 1395i(g)* and *1395t(f)*], shall certify (to the Railroad Retirement Board if the adjustment is to be made by decreasing subsequent payments under the Railroad Retirement Act of 1974) the amount of the overpayment as to which the adjustment is to be made. For purposes of clause (B) of paragraph (1), such provider of services or such other person shall, in the absence of evidence to the contrary, be deemed to be without fault if the Secretary's determination that more than such correct amount was paid was made subsequent to the third year following the year in which notice was sent to such individual that such amount had been paid; except that the Secretary may reduce such three-year period to not less than one year if he finds such reduction is consistent with the objectives of this *title [42 USCS §§ 1395* et seq.].

(c) Exception to subsection (b) payment adjustment. There shall be no adjustment as provided in subsection (b) (nor shall there be recovery) in any case where the incorrect payment has been made (including payments under section 1814(e) [*42 USCS § 1395f(e)*]) with respect to an individual who is without fault or where the adjustment (or recovery) would be made by decreasing payments to which another person who is without fault is entitled as provided in subsection (b)(4), if such adjustment (or recovery) would defeat the purposes of title II or title XVIII [*42 USCS §§ 401* et seq. or *1395* et seq.] or would be against equity and good conscience. Adjustment or recovery of an incorrect payment (or only such part of an incorrect payment as the Secretary determines to be inconsistent with the purposes of this *title [42 USCS §§ 1395* et seq.]) against an individual who is without fault shall be deemed to be against equity and good conscience if (A) the incorrect payment was made for expenses incurred for items or services for which payment may not be made under this *title [42 USCS §§ 1395* et seq.] by reason of the provisions of paragraph (1) or (9) of section 1862(a) [*42 USCS § 1395y(a)(1)* or (9)] and (B) if the Secretary's determination that such payment was incorrect was made subsequent to the third year following the year in which notice of such payment was sent to such individual; except that the Secretary may reduce such three-year period to not less than one year if he finds such reduction is consistent with the objectives of this *title [42 USCS §§ 1395* et seq.].

(d) Liability of certifying or disbursing officer for failure to recoup. No certifying or disbursing officer shall be held liable for any amount certified or paid by him to any provider of services or other person where the adjustment or recovery of such amount is waived under subsection (c) or where adjustment under subsection (b) is not completed prior to the death of all persons against whose benefits such adjustment is authorized.

(e) Settlement of claims for benefits under *42 USCS §§ 1395* et seq. on behalf of deceased individuals. If an individual, who received services for which payment may be made to such individual under this *title [42 USCS §§ 1395* et seq.], dies, and payment for such services was made (other than under this *title [42 USCS §§ 1395* et seq.]), and the individual died before any payment due him under this *title [42 USCS §§ 1395* et seq.] with respect to such services was completed, payment of the amount due (including the amount of any unnegotiated checks) shall be made--

(1) if the payment for such services was made (before or after such individual's death) by a person other than the deceased individual, to the person or persons determined by the Secretary under regulations to have paid for such services, or if the payment for such services was made by the deceased individual before his death, to the legal representative of the estate of such deceased individual, if any;

(2) if there is no person who meets the requirements of paragraph (1), to the person, if any, who is determined by the Secretary to be the surviving spouse of the deceased individual and who was either living in the same household with the deceased at the time of his death or was, for the month in which the deceased individual died, entitled to a monthly benefit on the basis of the same wages and self-employment income as was the deceased individual;

(3) if there is no person who meets the requirements of paragraph (1) or (2), or if the person who meets such requirements dies before the payment due him under this *title [42 USCS §§ 1395* et seq.] is completed, to the child or children, if any, of the deceased individual who were, for the month in which the deceased individual died, entitled to monthly benefits on the basis of the same wages and self-employment income as was the deceased individual (and, in case there is more than one such child, in equal parts to each such child);

(4) if there is no person who meets the requirements of paragraph (1), (2), or (3), or if each person who meets such requirements dies before the payment due him under this *title [42 USCS §§ 1395* et seq.] is completed, to the parent or parents, if any, of the deceased individual who were, for the month in which the deceased individual died, entitled to monthly benefits on the basis of the same wages and self-employment income as was the deceased individual (and, in case there is more than one such parent, in equal parts to each such parent);

(5) if there is no person who meets the requirements of paragraph (1), (2), (3), or (4), or if each person who meets such requirements dies before the payment due him under this *title [42 USCS §§ 1395* et seq.] is completed, to the person, if any, determined by the Secretary to be the surviving spouse of the deceased individual;

(6) if there is no person who meets the requirements of paragraph (1), (2), (3), (4), or (5), or if each person who meets such requirements dies before the payment due him under this *title [42 USCS §§ 1395* et seq.] is completed, to the person or persons, if any, determined by the Secretary to be the child or children of the deceased individual (and, in case there is more than one such child, in equal parts to each such child);

(7) if there is no person who meets the requirements of paragraph (1), (2), (3), (4), (5), or (6), or if each person who meets such requirements dies before the payment due him under this *title [42 USCS §§ 1395* et seq.] is completed, to the parent or parents, if any, of the deceased individual (and, in case there is more than one such parent, in equal parts to each such parent); or

(8) if there is no person who meets the requirements of paragraph (1), (2), (3), (4), (5), (6), or (7), or if each person who meets such requirements dies before the payment due him under this *title [42 USCS §§ 1395* et seq.] is completed, to the legal representatives of the estate of the deceased individual, if any.

(f) Settlement of claims for section 1395k benefits on behalf of deceased individuals. If an individual who received medical and other health services for which payment may be made under section 1832(a)(1) [*42 USCS § 1395k(a)(1)*] dies, and no assignment of the right to payment for such services was made by such individual before his death, and payment for such services has not been made--

(1) if the person or persons who furnished the services agree to the terms of assignment specified in section 1842(b)(3)(B)(ii) [*42 USCS § 1395u(b)(3)(B)(ii)*] with respect to the services, payment for such services shall be made to such person or persons, and

(2) if the person or persons who furnished the services do not agree to the terms of assignment specified in section 1842(b)(3)(B)(ii) [*42 USCS § 1395u(b)(3)(B)(ii)*] with respect to the services, payment for such services shall be made on the basis of an itemized bill to the person who has agreed to assume the legal obligation to make payment for such services and files a request for payment (with such accompanying evidence of such legal obligation as may be required in regulations),

but only in such amount and subject to such conditions as would be applicable if the individual who received the services had not died.

(g) Refund of premiums for deceased individuals. If an individual, who is enrolled under section 1818(c) of the Social Security Act [*42 USCS § 1395i-2(c)*] or under section 1837 [*42 USCS § 1395p*], dies, and premiums with respect to such enrollment have been received with respect to such individual for any month after the month of his death, such premiums shall be refunded to the person or persons determined by the Secretary under regulations to have paid such premiums or if payment for such premiums was made by the deceased individual before his death, to the legal representative of the estate of such deceased individual, if any. If there is no person who meets the requirements of the preceding sentence such premiums shall be refunded to the person or persons in the priorities specified in paragraphs (2) through (7) of subsection (e).

(h) Notwithstanding subsection (f) or any other provision of law, the Secretary shall permit a provider of services or supplier to appeal any determination of the Secretary under this *title [42 USCS §§ 1395* et seq.] relating to services rendered under this *title [42 USCS §§ 1395* et seq.] to an individual who subsequently dies if there is no other party available to appeal such determination.

HISTORY:

(Aug. 14, 1935, ch 531, Title XVIII, Part E[D][C], § 1870, as added July 30, 1965, P.L. 89-97, Title I, Part 1, § 102(a), 79 Stat. 331; Jan. 2, 1968, P.L. 90-248, Title I, Part 4, § 154(c), 81 Stat. 862; Oct. 30, 1972, P.L. 92-603, Title II, §§ 261(a), 266, 281(a), (b), 86 Stat. 1448, 1450, 1454, 1455; Oct. 16, 1974, P.L. 93-445, Title III, § 309, 88 Stat. 1358; Dec. 5, 1980, P.L. 96-499, Title IX, Part B, Subpart II, § 954(a), 94 Stat. 2647; Sept. 3, 1982, P.L. 97-248, Title I, Subtitle A, Part III, § 128(d)(1), 96 Stat. 367; Dec. 22, 1987, P.L. 100-203, Title IV, Subtitle A, Part 2, Subpart C, § 4039(h)(7), part 4, § 4096(a)(2), 101 Stat. 1330-83, 1330-139; July 1, 1988, P.L. 100-360, Title IV, Subtitle B, § 411(e)(3), (j)(4)(B), 102 Stat. 776, 791; Aug. 5, 1997, P.L. 105-33, Title IV, Subtitle A, Ch 1, Subch A, § 4001, 111 Stat. 275; Dec. 8, 2003, P.L. 108-173, Title I, § 101(a)(1), Title IX, Subtitle D, § 939(a), 117 Stat. 2071, 2416.)

§ 1395hh. Regulations

(a) Authority to prescribe regulations; ineffectiveness of substantive rules not promulgated by regulation.

(1) The Secretary shall prescribe such regulations as may be necessary to carry out the administration of the insurance programs under this *title [42 USCS §§ 1395* et seq.]. When used in this *title [42 USCS §§ 1395* et seq.], the term "regulations" means, unless the context otherwise requires, regulations prescribed by the Secretary.

(2) No rule, requirement, or other statement of policy (other than a national coverage determination) that establishes or changes a substantive legal standard governing the scope of benefits, the payment for services, or the eligibility of individuals, entities, or organizations to furnish or receive services or benefits under this title shall take effect unless it is promulgated by the Secretary by regulation under paragraph (1).

(3) (A) The Secretary, in consultation with the Director of the Office of Management and Budget, shall establish and publish a regular timeline for the publication of final regulations based on the previous publication of a proposed regulation or an interim final regulation.

(B) Such timeline may vary among different regulations based on differences in the complexity of the regulation, the number and scope of comments received, and other relevant factors, but shall not be longer than 3 years except under exceptional circumstances. If the Secretary intends to vary such timeline with respect to the publication of a final

regulation, the Secretary shall cause to have published in the Federal Register notice of the different timeline by not later than the timeline previously established with respect to such regulation. Such notice shall include a brief explanation of the justification for such variation.

(C) In the case of interim final regulations, upon the expiration of the regular timeline established under this paragraph for the publication of a final regulation after opportunity for public comment, the interim final regulation shall not continue in effect unless the Secretary publishes (at the end of the regular timeline and, if applicable, at the end of each succeeding 1-year period) a notice of continuation of the regulation that includes an explanation of why the regular timeline (and any subsequent 1-year extension) was not complied with. If such a notice is published, the regular timeline (or such timeline as previously extended under this paragraph) for publication of the final regulation shall be treated as having been extended for 1 additional year.

(D) The Secretary shall annually submit to Congress a report that describes the instances in which the Secretary failed to publish a final regulation within the applicable regular timeline under this paragraph and that provides an explanation for such failures.

(4) If the Secretary publishes a final regulation that includes a provision that is not a logical outgrowth of a previously published notice of proposed rulemaking or interim final rule, such provision shall be treated as a proposed regulation and shall not take effect until there is the further opportunity for public comment and a publication of the provision again as a final regulation.

(b) Notice of proposed regulations; public comment.

(1) Except as provided in paragraph (2), before issuing in final form any regulation under subsection (a), the Secretary shall provide for notice of the proposed regulation in the Federal Register and a period of not less than 60 days for public comment thereon.

(2) Paragraph (1) shall not apply where--

(A) a statute specifically permits a regulation to be issued in interim final form or otherwise with a shorter period for public comment,

(B) a statute establishes a specific deadline for the implementation of a provision and the deadline is less than 150 days after the date of the enactment of the statute in which the deadline is contained, or

(C) subsection (b) of *section 553 of title 5, United States Code*, does not apply pursuant to subparagraph (B) of such subsection.

(c) Publication of certain rules; public inspection; changes in data collection and retrieval.

(1) The Secretary shall publish in the Federal Register, not less frequently than every 3 months, a list of all manual instructions, interpretative rules, statements of policy, and guidelines of general applicability which--

(A) are promulgated to carry out this *title [42 USCS §§ 1395* et seq.], but

(B) are not published pursuant to subsection (a)(1) and have not been previously published in a list under this subsection.

(2) Effective June 1, 1988, each fiscal intermediary and carrier administering claims for extended care, post-hospital extended care, home health care, and durable medical equipment benefits under this *title [42 USCS §§ 1395* et seq.] shall make available to the public all interpretative materials, guidelines, and clarifications of policies which relate to payments for such benefits.

(3) The Secretary shall to the extent feasible make such changes in automated data collection and retrieval by the Secretary and fiscal intermediaries with agreements under section 1816 [*42 USCS § 1395h*] as are necessary to make easily accessible for the Secretary and other appropriate parties a data base which fairly and accurately reflects the provision of extended care, post-hospital extended care and home health care benefits pursuant to this *title [42 USCS §§ 1395* et seq.], including such categories as benefit denials, results of appeals, and other relevant factors, and selectable by such categories and by fiscal intermediary, service provider, and region.

(e) (1) (A) A substantive change in regulations, manual instructions, interpretative rules, statements of policy, or guidelines of general applicability under this title shall not be applied (by extrapolation or otherwise) retroactively to items and services furnished before the effective date of the change, unless the Secretary determines that--

(i) such retroactive application is necessary to comply with statutory requirements; or

(ii) failure to apply the change retroactively would be contrary to the public interest.

(B) (i) Except as provided in clause (ii), a substantive change referred to in subparagraph (A) shall not become effective before the end of the 30-day period that begins on the date that the Secretary has issued or published, as the case may be, the substantive change.

(ii) The Secretary may provide for such a substantive change to take effect on a date that precedes the end of the 30-day period under clause (i) if the Secretary finds that waiver of such 30-day period is necessary to comply with

statutory requirements or that the application of such 30-day period is contrary to the public interest. If the Secretary provides for an earlier effective date pursuant to this clause, the Secretary shall include in the issuance or publication of the substantive change a finding described in the first sentence, and a brief statement of the reasons for such finding.

(C) No action shall be taken against a provider of services or supplier with respect to noncompliance with such a substantive change for items and services furnished before the effective date of such a change.

(2) (A) If--

(i) a provider of services or supplier follows the written guidance (which may be transmitted electronically) provided by the Secretary or by a medicare contractor (as defined in section 1889(g) [*42 USCS § 1395zz(g)*]) acting within the scope of the contractor's contract authority, with respect to the furnishing of items or services and submission of a claim for benefits for such items or services with respect to such provider or supplier;

(ii) the Secretary determines that the provider of services or supplier has accurately presented the circumstances relating to such items, services, and claim to the contractor in writing; and

(iii) the guidance was in error;

the provider of services or supplier shall not be subject to any penalty or interest under this *title [42 USCS §§ 1395* et seq.] or the provisions of title XI [*42 USCS §§ 1301* et seq.] insofar as they relate to this *title [42 USCS §§ 1395* et seq.] (including interest under a repayment plan under section 1893 [*42 USCS § 1395ddd*] or otherwise) relating to the provision of such items or service or such claim if the provider of services or supplier reasonably relied on such guidance.

(B) Subparagraph (A) shall not be construed as preventing the recoupment or repayment (without any additional penalty) relating to an overpayment insofar as the overpayment was solely the result of a clerical or technical operational error.

(f) (1) Not later than 2 years after the date of the enactment of this subsection [enacted Dec. 8, 2003], and every 3 years thereafter, the Secretary shall submit to Congress a report with respect to the administration of this *title [42 USCS §§ 1395* et seq.] and areas of inconsistency or conflict among the various provisions under law and regulation.

(2) In preparing a report under paragraph (1), the Secretary shall collect--

(A) information from individuals entitled to benefits under part A [*42 USCS §§ 1395c* et seq.] or enrolled under part B [*42 USCS §§ 1395j* et seq.], or both, providers of services, and suppliers and from the Medicare Beneficiary Ombudsman with respect to such areas of inconsistency and conflict; and

(B) information from medicare contractors that tracks the nature of written and telephone inquiries.

(3) A report under paragraph (1) shall include a description of efforts by the Secretary to reduce such inconsistency or conflicts, and recommendations for legislation or administrative action that the Secretary determines appropriate to further reduce such inconsistency or conflicts.

HISTORY:

(Aug. 14, 1935, ch 531, Title XVIII, Part E[D][C], § 1871, as added July 30, 1965, P.L. 89-97, Title I, Part 1, § 102(a), 79 Stat. 331; Oct. 21, 1986, P.L. 99-509, Title IX, Subtitle D, Part 2, § 9321(e)(1), 100 Stat. 2016; Dec. 22, 1987, P.L. 100-203, Title IV, Subtitle A, Part 2, Subpart C, § 4035(b), (c), 101 Stat. 1330-78; Aug. 5, 1997, P.L. 105-33, Title IV, Subtitle A, Ch 1, Subch A, § 4001, 111 Stat. 275; Dec. 8, 2003, P.L. 108-173, Title I, § 101(a)(1), Title IX, Subtitle A, §§ 902(a)(1), (b)(1), 903(a)(1), (b)(1), (c)(1), 904(b), 117 Stat. 2071, 2375, 2376, 2377.)

§ 1395ii. Application of certain provisions of title II [42 USCS §§ 401 et seq.]

The provisions of sections 206 and 216(j), and of subsections (a), (d), (e), (h), (i), (j), (k), and (l) of section 205 [*42 USCS §§ 406*, *416(j)*, and *405(a)*, (d), (e), (h), (i), (j), (k), and (l)], shall also apply with respect to this *title [42 USCS §§ 1395* et seq.] to the same extent as they are applicable with respect to title II [*42 USCS §§ 401* et seq.], except that, in applying such provisions with respect to this *title [42 USCS §§ 1395* et seq.], any reference therein to the Commissioner of Social Security or the Social Security Administration shall be considered a reference to the Secretary or the Department of Health and Human Services, respectively.

HISTORY:

(Aug. 14, 1935, ch 531, Title XVIII, Part E[D][C], § 1872, as added July 30, 1965, P.L. 89-97, Title I, Part 1, § 102(a), 79 Stat. 332; Oct. 30, 1972, P.L. 92-603, Title II, § 242(a), 86 Stat. 1419; July 18, 1984, P.L. 98-369, Division B, Title III, Subtitle A, Part II, § 2354(b)(36), 98 Stat. 1102; Aug. 15, 1994, P.L. 103-296, Title I, § 108(c)(4), 108 Stat. 1485; Aug. 5, 1997, P.L. 105-33, Title IV, Subtitle A, Ch 1, Subch A, § 4001, 111 Stat. 275; Dec. 8, 2003, P.L. 108-173, Title I, § 101(a)(1), 117 Stat. 2071.)

§ 1395jj. Designation of organization or publication by name

Designation in this *title [42 USCS §§ 1395* et seq.], by name, of any nongovernmental organization or publication shall not be affected by change of name of such organization or publication, and shall apply to any successor organization or publication which the Secretary finds serves the purpose for which such designation is made.

HISTORY:

(Aug. 14, 1935, ch 531, Title XVIII, Part E[D][C], § 1873, as added July 30, 1965, P.L. 89-97, Title I, Part 1, § 102(a), 79 Stat. 332; Aug. 5, 1997, P.L. 105-33, Title IV, Subtitle A, Ch 1, Subch A, § 4001, 111 Stat. 275; Dec. 8, 2003, P.L. 108-173, Title I, § 101(a)(1), 117 Stat. 2071.)

§ 1395kk. Administration of insurance programs

(a) Functions of Secretary; performance directly or by contract. Except as otherwise provided in this *title [42 USCS §§ 1395* et seq.] and in the Railroad Retirement Act of 1974, the insurance programs established by this *title [42 USCS §§ 1395* et seq.] shall be administered by the Secretary. The Secretary may perform any of his functions under this *title [42 USCS §§ 1395* et seq.] directly, or by contract providing for payment in advance or by way of reimbursement, and in such installments, as the Secretary may deem necessary.

(b) Contracts to secure special data, actuarial information, etc. The Secretary may contract with any person, agency, or institution to secure on a reimbursable basis such special data, actuarial information, and other information as may be necessary in the carrying out of his functions under this *title [42 USCS §§ 1395* et seq.].

(c) Oaths and affirmations. In the course of any hearing, investigation, or other proceeding, that he is authorized to conduct under this *title [42 USCS §§ 1395* et seq.], the Secretary may administer oaths and affirmations.

(d) Inclusion of medicare provider and supplier payments in Federal Payment Levy Program.

(1) In general. The Centers for Medicare & Medicaid Services shall take all necessary steps to participate in the Federal Payment Levy Program under *section 6331(h) of the Internal Revenue Code of 1986* [*26 USCS § 6331(h)*] as soon as possible and shall ensure that--

(A) at least 50 percent of all payments under parts A and B [*42 USCS §§ 1395c* et seq. and *1395j* et seq.] are processed through such program beginning within 1 year after the date of the enactment of this section;

(B) at least 75 percent of all payments under parts A and B [*42 USCS §§ 1395c* et seq. and *1395j* et seq.] are processed through such program beginning within 2 years after such date; and

(C) all payments under parts A and B [*42 USCS §§ 1395c* et seq. and *1395j* et seq.] are processed through such program beginning not later than September 30, 2011.

(2) Assistance. The Financial Management Service and the Internal Revenue Service shall provide assistance to the Centers for Medicare & Medicaid Services to ensure that all payments described in paragraph (1) are included in the Federal Payment Levy Program by the deadlines specified in that subsection.

HISTORY:

(Aug. 14, 1935, ch 531, Title XVIII, Part E[D][C], § 1874, as added July 30, 1965, P.L. 89-97, Title I, Part 1, §§ 102(a), 111(a), 79 Stat. 332, 340; Oct. 30, 1972, P.L. 92-603, Title II, § 289, 86 Stat. 1457; Oct. 16, 1974, P.L. 93-445, Title III, § 310, 88 Stat. 1359; Aug. 5, 1997, P.L. 105-33, Title IV, Subtitle A, Ch 1, Subch A, § 4001, 111 Stat. 275; Dec. 8, 2003, P.L. 108-173, Title I, § 101(a)(1), 117 Stat. 2071; July 15, 2008, P.L. 110-275, Title I, Subtitle F, § 189(a), 122 Stat. 2590.)

§ 1395kk-1. Contracts with medicare administrative contractors

(a) Authority.

(1) Authority to enter into contracts. The Secretary may enter into contracts with any eligible entity to serve as a medicare administrative contractor with respect to the performance of any or all of the functions described in paragraph (4) or parts of those functions (or, to the extent provided in a contract, to secure performance thereof by other entities).

(2) Eligibility of entities. An entity is eligible to enter into a contract with respect to the performance of a particular function described in paragraph (4) only if--

(A) the entity has demonstrated capability to carry out such function;

(B) the entity complies with such conflict of interest standards as are generally applicable to Federal acquisition and procurement;

(C) the entity has sufficient assets to financially support the performance of such function; and

(D) the entity meets such other requirements as the Secretary may impose.

(3) Medicare administrative contractor defined. For purposes of this title and title XI [*42 USCS §§ 1395* et seq. and *1301* et seq.]--

(A) In general. The term "medicare administrative contractor" means an agency, organization, or other person with a contract under this section.

(B) Appropriate medicare administrative contractor. With respect to the performance of a particular function in relation to an individual entitled to benefits under part A [*42 USCS §§ 1395c* et seq.] or enrolled under part B [*42 USCS §§ 1395j* et seq.], or both, a specific provider of services or supplier (or class of such providers of services or suppliers), the "appropriate" medicare administrative contractor is the medicare administrative contractor that has a contract under this section with respect to the performance of that function in relation to that individual, provider of services or supplier or class of provider of services or supplier.

(4) Functions described. The functions referred to in paragraphs (1) and (2) are payment functions (including the function of developing local coverage determinations, as defined in section 1869(f)(2)(B) [*42 USCS § 1395ff(f)(2)(B)*]), provider services functions, and functions relating to services furnished to individuals entitled to benefits under part A [*42 USCS §§ 1395c* et seq.] or enrolled under part B [*42 USCS §§ 1395j* et seq.], or both, as follows:

(A) Determination of payment amounts. Determining (subject to the provisions of section 1878 and to such review by the Secretary as may be provided for by the contracts) the amount of the payments required pursuant to this *title [42 USCS §§ 1395* et seq.] to be made to providers of services, suppliers and individuals.

(B) Making payments. Making payments described in subparagraph (A) (including receipt, disbursement, and accounting for funds in making such payments).

(C) Beneficiary education and assistance. Providing education and outreach to individuals entitled to benefits under part A [*42 USCS §§ 1395c* et seq.] or enrolled under part B [*42 USCS §§ 1395j* et seq.], or both, and providing assistance to those individuals with specific issues, concerns, or problems.

(D) Provider consultative services. Providing consultative services to institutions, agencies, and other persons to enable them to establish and maintain fiscal records necessary for purposes of this *title [42 USCS §§ 1395* et seq.] and otherwise to qualify as providers of services or suppliers.

(E) Communication with providers. Communicating to providers of services and suppliers any information or instructions furnished to the medicare administrative contractor by the Secretary, and facilitating communication between such providers and suppliers and the Secretary.

(F) Provider education and technical assistance. Performing the functions relating to provider education, training, and technical assistance.

(G) Additional functions. Performing such other functions, including (subject to paragraph (5)) functions under the Medicare Integrity Program under section 1893, as are necessary to carry out the purposes of this *title [42 USCS §§ 1395* et seq.].

(5) Relationship to MIP contracts.

(A) Nonduplication of duties. In entering into contracts under this section, the Secretary shall assure that functions of medicare administrative contractors in carrying out activities under parts A and B [*42 USCS §§ 1395c* et seq. and *1395j* et seq.] do not duplicate activities carried out under a contract entered into under the Medicare Integrity Program under section 1893 [*42 USCS § 1395ddd*]. The previous sentence shall not apply with respect to the activity described in section 1893(b)(5) [*42 USCS § 1395ddd(b)(5)*] (relating to prior authorization of certain items of durable medical equipment under section 1834(a)(15) [*42 USCS § 1395i-5(a)(15)*]).

(B) Construction. An entity shall not be treated as a medicare administrative contractor merely by reason of having entered into a contract with the Secretary under section 1893 [*42 USCS § 1395ddd*].

(6) Application of Federal Acquisition Regulation. Except to the extent inconsistent with a specific requirement of this section, the Federal Acquisition Regulation applies to contracts under this section.

(b) Contracting requirements.

(1) Use of competitive procedures.

(A) In general. Except as provided in laws with general applicability to Federal acquisition and procurement or in subparagraph (B), the Secretary shall use competitive procedures when entering into contracts with medicare administrative contractors under this section, taking into account performance quality as well as price and other factors.

(B) Renewal of contracts. The Secretary may renew a contract with a medicare administrative contractor under this section from term to term without regard to *section 5 of title 41, United States Code*, or any other provision of law requiring competition, if the medicare administrative contractor has met or exceeded the performance requirements

applicable with respect to the contract and contractor, except that the Secretary shall provide for the application of competitive procedures under such a contract not less frequently than once every 5 years.

(C) Transfer of functions. The Secretary may transfer functions among medicare administrative contractors consistent with the provisions of this paragraph. The Secretary shall ensure that performance quality is considered in such transfers. The Secretary shall provide public notice (whether in the Federal Register or otherwise) of any such transfer (including a description of the functions so transferred, a description of the providers of services and suppliers affected by such transfer, and contact information for the contractors involved).

(D) Incentives for quality. The Secretary shall provide incentives for medicare administrative contractors to provide quality service and to promote efficiency.

(2) Compliance with requirements. No contract under this section shall be entered into with any medicare administrative contractor unless the Secretary finds that such medicare administrative contractor will perform its obligations under the contract efficiently and effectively and will meet such requirements as to financial responsibility, legal authority, quality of services provided, and other matters as the Secretary finds pertinent.

(3) Performance requirements.

(A) Development of specific performance requirements.

(i) In general. The Secretary shall develop contract performance requirements to carry out the specific requirements applicable under this *title [42 USCS §§ 1395* et seq.] to a function described in subsection (a)(4) and shall develop standards for measuring the extent to which a contractor has met such requirements. Such requirements shall include specific performance duties expected of a medical director of a medicare administrative contractor, including requirements relating to professional relations and the availability of such director to conduct medical determination activities within the jurisdiction of such a contractor.

(ii) Consultation. In developing such performance requirements and standards for measurement, the Secretary shall consult with providers of services, organizations representative of beneficiaries under this *title [42 USCS §§ 1395* et seq.], and organizations and agencies performing functions necessary to carry out the purposes of this section with respect to such performance requirements.

(iii) Publication of standards. The Secretary shall make such performance requirements and measurement standards available to the public.

(B) Considerations. The Secretary shall include, as one of the standards developed under subparagraph (A), provider and beneficiary satisfaction levels.

(C) Inclusion in contracts. All contractor performance requirements shall be set forth in the contract between the Secretary and the appropriate medicare administrative contractor. Such performance requirements--

(i) shall reflect the performance requirements published under subparagraph (A), but may include additional performance requirements;

(ii) shall be used for evaluating contractor performance under the contract; and

(iii) shall be consistent with the written statement of work provided under the contract.

(4) Information requirements. The Secretary shall not enter into a contract with a medicare administrative contractor under this section unless the contractor agrees--

(A) to furnish to the Secretary such timely information and reports as the Secretary may find necessary in performing his functions under this *title [42 USCS §§ 1395* et seq.]; and

(B) to maintain such records and afford such access thereto as the Secretary finds necessary to assure the correctness and verification of the information and reports under subparagraph (A) and otherwise to carry out the purposes of this *title [42 USCS §§ 1395* et seq.].

(5) Surety bond. A contract with a medicare administrative contractor under this section may require the medicare administrative contractor, and any of its officers or employees certifying payments or disbursing funds pursuant to the contract, or otherwise participating in carrying out the contract, to give surety bond to the United States in such amount as the Secretary may deem appropriate.

(c) Terms and conditions.

(1) In general. A contract with any medicare administrative contractor under this section may contain such terms and conditions as the Secretary finds necessary or appropriate and may provide for advances of funds to the medicare administrative contractor for the making of payments by it under subsection (a)(4)(B).

(2) Prohibition on mandates for certain data collection. The Secretary may not require, as a condition of entering into, or renewing, a contract under this section, that the medicare administrative contractor match data obtained other than in its activities under this *title [42 USCS §§ 1395* et seq.] with data used in the administration of this *title [42 USCS §§ 1395* et seq.] for purposes of identifying situations in which the provisions of section 1862(b) may apply.

(d) Limitation on liability of medicare administrative contractors and certain officers.

(1) Certifying officer. No individual designated pursuant to a contract under this section as a certifying officer shall, in the absence of the reckless disregard of the individual's obligations or the intent by that individual to defraud the United States, be liable with respect to any payments certified by the individual under this section.

(2) Disbursing officer. No disbursing officer shall, in the absence of the reckless disregard of the officer's obligations or the intent by that officer to defraud the United States, be liable with respect to any payment by such officer under this section if it was based upon an authorization (which meets the applicable requirements for such internal controls established by the Comptroller General of the United States) of a certifying officer designated as provided in paragraph (1) of this subsection.

(3) Liability of medicare administrative contractor.

(A) In general. No medicare administrative contractor shall be liable to the United States for a payment by a certifying or disbursing officer unless, in connection with such payment, the medicare administrative contractor acted with reckless disregard of its obligations under its medicare administrative contract or with intent to defraud the United States.

(B) Relationship to False Claims Act. Nothing in this subsection shall be construed to limit liability for conduct that would constitute a violation of sections 3729 through 3731 of title 31, United States Code.

(4) Indemnification by Secretary.

(A) In general. Subject to subparagraphs (B) and (D), in the case of a medicare administrative contractor (or a person who is a director, officer, or employee of such a contractor or who is engaged by the contractor to participate directly in the claims administration process) who is made a party to any judicial or administrative proceeding arising from or relating directly to the claims administration process under this *title [42 USCS §§ 1395* et seq.], the Secretary may, to the extent the Secretary determines to be appropriate and as specified in the contract with the contractor, indemnify the contractor and such persons.

(B) Conditions. The Secretary may not provide indemnification under subparagraph (A) insofar as the liability for such costs arises directly from conduct that is determined by the judicial proceeding or by the Secretary to be criminal in nature, fraudulent, or grossly negligent. If indemnification is provided by the Secretary with respect to a contractor before a determination that such costs arose directly from such conduct, the contractor shall reimburse the Secretary for costs of indemnification.

(C) Scope of indemnification. Indemnification by the Secretary under subparagraph (A) may include payment of judgments, settlements (subject to subparagraph (D)), awards, and costs (including reasonable legal expenses).

(D) Written approval for settlements or compromises. A contractor or other person described in subparagraph (A) may not propose to negotiate a settlement or compromise of a proceeding described in such subparagraph without the prior written approval of the Secretary to negotiate such settlement or compromise. Any indemnification under subparagraph (A) with respect to amounts paid under a settlement or compromise of a proceeding described in such subparagraph are conditioned upon prior written approval by the Secretary of the final settlement or compromise.

(E) Construction. Nothing in this paragraph shall be construed--

(i) to change any common law immunity that may be available to a medicare administrative contractor or person described in subparagraph (A); or

(ii) to permit the payment of costs not otherwise allowable, reasonable, or allocable under the Federal Acquisition Regulation.

(e) Requirements for information security.

(1) Development of information security program. A medicare administrative contractor that performs the functions referred to in subparagraphs (A) and (B) of subsection (a)(4) (relating to determining and making payments) shall implement a contractor-wide information security program to provide information security for the operation and assets of the contractor with respect to such functions under this *title [42 USCS §§ 1395* et seq.]. An information security program under this paragraph shall meet the requirements for information security programs imposed on Federal agencies under paragraphs (1) through (8) of *section 3544(b) of title 44, United States Code* (other than the requirements under paragraphs (2)(D)(i), (5)(A), and (5)(B) of such section).

(2) Independent audits.

(A) Performance of annual evaluations. Each year a medicare administrative contractor that performs the functions referred to in subparagraphs (A) and (B) of subsection (a)(4) (relating to determining and making payments) shall undergo an evaluation of the information security of the contractor with respect to such functions under this *title [42 USCS §§ 1395* et seq.]. The evaluation shall--

(i) be performed by an entity that meets such requirements for independence as the Inspector General of the Department of Health and Human Services may establish; and

(ii) test the effectiveness of information security control techniques of an appropriate subset of the contractor's information systems (as defined in *section 3502(8) of title 44, United States Code*) relating to such functions under this

title and an assessment of compliance with the requirements of this subsection and related information security policies, procedures, standards and guidelines, including policies and procedures as may be prescribed by the Director of the Office of Management and Budget and applicable information security standards promulgated under *section 11331 of title 40, United States Code.*

(B) Deadline for initial evaluation.

(i) New contractors. In the case of a medicare administrative contractor covered by this subsection that has not previously performed the functions referred to in subparagraphs (A) and (B) of subsection (a)(4) (relating to determining and making payments) as a fiscal intermediary or carrier under section 1816 or 1842 [*42 USCS § 1395h* or *1395u*], the first independent evaluation conducted pursuant to subparagraph (A) shall be completed prior to commencing such functions.

(ii) Other contractors. In the case of a medicare administrative contractor covered by this subsection that is not described in clause (i), the first independent evaluation conducted pursuant to subparagraph (A) shall be completed within 1 year after the date the contractor commences functions referred to in clause (i) under this section.

(C) Reports on evaluations.

(i) To the Department of Health and Human Services. The results of independent evaluations under subparagraph (A) shall be submitted promptly to the Inspector General of the Department of Health and Human Services and to the Secretary.

(ii) To Congress. The Inspector General of the Department of Health and Human Services shall submit to Congress annual reports on the results of such evaluations, including assessments of the scope and sufficiency of such evaluations.

(iii) Agency reporting. The Secretary shall address the results of such evaluations in reports required under *section 3544(c) of title 44, United States Code.*

(f) Incentives to improve contractor performance in provider education and outreach. The Secretary shall use specific claims payment error rates or similar methodology of medicare administrative contractors in the processing or reviewing of medicare claims in order to give such contractors an incentive to implement effective education and outreach programs for providers of services and suppliers.

(g) Communications with beneficiaries, providers of services and suppliers.

(1) Communication strategy. The Secretary shall develop a strategy for communications with individuals entitled to benefits under part A [*42 USCS §§ 1395c* et seq.] or enrolled under part B [*42 USCS §§ 1395j* et seq.], or both, and with providers of services and suppliers under this *title [42 USCS §§ 1395* et seq.].

(2) Response to written inquiries. Each medicare administrative contractor shall, for those providers of services and suppliers which submit claims to the contractor for claims processing and for those individuals entitled to benefits under part A [*42 USCS §§ 1395c* et seq.] or enrolled under part B [*42 USCS §§ 1395j* et seq.], or both, with respect to whom claims are submitted for claims processing, provide general written responses (which may be through electronic transmission) in a clear, concise, and accurate manner to inquiries of providers of services, suppliers, and individuals entitled to benefits under part A [*42 USCS §§ 1395c* et seq.] or enrolled under part B [*42 USCS §§ 1395j* et seq.], or both, concerning the programs under this title within 45 business days of the date of receipt of such inquiries.

(3) Response to toll-free lines. The Secretary shall ensure that each medicare administrative contractor shall provide, for those providers of services and suppliers which submit claims to the contractor for claims processing and for those individuals entitled to benefits under part A [*42 USCS §§ 1395c* et seq.] or enrolled under part B [*42 USCS §§ 1395j* et seq.], or both, with respect to whom claims are submitted for claims processing, a toll-free telephone number at which such individuals, providers of services, and suppliers may obtain information regarding billing, coding, claims, coverage, and other appropriate information under this title.

(4) Monitoring of contractor responses.

(A) In general. Each medicare administrative contractor shall, consistent with standards developed by the Secretary under subparagraph (B)--

(i) maintain a system for identifying who provides the information referred to in paragraphs (2) and (3); and

(ii) monitor the accuracy, consistency, and timeliness of the information so provided.

(B) Development of standards.

(i) In general. The Secretary shall establish and make public standards to monitor the accuracy, consistency, and timeliness of the information provided in response to written and telephone inquiries under this subsection. Such standards shall be consistent with the performance requirements established under subsection (b)(3).

(ii) Evaluation. In conducting evaluations of individual medicare administrative contractors, the Secretary shall take into account the results of the monitoring conducted under subparagraph (A) taking into account as performance requirements the standards established under clause (i). The Secretary shall, in consultation with organizations

representing providers of services, suppliers, and individuals entitled to benefits under part A [*42 USCS §§ 1395c* et seq.] or enrolled under part B [*42 USCS §§ 1395j* et seq.], or both, establish standards relating to the accuracy, consistency, and timeliness of the information so provided.

(C) Direct monitoring. Nothing in this paragraph shall be construed as preventing the Secretary from directly monitoring the accuracy, consistency, and timeliness of the information so provided.

(5) Authorization of appropriations. There are authorized to be appropriated such sums as are necessary to carry out this subsection.

(h) Conduct of prepayment review.

(1) Conduct of random prepayment review.

(A) In general. A medicare administrative contractor may conduct random prepayment review only to develop a contractor-wide or program-wide claims payment error rates or under such additional circumstances as may be provided under regulations, developed in consultation with providers of services and suppliers.

(B) Use of standard protocols when conducting prepayment reviews. When a medicare administrative contractor conducts a random prepayment review, the contractor may conduct such review only in accordance with a standard protocol for random prepayment audits developed by the Secretary.

(C) Construction. Nothing in this paragraph shall be construed as preventing the denial of payments for claims actually reviewed under a random prepayment review.

(D) Random prepayment review. For purposes of this subsection, the term "random prepayment review" means a demand for the production of records or documentation absent cause with respect to a claim.

(2) Limitations on non-random prepayment review.

(A) Limitations on initiation of non-random prepayment review. A medicare administrative contractor may not initiate non-random prepayment review of a provider of services or supplier based on the initial identification by that provider of services or supplier of an improper billing practice unless there is a likelihood of sustained or high level of payment error under section 1893(f)(3)(A) [*42 USCS § 1395ddd(f)(3)(A)*].

(B) Termination of non-random prepayment review. The Secretary shall issue regulations relating to the termination, including termination dates, of non-random prepayment review. Such regulations may vary such a termination date based upon the differences in the circumstances triggering prepayment review.

HISTORY:

(Aug. 14, 1935, ch 531, Title XVIII, Part E, § 1874A, as added and amended Dec. 8, 2003, P.L. 108-173, Title IX, Subtitle B, §§ 911(a)(1), 912(a), Subtitle C, §§ 921(b)(1), (c)(1), Subtitle D, §§ 934(a), 940A(b), 117 Stat. 2378, 2387, 2389, 2406, 2417.)

§ 1395ll. Studies and recommendations

(a) Health care of the aged and disabled. The Secretary shall carry on studies and develop recommendations to be submitted from time to time to the Congress relating to health care of the aged and the disabled, including studies and recommendations concerning (1) the adequacy of existing personnel and facilities for health care for purposes of the programs under parts A and B [*42 USCS §§ 1395c* et seq. and *1395j* et seq.]; (2) methods for encouraging the further development of efficient and economical forms of health care which are a constructive alternative to inpatient hospital care; and (3) the effects of the deductibles and coinsurance provisions upon beneficiaries, persons who provide health services, and the financing of the program.

(b) Operation and administration of insurance programs [Caution: For provisions applicable to accreditations of hospitals granted before July 15, 2010, see 2008 amendment note below.]. The Secretary shall make a continuing study of the operation and administration of this *title [42 USCS §§ 1395* et seq.] (including a validation of the accreditation process of national accreditation bodies under section 1865(a)[,] the operation and administration of health maintenance organizations authorized by section 226 of the Social Security Amendments of 1972, the experiments and demonstration projects authorized by section 402 of the Social Security Amendments of 1967 and the experiments and demonstration projects authorized by section 222(a) of the Social Security Amendments of 1972) [*42 USCS § 1395b-1* note], and shall transmit to the Congress annually a report concerning the operation of such programs.

HISTORY:

(Aug. 14, 1935, ch 531, Title XVIII, Part E[D][C], § 1875, as added July 30, 1965, P.L. 89-97, Title I, Part 1, § 102(a), 79 Stat. 332; Jan. 2, 1968, P.L. 90-248, Title IV, § 402(c), 81 Stat. 931; Oct. 30, 1972, P.L. 92-603, Title II, §§ 201(c)(7), 222(c), 226(d), 244(d), 86 Stat. 1373, 1393, 1404, 1423; July 18, 1984, P.L. 98-369, Division B, Title III,

Subtitle A, Part II, § 2354(b)(17), 98 Stat. 1101; Oct. 21, 1986, P.L. 99-509, Title IX, Subtitle D, Part 2, § 9316(a), 100 Stat. 2006; Dec. 22, 1987, P.L. 100-203, Title IV, Subtitle A, Part 3, Subpt. D, § 4085(i)(20), 101 Stat. 1330-133; Nov. 10, 1988, P.L. 100-647, Title VIII, Subtitle E, Part II, § 8413, 102 Stat. 3801; Dec. 13, 1989, P.L. 101-234, Title III, § 301(b)(5), (d)(2), 103 Stat. 1985, 1986; Dec. 19, 1989, P.L. 101-239, Title VI, Subtitle A, Part 2, Subpart A, § 6103(b)(3)(A), 103 Stat. 2199; Aug. 5, 1997, P.L. 105-33, Title IV, Subtitle A, Ch 1, Subch A, § 4001, 111 Stat. 275; Dec. 8, 2003, P.L. 108-173, Title I, § 101(a)(1), (e)(7), 117 Stat. 2071, 2152; July 15, 2008, P.L. 110-275, Title I, Subtitle B, § 125(b)(4), 122 Stat. 2519.)

§ 1395mm. Payments to health maintenance organizations and competitive medical plans

(a) Rates and adjustments.

(1) (A) The Secretary shall annually determine, and shall announce (in a manner intended to provide notice to interested parties) not later than September 7 before the calendar year concerned--

(i) a per capita rate of payment for each class of individuals who are enrolled under this section with an eligible organization which has entered into a risk-sharing contract and who are entitled to benefits under part A [*42 USCS §§ 1395c* et seq.] and enrolled under part B [*42 USCS §§ 1395j* et seq.], and

(ii) a per capita rate of payment for each class of individuals who are so enrolled with such an organization and who are enrolled under part B [*42 USCS §§ 1395j* et seq.] only.

For purposes of this section, the term "risk-sharing contract" means a contract entered into under subsection (g) and the term "reasonable cost reimbursement contract" means a contract entered into under subsection (h).

(B) The Secretary shall define appropriate classes of members, based on age, disability status, and such other factors as the Secretary determines to be appropriate, so as to ensure actuarial equivalence. The Secretary may add to, modify, or substitute for such classes, if such changes will improve the determination of actuarial equivalence.

(C) The annual per capita rate of payment for each such class shall be equal to 95 percent of the adjusted average per capita cost (as defined in paragraph (4)) for that class.

(D) In the case of an eligible organization with a risk-sharing contract, the Secretary shall make monthly payments in advance and in accordance with the rate determined under subparagraph (C) and except as provided in subsection (g)(2), to the organization for each individual enrolled with the organization under this section.

(E) (i) The amount of payment under this paragraph may be retroactively adjusted to take into account any difference between the actual number of individuals enrolled in the plan under this section and the number of such individuals estimated to be so enrolled in determining the amount of the advance payment.

(ii) (I) Subject to subclause (II), the Secretary may make retroactive adjustments under clause (i) to take into account individuals enrolled during the period beginning on the date on which the individual enrolls with an eligible organization (which has a risk-sharing contract under this section) under a health benefit plan operated, sponsored, or contributed to by the individual's employer or former employer (or the employer or former employer of the individual's spouse) and ending on the date on which the individual is enrolled in the plan under this section, except that for purposes of making such retroactive adjustments under this clause, such period may not exceed 90 days.

(II) No adjustment may be made under subclause (I) with respect to any individual who does not certify that the organization provided the individual with the explanation described in subsection (c)(3)(E) at the time the individual enrolled with the organization.

(F) (i) At least 45 days before making the announcement under subparagraph (A) for a year (beginning with the announcement for 1991), the Secretary shall provide for notice to eligible organizations of proposed changes to be made in the methodology or benefit coverage assumptions from the methodology and assumptions used in the previous announcement and shall provide such organizations an opportunity to comment on such proposed changes.

(ii) In each announcement made under subparagraph (A) for a year (beginning with the announcement for 1991), the Secretary shall include an explanation of the assumptions (including any benefit coverage assumptions) and changes in methodology used in the announcement in sufficient detail so that eligible organizations can compute per capita rates of payment for classes of individuals located in each county (or equivalent area) which is in whole or in part within the service area of such an organization.

(2) With respect to any eligible organization which has entered into a reasonable cost reimbursement contract, payments shall be made to such plan in accordance with subsection (h)(2) rather than paragraph (1).

(3) Subject to subsection (c)(2)(B)(ii) and (c)(7), payments under a contract to an eligible organization under paragraph (1) or (2) shall be instead of the amounts which (in the absence of the contract) would be otherwise payable, pursuant to sections 1814(b) and 1833(a) [*42 USCS §§ 1395f(b)* and *1395l(a)*], for services furnished by or through the organization to individuals enrolled with the organization under this section.

(4) For purposes of this section, the term "adjusted average per capita cost" means the average per capita amount that the Secretary estimates in advance (on the basis of actual experience, or retrospective actuarial equivalent based upon an

adequate sample and other information and data, in a geographic area served by an eligible organization or in a similar area, with appropriate adjustments to assure actuarial equivalence) would be payable in any contract year for services covered under parts A and B [*42 USCS §§ 1395c* et seq. and *1395j* et seq.], or part B [*42 USCS §§ 1395j* et seq.] only, and types of expenses otherwise reimbursable under parts A and B [*42 USCS §§ 1395c* et seq. and *1395j* et seq.], or part B [*42 USCS §§ 1395j* et seq.] only (including administrative costs incurred by organizations described in sections 1816 and 1842 [*42 USCS §§ 1395h* and *1395u*]), if the services were to be furnished by other than an eligible organization or, in the case of services covered only under section 1861(s)(2)(H) [*42 USCS § 1395x(s)(2)(H)*], if the services were to be furnished by a physician or as an incident to a physician's service.

(5) The payment to an eligible organization under this section for individuals enrolled under this section with the organization and entitled to benefits under part A [*42 USCS §§ 1395c* et seq.] and enrolled under part B [*42 USCS §§ 1395j* et seq.] shall be made from the Federal Hospital Insurance Trust Fund and the Federal Supplementary Medical Insurance Trust Fund. The portion of that payment to the organization for a month to be paid by each trust fund shall be determined as follows:

(A) In regard to expenditures by eligible organizations having risk-sharing contracts, the allocation shall be determined each year by the Secretary based on the relative weight that benefits from each fund contribute to the adjusted average per capita cost.

(B) In regard to expenditures by eligible organizations operating under a reasonable cost reimbursement contract, the initial allocation shall be based on the plan's most recent budget, such allocation to be adjusted, as needed, after cost settlement to reflect the distribution of actual expenditures.

The remainder of that payment shall be paid by the former trust fund.

(6) Subject to subsections (c)(2)(B)(ii) and (c)(7), if an individual is enrolled under this section with an eligible organization having a risk-sharing contract, only the eligible organization shall be entitled to receive payments from the Secretary under this *title [42 USCS §§ 1395* et seq.] for services furnished to the individual.

(b) Definitions; requirements. For purposes of this section, the term "eligible organization" means a public or private entity (which may be a health maintenance organization or a competitive medical plan), organized under the laws of any State, which--

(1) is a qualified health maintenance organization (as defined in section 1310(d) of the Public Health Service Act [*42 USCS § 300e-9(d)*]), or

(2) meets the following requirements:

(A) The entity provides to enrolled members at least the following health care services:

(i) Physicians' services performed by physicians (as defined in section 1861(r)(1) [*42 USCS § 1395x(r)(1)*]).

(ii) Inpatient hospital services.

(iii) Laboratory, X-ray, emergency, and preventive services.

(iv) Out-of-area coverage.

(B) The entity is compensated (except for deductibles, coinsurance, and copayments) for the provision of health care services to enrolled members by a payment which is paid on a periodic basis without regard to the date the health care services are provided and which is fixed without regard to the frequency, extent, or kind of health care service actually provided to a member.

(C) The entity provides physicians' services primarily (i) directly through physicians who are either employees or partners of such organization, or (ii) through contracts with individual physicians or one or more groups of physicians (organized on a group practice or individual practice basis).

(D) The entity assumes full financial risk on a prospective basis for the provision of the health care services listed in subparagraph (A), except that such entity may--

(i) obtain insurance or make other arrangements for the cost of providing to any enrolled member health care services listed in subparagraph (A) the aggregate value of which exceeds $ 5,000 in any year,

(ii) obtain insurance or make other arrangements for the cost of health care service listed in subparagraph (A) provided to its enrolled members other than through the entity because medical necessity required their provision before they could be secured through the entity,

(iii) obtain insurance or make other arrangements for not more than 90 percent of the amount by which its costs for any of its fiscal years exceed 115 percent of its income for such fiscal year, and

(iv) make arrangements with physicians or other health professionals, health care institutions, or any combination of such individuals or institutions to assume all or part of the financial risk on a prospective basis for the provision of basic health services by the physicians or other health professionals or through the institutions.

(E) The entity has made adequate provision against the risk of insolvency, which provision is satisfactory to the Secretary.

Paragraph (2)(A)(ii) shall not apply to an entity which had contracted with a single State agency administering a State plan approved under title XIX [*42 USCS §§ 1396* et seq.] for the provision of services (other than inpatient hospital services) to individuals eligible for such services under such State plan on a prepaid risk basis prior to 1970.

(c) Enrollment in plan; duties of organization to enrollees.

(1) The Secretary may not enter into a contract under this section with an eligible organization unless it meets the requirements of this subsection and subsection (e) with respect to members enrolled under this section.

(2)

(A) The organization must provide to members enrolled under this section, through providers and other persons that meet the applicable requirements of this *title [42 USCS §§ 1395* et seq.] and part A of title XI [*42 USCS §§ 1301* et seq.]--

(i) only those services covered under parts A and B of this *title [42 USCS §§ 1395c* et seq. and *1395j* et seq.], for those members entitled to benefits under part A [*42 USCS §§ 1395c* et seq.] and enrolled under part B [*42 USCS §§ 1395j* et seq.], or

(ii) only those services covered under part B [*42 USCS §§ 1395j* et seq.], for those members enrolled only under such part,

which are available to individuals residing in the geographic area served by the organization, except that (I) the organization may provide such members with such additional health care services as the members may elect, at their option, to have covered, and (II) in the case of an organization with a risk-sharing contract, the organization may provide such members with such additional health care services as the Secretary may approve. The Secretary shall approve any such additional health care services which the organization proposes to offer to such members, unless the Secretary determines that including such additional services will substantially discourage enrollment by covered individuals with the organization.

(B) If there is a national coverage determination made in the period beginning on the date of an announcement under subsection (a)(1)(A) and ending on the date of the next announcement under such subsection that the Secretary projects will result in a significant change in the costs to the organization of providing the benefits that are the subject of such national coverage determination and that was not incorporated in the determination of the per capita rate of payment included in the announcement made at the beginning of such period--

(i) such determination shall not apply to risk-sharing contracts under this section until the first contract year that begins after the end of such period; and

(ii) if such coverage determination provides for coverage of additional benefits or under additional circumstances, subsection (a)(3) shall not apply to payment for such additional benefits or benefits provided under such additional circumstances until the first contract year that begins after the end of such period,

unless otherwise required by law.

(3)

(A) (i) Each eligible organization must have an open enrollment period, for the enrollment of individuals under this section, of at least 30 days duration every year and including the period or periods specified under clause (ii), and must provide that at any time during which enrollments are accepted, the organization will accept up to the limits of its capacity (as determined by the Secretary) and without restrictions, except as may be authorized in regulations, individuals who are eligible to enroll under subsection (d) in the order in which they apply for enrollment, unless to do so would result in failure to meet the requirements of subsection (f) or would result in the enrollment of enrollees substantially nonrepresentative, as determined in accordance with regulations of the Secretary, of the population in the geographic area served by the organization.

(ii) (I) If a risk-sharing contract under this section is not renewed or is otherwise terminated, eligible organizations with risk-sharing contracts under this section and serving a part of the same service area as under the terminated contract are required to have an open enrollment period for individuals who were enrolled under the terminated contract as of the date of notice of such termination. If a risk-sharing contract under this section is renewed in a manner that discontinues coverage for individuals residing in part of the service area, eligible organizations with risk-sharing contracts under this section and enrolling individuals residing in that part of the service area are required to have an open enrollment period for individuals residing in the part of the service area who were enrolled under the contract as of the date of notice of such discontinued coverage.

(II) The open enrollment periods required under subclause (I) shall be for 30 days and shall begin 30 days after the date that the Secretary provides notice of such requirement.

(III) Enrollment under this clause shall be effective 30 days after the end of the open enrollment period, or, if the Secretary determines that such date is not feasible, such other date as the Secretary specifies.

(B) An individual may enroll under this section with an eligible organization in such manner as may be prescribed in regulations and may terminate his enrollment with the eligible organization as of the beginning of the first calendar

month following the date on which the request is made for such termination (or, in the case of financial insolvency of the organization, as may be prescribed by regulations) or, in the case of such an organization with a reasonable cost reimbursement contract, as may be prescribed by regulations. In the case of an individual's termination of enrollment, the organization shall provide the individual with a copy of the written request for termination of enrollment and a written explanation of the period (ending on the effective date of the termination) during which the individual continues to be enrolled with the organization and may not receive benefits under this title other than through the organization.

(C) The Secretary may prescribe the procedures and conditions under which an eligible organization that has entered into a contract with the Secretary under this subsection may inform individuals eligible to enroll under this section with the organization about the organization, or may enroll such individuals with the organization. No brochures, application forms, or other promotional or informational material may be distributed by an organization to (or for the use of) individuals eligible to enroll with the organization under this section unless (i) at least 45 days before its distribution, the organization has submitted the material to the Secretary for review and (ii) the Secretary has not disapproved the distribution of the material. The Secretary shall review all such material submitted and shall disapprove such material if the Secretary determines, in the Secretary's discretion, that the material is materially inaccurate or misleading or otherwise makes a material misrepresentation.

(D) The organization must provide assurances to the Secretary that it will not expel or refuse to re-enroll any such individual because of the individual's health status or requirements for health care services, and that it will notify each such individual of such fact at the time of the individual's enrollment.

(E) Each eligible organization shall provide each enrollee, at the time of enrollment and not less frequently than annually thereafter, an explanation of the enrollee's rights under this section, including an explanation of--

(i) the enrollee's rights to benefits from the organization,

(ii) the restrictions on payments under this *title [42 USCS §§ 1395* et seq.] for services furnished other than by or through the organization,

(iii) out-of-area coverage provided by the organization,

(iv) the organization's coverage of emergency services and urgently needed care, and

(v) appeal rights of enrollees.

(F) Each eligible organization that provides items and services pursuant to a contract under this section shall provide assurances to the Secretary that in the event the organization ceases to provide such items and services, the organization shall provide or arrange for supplemental coverage of benefits under this *title [42 USCS §§ 1395* et seq.] related to a pre-existing condition with respect to any exclusion period, to all individuals enrolled with the entity who receive benefits under this *title [42 USCS §§ 1395* et seq.], for the lesser of six months or the duration of such period.

(G) (i) Each eligible organization having a risk-sharing contract under this section shall notify individuals eligible to enroll with the organization under this section and individuals enrolled with the organization under this section that--

(I) the organization is authorized by law to terminate or refuse to renew the contract, and

(II) termination or nonrenewal of the contract may result in termination of the enrollments of individuals enrolled with the organization under this section.

(ii) The notice required by clause (i) shall be included in--

(I) any marketing materials described in subparagraph (C) that are distributed by an eligible organization to individuals eligible to enroll under this section with the organization, and

(II) any explanation provided to enrollees by the organization pursuant to subparagraph (E).

(4) The organization must--

(A) make the services described in paragraph (2) (and such other health care services as such individuals have contracted for) (i) available and accessible to each such individual, within the area served by the organization, with reasonable promptness and in a manner which assures continuity, and (ii) when medically necessary, available and accessible twenty-four hours a day and seven days a week, and

(B) provide for reimbursement with respect to services which are described in subparagraph (A) and which are provided to such an individual other than through the organization, if (i) the services were medically necessary and immediately required because of an unforeseen illness, injury, or condition and (ii) it was not reasonable given the circumstances to obtain the services through the organization.

(5)

(A) The organization must provide meaningful procedures for hearing and resolving grievances between the organization (including any entity or individual through which the organization provides health care services) and members enrolled with the organization under this section.

(B) A member enrolled with an eligible organization under this section who is dissatisfied by reason of his failure to receive any health service to which he believes he is entitled and at no greater charge than he believes he is required to pay is entitled, if the amount in controversy is $ 100 or more, to a hearing before the Secretary to the same extent as is provided in section 205(b) [*42 USCS § 405(b)*], and in any such hearing the Secretary shall make the eligible

organization a party. If the amount in controversy is $ 1,000 or more, the individual or eligible organization shall, upon notifying the other party, be entitled to judicial review of the Secretary's final decision as provided in section 205(g) [*42 USCS § 405(g)*], and both the individual and the eligible organization shall be entitled to be parties to that judicial review. In applying sections 205(b) and 205(g) [*42 USCS § 405(b)* and (g)] as provided in this subparagraph, and in applying section 205(l) [*42 USCS § 405(l)*] thereto, any reference therein to the Commissioner of Social Security or the Social Security Administration shall be considered a reference to the Secretary or the Department of Health and Human Services, respectively. The provisions of section 1869(b)(1)(E)(iii) [*42 USCS § 1395ff(b)(1)(E)(iii)*] shall apply with respect to dollar amounts specified in the first 2 sentences of this subparagraph in the same manner as they apply to the dollar amounts specified in section 1869(b)(1)(E)(i) [*42 USCS § 1395ff(b)(1)(E)(i)*].

(6) The organization must have arrangements, established in accordance with regulations of the Secretary, for an ongoing quality assurance program for health care services it provides to such individuals, which program (A) stresses health outcomes and (B) provides review by physicians and other health care professionals of the process followed in the provision of such health care services.

(7) A risk-sharing contract under this section shall provide that in the case of an individual who is receiving inpatient hospital services from a subsection (d) hospital (as defined in section 1886(d)(1)(B) [*42 USCS § 1395ww(d)(1)(B)*]) as of the effective date of the individual's--

(A) enrollment with an eligible organization under this section--

(i) payment for such services until the date of the individual's discharge shall be made under this *title [42 USCS §§ 1395* et seq.] as if the individual were not enrolled with the organization,

(ii) the organization shall not be financially responsible for payment for such services until the date after the date of the individual's discharge, and

(iii) the organization shall nonetheless be paid the full amount otherwise payable to the organization under this section; or

(B) termination of enrollment with an eligible organization under this section--

(i) the organization shall be financially responsible for payment for such services after such date and until the date of the individual's discharge,

(ii) payment for such services during the stay shall not be made under section 1886(d) [*42 USCS § 1395ww(d)*], and

(iii) the organization shall not receive any payment with respect to the individual under this section during the period the individual is not enrolled.

(8) A contract under this section shall provide that the eligible organization shall meet the requirement of section 1866(f) [*42 USCS § 1395cc(f)*] (relating to maintaining written policies and procedures respecting advance directives).

(d) Right to enroll with contracting organization in geographic area. Subject to the provisions of subsection (c)(3), every individual entitled to benefits under part A [*42 USCS §§ 1395c* et seq.] and enrolled under part B [*42 USCS §§ 1395j* et seq.] or enrolled under part B [*42 USCS §§ 1395j* et seq.] only (other than an individual medically determined to have end-stage renal disease) shall be eligible to enroll under this section with any eligible organization with which the Secretary has entered into a contract under this section and which serves the geographic area in which the individual resides.

(e) Limitation on charges; election of coverage; "adjusted community rate" defined; workmen's compensation and insurance benefits.

(1) In no case may--

(A) the portion of an eligible organization's premium rate and the actuarial value of its deductibles, coinsurance, and copayments charged (with respect to services covered under parts A and B [*42 USCS §§ 1395c* et seq. and *1395j* et seq.]) to individuals who are enrolled under this section with the organization and who are entitled to benefits under part A [*42 USCS §§ 1395c* et seq.] and enrolled under part B [*42 USCS §§ 1395j* et seq.], or

(B) the portion of its premium rate and the actuarial value of its deductibles, coinsurance, and copayments charged (with respect to services covered under part B [*42 USCS §§ 1395j* et seq.]) to individuals who are enrolled under this section with the organization and enrolled under part B [*42 USCS §§ 1395j* et seq.] only

exceed the actuarial value of the coinsurance and deductibles that would be applicable on the average to individuals enrolled under this section with the organization (or, if the Secretary finds that adequate data are not available to determine that actuarial value, the actuarial value of the coinsurance and deductibles applicable on the average to individuals in the area, in the State, or in the United States, eligible to enroll under this section with the organization, or other appropriate data) and entitled to benefits under part A [*42 USCS §§ 1395c* et seq.] and enrolled under part B [*42 USCS §§ 1395j* et seq.], or enrolled under part B [*42 USCS §§ 1395j* et seq.] only, respectively, if they were not members of an eligible organization.

(2) If the eligible organization provides to its members enrolled under this section services in addition to services covered under parts A and B of this *title [42 USCS §§ 1395c* et seq. and *1395j* et seq.], election of coverage for such additional services (unless such services have been approved by the Secretary under subsection (c)(2)) shall be optional for such members and such organization shall furnish such members with information on the portion of its premium rate or other charges applicable to such additional services. In no case may the sum of--

(A) the portion of such organization's premium rate charged, with respect to such additional services, to members enrolled under this section, and

(B) the actuarial value of its deductibles, coinsurance, and copayments charged, with respect to such services to such members

exceed the adjusted community rate for such services.

(3) For purposes of this section, the term "adjusted community rate" for a service or services means, at the election of an eligible organization, either--

(A) the rate of payment for that service or services which the Secretary annually determines would apply to a member enrolled under this section with an eligible organization if the rate of payment were determined under a "community rating system" (as defined in section 1302(8) of the Public Health Service Act [*42 USCS § 300e-1(8)*], other than subparagraph (C)), or

(B) such portion of the weighted aggregate premium, which the Secretary annually estimates would apply to a member enrolled under this section with the eligible organization, as the Secretary annually estimates is attributable to that service or services,

but adjusted for differences between the utilization characteristics of the members enrolled with the eligible organization under this section and the utilization characteristics of the other members of the organization (or, if the Secretary finds that adequate data are not available to adjust for those differences, the differences between the utilization characteristics of members in other eligible organizations, or individuals in the area, in the State, or in the United States, eligible to enroll under this section with an eligible organization and the utilization characteristics of the rest of the population in the area, in the State, or in the United States, respectively).

(4) Notwithstanding any other provision of law, the eligible organization may (in the case of the provision of services to a member enrolled under this section for an illness or injury for which the member is entitled to benefits under a workmen's compensation law or plan of the United States or a State, under an automobile or liability insurance policy or plan, including a self-insured plan, or under no fault insurance) charge or authorize the provider of such services to charge, in accordance with the charges allowed under such law or policy--

(A) the insurance carrier, employer, or other entity which under such law, plan, or policy is to pay for the provision of such services, or

(B) such member to the extent that the member has been paid under such law, plan, or policy for such services.

(f) Membership requirements.

(1) For contract periods beginning before January 1, 1999, each eligible organization with which the Secretary enters into a contract under this section shall have, for the duration of such contract, an enrolled membership at least one-half of which consists of individuals who are not entitled to benefits under this *title [42 USCS §§ 1395* et seq.].

(2) Subject to paragraph (4), the Secretary may modify or waive the requirement imposed by paragraph (1)--

(A) to the extent that more than 50 percent of the population of the area served by the organization consists of individuals who are entitled to benefits under this *title [42 USCS §§ 1395* et seq.] or under a State plan approved under title XIX [*42 USCS §§ 1396* et seq.], or

(B) in the case of an eligible organization that is owned and operated by a governmental entity, only with respect to a period of three years beginning on the date the organization first enters into a contract under this section, and only if the organization has taken and is making reasonable efforts to enroll individuals who are not entitled to benefits under this *title [42 USCS §§ 1395* et seq.] or under a State plan approved under title XIX [*42 USCS §§ 1396* et seq.].

(3) If the Secretary determines that an eligible organization has failed to comply with the requirements of this subsection, the Secretary may provide for the suspension of enrollment of individuals under this section or of payment to the organization under this section for individuals newly enrolled with the organization, after the date the Secretary notifies the organization of such noncompliance.

(4) Effective for contract periods beginning after December 31, 1996, the Secretary may waive or modify the requirement imposed by paragraph (1) to the extent the Secretary finds that it is in the public interest.

(g) Risk-sharing contract.

(1) The Secretary may enter a risk-sharing contract with any eligible organization, as defined in subsection (b), which has at least 5,000 members, except that the Secretary may enter into such a contract with an eligible organization that has fewer members if the organization primarily serves members residing outside of urbanized areas.

(2) Each risk-sharing contract shall provide that--

(A) if the adjusted community rate, as defined in subsection (e)(3), for services under parts A and B [*42 USCS §§ 1395c* et seq. and *1395j* et seq.] (as reduced for the actuarial value of the coinsurance and deductibles under those parts) for members enrolled under this section with the organization and entitled to benefits under part A [*42 USCS §§ 1395c* et seq.] and enrolled in part B [*42 USCS §§ 1395j* et seq.], or

(B) if the adjusted community rate for services under part B [*42 USCS §§ 1395j* et seq.] (as reduced for the actuarial value of the coinsurance and deductibles under that part) for members enrolled under this section with the organization and entitled to benefits under part B [*42 USCS §§ 1395j* et seq.] only

is less than the average of the per capita rates of payment to be made under subsection (a)(1) at the beginning of an annual contract period for members enrolled under this section with the organization and entitled to benefits under part A [*42 USCS §§ 1395c* et seq.] and enrolled in part B [*42 USCS §§ 1395j* et seq.], or enrolled in part B [*42 USCS §§ 1395j* et seq.] only, respectively, the eligible organization shall provide to members enrolled under a risk-sharing contract under this section with the organization and entitled to benefits under part A [*42 USCS §§ 1395c* et seq.] and enrolled in part B [*42 USCS §§ 1395j* et seq.], or enrolled in part B [*42 USCS §§ 1395j* et seq.] only, respectively, the additional benefits described in paragraph (3) which are selected by the eligible organization and which the Secretary finds are at least equal in value to the difference between that average per capita payment and the adjusted community rate (as so reduced); except that this paragraph shall not apply with respect to any organization which elects to receive a lesser payment to the extent that there is no longer a difference between the average per capita payment and adjusted community rate (as so reduced). and except that an organization (with the approval of the Secretary) may provide that a part of the value of such additional benefits be withheld and reserved by the Secretary as provided in paragraph (5). If the Secretary finds that there is insufficient enrollment experience to determine an average of the per capita rates of payment to be made under subsection (a)(1) at the beginning of a contract period, the Secretary may determine such an average based on the enrollment experience of other contracts entered into under this section.

(3) The additional benefits referred to in paragraph (2) are--

(A) the reduction of the premium rate or other charges made with respect to services furnished by the organization to members enrolled under this section, or

(B) the provision of additional health benefits,

or both.

(4) [Repealed]

(5) An organization having a risk-sharing contract under this section may (with the approval of the Secretary) provide that a part of the value of additional benefits otherwise required to be provided by reason of paragraph (2) be withheld and reserved in the Federal Hospital Insurance Trust Fund and in the Federal Supplementary Medical Insurance Trust Fund (in such proportions as the Secretary determines to be appropriate) by the Secretary for subsequent annual contract periods, to the extent required to stabilize and prevent undue fluctuations in the additional benefits offered in those subsequent periods by the organization in accordance with paragraph (3). Any of such value of additional benefits which is not provided to members of the organization in accordance with paragraph (3) prior to the end of such period, shall revert for the use of such trust funds.

(6)

(A) A risk-sharing contract under this section shall require the eligible organization to provide prompt payment (consistent with the provisions of sections 1816(c)(2) and 1842(c)(2) [*42 USCS §§ 1395h(c)(2)* and *1395u(c)(2)*]) of claims submitted for services and supplies furnished to individuals pursuant to such contract, if the services or supplies are not furnished under a contract between the organization and the provider or supplier.

(B) In the case of an eligible organization which the Secretary determines, after notice and opportunity for a hearing, has failed to make payments of amounts in compliance with subparagraph (A), the Secretary may provide for direct payment of the amounts owed to providers and suppliers for such covered services furnished to individuals enrolled under this section under the contract. If the Secretary provides for such direct payments, the Secretary shall provide for an appropriate reduction in the amount of payments otherwise made to the organization under this section to reflect the amount of the Secretary's payments (and costs incurred by the Secretary in making such payments).

(h) Reasonable cost reimbursement contract; requirements.

(1) If--

(A) the Secretary is not satisfied that an eligible organization has the capacity to bear the risk of potential losses under a risk-sharing contract under this section, or

(B) the eligible organization so elects or has an insufficient number of members to be eligible to enter into a risk-sharing contract under subsection (g)(1),

the Secretary may, if he is otherwise satisfied that the eligible organization is able to perform its contractual obligations effectively and efficiently, enter into a contract with such organization pursuant to which such organization

is reimbursed on the basis of its reasonable cost (as defined in section 1861(v) [*42 USCS § 1395x(v)*]) in the manner prescribed in paragraph (3).

(2) A reasonable cost reimbursement contract under this subsection may, at the option of such organization, provide that the Secretary--

(A) will reimburse hospitals and skilled nursing facilities either for the reasonable cost (as determined under section 1861(v) [*42 USCS § 1395x(v)*]) or for payment amounts determined in accordance with section 1886 [*42 USCS § 1395ww*], as applicable, of services furnished to individuals enrolled with such organization pursuant to subsection (d), and

(B) will deduct the amount of such reimbursement from payment which would otherwise be made to such organization.

If such an eligible organization pays a hospital or skilled nursing facility directly, the amount paid shall not exceed the reasonable cost of the services (as determined under section 1861(v) [*42 USCS § 1395x(v)*]) or the amount determined under section 1886 [*42 USCS § 1395ww*], as applicable, unless such organization demonstrates to the satisfaction of the Secretary that such excess payments are justified on the basis of advantages gained by the organization.

(3) Payments made to an organization with a reasonable cost reimbursement contract shall be subject to appropriate retroactive corrective adjustment at the end of each contract year so as to assure that such organization is paid for the reasonable cost actually incurred (excluding any part of incurred cost found to be unnecessary in the efficient delivery of health services) or the amounts otherwise determined under section 1886 [*42 USCS § 1395ww*] for the types of expenses otherwise reimbursable under this *title [42 USCS §§ 1395* et seq.] for providing services covered under this *title [42 USCS §§ 1395* et seq.] to individuals described in subsection (a)(1).

(4) Any reasonable cost reimbursement contract with an eligible organization under this subsection shall provide that the Secretary shall require, at such time following the expiration of each accounting period of the eligible organization (and in such form and in such detail) as he may prescribe--

(A) that the organization report to him in an independently certified financial statement its per capita incurred cost based on the types of components of expenses otherwise reimbursable under this *title [42 USCS §§ 1395* et seq.] for providing services described in subsection (a)(1), including therein, in accordance with accounting procedures prescribed by the Secretary, its methods of allocating costs between individuals enrolled under this section and other individuals enrolled with such organization;

(B) that failure to report such information as may be required may be deemed to constitute evidence of likely overpayment on the basis of which appropriate collection action may be taken;

(C) that in any case in which an eligible organization is related to another organization by common ownership or control, a consolidated financial statement shall be filed and that the allowable costs for such organization may not include costs for the types of expense otherwise reimbursable under this *title [42 USCS §§ 1395* et seq.], in excess of those which would be determined to be reasonable in accordance with regulations (providing for limiting reimbursement to costs rather than charges to the eligible organization by related organizations and owners) issued by the Secretary; and

(D) that in any case in which compensation is paid by an eligible organization substantially in excess of what is normally paid for similar services by similar practitioners (regardless of method of compensation), such compensation may as appropriate be considered to constitute a distribution of profits.

(5)

(A) After the date of the enactment of this paragraph [enacted Aug. 5, 1997], the Secretary may not enter into a reasonable cost reimbursement contract under this subsection (if the contract is not in effect as of such date), except for a contract with an eligible organization which, immediately previous to entering into such contract, had an agreement in effect under section 1833(a)(1)(A) [*42 USCS § 1395l(a)(1)(A)*].

(B) Subject to subparagraph (C), the Secretary shall approve an application for a modification to a reasonable cost contract under this section in order to expand the service area of such contract if--

(i) such application is submitted to the Secretary on or before September 1, 2003; and

(ii) the Secretary determines that the organization with the contract continues to meet the requirements applicable to such organizations and contracts under this section.

(C)

(i) Subject to clause (ii), a reasonable cost reimbursement contract under this subsection may be extended or renewed indefinitely.

(ii) For any period beginning on or after January 1, 2010, a reasonable cost reimbursement contract under this subsection may not be extended or renewed for a service area insofar as such area during the entire previous year was within the service area of--

(I) 2 or more MA regional plans described in clause (iii), provided that all such plans are not offered by the same Medicare Advantage organization; or

(II) 2 or more MA local plans described in clause (iii), provided that all such plans are not offered by the same Medicare Advantage organization.

(iii) A plan described in this clause for a year for a service area is a plan described in section 1851(a)(2)(A)(i) [*42 USCS § 1395w-21(a)(2)(A)(i)*] if the service area for the year meets the following minimum enrollment requirements:

(I) With respect to any portion of the area involved that is within a Metropolitan Statistical Area with a population of more than 250,000 and counties contiguous to such Metropolitan Statistical Area that are not in another Metropolitan Statistical Area with a population of more than 250,000, 5,000 individuals. If the service area includes a portion in more than 1 Metropolitan Statistical Area with a population of more than 250,000, the minimum enrollment determination under the preceding sentence shall be made with respect to each such Metropolitan Statistical Area (and such applicable contiguous counties to such Metropolitan Statistical Area).

(II) With respect to any other portion of such area, 1,500 individuals.

(i) Duration; termination, effective date, and terms of contract; powers and duties of Secretary.

(1) Each contract under this section shall be for a term of at least one year, as determined by the Secretary, and may be made automatically renewable from term to term in the absence of notice by either party of intention to terminate at the end of the current term; except that in accordance with procedures established under paragraph (9), the Secretary may at any time terminate any such contract or may impose the intermediate sanctions described in paragraph (6)(B) or (6)(C) (whichever is applicable) on the eligible organization if the Secretary determines that the organization--

(A) has failed substantially to carry out the contract;

(B) is carrying out the contract in a manner substantially inconsistent with the efficient and effective administration of this section; or

(C) no longer substantially meets the applicable conditions of subsections (b), (c), (e), and (f).

(2) The effective date of any contract executed pursuant to this section shall be specified in the contract.

(3) Each contract under this section--

(A) shall provide that the Secretary, or any person or organization designated by him--

(i) shall have the right to inspect or otherwise evaluate (I) the quality, appropriateness, and timeliness of services performed under the contract and (II) the facilities of the organization when there is reasonable evidence of some need for such inspection, and

(ii) shall have the right to audit and inspect any books and records of the eligible organization that pertain (I) to the ability of the organization to bear the risk of potential financial losses, or (II) to services performed or determinations of amounts payable under the contract;

(B) shall require the organization with a risk-sharing contract to provide (and pay for) written notice in advance of the contract's termination, as well as a description of alternatives for obtaining benefits under this *title [42 USCS §§ 1395* et seq.], to each individual enrolled under this section with the organization; and

(C) (i) shall require the organization to comply with subsections (a) and (c) of section 1318 of the Public Health Service Act [*42 USCS § 300e-17(a)* and (c)] (relating to disclosure of certain financial information) and with the requirement of section 1301(c)(8) of such Act (relating to liability arrangements to protect members);

(ii) shall require the organization to provide and supply information (described in section 1866(b)(2)(C)(ii) [*42 USCS § 1395cc(b)(2)(C)(ii)*]) in the manner such information is required to be provided or supplied under that section;

(iii) shall require the organization to notify the Secretary of loans and other special financial arrangements which are made between the organization and subcontractors, affiliates, and related parties; and

(D) shall contain such other terms and conditions not inconsistent with this section (including requiring the organization to provide the Secretary with such information) as the Secretary may find necessary and appropriate.

(4) The Secretary may not enter into a risk-sharing contract with an eligible organization if a previous risk-sharing contract with that organization under this section was terminated at the request of the organization within the preceding five-year period, except in circumstances which warrant special consideration, as determined by the Secretary.

(5) The authority vested in the Secretary by this section may be performed without regard to such provisions of law or regulations relating to the making, performance, amendment, or modification of contracts of the United States as the Secretary may determine to be inconsistent with the furtherance of the purpose of this *title [42 USCS §§ 1395* et seq.].

(6) (A) If the Secretary determines that an eligible organization with a contract under this section--

(i) fails substantially to provide medically necessary items and services that are required (under law or under the contract) to be provided to an individual covered under the contract, if the failure has adversely affected (or has substantial likelihood of adversely affecting) the individual;

(ii) imposes premiums on individuals enrolled under this section in excess of the premiums permitted;

(iii) acts to expel or to refuse to re-enroll an individual in violation of the provisions of this section;

(iv) engages in any practice that would reasonably be expected to have the effect of denying or discouraging enrollment (except as permitted by this section) by eligible individuals with the organization whose medical condition or history indicates a need for substantial future medical services;

(v) misrepresents or falsifies information that is furnished--

(I) to the Secretary under this section, or

(II) to an individual or to any other entity under this section;

(vi) fails to comply with the requirements of subsection (g)(6)(A) or paragraph (8); or

(vii) in the case of a risk-sharing contract, employs or contracts with any individual or entity that is excluded from participation under this *title [42 USCS §§ 1395* et seq.] under section 1128 or 1128A [*42 USCS § 1320a-7* or *1320a-7a*] for the provision of health care, utilization review, medical social work, or administrative services or employs or contracts with any entity for the provision (directly or indirectly) through such an excluded individual or entity of such services;

the Secretary may provide, in addition to any other remedies authorized by law, for any of the remedies described in subparagraph (B).

(B) The remedies described in this subparagraph are--

(i) civil money penalties of not more than $ 25,000 for each determination under subparagraph (A) or, with respect to a determination under clause (iv) or (v)(I) of such subparagraph, of not more than $ 100,000 for each such determination, plus, with respect to a determination under subparagraph (A)(ii), double the excess amount charged in violation of such subparagraph (and the excess amount charged shall be deducted from the penalty and returned to the individual concerned), and plus, with respect to a determination under subparagraph (A)(iv), $ 15,000 for each individual not enrolled as a result of the practice involved,

(ii) suspension of enrollment of individuals under this section after the date the Secretary notifies the organization of a determination under subparagraph (A) and until the Secretary is satisfied that the basis for such determination has been corrected and is not likely to recur, or

(iii) suspension of payment to the organization under this section for individuals enrolled after the date the Secretary notifies the organization of a determination under subparagraph (A) and until the Secretary is satisfied that the basis for such determination has been corrected and is not likely to recur.

(C) In the case of an eligible organization for which the Secretary makes a determination under paragraph (1), the basis of which is not described in subparagraph (A), the Secretary may apply the following intermediate sanctions:

(i) Civil money penalties of not more than $ 25,000 for each determination under paragraph (1) if the deficiency that is the basis of the determination has directly adversely affected (or has the substantial likelihood of adversely affecting) an individual covered under the organization's contract.

(ii) Civil money penalties of not more than $ 10,000 for each week beginning after the initiation of procedures by the Secretary under paragraph (9) during which the deficiency that is the basis of a determination under paragraph (1) exists.

(iii) Suspension of enrollment of individuals under this section after the date the Secretary notifies the organization of a determination under paragraph (1) and until the Secretary is satisfied that the deficiency that is the basis for the determination has been corrected and is not likely to recur.

(D) The provisions of section 1128A [*42 USCS § 1320a-7a*] (other than subsections (a) and (b)) shall apply to a civil money penalty under subparagraph (B)(i) or (C)(i) in the same manner as such provisions apply to a civil money penalty or proceeding under section 1128A(a) [*42 USCS § 1320a-7a(a)*].

(7) (A) Each risk-sharing contract with an eligible organization under this section shall provide that the organization will maintain a written agreement with a utilization and quality control peer review organization (which has a contract with the Secretary under part B of title XI [*42 USCS §§ 1320c* et seq.] for the area in which the eligible organization is located) or with an entity selected by the Secretary under section 1154(a)(4)(C) [*42 USCS § 1320c-3(a)(4)(C)*] under which the review organization will perform functions under section 1154(a)(4)(B) [*42 USCS § 1320c-3(a)(4)(B)*] and section 1154(a)(14) [*42 USCS § 1320c-3(a)(14)*] (other than those performed under contracts described in section 1866(a)(1)(F) [*42 USCS 1395cc(a)(1)(F)*]) with respect to services, furnished by the eligible organization, for which payment may be made under this *title [42 USCS §§ 1395* et seq.].

(B) For purposes of payment under this *title [42 USCS §§ 1395* et seq.], the cost of such agreement to the eligible organization shall be considered a cost incurred by a provider of services in providing covered services under this *title [42 USCS §§ 1395* et seq.] and shall be paid directly by the Secretary to the review organization on behalf of such eligible organization in accordance with a schedule established by the Secretary.

(C) Such payments--

(i) shall be transferred in appropriate proportions from the Federal Hospital Insurance Trust Fund and from the Supplementary Medical Insurance Trust Fund, without regard to amounts appropriated in advance in appropriation Acts, in the same manner as transfers are made for payment for services provided directly to beneficiaries, and

(ii) shall not be less in the aggregate for such organizations for a fiscal year than the amounts the Secretary determines to be sufficient to cover the costs of such organizations' conducting activities described in subparagraph (A) with respect to such eligible organizations under part B of title XI [*42 USCS §§ 1320c* et seq.].

(8) (A) Each contract with an eligible organization under this section shall provide that the organization may not operate any physician incentive plan (as defined in subparagraph (B)) unless the following requirements are met:

(i) No specific payment is made directly or indirectly under the plan to a physician or physician group as an inducement to reduce or limit medically necessary services provided with respect to a specific individual enrolled with the organization.

(ii) If the plan places a physician or physician group at substantial financial risk (as determined by the Secretary) for services not provided by the physician or physician group, the organization--

(I) provides stop-loss protection for the physician or group that is adequate and appropriate, based on standards developed by the Secretary that take into account the number of physicians placed at such substantial financial risk in the group or under the plan and the number of individuals enrolled with the organization who receive services from the physician or the physician group, and

(II) conducts periodic surveys of both individuals enrolled and individuals previously enrolled with the organization to determine the degree of access of such individuals to services provided by the organization and satisfaction with the quality of such services.

(iii) The organization provides the Secretary with descriptive information regarding the plan, sufficient to permit the Secretary to determine whether the plan is in compliance with the requirements of this subparagraph.

(B) In this paragraph, the term "physician incentive plan" means any compensation arrangement between an eligible organization and a physician or physician group that may directly or indirectly have the effect of reducing or limiting services provided with respect to individuals enrolled with the organization.

(9) The Secretary may terminate a contract with an eligible organization under this section or may impose the intermediate sanctions described in paragraph (6) on the organization in accordance with formal investigation and compliance procedures established by the Secretary under which--

(A) the Secretary first provides the organization with the reasonable opportunity to develop and implement a corrective action plan to correct the deficiencies that were the basis of the Secretary's determination under paragraph (1) and the organization fails to develop or implement such a plan;

(B) in deciding whether to impose sanctions, the Secretary considers aggravating factors such as whether an organization has a history of deficiencies or has not taken action to correct deficiencies the Secretary has brought to the organization's attention;

(C) there are no unreasonable or unnecessary delays between the finding of a deficiency and the imposition of sanctions; and

(D) the Secretary provides the organization with reasonable notice and opportunity for hearing (including the right to appeal an initial decision) before imposing any sanction or terminating the contract.

(j) Payment in full and limitation on actual charges; physicians, providers of services, or renal dialysis facilities not under contract with organization.

(1)

(A) In the case of physicians' services or renal dialysis services described in paragraph (2) which are furnished by a participating physician to an individual enrolled with an eligible organization under this section and enrolled under part B [*42 USCS §§ 1395j* et seq.], the applicable participation agreement is deemed to provide that the physician or provider of services or renal dialysis facility will accept as payment in full from the eligible organization the amount that would be payable to the physician or provider of services or renal dialysis facility under part B [*42 USCS §§ 1395j* et seq.] and from the individual under such part, if the individual were not enrolled with an eligible organization under this section.

(B) In the case of physicians' services described in paragraph (2) which are furnished by a nonparticipating physician, the limitations on actual charges for such services otherwise applicable under part B [*42 USCS §§ 1395j* et seq.] (to services furnished by individuals not enrolled with an eligible organization under this section) shall apply in the same manner as such limitations apply to services furnished to individuals not enrolled with such an organization.

(2) The physicians' services described in this paragraph are physicians' services which are furnished to an enrollee of an eligible organization under this section by a physician, provider of services, or renal dialysis facility who is not under a contract with the organization.

(k) Risk-sharing contracts.

(1) Except as provided in paragraph (2)--

(A) on or after the date standards for Medicare + Choice organizations and plans are first established under section 1856(b)(1) [*42 USCS § 1395w-26(b)(1)*], the Secretary shall not enter into any risk-sharing contract under this section with an eligible organization; and

(B) for any contract year beginning on or after January 1, 1999, the Secretary shall not renew any such contract.

(2) An individual who is enrolled in part B [*42 USCS §§ 1395j* et seq.] only and is enrolled in an eligible organization with a risk-sharing contract under this section on December 31, 1998, may continue enrollment in such organization in accordance with regulations described in section 1856(b)(1) [*42 USCS § 1395w-26(b)(1)*].

(3) Notwithstanding subsection (a), the Secretary shall provide that payment amounts under risk-sharing contracts under this section for months in a year (beginning with January 1998) shall be computed--

(A) with respect to individuals entitled to benefits under both parts A and B, by substituting payment rates under section 1853(a) [*42 USCS § 1395w-23(a)*] for the payment rates otherwise established under section 1876(a) [*42 USCS § 1395mm(a)*], and

(B) with respect to individuals only entitled to benefits under part B [*42 USCS §§ 1395j* et seq.], by substituting an appropriate proportion of such rates (reflecting the relative proportion of payments under this title attributable to such part) for the payment rates otherwise established under subsection (a).

(4) The following requirements shall apply to eligible organizations with risk-sharing contracts under this section in the same manner as they apply to Medicare + Choice organizations under part C [*42 USCS §§ 1395w-21* et seq.]:

(A) Data collection requirements under section 1853(a)(3)(B) [*42 USCS § 1395w-23(a)(3)(B)*].

(B) Restrictions on imposition of premium taxes under section 1854(g) [*42 USCS § 1395w-24(g)*] in relating to payments to such organizations under this section.

(C) The requirement to accept enrollment of new enrollees during November 1998 under section 1851(e)(6) [*42 USCS § 1395w-21(e)(6)*].

(D) Payments under section 1857(e)(2) [*42 USCS § 1395w-27(e)(2)*].

HISTORY:

(Aug. 14, 1935, ch 531, Title XVIII, Part E[D][C], § 1876, as added Oct. 30, 1972, P.L. 92-603, Title II, §§ 226(a), 278(b)(3), 86 Stat. 1396, 1453; Dec. 31, 1973, P.L. 93-233, § 18(m), (n), 87 Stat. 970, 971; Oct. 8, 1976, P.L. 94-460, Title II, § 201(a)-(d), 90 Stat. 1956; June 13, 1978, P.L. 95-292, § 5, 92 Stat. 315; Sept. 3, 1982, P.L. 97-248, Title I, Subtitle A, Part I, Subpart B, § 114(a), 96 Stat. 341; Jan. 12, 1983, P.L. 97-448, Title III, § 309(b)(12), 96 Stat. 2409; April 20, 1983, P.L. 98-21, Title VI, §§ 602(g), 606(a)(2)(H), 97 Stat. 164, 171; July 18, 1984, P.L. 98-369, Division B, Title III, Subtitle A, Part II, §§ 2350(a)(1), (b)(1), (2), (c), 2354(b)(37), (38), 98 Stat. 1097, 1098, 1102; April 7, 1986, P.L. 99-272, Title IX, Subtitle A, Part 2, Subpart B, § 9211(a)-(d), 100 Stat. 178; Oct. 21, 1986, P.L. 99-509, Title IX, Subtitle D, Part 2, § 9312(b)(1), (c)(1), (2), (d)(1), (e)(1), (f), Part 4, § 9353(e)(2), 100 Stat. 1999-2001, 2047; Oct. 22, 1986, P.L. 99-514, Title XVIII, Subtitle C, Ch 1, § 1895(b)(11)(A), 100 Stat. 2934; Dec. 22, 1987, P.L. 100-203, Title IV, Subtitle A, Part 2, Subpt. A, §§ 4011(a)(1), (b)(1), 4012(b), 4014, 4018(a), 4039(h)(8), 101 Stat. 1330-60, 1330-61, 1330-65; July 1, 1988, P.L. 100-360, Title II, Subtitle A, § 202(f), Subtitle B, § 211(c)(3), Subtitle C, § 224, Title IV, Subtitle B, § 411(c)(1), (3), (4), (6), (e)(3), 102 Stat. 717, 738, 748, 773, 776; Oct. 13, 1988, P.L. 100-485, Title VI, § 608(d)(19)(B), 102 Stat. 2419; Nov. 10, 1988, P.L. 100-647, Title VIII, Subtitle E, Part II, § 8412(a), 102 Stat. 3801; Dec. 13, 1989, P.L. 101-234, Title II, §§ 201(a)(1), 202(a), 103 Stat. 1981; Dec. 19, 1989, P.L. 101-239, Title VI, Subtitle A, Part 3, Subpart A, § 6206(a)(1), (b)(1), Subpart B, § 6212(b)(1), (c)(2), Subtitle B, Part 2, § 6411(d)(3)(A), 103 Stat. 2244, 2250, 2271; Nov. 5, 1990, P.L. 101-508, Title IV, Subtitle A, Part 3, §§ 4204(a)(1), (2), (c)(1), (2), (d)(1), (e)(1), 4206(b)(1), 104 Stat. 1388-108, 1388-116; Aug. 15, 1994, P.L. 103-296, Title I, § 108(c)(6), 108 Stat. 1486; Oct. 31, 1994, P.L. 103-432, Title I, Subtitle C, § 157(b)(1), (4), 108 Stat. 4442; Aug. 21, 1996, P.L. 104-191, Title II, Subtitle B, § 215(a), (b), Subtitle D, § 231(g), 110 Stat. 2005, 2014; Aug. 5, 1997, P.L. 105-33, Title IV, Subtitle A, Ch 1, Subch A, §§ 4001, 4002(a), (b)(1), (2)(A), 111 Stat. 275, 328; Nov. 29, 1999, P.L. 106-113, Div B, § 1000(a)(6), 113 Stat. 1536; Dec. 21, 2000, P.L. 106-554, § 1(a)(6), 114 Stat. 2763; Dec. 8, 2003, P.L. 108-173, Title I, § 101(a)(1), Title II, Subtitle D, § 234, Title VII, Subtitle D, § 736(d)(2), Title IX, Subtitle D, § 940(b)(2)(B), 117 Stat. 2071, 2209, 2357, 2417; Dec. 29, 2007, P.L. 110-173, Title I, § 109, 121 Stat. 2497; July 15, 2008, P.L. 110-275, Title I, Subtitle D, § 167(a)-(c), 122 Stat. 2575.)

§ 1395nn. Limitation on certain physician referrals

(a) Prohibition of certain referrals.

(1) In general. Except as provided in subsection (b), if a physician (or an immediate family member of such physician) has a financial relationship with an entity specified in paragraph (2), then--

(A) the physician may not make a referral to the entity for the furnishing of designated health services for which payment otherwise may be made under this *title [42 USCS §§ 1395* et seq.], and

(B) the entity may not present or cause to be presented a claim under this *title [42 USCS §§ 1395* et seq.] or bill to any individual, third party payor, or other entity for designated health services furnished pursuant to a referral prohibited under subparagraph (A).

(2) Financial relationship specified. For purposes of this section, a financial relationship of a physician (or an immediate family member of such physician) with an entity specified in this paragraph is--

(A) except as provided in subsections (c) and (d), an ownership or investment interest in the entity, or

(B) except as provided in subsection (e), a compensation arrangement (as defined in subsection (h)(1)) between the physician (or an immediate family member of such physician) and the entity.

An ownership or investment interest described in subparagraph (A) may be through equity, debt, or other means and includes an interest in an entity that holds an ownership or investment interest in any entity providing the designated health service.

(b) General exceptions to both ownership and compensation arrangement prohibitions. Subsection (a)(1) shall not apply in the following cases:

(1) Physicians' services. In the case of physicians' services (as defined in section 1861(q) [*42 USCS § 1395x(q)*]) provided personally by (or under the personal supervision of) another physician in the same group practice (as defined in subsection (h)(4)) as the referring physician.

(2) In-office ancillary services. In the case of services (other than durable medical equipment (excluding infusion pumps) and parenteral and enteral nutrients, equipment, and supplies)--

(A) that are furnished--

(i) personally by the referring physician, personally by a physician who is a member of the same group practice as the referring physician, or personally by individuals who are directly supervised by the physician or by another physician in the group practice, and

(ii) (I) in a building in which the referring physician (or another physician who is a member of the same group practice) furnishes physicians' services unrelated to the furnishing of designated health services, or

(II) in the case of a referring physician who is a member of a group practice, in another building which is used by the group practice--

(aa) for the provision of some or all of the group's clinical laboratory services, or

(bb) for the centralized provision of the group's designated health services (other than clinical laboratory services),

unless the Secretary determines other terms and conditions under which the provision of such services does not present a risk of program or patient abuse, and

(B) that are billed by the physician performing or supervising the services, by a group practice of which such physician is a member under a billing number assigned to the group practice, or by an entity that is wholly owned by such physician or such group practice,

if the ownership or investment interest in such services meets such other requirements as the Secretary may impose by regulation as needed to protect against program or patient abuse.

(3) Prepaid plans. In the case of services furnished by an organization--

(A) with a contract under section 1876 [*42 USCS § 1395mm*] to an individual enrolled with the organization,

(B) described in section 1833(a)(1)(A) [*42 USCS § 1395l(a)(1)(A)*] to an individual enrolled with the organization,

(C) receiving payments on a prepaid basis, under a demonstration project under section 402(a) of the Social Security Amendments of 1967 [*42 USCS § 1395b-1(a)*] or under section 222(a) of the Social Security Amendments of 1972 [*42 USCS § 1395b-1* note], to an individual enrolled with the organization,

(D) that is a qualified health maintenance organization (within the meaning of section 1310(d) of the Public Health Service Act [*42 USCS § 300e-9(d)*]) to an individual enrolled with the organization, or

(E) that is a Medicare + Choice organization under part C [*42 USCS §§ 1395w-21* et seq.] that is offering a coordinated care plan described in section 1851(a)(2)(A) [*42 USCS § 1395w-21(a)(2)(A)*] to an individual enrolled with the organization.

(4) Other permissible exceptions. In the case of any other financial relationship which the Secretary determines, and specifies in regulations, does not pose a risk of program or patient abuse.

(5) Electronic prescribing. An exception established by regulation under section 1860D-3(e)(6) [1860D-4(e)(6)] [*42 USCS § 1395w-104(e)(6)*].

(c) General exception related only to ownership or investment prohibition for ownership in publicly traded securities and mutual funds. Ownership of the following shall not be considered to be an ownership or investment interest described in subsection (a)(2)(A):

(1) Ownership of investment securities (including shares or bonds, debentures, notes, or other debt instruments) which may be purchased on terms generally available to the public and which are--

(A) (i) securities listed on the New York Stock Exchange, the American Stock Exchange, or any regional exchange in which quotations are published on a daily basis, or foreign securities listed on a recognized foreign, national, or regional exchange in which quotations are published on a daily basis, or

(ii) traded under an automated interdealer quotation system operated by the National Association of Securities Dealers, and

(B) in a corporation that had, at the end of the corporation's most recent fiscal year, or on average during the previous 3 fiscal years, stockholder equity exceeding $ 75,000,000.

(2) Ownership of shares in a regulated investment company as defined in *section 851(a) of the Internal Revenue Code of 1986* [*26 USCS § 851(a)*], if such company had, at the end of the company's most recent fiscal year, or on average during the previous 3 fiscal years, total assets exceeding $ 75,000,000.

(d) Additional exceptions related only to ownership or investment prohibition. The following, if not otherwise excepted under subsection (b), shall not be considered to be an ownership or investment interest described in subsection (a)(2)(A):

(1) Hospitals in Puerto Rico. In the case of designated health services provided by a hospital located in Puerto Rico.

(2) Rural providers. In the case of designated health services furnished in a rural area (as defined in section 1886(d)(2)(D) [*42 USCS § 1395ww(d)(2)(D)*]) by an entity, if--

(A) substantially all of the designated health services furnished by the entity are furnished to individuals residing in such a rural area; and

(B) effective for the 18-month period beginning on the date of the enactment of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 [enacted Dec. 8, 2003], the entity is not a specialty hospital (as defined in subsection (h)(7)).

(3) Hospital ownership. In the case of designated health services provided by a hospital (other than a hospital described in paragraph (1)) if--

(A) the referring physician is authorized to perform services at the hospital;

(B) effective for the 18-month period beginning on the date of the enactment of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 [enacted Dec. 8, 2003], the hospital is not a specialty hospital (as defined in subsection (h)(7)); and

(C) the ownership or investment interest is in the hospital itself (and not merely in a subdivision of the hospital).

(e) Exceptions relating to other compensation arrangements. The following shall not be considered to be a compensation arrangement described in subsection (a)(2)(B):

(1) Rental of office space; rental of equipment.

(A) Office space. Payments made by a lessee to a lessor for the use of premises if--

(i) the lease is set out in writing, signed by the parties, and specifies the premises covered by the lease,

(ii) the space rented or leased does not exceed that which is reasonable and necessary for the legitimate business purposes of the lease or rental and is used exclusively by the lessee when being used by the lessee, except that the lessee may make payments for the use of space consisting of common areas if such payments do not exceed the lessee's pro rata share of expenses for such space based upon the ratio of the space used exclusively by the lessee to the total amount of space (other than common areas) occupied by all persons using such common areas,

(iii) the lease provides for a term of rental or lease for at least 1 year,

(iv) the rental charges over the term of the lease are set in advance, are consistent with fair market value, and are not determined in a manner that takes into account the volume or value of any referrals or other business generated between the parties,

(v) the lease would be commercially reasonable even if no referrals were made between the parties, and

(vi) the lease meets such other requirements as the Secretary may impose by regulation as needed to protect against program or patient abuse.

(B) Equipment. Payments made by a lessee of equipment to the lessor of the equipment for the use of the equipment if--

(i) the lease is set out in writing, signed by the parties, and specifies the equipment covered by the lease,

(ii) the equipment rented or leased does not exceed that which is reasonable and necessary for the legitimate business purposes of the lease or rental and is used exclusively by the lessee when being used by the lessee,

(iii) the lease provides for a term of rental or lease of at least 1 year,

(iv) the rental charges over the term of the lease are set in advance, are consistent with fair market value, and are not determined in a manner that takes into account the volume or value of any referrals or other business generated between the parties,

(v) the lease would be commercially reasonable even if no referrals were made between the parties, and

(vi) the lease meets such other requirements as the Secretary may impose by regulation as needed to protect against program or patient abuse.

(2) Bona fide employment relationships. Any amount paid by an employer to a physician (or an immediate family member of such physician) who has a bona fide employment relationship with the employer for the provision of services if--

(A) the employment is for identifiable services,

(B) the amount of the remuneration under the employment--

(i) is consistent with the fair market value of the services, and

(ii) is not determined in a manner that takes into account (directly or indirectly) the volume or value of any referrals by the referring physician,

(C) the remuneration is provided pursuant to an agreement which would be commercially reasonable even if no referrals were made to the employer, and

(D) the employment meets such other requirements as the Secretary may impose by regulation as needed to protect against program or patient abuse.

Subparagraph (B)(ii) shall not prohibit the payment of remuneration in the form of a productivity bonus based on services performed personally by the physician (or an immediate family member of such physician).

(3) Personal service arrangements.

(A) In general. Remuneration from an entity under an arrangement (including remuneration for specific physicians' services furnished to a nonprofit blood center) if--

(i) the arrangement is set out in writing, signed by the parties, and specifies the services covered by the arrangement,

(ii) the arrangement covers all of the services to be provided by the physician (or an immediate family member of such physician) to the entity,

(iii) the aggregate services contracted for do not exceed those that are reasonable and necessary for the legitimate business purposes of the arrangement,

(iv) the term of the arrangement is for at least 1 year,

(v) the compensation to be paid over the term of the arrangement is set in advance, does not exceed fair market value, and except in the case of a physician incentive plan described in subparagraph (B), is not determined in a manner that takes into account the volume or value of any referrals or other business generated between the parties,

(vi) the services to be performed under the arrangement do not involve the counseling or promotion or a business arrangement or other activity that violates any State or Federal law, and

(vii) the arrangement meets such other requirements as the Secretary may impose by regulation as needed to protect against program or patient abuse.

(B) Physician incentive plan exception.

(i) In general. In the case of a physician incentive plan (as defined in clause (ii)) between a physician and an entity, the compensation may be determined in a manner (through a withhold, capitation, bonus, or otherwise) that takes into account directly or indirectly the volume or value of any referrals or other business generated between the parties, if the plan meets the following requirements:

(I) No specific payment is made directly or indirectly under the plan to a physician or a physician group as an inducement to reduce or limit medically necessary services provided with respect to a specific individual enrolled with the entity.

(II) In the case of a plan that places a physician or a physician group at substantial financial risk as determined by the Secretary pursuant to section 1876(i)(8)(A)(ii) [*42 USCS § 1395mm(i)(8)(A)(ii)*], the plan complies with any requirements the Secretary may impose pursuant to such section.

(III) Upon request by the Secretary, the entity provides the Secretary with access to descriptive information regarding the plan, in order to permit the Secretary to determine whether the plan is in compliance with the requirements of this clause.

(ii) Physician incentive plan defined. For purposes of this subparagraph, the term "physician incentive plan" means any compensation arrangement between an entity and a physician or physician group that may directly or indirectly have the effect of reducing or limiting services provided with respect to individuals enrolled with the entity.

(4) Remuneration unrelated to the provision of designated health services. In the case of remuneration which is provided by a hospital to a physician if such remuneration does not relate to the provision of designated health services.

(5) Physician recruitment. In the case of remuneration which is provided by a hospital to a physician to induce the physician to relocate to the geographic area served by the hospital in order to be a member of the medical staff of the hospital, if--

(A) the physician is not required to refer patients to the hospital,

(B) the amount of the remuneration under the arrangement is not determined in a manner that takes into account (directly or indirectly) the volume or value of any referrals by the referring physician, and

(C) the arrangement meets such other requirements as the Secretary may impose by regulation as needed to protect against program or patient abuse.

(6) Isolated transactions. In the case of an isolated financial transaction, such as a one-time sale of property or practice, if--

(A) the requirements described in subparagraphs (B) and (C) of paragraph (2) are met with respect to the entity in the same manner as they apply to an employer, and

(B) the transaction meets such other requirements as the Secretary may impose by regulation as needed to protect against program or patient abuse.

(7) Certain group practice arrangements with a hospital.

[(A)] In general. An arrangement between a hospital and a group under which designated health services are provided by the group but are billed by the hospital if--

(i) with respect to services provided to an inpatient of the hospital, the arrangement is pursuant to the provision of inpatient hospital services under section 1861(b)(3) [*42 USCS § 1395x(b)(3)*],

(ii) the arrangement began before December 19, 1989, and has continued in effect without interruption since such date,

(iii) with respect to the designated health services covered under the arrangement, substantially all of such services furnished to patients of the hospital are furnished by the group under the arrangement,

(iv) the arrangement is pursuant to an agreement that is set out in writing and that specifies the services to be provided by the parties and the compensation for services provided under the agreement,

(v) the compensation paid over the term of the agreement is consistent with fair market value and the compensation per unit of services is fixed in advance and is not determined in a manner that takes into account the volume or value of any referrals or other business generated between the parties,

(vi) the compensation is provided pursuant to an agreement which would be commercially reasonable even if no referrals were made to the entity, and

(vii) the arrangement between the parties meets such other requirements as the Secretary may impose by regulation as needed to protect against program or patient abuse.

(8) Payments by a physician for items and services. Payments made by a physician--

(A) to a laboratory in exchange for the provision of clinical laboratory services, or

(B) to an entity as compensation for other items or services if the items or services are furnished at a price that is consistent with fair market value.

(f) Reporting requirements. Each entity providing covered items or services for which payment may be made under this *title [42 USCS §§ 1395* et seq.] shall provide the Secretary with the information concerning the entity's ownership, investment, and compensation arrangements, including--

(1) the covered items and services provided by the entity, and

(2) the names and unique physician identification numbers of all physicians with an ownership or investment interest (as described in subsection (a)(2)(A)), or with a compensation arrangement (as described in subsection (a)(2)(B)), in the entity, or whose immediate relatives have such an ownership or investment interest or who have such a compensation relationship with the entity.

Such information shall be provided in such form, manner, and at such times as the Secretary shall specify. The requirement of this subsection shall not apply to designated health services provided outside the United States or to entities which the Secretary determines provides [provide] services for which payment may be made under this *title [42 USCS §§ 1395* et seq.] very infrequently.

(g) Sanctions.

(1) Denial of payment. No payment may be made under this *title [42 USCS §§ 1395* et seq.] for a designated health service which is provided in violation of subsection (a)(1).

(2) Requiring refunds for certain claims. If a person collects any amounts that were billed in violation of subsection (a)(1), the person shall be liable to the individual for, and shall refund on a timely basis to the individual, any amounts so collected.

(3) Civil money penalty and exclusion for improper claims. Any person that presents or causes to be presented a bill or a claim for a service that such person knows or should know is for a service for which payment may not be made under paragraph (1) or for which a refund has not been made under paragraph (2) shall be subject to a civil money penalty of not more than $ 15,000 for each such service. The provisions of section 1128A [*42 USCS § 1320a-7a*] (other than the first sentence of subsection (a) and other than subsection (b)) shall apply to a civil money penalty under the previous sentence in the same manner as such provisions apply to a penalty or proceeding under section 1128A(a) [*42 USCS § 1320a-7a(a)*].

(4) Civil money penalty and exclusion for circumvention schemes. Any physician or other entity that enters into an arrangement or scheme (such as a cross-referral arrangement) which the physician or entity knows or should know has a principal purpose of assuring referrals by the physician to a particular entity which, if the physician directly made referrals to such entity, would be in violation of this section, shall be subject to a civil money penalty of not more than $ 100,000 for each such arrangement or scheme. The provisions of section 1128A [*42 USCS § 1320a-7a*] (other than the first sentence of subsection (a) and other than subsection (b)) shall apply to a civil money penalty under the previous sentence in the same manner as such provisions apply to a penalty or proceeding under section 1128A(a) [*42 USCS § 1320a-7a(a)*].

(5) Failure to report information. Any person who is required, but fails, to meet a reporting requirement of subsection (f) is subject to a civil money penalty of not more than $ 10,000 for each day for which reporting is required to have been made. The provisions of section 1128A [*42 USCS § 1320a-7a*] (other than the first sentence of subsection (a) and other than subsection (b)) shall apply to a civil money penalty under the previous sentence in the same manner as such provisions apply to a penalty or proceeding under section 1128A(a) [*42 USCS § 1320a-7a(a)*].

(6) Advisory opinions.

(A) In general. The Secretary shall issue written advisory opinions concerning whether a referral relating to designated health services (other than clinical laboratory services) is prohibited under this section. Each advisory opinion issued by the Secretary shall be binding as to the Secretary and the party or parties requesting the opinion.

(B) Application of certain rules. The Secretary shall, to the extent practicable, apply the rules under subsections (b)(3) and (b)(4) and take into account the regulations promulgated under subsection (b)(5) of section 1128D [*42 USCS § 1320a-7d(b)(5)*] in the issuance of advisory opinions under this paragraph.

(C) Regulations. In order to implement this paragraph in a timely manner, the Secretary may promulgate regulations that take effect on an interim basis, after notice and pending opportunity for public comment.

(D) Applicability. This paragraph shall apply to requests for advisory opinions made after the date which is 90 days after the date of the enactment of this paragraph [enacted Aug. 5, 1997] and before the close of the period described in section 1128D(b)(6) [*42 USCS § 1320a-7d(b)(6)*].

(h) Definitions and special rules. For purposes of this section:

(1) Compensation arrangement; remuneration.

(A) The term "compensation arrangement" means any arrangement involving any remuneration between a physician (or an immediate family member of such physician) and an entity other than an arrangement involving only remuneration described in subparagraph (C).

(B) The term "remuneration" includes any remuneration, directly or indirectly, overtly or covertly, in cash or in kind.

(C) Remuneration described in this subparagraph is any remuneration consisting of any of the following:

(i) The forgiveness of amounts owed for inaccurate tests or procedures, mistakenly performed tests or procedures, or the correction of minor billing errors.

(ii) The provision of items, devices, or supplies that are used solely to--

(I) collect, transport, process, or store specimens for the entity providing the item, device, or supply, or

(II) order or communicate the results of tests or procedures for such entity.

(iii) A payment made by an insurer or a self-insured plan to a physician to satisfy a claim, submitted on a fee for service basis, for the furnishing of health services by that physician to an individual who is covered by a policy with the insurer or by the self-insured plan, if--

(I) the health services are not furnished, and the payment is not made, pursuant to a contract or other arrangement between the insurer or the plan and the physician,

(II) the payment is made to the physician on behalf of the covered individual and would otherwise be made directly to such individual,

(III) the amount of the payment is set in advance, does not exceed fair market value, and is not determined in a manner that takes into account directly or indirectly the volume or value of any referrals, and

(IV) the payment meets such other requirements as the Secretary may impose by regulation as needed to protect against program or patient abuse.

(2) Employee. An individual is considered to be "employed by" or an "employee" of an entity if the individual would be considered to be an employee of the entity under the usual common law rules applicable in determining the employer-employee relationship (as applied for purposes of *section 3121(d)(2) of the Internal Revenue Code of 1986 [26 USCS § 3121(d)(2)]*).

(3) Fair market value. The term "fair market value" means the value in arms length transactions, consistent with the general market value, and, with respect to rentals or leases, the value of rental property for general commercial purposes (not taking into account its intended use) and, in the case of a lease of space, not adjusted to reflect the additional value the prospective lessee or lessor would attribute to the proximity or convenience to the lessor where the lessor is a potential source of patient referrals to the lessee.

(4) Group practice.

(A) Definition of group practice. The term "group practice" means a group of 2 or more physicians legally organized as a partnership, professional corporation, foundation, not-for-profit corporation, faculty practice plan, or similar association--

(i) in which each physician who is a member of the group provides substantially the full range of services which the physician routinely provides, including medical care, consultation, diagnosis, or treatment, through the joint use of shared office space, facilities, equipment and personnel,

(ii) for which substantially all of the services of the physicians who are members of the group are provided through the group and are billed under a billing number assigned to the group and amounts so received are treated as receipts of the group,

(iii) in which the overhead expenses of and the income from the practice are distributed in accordance with methods previously determined,

(iv) except as provided in subparagraph (B)(i), in which no physician who is a member of the group directly or indirectly receives compensation based on the volume or value of referrals by the physician,

(v) in which members of the group personally conduct no less than 75 percent of the physician-patient encounters of the group practice, and

(vi) which meets such other standards as the Secretary may impose by regulation.

(B) Special rules.

(i) Profits and productivity bonuses. A physician in a group practice may be paid a share of overall profits of the group, or a productivity bonus based on services personally performed or services incident to such personally performed services, so long as the share or bonus is not determined in any manner which is directly related to the volume or value of referrals by such physician.

(ii) Faculty practice plans. In the case of a faculty practice plan associated with a hospital, institution of higher education, or medical school with an approved medical residency training program in which physician members may provide a variety of different specialty services and provide professional services both within and outside the group, as well as perform other tasks such as research, subparagraph (A) shall be applied only with respect to the services provided within the faculty practice plan.

(5) Referral; referring physician.

(A) Physicians' services. Except as provided in subparagraph (C), in the case of an item or service for which payment may be made under part B, the request by a physician for the item or service, including the request by a physician for a consultation with another physician (and any test or procedure ordered by, or to be performed by (or under the supervision of) that other physician), constitutes a "referral" by a "referring physician".

(B) Other items. Except as provided in subparagraph (C), the request or establishment of a plan of care by a physician which includes the provision of the designated health service constitutes a "referral" by a "referring physician".

(C) Clarification respecting certain services integral to a consultation by certain specialists. A request by a pathologist for clinical diagnostic laboratory tests and pathological examination services, a request by a radiologist for diagnostic radiology services, and a request by a radiation oncologist for radiation therapy, if such services are furnished by (or under the supervision of) such pathologist, radiologist, or radiation oncologist pursuant to a consultation requested by another physician does not constitute a "referral" by a "referring physician".

(6) Designated health services. The term "designated health services" means any of the following items or services:

(A) Clinical laboratory services.

(B) Physical therapy services.

(C) Occupational therapy services.

(D) Radiology services, including magnetic resonance imaging, computerized axial tomography scans, and ultrasound services.

(E) Radiation therapy services and supplies.

(F) Durable medical equipment and supplies.

(G) Parenteral and enteral nutrients, equipment, and supplies.

(H) Prosthetics, orthotics, and prosthetic devices and supplies.

(I) Home health services.

(J) Outpatient prescription drugs.

(K) Inpatient and outpatient hospital services.

(L) **[Caution: This subparagraph applies to services furnished on or after July 1, 2009, as provided by § 143(c) of Act July 15, 2008, P.L. 110-275, which appears as *42 USCS § 1395k* note.]** Outpatient speech-language pathology services.

(7) Specialty hospital.

(A) In general. For purposes of this section, except as provided in subparagraph (B), the term "specialty hospital" means a subsection (d) hospital (as defined in section 1886(d)(1)(B) [*42 USCS § 1395ww(d)(1)(B)*]) that is primarily or exclusively engaged in the care and treatment of one of the following categories:

(i) Patients with a cardiac condition.

(ii) Patients with an orthopedic condition.

(iii) Patients receiving a surgical procedure.

(iv) Any other specialized category of services that the Secretary designates as inconsistent with the purpose of permitting physician ownership and investment interests in a hospital under this section.

(B) Exception. For purposes of this section, the term "specialty hospital" does not include any hospital--

(i) determined by the Secretary--

(I) to be in operation before November 18, 2003; or

(II) under development as of such date;

(ii) for which the number of physician investors at any time on or after such date is no greater than the number of such investors as of such date;

(iii) for which the type of categories described in subparagraph (A) at any time on or after such date is no different than the type of such categories as of such date;

(iv) for which any increase in the number of beds occurs only in the facilities on the main campus of the hospital and does not exceed 50 percent of the number of beds in the hospital as of November 18, 2003, or 5 beds, whichever is greater; and

(v) that meets such other requirements as the Secretary may specify.

HISTORY:

(Aug. 14, 1935, ch 531, Title XVIII, Part E[D][C], § 1877, as added Dec. 19, 1989, P.L. 101-239, Title VI, Subtitle A, Part 3, Subpart A, § 6204(a), 103 Stat. 2236; Nov. 5, 1990, P.L. 101-508, Title IV, Subtitle A, Part 3, § 4207(e)(1)-(3), (k)(2), 104 Stat. 1388-122, 1388-124; Aug. 10, 1993, P.L. 103-66, Title XIII, Ch 2, Subch A, Part III, § 13562(a), 107 Stat. 596; Oct. 31, 1994, P.L. 103-432, Title I, Subtitle C, §§ 152(a), (b), 160(d)(4), 108 Stat. 4436, 4444; Aug. 5, 1997, P.L. 105-33, Title IV, Subtitle A, Chapter 1, Subchapter A, § 4001, Subtitle D, Ch 2, § 4314, 111 Stat. 275, 389; Nov. 29, 1999, P.L. 106-113, Div B, § 1000(a)(6), 113 Stat. 1536; Dec. 8, 2003, P.L. 108-173, Title I, § 101(a)(1), (e)(8)(B), Title V, Subtitle A, § 507(a), 117 Stat. 2071, 2152, 2295; July 15, 2008, P.L. 110-275, Title I, Subtitle C, Part II, § 143(b)(9), 122 Stat. 2543.)

§ 1395oo. Provider Reimbursement Review Board

(a) Establishment. Any provider of services which has filed a required cost report within the time specified in regulations may obtain a hearing with respect to such cost report by a Provider Reimbursement Review Board (hereinafter referred to as the "Board") which shall be established by the Secretary in accordance with subsection (h) and (except as provided in subsection (g)(2)) any hospital which receives payments in amounts computed under subsection (b) or (d) of section 1886 [*42 USCS § 1395ww(b)* or (d)] and which has submitted such reports within such time as the Secretary may require in order to make payment under such section may obtain a hearing with respect to such payment by the Board, if--

(1) such provider--

(A) (i) is dissatisfied with a final determination of the organization serving as its fiscal intermediary pursuant to section 1816 [*42 USCS § 1395h*] as to the amount of total program reimbursement due the provider for the items and services furnished to individuals for which payment may be made under this *title [42 USCS §§ 1395* et seq.] for the period covered by such report, or

(ii) is dissatisfied with a final determination of the Secretary as to the amount of the payment under subsection (b) or (d) of section 1886 [*42 USCS § 1395ww(b)* or (d)],

(B) has not received such final determination from such intermediary on a timely basis after filing such report, where such report complied with the rules and regulations of the Secretary relating to such report, or

(C) has not received such final determination on a timely basis after filing a supplementary cost report, where such cost report did not so comply and such supplementary cost report did so comply,

(2) the amount in controversy is $ 10,000 or more, and

(3) such provider files a request for a hearing within 180 days after notice of the intermediary's final determination under paragraph (1)(A)(i), or, with respect to appeals under paragraph (1)(A)(ii), 180 days after notice of the Secretary's final determination, or with respect to appeals pursuant to paragraph (1)(B) or (C), within 180 days after notice of such determination would have been received if such determination had been made on a timely basis.

(b) Appeals by groups. The provisions of subsection (a) shall apply to any group of providers of services if each provider of services in such group would, upon the filing of an appeal (but without regard to the $ 10,000 limitation), be entitled to such a hearing, but only if the matters in controversy involve a common question of fact or interpretation of law or regulations and the amount in controversy is, in the aggregate, $ 50,000 or more.

(c) Right to counsel; rules of evidence. At such hearing, the provider of services shall have the right to be represented by counsel, to introduce evidence, and to examine and cross-examine witnesses. Evidence may be received at any such hearing even though inadmissible under rules of evidence applicable to court procedure.

(d) Decisions of Board. A decision by the Board shall be based upon the record made at such hearing, which shall include the evidence considered by the intermediary and such other evidence as may be obtained or received by the Board, and shall be supported by substantial evidence when the record is viewed as a whole. The Board shall have the power to affirm, modify, or reverse a final determination of the fiscal intermediary with respect to a cost report and to make any other revisions on matters covered by such cost report (including revisions adverse to the provider of services) even though such matters were not considered by the intermediary in making such final determination.

(e) Rules and regulations. The Board shall have full power and authority to make rules and establish procedures, not inconsistent with the provisions of this *title [42 USCS §§ 1395* et seq.] or regulations of the Secretary, which are necessary or appropriate to carry out the provisions of this section. In the course of any hearing the Board may administer oaths and affirmations. The provisions of subsections (d) and (e) of section 205 [*42 USCS § 405(d)* and (e)] with respect to subpenas shall apply to the Board to the same extent as they apply to the Secretary with respect to title II [*42 USCS §§ 401* et seq.].

(f) Finality of decision; judicial review; determinations of Board authority; jurisdiction; venue; interest on amount in controversy.

(1) A decision of the Board shall be final unless the Secretary, on his own motion, and within 60 days after the provider of services is notified of the Board's decision, reverses, affirms, or modifies the Board's decision. Providers shall have the right to obtain judicial review of any final decision of the Board, or of any reversal, affirmance, or modification by the Secretary, by a civil action commenced within 60 days of the date on which notice of any final decision by the Board or of any reversal, affirmance, or modification by the Secretary is received. Providers shall also have the right to obtain judicial review of any action of the fiscal intermediary which involves a question of law or regulations relevant to the matters in controversy whenever the Board determines (on its own motion or at the request of a provider of services as described in the following sentence) that it is without authority to decide the question, by a civil action commenced within sixty days of the date on which notification of such determination is received. If a provider of services may obtain a hearing under subsection (a) and has filed a request for such a hearing, such provider may file a request for a determination by the Board of its authority to decide the question of law or regulations relevant to the matters in controversy (accompanied by such documents and materials as the Board shall require for purposes of rendering such determination). The Board shall render such determination in writing within thirty days after the Board receives the request and such accompanying documents and materials, and the determination shall be considered a final decision and not subject to review by the Secretary. If the Board fails to render such determination within such period, the provider may bring a civil action (within sixty days of the end of such period) with respect to the matter in controversy contained in such request for a hearing. Such action shall be brought in the district court of the United States for the judicial district in which the provider is located (or, in an action brought jointly by several providers, the judicial district in which the greatest number of such providers are located) or in the District Court for the District of Columbia and shall be tried pursuant to the applicable provisions under chapter 7 of title 5, United States Code [*5 USCS §§ 701* et seq.], notwithstanding any other provisions in section 205 [*42 USCS § 405*]. Any appeal to the Board or action for judicial review by providers which are under common ownership or control or which have obtained a hearing under

subsection (b) must be brought by such providers as a group with respect to any matter involving an issue common to such providers.

(2) Where a provider seeks judicial review pursuant to paragraph (1), the amount in controversy shall be subject to annual interest beginning on the first day of the first month beginning after the 180-day period as determined pursuant to subsection (a)(3) and equal to the rate of interest on obligations issued for purchase by the Federal Hospital Insurance Trust Fund for the month in which the civil action authorized under paragraph (1) is commenced, to be awarded by the reviewing court in favor of the prevailing party.

(3) No interest awarded pursuant to paragraph (2) shall be deemed income or cost for the purposes of determining reimbursement due providers under this Act.

(g) Certain findings not reviewable.

(1) The finding of a fiscal intermediary that no payment may be made under this *title [42 USCS §§ 1395* et seq.] for any expenses incurred for items or services furnished to an individual because such items or services are listed in section 1862 [*42 USCS § 1395y*] shall not be reviewed by the Board, or by any court pursuant to an action brought under subsection (f).

(2) The determinations and other decisions described in section 1886(d)(7) [*42 USCS § 1395ww(d)(7)*] shall not be reviewed by the Board or by any court pursuant to an action brought under subsection (f) or otherwise.

(h) Composition and compensation. The Board shall be composed of five members appointed by the Secretary without regard to the provisions of title 5, United States Code, governing appointments in the competitive services. Two of such members shall be representative of providers of services. All of the members of the Board shall be persons knowledgeable in the field of payment of providers of services, and at least one of them shall be a certified public accountant. Members of the Board shall be entitled to receive compensation at rates fixed by the Secretary, but not exceeding the rate specified (at the time the service involved is rendered by such members) for grade GS-18 in *section 5332 of title 5, United States Code*. The term of office shall be three years, except that the Secretary shall appoint the initial members of the Board for shorter terms to the extent necessary to permit staggered terms of office.

(i) Technical and clerical assistance. The Board is authorized to engage such technical assistance as may be required to carry out its functions, and the Secretary shall, in addition, make available to the Board such secretarial, clerical, and other assistance as the Board may require to carry out its functions.

(j) "Provider of services" defined. In this section, the term "provider of services" includes a rural health clinic and a Federally qualified health center.

HISTORY:

(Aug. 14, 1935, ch 531, Title XVIII, Part E[D][C], § 1878, as added Oct. 30, 1972, P.L. 92-603, Title II, § 243(a), 86 Stat. 1420; Oct. 26, 1974, P.L. 93-484, § 3(a), 88 Stat. 1459; Dec. 5, 1980, P.L. 96-499, Title IX, Part B, Subpart II, § 955, 94 Stat. 2647; April 20, 1983, P.L. 98-21, Title VI, § 602(h), 97 Stat. 165; July 18, 1984, P.L. 98-369, Division B, Title III, Subtitle A, Part II, §§ 2351(a)(1), (b)(1), 2354(b)(39), (40), 98 Stat. 1098, 1102; Nov. 5, 1990, P.L. 101-508, Title IV, Subtitle A, Part 2, Subpart B, § 4161(a)(6), (b)(4), 104 Stat. 1388-94; Aug. 10, 1993, P.L. 103-66, Title XIII, Ch 2, Subch A, Part I, § 13503(c)(1)(B), 107 Stat. 579; Aug. 5, 1997, P.L. 105-33, Title IV, Subtitle A, Ch 1, Subch A, § 4001, 111 Stat. 275; Dec. 8, 2003, P.L. 108-173, Title I, § 101(a)(1), 117 Stat. 2071.)

§ 1395pp. Limitation on liability where claims are disallowed

(a) Conditions prerequisite to payment for items and services notwithstanding determination of disallowance [Caution: For application of 1986 amendment of subsection, see § 9305(g)(3) of Act Oct. 21, 1986, P.L. 99-509, which appears as a note to this section.]. Where--

(1) a determination is made that, by reason of section 1862(a)(1) or (9) [*42 USCS § 1395y(a)(1)* or (9)] or by reason of a coverage denial described in subsection (g), payment may not be made under part A or part B of this *title [42 USCS §§ 1395c* et seq. or *1395j* et seq.] for any expenses incurred for items or services furnished an individual by a provider of services or by another person pursuant to an assignment under section 1842(b)(3)(B)(ii) [*42 USCS § 1395u(b)(3)(B)(ii)*], and

(2) both such individual and such provider of services or such other person, as the case may be, did not know, and could not reasonably have been expected to know, that payment would not be made for such items or services under such part A or part B [*42 USCS §§ 1395c* et seq. or *1395j* et seq.],

then to the extent permitted by this *title [42 USCS §§ 1395* et seq.], payment shall, notwithstanding such determination, be made for such items or services (and for such period of time as the Secretary finds will carry out the objectives of this *title [42 USCS §§ 1395* et seq.]), as though section 1862(a)(1) and section 1862(a)(9) [*42 USCS § 1395y(a)(1)* and (9)] did not apply and as though the coverage denial described in subsection (g) had not occurred. In each such case the Secretary shall notify both such individual and such provider of services or such other person, as the case may be, of the conditions under which payment for such items or services was made and in the case of comparable situations arising thereafter with respect to such individual or such provider or such other person, each shall, by reason of such notice (or similar notices provided before the enactment of this section [enacted Oct. 30, 1972]), be deemed to have knowledge that payment cannot be made for such items or services or reasonably comparable items or services. Any provider or other person furnishing items or services for which payment may not be made by reason of section 1862(a)(1) or (9) [*42 USCS § 1395y(a)(1)* or (9)] or by reason of a coverage denial described in subsection (g) shall be deemed to have knowledge that payment cannot be made for such items or services if the claim relating to such items or services involves a case, provider or other person furnishing services, procedure, or test, with respect to which such provider or other person has been notified by the Secretary (including notification by a utilization and quality control peer review organization) that a pattern of inappropriate utilization has occurred in the past, and such provider or other person has been allowed a reasonable time to correct such inappropriate utilization.

(b) Knowledge of person or provider that payment could not be made; indemnification of individual. In any case in which the provisions of paragraphs (1) and (2) of subsection (a) are met, except that such provider or such other person, as the case may be, knew, or could be expected to know, that payment for such services or items could not be made under such part A or part B [*42 USCS §§ 1395c* et seq. or *1395j* et seq.], then the Secretary shall, upon proper application filed within such time as may be prescribed in regulations, indemnify the individual (referred to in such paragraphs), for any payments received from such individual by such provider or such other person, as the case may be, for such items or services. Any payments made by the Secretary as indemnification shall be deemed to have been made to such provider or such other person, as the case may be, under applicable provisions of law. In each such case the Secretary shall notify such individual of the conditions under which indemnification is made and in the case of comparable situations arising thereafter with respect to such individual, he shall, by reason of such notice (or similar notices provided before the enactment of this section [enacted Oct. 30, 1972]), be deemed to have knowledge that payment cannot be made for such items or services. No item or service for which an individual is indemnified under this subsection shall be taken into account in applying any limitation on the amount of items and services for which payment may be made to or on behalf of the individual under this *title [42 USCS §§ 1395* et seq.].

(c) Knowledge of both provider and individual to whom items or services were furnished that payment could not be made [Caution: For application of 1986 amendment of subsection, see § 9305(g)(3) of Act Oct. 21, 1986, P.L. 99-509, which appears as a note to this section.]. No payments shall be made under this *title [42 USCS §§ 1395* et seq.] in any cases in which the provisions of paragraph (1) of subsection (a) are met, but both the individual to whom the items or services were furnished and the provider of service or other person, as the case may be, who furnished the items or services knew, or could reasonably have been expected to know, that payment could not be made for items or services under part A or part B [*42 USCS §§ 1395c* et seq. or *1395j* et seq.] by reason of section 1862(a)(1) or (a)(9) [*42 USCS § 1395y(a)(1)* or (9)] or by reason of a coverage denial described in subsection (g).

(d) Exercise of rights. In any case arising under subsection (b) (but without regard to whether payments have been made by the individual to the provider or other person) or subsection (c), the provider or other person shall have the same rights that an individual has under sections 1869(b) [*42 USCS § 1395ff(b)*] and 1842(b)(3)(C) [*42 USCS § 1395u(b)(3)(C)*] (as may be applicable) when the amount of benefit or payments is in controversy, except that such rights may, under prescribed regulations, be exercised by such provider or other person only after the Secretary determines that the individual will not exercise such rights under such sections [*42 USCS §§ 1395u(b)(3)(C)* and *1395ff(b)*].

(e) Payment where beneficiary not a fault. Where payment for inpatient hospital services or extended care services may not be made under part A of this *title [42 USCS §§ 1395c* et seq.] on behalf of an individual entitled to benefits under such part solely because of an unintentional, inadvertent, or erroneous action with respect to the transfer of such individual from a hospital or skilled nursing facility that meets the requirements of section 1861(e) or (j) [*42 USCS § 1395x(e)* or (j)] by such a provider of services acting in good faith in accordance with the advice of a utilization review committee, quality control and peer review organization, or fiscal intermediary, or on the basis of a clearly erroneous administrative decision by a provider of services, the Secretary shall take such action with respect to the payment of

such benefits as he determines may be necessary to correct the effects of such unintentional, inadvertent, or erroneous action.

(f) Presumption with respect to coverage denial; rebuttal requirements; "fiscal intermediary" defined [Caution: For application of 1986 amendment adding this subsection, see § 9305(g)(3) of Act Oct. 21, 1986, P.L. 99-509, which appears as a note to this section.].

(1) A home health agency which meets the applicable requirements of paragraphs (3) and (4) shall be presumed to meet the requirement of subsection (a)(2).

(2) The presumption of paragraph (1) with respect to specific services may be rebutted by actual or imputed knowledge of the facts described in subsection (a)(2), including any of the following:

(A) Notice by the fiscal intermediary of the fact that payment may not be made under this title with respect to the services.

(B) It is clear and obvious that the provider should have known at the time the services were furnished that they were excluded from coverage.

(3) The requirements of this paragraph are as follows:

(A) The agency complies with requirements of the Secretary under this *title [42 USCS §§ 1395* et seq.] respecting timely submittal of bills for payment and medical documentation.

(B) The agency program has reasonable procedures to notify promptly each patient (and the patient's physician) where it is determined that a patient is being or will be furnished items or services which are excluded from coverage under this *title [42 USCS §§ 1395* et seq.].

(4) (A) The requirement of this paragraph is that, on the basis of bills submitted by a home health agency during the previous quarter, the rate of denial of bills for the agency by reason of a coverage denial described in subsection (g) does not exceed 2.5 percent, computed based on visits for home health services billed.

(B) For purposes of determining the rate of denial of bills for a home health agency under subparagraph (A), a bill shall not be considered to be denied until the expiration of the 60-day period that begins on the date such bill is denied by the fiscal intermediary, or, with respect to such a denial for which the agency requests reconsideration, until the fiscal intermediary issues a decision denying payment for such bill.

(5) In this subsection, the term "fiscal intermediary" means, with respect to a home health agency, an agency or organization with an agreement under section 1816 [*42 USCS § 1395h*] with respect to the agency.

(6) The Secretary shall monitor the proportion of denied bills submitted by home health agencies for which reconsideration is requested, and shall notify Congress if the proportion of denials reversed upon reconsideration increases significantly.

(g) Coverage denial defined [Caution: For application of 1986 amendment adding this subsection, see § 9305(g)(3) of Act Oct. 21, 1986, P.L. 99-509, which appears as a note to this section.]. The coverage denial described in this subsection is--

(1) with respect to the provision of home health services to an individual, a failure to meet the requirements of section 1814(a)(2)(C) or section 1835(a)(2)(A) [*42 USCS § 1395f(a)(2)(C)* or *1395n(a)(2)(A)*] in that the individual--

(A) is or was not confined to his home, or

(B) does or did not need skilled nursing care on an intermittent basis; and

(2) with respect to the provision of hospice care to an individual, a determination that the individual is not terminally ill.

(h) Assigned claims. If a supplier of medical equipment and supplies (as defined in section 1834(j)(5) [*42 USCS § 1395m(j)(5)*])--

(1) furnishes an item or service to a beneficiary for which no payment may be made by reason of section 1834(j)(1) [*42 USCS § 1395m(j)(1)*];

(2) furnishes an item or service to a beneficiary for which payment is denied in advance under section 1834(a)(15) [*42 USCS § 1395m(a)(15)*]; or

(3) furnishes an item or service to a beneficiary for which no payment may be made by reason of section 1834(a)(17)(B) [*42 USCS § 1395m(a)(17)(B)*],

any expenses incurred for items and services furnished to an individual by such a supplier on an assignment-related basis shall be the responsibility of such supplier. The individual shall have no financial responsibility for such expenses and the supplier shall refund on a timely basis to the individual (and shall be liable to the individual for) any amounts collected from the individual for such items or services. The provisions of section 1834(a)(18) [*42 USCS §*

1395m(a)(18)] shall apply to refunds required under the previous sentence in the same manner as such provisions apply to refunds under such section.

HISTORY:

(Aug. 14, 1935, ch 531, Title XVIII, Part E[D][C], § 1879, as added Oct. 30, 1972, P.L. 92-603, Title II, § 213(a), 86 Stat. 1384; Dec. 5, 1980, P.L. 96-499, Title IX, Part B, Subpart II, § 956(a), 94 Stat. 2648; Sept. 3, 1982, P.L. 97-248, Title I, Subtitle C, §§ 145, 148(e), 96 Stat. 393, 394; Oct. 21, 1986, P.L. 99-509, Title IX, Subtitle D, Part 1, § 9305(g)(1), Part 3, § 9341(a)(3), 100 Stat. 1991, 2037; Dec. 22, 1987, P.L. 100-203, Title IV, Subtitle A, Part 4, § 4096(b), 101 Stat. 1330-139; Dec. 19, 1989, P.L. 101-239, Title VI, Subtitle A, Part 3, Subpart B, § 6214(a), (b), 103 Stat. 2252; Oct. 31, 1994, P.L. 103-432, Title I, Subtitle B, Part II, § 133(b), 108 Stat. 4421; Aug. 5, 1997, P.L. 105-33, Title IV, Subtitle A, Ch 1, Subch A, § 4001, Subtitle D, Ch 4, § 4447, 111 Stat. 275, 424; Dec. 8, 2003, P.L. 108-173, Title I, § 101(a)(1), 117 Stat. 2071.)

§ 1395qq. Indian Health Service facilities

(a) Eligibility for payments; conditions and requirements. A hospital or skilled nursing facility of the Indian Health Service, whether operated by such Service or by an Indian tribe or tribal organization (as those terms are defined in section 4 of the Indian Health Care Improvement Act [*25 USCS § 1603*]), shall be eligible for payments under this *title [42 USCS §§ 1395* et seq.], notwithstanding sections 1814(c) [*42 USCS § 1395f(c)*] and 1835(d) [*42 USCS § 1395n(d)*], if and for so long as it meets all of the conditions and requirements for such payments which are applicable generally to hospitals or skilled nursing facilities (as the case may be) under this *title [42 USCS §§ 1395* et seq.].

(b) Eligibility based on submission of plan to achieve compliance with conditions and requirements; twelve-month period. Notwithstanding subsection (a), a hospital or skilled nursing facility of the Indian Health Service which does not meet all of the conditions and requirements of this *title [42 USCS §§ 1395* et seq.] which are applicable generally to hospitals or skilled nursing facilities (as the case may be), but which submits to the Secretary within six months after the date of the enactment of this section [enacted Sept. 30, 1976] an acceptable plan for achieving compliance with such conditions and requirements, shall be deemed to meet such conditions and requirements (and to be eligible for payments under this *title [42 USCS §§ 1395* et seq.]), without regard to the extent of its actual compliance with such conditions and requirements, during the first 12 months after the month in which such plan is submitted.

(c) Payments into special fund for improvements to achieve compliance with conditions and requirements; certification of compliance by Secretary. Notwithstanding any other provision of this *title [42 USCS §§ 1395* et seq.], payments to which any hospital or skilled nursing facility of the Indian Health Service is entitled by reason of this section shall be placed in a special fund to be held by the Secretary and used by him (to such extent or in such amounts as are provided in appropriation Acts) exclusively for the purpose of making any improvements in the hospitals and skilled nursing facilities of such Service which may be necessary to achieve compliance with the applicable conditions and requirements of this *title [42 USCS §§ 1395* et seq.]. The preceding sentence shall cease to apply when the Secretary determines and certifies that substantially all of the hospitals and skilled nursing facilities of such Service in the United States are in compliance with such conditions and requirements.

(d) Report by Secretary; status of facilities in complying with conditions and requirements. The annual report of the Secretary which is required by section 701 [801] of the Indian Health Care Improvement Act [*25 USCS § 1671*] shall include (along with the matters specified in section 403 of such Act [*25 USCS § 1671* note]) a detailed statement of the status of the hospitals and skilled nursing facilities of the Service in terms of their compliance with the applicable conditions and requirements of this *title [42 USCS §§ 1395* et seq.] and of the progress being made by such hospitals and facilities (under plans submitted under subsection (b) and otherwise) toward the achievement of such compliance.

(e) Payment of physician and nonphysician services in certain Indian providers.

(1) (A) Notwithstanding section 1835(d) [*42 USCS § 1395n(d)*], subject to subparagraph (B), the Secretary shall make payment under part B [*42 USCS §§ 1395j* et seq.] to a hospital or an ambulatory care clinic (whether provider-based or freestanding) that is operated by the Indian Health Service or by an Indian tribe or tribal organization (as defined for purposes of subsection (a)) for services described in paragraph (2) (and for items and services furnished during the 5-year period beginning on January 1, 2005, all items and services for which payment may be made under part B [*42 USCS §§ 1395j* et seq.]) furnished in or at the direction of the hospital or clinic under the same situations, terms, and conditions as would apply if the services were furnished in or at the direction of such a hospital or clinic that was not operated by such Service, tribe, or organization.

(B) Payment shall not be made for services under subparagraph (A) to the extent that payment is otherwise made for such services under this *title [42 USCS §§ 1395* et seq.].

(2) The services described in this paragraph are the following:

(A) Services for which payment is made under section 1848 [*42 USCS § 1395w-4*].

(B) Services furnished by a practitioner described in section 1842(b)(18)(C) [*42 USCS § 1395u(b)(18)(C)*] for which payment under part B [*42 USCS §§ 1395j* et seq.] is made under a fee schedule.

(C) Services furnished by a physical therapist or occupational therapist as described in section 1861(p) [*42 USCS § 1395x(p)*] for which payment under part B [*42 USCS §§ 1395j* et seq.] is made under a fee schedule.

(3) Subsection (c) shall not apply to payments made under this subsection.

(f) Direct billing by Alaska Native and American Indian organizations. For provisions relating to the authority of certain Indian tribes, tribal organizations, and Alaska Native health organizations to elect to directly bill for, and receive payment for, health care services provided by a hospital or clinic of such tribes or organizations and for which payment may be made under this *title [42 USCS §§ 1395* et seq.], see section 405 of the Indian Health Care Improvement Act (*25 U.S.C. 1645*).

HISTORY:

(Aug. 14, 1935, ch 531, Title XVIII, Part E[D][C], § 1880, as added Sept. 30, 1976, P.L. 94-437, Title IV, § 401(b), 90 Stat. 1408; Aug. 5, 1997, P.L. 105-33, Title IV, Subtitle A, Ch 1, Subch A, § 4001, 111 Stat. 275; Nov. 1, 2000, P.L. 106-417, § 3(b)(1), 114 Stat. 1815; Dec. 21, 2000, P.L. 106-554, § 1(a)(6), 114 Stat. 2763; Dec. 8, 2003, P.L. 108-173, Title I, § 101(a)(1), Title VI, Subtitle C, § 630, 117 Stat. 2071, 2321.)

§ 1395rr. End stage renal disease program

(a) Type, duration, and scope of benefits. The benefits provided by parts A and B of this *title [42 USCS §§ 1395c* et seq. and *1395j* et seq.] shall include benefits for individuals who have been determined to have end stage renal disease as provided in section 226A [*42 USCS § 426-1*], and benefits for kidney donors as provided in subsection (d) of this section. Notwithstanding any other provision of this *title [42 USCS §§ 1395* et seq.], the type, duration, and scope of the benefit provided by parts A and B [*42 USCS §§ 1395c* et seq. and *1395j* et seq.] with respect to individuals who have been determined to have end stage renal disease and who are entitled to such benefits without regard to section 226A [*42 USCS § 426-1*] shall in no case be less than the type, duration, and scope of the benefits so provided for individuals entitled to such benefits solely by reason of that section.

(b) Payments with respect to services; dialysis; regulations; physicians' services; target reimbursement rates; home dialysis supplies and equipment; self-care home dialysis support services; self-care dialysis units; hepatitis B vaccine.

(1) Payments under this *title [42 USCS §§ 1395* et seq.] with respect to services, in addition to services for which payment would otherwise be made under this *title [42 USCS §§ 1395* et seq.], furnished to individuals who have been determined to have end stage renal disease shall include (A) payments on behalf of such individuals to providers of services and renal dialysis facilities which meet such requirements as the Secretary shall by regulation prescribe for institutional dialysis services and supplies (including self-dialysis services in a self-care dialysis unit maintained by the provider or facility), transplantation services, self-care home dialysis support services which are furnished by the provider or facility, and routine professional services performed by a physician during a maintenance dialysis episode if payments for his other professional services furnished to an individual who has end stage renal disease are made on the basis specified in paragraph (3)(A) of this subsection, (B) payments to or on behalf of such individuals for home dialysis supplies and equipment, and (C) payments to a supplier of home dialysis supplies and equipment that is not a provider of services, a renal dialysis facility, or a physician for self-administered erythropoietin as described in section 1861(s)(2)(P) if the Secretary finds that the patient receiving such drug from such a supplier can safely and effectively administer the drug (in accordance with the applicable methods and standards established by the Secretary pursuant to such section). The requirements prescribed by the Secretary under subparagraph (A) shall include requirements for a minimum utilization rate for transplantations.

(2) (A) With respect to payments for dialysis services furnished by providers of services and renal dialysis facilities to individuals determined to have end stage renal disease for which payments may be made under part B of this *title [42 USCS §§ 1395j* et seq.], such payments (unless otherwise provided in this section) shall be equal to 80 percent of the amounts determined in accordance with subparagraph (B); and with respect to payments for services for which payments may be made under part A of this *title [42 USCS §§ 1395c* et seq.], the amounts of such payments (which amounts shall not exceed, in respect to costs in procuring organs attributable to payments made to an organ procurement agency or histocompatibility laboratory, the costs incurred by that agency or laboratory) shall be determined in

accordance with section 1861(v) [*42 USCS § 1395x(v)*] or *section 1886* [*42 USCS § 1395ww*] (if applicable). Payments shall be made to a renal dialysis facility only if it agrees to accept such payments as payment in full for covered services, except for payment by the individual of 20 percent of the estimated amounts for such services calculated on the basis established by the Secretary under subparagraph (B) and the deductible amount imposed by section 1833(b) [*42 USCS § 1395l(b)*].

(B) The Secretary shall prescribe in regulations any methods and procedures to (i) determine the costs incurred by providers of services and renal dialysis facilities in furnishing covered services to individuals determined to have end stage renal disease, and (ii) determine, on a cost-related basis or other economical and equitable basis (including any basis authorized under section 1861(v) [*42 USCS § 1395x(v)*]) and consistent with any regulations promulgated under paragraph (7), the amounts of payments to be made for part B [*42 USCS §§ 1395j* et seq.] services furnished by such providers and facilities to such individuals.

(C) Such regulations, in the case of services furnished by proprietary providers and facilities (other than hospital outpatient departments) may include, if the Secretary finds it feasible and appropriate, provision for recognition of a reasonable rate of return on equity capital, providing such rate of return does not exceed the rate of return stipulated in section 1861(v)(1)(B) [*42 USCS § 1395x(v)(1)(B)*].

(D) For purposes of section 1878 [*42 USCS § 1395oo*], a renal dialysis facility shall be treated as a provider of services.

(3) With respect to payments for physicians' services furnished to individuals determined to have end stage renal disease, the Secretary shall pay 80 percent of the amounts calculated for such services--

(A) on a reasonable charge basis (but may, in such case, make payment on the basis of the prevailing charges of other physicians for comparable services or, for services furnished on or after January 1, 1992, on the basis described in section 1848 [*42 USCS § 1395w-4*]) except that payment may not be made under this subparagraph for routine services furnished during a maintenance dialysis episode, or

(B) on a comprehensive monthly fee or other basis (which effectively encourages the efficient delivery of dialysis services and provides incentives for the increased use of home dialysis) for an aggregate of services provided over a period of time (as defined in regulations).

(4) (A) Pursuant to agreements with approved providers of services and renal dialysis facilities, the Secretary may make payments to such providers and facilities for the cost of home dialysis supplies and equipment and self-care home dialysis support services furnished to patients whose self-care home dialysis is under the direct supervision of such provider or facility, on the basis of a target reimbursement rate (as defined in paragraph (6)) or on the basis of a method established under paragraph (7).

(B) The Secretary shall make payments to a supplier of home dialysis supplies and equipment furnished to a patient whose self-care home dialysis is not under the direct supervision of an approved provider of services or renal dialysis facility only in accordance with a written agreement under which--

(i) the patient certifies that the supplier is the sole provider of such supplies and equipment to the patient,

(ii) the supplier agrees to receive payment for the cost of such supplies and equipment only on an assignment-related basis, and

(iii) the supplier certifies that it has entered into a written agreement with an approved provider of services or renal dialysis facility under which such provider or facility agrees to furnish to such patient all self-care home dialysis support services and all other necessary dialysis services and supplies, including institutional dialysis services and supplies and emergency services.

(5) An agreement under paragraph (4) shall require, in accordance with regulations prescribed by the Secretary, that the provider or facility will--

(A) assume full responsibility for directly obtaining or arranging for the provision of--

(i) such medically necessary dialysis equipment as is prescribed by the attending physician;

(ii) dialysis equipment maintenance and repair services;

(iii) the purchase and delivery of all necessary medical supplies; and

(iv) where necessary, the services of trained home dialysis aides;

(B) perform all such administrative functions and maintain such information and records as the Secretary may require to verify the transactions and arrangements described in subparagraph (A);

(C) submit such cost reports, data, and information as the Secretary may require with respect to the costs incurred for equipment, supplies, and services furnished to the facility's home dialysis patient population; and

(D) provide for full access for the Secretary to all such records, data, and information as he may require to perform his functions under this section.

(6) The Secretary shall establish, for each calendar year, commencing with January 1, 1979, a target reimbursement rate for home dialysis which shall be adjusted for regional variations in the cost of providing home dialysis. In establishing such a rate, the Secretary shall include--

(A) the Secretary's estimate of the cost of providing medically necessary home dialysis supplies and equipment;

(B) an allowance, in an amount determined by the Secretary, to cover the cost of providing personnel to aid in home dialysis; and

(C) an allowance, in an amount determined by the Secretary, to cover administrative costs and to provide an incentive for the efficient delivery of home dialysis;

but in no event (except as may be provided in regulations under paragraph (7)) shall such target rate exceed 75 percent of the national average payment, adjusted for regional variations, for maintenance dialysis services furnished in approved providers and facilities during the preceding fiscal year. Any such target rate so established shall be utilized, without renegotiation of the rate, throughout the calendar year for which it is established. During the last quarter of each calendar year, the Secretary shall establish a home dialysis target reimbursement rate for the next calendar year based on the most recent data available to the Secretary at the time. In establishing any rate under this paragraph, the Secretary may utilize a competitive-bid procedure, a prenegotiated rate procedure, or any other procedure (including methods established under paragraph (7)) which the Secretary determines is appropriate and feasible in order to carry out this paragraph in an effective and efficient manner.

(7) Subject to paragraph (12), the Secretary shall provide by regulation for a method (or methods) for determining prospectively the amounts of payments to be made for dialysis services furnished by providers of services and renal dialysis facilities to individuals in a facility and to such individuals at home. Such method (or methods) shall provide for the prospective determination of a rate (or rates) for each mode of care based on a single composite weighted formula (which takes into account the mix of patients who receive dialysis services at a facility or at home and the relative costs of providing such services in such settings) for hospital-based facilities and such a single composite weighted formula for other renal dialysis facilities, or based on such other method or combination of methods which differentiate between hospital-based facilities and other renal dialysis facilities and which the Secretary determines, after detailed analysis, will more effectively encourage the more efficient delivery of dialysis services and will provide greater incentives for increased use of home dialysis than through the single composite weighted formulas. The amount of a payment made under any method other than a method based on a single composite weighted formula may not exceed the amount (or, in the case of continuous cycling peritoneal dialysis, 130 percent of the amount) of the median payment that would have been made under the formula for hospital-based facilities. Subject to section 422(a)(2) of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 [note to this section], the Secretary shall provide for such exceptions to such methods as may be warranted by unusual circumstances (including the special circumstances of sole facilities located in isolated, rural areas and of pediatric facilities). Each application for such an exception shall be deemed to be approved unless the Secretary disapproves it by not later than 60 working days after the date the application is filed. The Secretary may provide that such method will serve in lieu of any target reimbursement rate that would otherwise be established under paragraph (6). The Secretary shall reduce the amount of each composite rate payment under this paragraph for each treatment by 50 cents (subject to such adjustments as may be required to reflect modes of dialysis other than hemodialysis) and provide for payment of such amount to the organizations (designated under subsection (c)(1)(A)) for such organizations' necessary and proper administrative costs incurred in carrying out the responsibilities described in subsection (c)(2). The Secretary shall provide that amounts paid under the previous sentence shall be distributed to the organizations described in subsection (c)(1)(A) to ensure equitable treatment of all such network organizations. The Secretary in distributing any such payments to network organizations shall take into account--

(A) the geographic size of the network area;

(B) the number of providers of end stage renal disease services in the network area;

(C) the number of individuals who are entitled to end stage renal disease services in the network area; and

(D) the proportion of the aggregate administrative funds collected in the network area.

The Secretary shall increase the amount of each composite rate payment for dialysis services furnished during 2000 by 1.2 percent above such composite rate payment amounts for such services furnished on December 31, 1999, for such services furnished on or after January 1, 2001, and before January 1, 2005, by 2.4 percent above such composite rate payment amounts for such services furnished on December 31, 2000, and for such services furnished on or after January 1, 2005, by 1.6 percent above such composite rate payment amounts for such services furnished on December 31, 2004.

(8) For purposes of this *title [42 USCS §§ 1395* et seq.], the term "home dialysis supplies and equipment" means medically necessary supplies and equipment (including supportive equipment) required by an individual suffering from end stage renal disease in connection with renal dialysis carried out in his home (as defined in regulations), including obtaining, installing, and maintaining such equipment.

(9) For purposes of this *title [42 USCS §§ 1395* et seq.], the term "self-care home dialysis support services", to the extent permitted in regulation, means--

(A) periodic monitoring of the patient's home adaptation, including visits by qualified provider or facility personnel (as defined in regulations), so long as this is done in accordance with a plan prepared and periodically reviewed by a professional team (as defined in regulations) including the individual's physician;

(B) installation and maintenance of dialysis equipment;

(C) testing and appropriate treatment of the water; and

(D) such additional supportive services as the Secretary finds appropriate and desirable.

(10) For purposes of this *title [42 USCS §§ 1395* et seq.], the term "self-care dialysis unit" means a renal dialysis facility or a distinct part of such facility or of a provider of services, which has been approved by the Secretary to make self-dialysis services, as defined by the Secretary in regulations, available to individuals who have been trained for self-dialysis. A self-care dialysis unit must, at a minimum, furnish the services, equipment and supplies needed for self-care dialysis, have patient-staff ratios which are appropriate to self-dialysis (allowing for such appropriate lesser degree of ongoing medical supervision and assistance of ancillary personnel than is required for full care maintenance dialysis), and meet such other requirements as the Secretary may prescribe with respect to the quality and cost-effectiveness of services.

(11)

(A) Hepatitis B vaccine and its administration, when provided to a patient determined to have end stage renal disease, shall not be included as dialysis services for purposes of payment under any prospective payment amount or comprehensive fee established under this section. Payment for such vaccine and its administration shall be made separately in accordance with section 1833 [*42 USCS § 1395l*].

(B) Erythropoietin, when provided to a patient determined to have end stage renal disease, shall not be included as a dialysis service for purposes of payment under any prospective payment amount or comprehensive fee established under this section, and subject to paragraphs (12) and (13) payment for such item shall be made separately--

(i) in the case of erythropoietin provided by a physician, in accordance with section 1833 [*42 USCS § 1395l*]; and

(ii) in the case of erythropoietin provided by a provider of services, renal dialysis facility, or other supplier of home dialysis supplies and equipment--

(I) for erythropoietin provided during 1994, in an amount equal to $ 10 per thousand units (rounded to the nearest 100 units), and

(II) for erythropoietin provided during a subsequent year, in an amount determined to be appropriate by the Secretary, except that such amount may not exceed the amount determined under this clause for the previous year increased by the percentage increase (if any) in the implicit price deflator for gross national product (as published by the Department of Commerce) for the second quarter of the preceding year over the implicit price deflator for the second quarter of the second preceding year.

(C) The amount payable to a supplier of home dialysis supplies and equipment that is not a provider of services, a renal dialysis facility, or a physician for erythropoietin shall be determined in the same manner as the amount payable to a renal dialysis facility for such item.

(12) (A) Subject to paragraph (14), in lieu of payment under paragraph (7) beginning with services furnished on January 1, 2005, the Secretary shall establish a basic case-mix adjusted prospective payment system for dialysis services furnished by providers of services and renal dialysis facilities in a year to individuals in a facility and to such individuals at home. The case-mix under such system shall be for a limited number of patient characteristics. Under such system, the payment rate for dialysis services furnished on or after January 1, 2009, by providers of services shall be the same as the payment rate (computed without regard to this sentence) for such services furnished by renal dialysis facilities, and in applying the geographic index under subparagraph (D) to providers of services, the labor share shall be based on the labor share otherwise applied for renal dialysis facilities.

(B) The system described in subparagraph (A) shall include--

(i) the services comprising the composite rate established under paragraph (7); and

(ii) the difference between payment amounts under this *title [42 USCS §§ 1395* et seq.] for separately billed drugs and biologicals (including erythropoietin) and acquisition costs of such drugs and biologicals, as determined by the Inspector General reports to the Secretary as required by section 623(c) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 [note to this section]--

(I) beginning with 2005, for such drugs and biologicals for which a billing code exists prior to January 1, 2004; and

(II) beginning with 2007, for such drugs and biologicals for which a billing code does not exist prior to January 1, 2004,

adjusted to 2005, or 2007, respectively, as determined to be appropriate by the Secretary.

(C) (i) In applying subparagraph (B)(ii) for 2005, such payment amounts under this *title [42 USCS §§ 1395* et seq.] shall be determined using the methodology specified in paragraph (13)(A)(i).

(ii) For 2006, the Secretary shall provide for an adjustment to the payments under clause (i) to reflect the difference between the payment amounts using the methodology under paragraph (13)(A)(i) and the payment amount determined using the methodology applied by the Secretary under paragraph (13)(A)(iii) of such paragraph, as estimated by the Secretary.

(D) The Secretary shall adjust the payment rates under such system by a geographic index as the Secretary determines to be appropriate. If the Secretary applies a geographic index under this paragraph that differs from the index applied under paragraph (7) the Secretary shall phase-in the application of the index under this paragraph over a multiyear period.

(E) (i) Such system shall be designed to result in the same aggregate amount of expenditures for such services, as estimated by the Secretary, as would have been made for 2005 if this paragraph did not apply.

(ii) The adjustment made under subparagraph (B)(ii)(II) shall be done in a manner to result in the same aggregate amount of expenditures after such adjustment as would otherwise have been made for such services for 2006 or 2007, respectively, as estimated by the Secretary, if this paragraph did not apply.

(F) Beginning with 2006, the Secretary shall annually increase the basic case-mix adjusted payment amounts established under this paragraph, by an amount determined by--

(i) applying the estimated growth in expenditures for drugs and biologicals (including erythropoietin) that are separately billable to the component of the basic case-mix adjusted system described in subparagraph (B)(ii); and

(ii) converting the amount determined in clause (i) to an increase applicable to the basic case-mix adjusted payment amounts established under subparagraph (B).

Except as provided in subparagraph (G), nothing in this paragraph or paragraph (14) shall be construed as providing for an update to the composite rate component of the basic case-mix adjusted system under subparagraph (B) or under the system under paragraph (14).

(G) The Secretary shall increase the amount of the composite rate component of the basic case-mix adjusted system under subparagraph (B) for dialysis services--

(i) furnished on or after January 1, 2006, and before April 1, 2007, by 1.6 percent above the amount of such composite rate component for such services furnished on December 31, 2005;

(ii) furnished on or after April 1, 2007, and before January 1, 2009, by 1.6 percent above the amount of such composite rate component for such services furnished on March 31, 2007;

(iii) furnished on or after January 1, 2009, and before January 1, 2010, by 1.0 percent above the amount of such composite rate component for such services furnished on December 31, 2008; and

(iv) furnished on or after January 1, 2010, by 1.0 percent above the amount of such composite rate component for such services furnished on December 31, 2009.

(H) There shall be no administrative or judicial review under section 1869 [*42 USCS § 1395ff*], section 1878 [*42 USCS § 1395oo*], or otherwise, of the case-mix system, relative weights, payment amounts, the geographic adjustment factor, or the update for the system established under this paragraph, or the determination of the difference between medicare payment amounts and acquisition costs for separately billed drugs and biologicals (including erythropoietin) under this paragraph and paragraph (13).

(13) (A) Subject to paragraph (14), the payment amounts under this *title [42 USCS §§ 1395* et seq.] for separately billed drugs and biologicals furnished in a year, beginning with 2004, are as follows:

(i) For such drugs and biologicals (other than erythropoietin) furnished in 2004, the amount determined under section 1842(o)(1)(A)(v) [USCS § 1395u(o)(1)(A)(v)] for the drug or biological.

(ii) For such drugs and biologicals (including erythropoietin) furnished in 2005, the acquisition cost of the drug or biological, as determined by the Inspector General reports to the Secretary as required by section 623(c) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 [note to this section]. Insofar as the Inspector General has not determined the acquisition cost with respect to a drug or biological, the Secretary shall determine the payment amount for such drug or biological.

(iii) For such drugs and biologicals (including erythropoietin) furnished in 2006 and subsequent years, such acquisition cost or the amount determined under section 1847A [*42 USCS § 1395w-3a*] for the drug or biological, as the Secretary may specify.

(B) Drugs and biologicals (including erythropoietin) which were separately billed under this subsection on the day before the date of the enactment of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 [enacted Dec. 8, 2003] shall continue to be separately billed on and after such date, subject to paragraph (14).

(14) (A) (i) Subject to subparagraph (E), for services furnished on or after January 1, 2011, the Secretary shall implement a payment system under which a single payment is made under this title to a provider of services or a renal dialysis facility for renal dialysis services (as defined in subparagraph (B)) in lieu of any other payment (including a payment adjustment under paragraph (12)(B)(ii)) and for such services and items furnished pursuant to paragraph (4).

(ii) In implementing the system under this paragraph the Secretary shall ensure that the estimated total amount of payments under this title for 2011 for renal dialysis services shall equal 98 percent of the estimated total amount of payments for renal dialysis services, including payments under paragraph (12)(B)(ii), that would have been made under this title with respect to services furnished in 2011 if such system had not been implemented. In making the estimation under subclause (I), the Secretary shall use per patient utilization data from 2007, 2008, or 2009, whichever has the lowest per patient utilization.

(B) For purposes of this paragraph, the term "renal dialysis services" includes--

(i) items and services included in the composite rate for renal dialysis services as of December 31, 2010;

(ii) erythropoiesis stimulating agents and any oral form of such agents that are furnished to individuals for the treatment of end stage renal disease;

(iii) other drugs and biologicals that are furnished to individuals for the treatment of end stage renal disease and for which payment was (before the application of this paragraph) made separately under this title, and any oral equivalent form of such drug or biological; and

(iv) diagnostic laboratory tests and other items and services not described in clause (i) that are furnished to individuals for the treatment of end stage renal disease.

Such term does not include vaccines.

(C) The system under this paragraph may provide for payment on the basis of services furnished during a week or month or such other appropriate unit of payment as the Secretary specifies.

(D) Such system--

(i) shall include a payment adjustment based on case mix that may take into account patient weight, body mass index, comorbidities, length of time on dialysis, age, race, ethnicity, and other appropriate factors;

(ii) shall include a payment adjustment for high cost outliers due to unusual variations in the type or amount of medically necessary care, including variations in the amount of erythropoiesis stimulating agents necessary for anemia management;

(iii) shall include a payment adjustment that reflects the extent to which costs incurred by low-volume facilities (as defined by the Secretary) in furnishing renal dialysis services exceed the costs incurred by other facilities in furnishing such services, and for payment for renal dialysis services furnished on or after January 1, 2011, and before January 1, 2014, such payment adjustment shall not be less than 10 percent; and

(iv) may include such other payment adjustments as the Secretary determines appropriate, such as a payment adjustment--

(I) for pediatric providers of services and renal dialysis facilities;

(II) by a geographic index, such as the index referred to in paragraph (12)(D), as the Secretary determines to be appropriate; and

(III) for providers of services or renal dialysis facilities located in rural areas.

The Secretary shall take into consideration the unique treatment needs of children and young adults in establishing such system.

(E) (i) The Secretary shall provide for a four-year phase-in (in equal increments) of the payment amount under the payment system under this paragraph, with such payment amount being fully implemented for renal dialysis services furnished on or after January 1, 2014.

(ii) A provider of services or renal dialysis facility may make a one-time election to be excluded from the phase-in under clause (i) and be paid entirely based on the payment amount under the payment system under this paragraph. Such an election shall be made prior to January 1, 2011, in a form and manner specified by the Secretary, and is final and may not be rescinded.

(iii) The Secretary shall make an adjustment to the payments under this paragraph for years during which the phase-in under clause (i) is applicable so that the estimated total amount of payments under this paragraph, including payments under this subparagraph, shall equal the estimated total amount of payments that would otherwise occur under this paragraph without such phase-in.

(F) (i) Subject to clause (ii), beginning in 2012, the Secretary shall annually increase payment amounts established under this paragraph by an ESRD market basket percentage increase factor for a bundled payment system for renal dialysis services that reflects changes over time in the prices of an appropriate mix of goods and services included in renal dialysis services minus 1.0 percentage point.

(ii) For years during which a phase-in of the payment system pursuant to subparagraph (E) is applicable, the following rules shall apply to the portion of the payment under the system that is based on the payment of the composite rate that would otherwise apply if the system under this paragraph had not been enacted:

(I) The update under clause (i) shall not apply.

(II) The Secretary shall annually increase such composite rate by the ESRD market basket percentage increase factor described in clause (i) minus 1.0 percentage point.

(G) There shall be no administrative or judicial review under section 1869 [*42 USCS § 1395ff*], section 1878 [*42 USCS § 1395oo*], or otherwise of the determination of payment amounts under subparagraph (A), the establishment of an appropriate unit of payment under subparagraph (C), the identification of renal dialysis services included in the bundled payment, the adjustments under subparagraph (D), the application of the phase-in under subparagraph (E), and the establishment of the market basket percentage increase factors under subparagraph (F).

(H) Erythropoiesis stimulating agents and other drugs and biologicals shall be treated as prescribed and dispensed or administered and available only under part B [*42 USCS §§ 1395j* et seq.] if they are--

(i) furnished to an individual for the treatment of end stage renal disease; and

(ii) included in subparagraph (B) for purposes of payment under this paragraph.

(c) Renal disease network areas; coordinating councils, executive committees, and medical review boards; national end stage renal disease medical information system; functions of network organizations.

(1) (A) (i) For the purpose of assuring effective and efficient administration of the benefits provided under this section, the Secretary shall, in accordance with such criteria as he finds necessary to assure the performance of the responsibilities and functions specified in paragraph (2)--

(I) establish at least 17 end stage renal disease network areas, and

(II) for each such area, designate a network administrative organization which, in accordance with regulations of the Secretary, shall establish (aa) a network council of renal dialysis and transplant facilities located in the area and (bb) a medical review board, which has a membership including at least one patient representative and physicians, nurses, and social workers engaged in treatment relating to end stage renal disease.

The Secretary shall publish in the Federal Register a description of the geographic area that he determines, after consultation with appropriate professional and patient organizations, constitutes each network area and the criteria on the basis of which such determination is made.

(ii) (I) In order to determine whether the Secretary should enter into, continue, or terminate an agreement with a network administrative organization designated for an area established under clause (i), the Secretary shall develop and publish in the Federal Register standards, criteria, and procedures to evaluate an applicant organization's capabilities to perform (and, in the case of an organization with which such an agreement is in effect, actual performance of) the responsibilities described in paragraph (2). The Secretary shall evaluate each applicant based on quality and scope of services and may not accord more than 20 percent of the weight of the evaluation to the element of price.

(II) An agreement with a network administrative organization may be terminated by the Secretary only if he finds, after applying such standards and criteria, that the organization has failed to perform its prescribed responsibilities effectively and efficiently. If such an agreement is to be terminated, the Secretary shall select a successor to the agreement on the basis of competitive bidding and in a manner that provides an orderly transition.

(B) At least one patient representative shall serve as a member of each network council and each medical review board.

(C) The Secretary shall, in regulations, prescribe requirements with respect to membership in network organizations by individuals (and the relatives of such individuals) (i) who have an ownership or control interest in a facility or provider which furnishes services referred to in section 1861(s)(2)(F) [*42 USCS § 1395x(s)(2)(F)*], or (ii) who have received remuneration from any such facility or provider in excess of such amounts as constitute reasonable compensation for services (including time and effort relative to the provision of professional medical services) or goods supplied to such facility or provider; and such requirements shall provide for the definition, disclosure, and, to the maximum extent consistent with effective administration, prevention of potential or actual financial or professional conflicts of interest with respect to decisions concerning the appropriateness, nature, or site of patient care.

(2) The network organizations of each network shall be responsible, in addition to such other duties and functions as may be prescribed by the Secretary, for--

(A) encouraging, consistent with sound medical practice, the use of those treatment settings most compatible with the successful rehabilitation of the patient and the participation of patients, providers of services, and renal disease facilities in vocational rehabilitation programs;

(B) developing criteria and standards relating to the quality and appropriateness of patient care and with respect to working with patients, facilities, and providers in encouraging participation in vocational rehabilitation programs; and network goals with respect to the placement of patients in self-care settings and undergoing or preparing for transplantation;

(C) evaluating the procedure by which facilities and providers in the network assess the appropriateness of patients for proposed treatment modalities;

(D) implementing a procedure for evaluating and resolving patient grievances;

(E) conducting on-site reviews of facilities and providers as necessary (as determined by a medical review board or the Secretary), utilizing standards of care established by the network organization to assure proper medical care;

(F) collecting, validating, and analyzing such data as are necessary to prepare the reports required by subparagraph (H) and to assure the maintenance of the registry established under paragraph (7);

(G) identifying facilities and providers that are not cooperating toward meeting network goals and assisting such facilities and providers in developing appropriate plans for correction and reporting to the Secretary on facilities and providers that are not providing appropriate medical care; and

(H) submitting an annual report to the Secretary on July 1 of each year which shall include a full statement of the network's goals, data on the network's performance in meeting its goals (including data on the comparative performance of facilities and providers with respect to the identification and placement of suitable candidates in self-care settings and transplantation and encouraging participation in vocational rehabilitation programs), identification of those facilities that have consistently failed to cooperate with network goals, and recommendations with respect to the need for additional or alternative services or facilities in the network in order to meet the network goals, including self-dialysis training, transplantation, and organ procurement facilities.

(3) Where the Secretary determines, on the basis of the data contained in the network's annual report and such other relevant data as may be available to him, that a facility or provider has consistently failed to cooperate with network plans and goals or to follow the recommendations of the medical review board, he may terminate or withhold certification of such facility or provider (for purposes of payment for services furnished to individuals with end stage renal disease) until he determines that such provider or facility is making reasonable and appropriate efforts to cooperate with the network's plans and goals. If the Secretary determines that the facility's or provider's failure to cooperate with network plans and goals does not jeopardize patient health or safety or justify termination of certification, he may instead, after reasonable notice to the provider or facility and to the public, impose such other sanctions as he determines to be appropriate, which sanctions may include denial of reimbursement with respect to some or all patients admitted to the facility after the date of notice to the facility or provider, and graduated reduction in reimbursement for all patients.

(4) The Secretary shall, in determining whether to certify additional facilities or expansion of existing facilities within a network, take into account the network's goals and performance as reflected in the network's annual report.

(5) The Secretary, after consultation with appropriate professional and planning organizations, shall provide such guidelines with respect to the planning and delivery of renal disease services as are necessary to assist network organizations in their development of their respective networks' goals to promote the optimum use of self-dialysis and transplantation by suitable candidates for such modalities.

(6) It is the intent of the Congress that the maximum practical number of patients who are medically, socially, and psychologically suitable candidates for home dialysis or transplantation should be so treated and that the maximum practical number of patients who are suitable candidates for vocational rehabilitation services be given access to such services and encouraged to return to gainful employment. The Secretary shall consult with appropriate professional and network organizations and consider available evidence relating to developments in research, treatment methods, and technology for home dialysis and transplantation.

(7) The Secretary shall establish a national end stage renal disease registry the purpose of which shall be to assemble and analyze the data reported by network organizations, transplant centers, and other sources on all end stage renal disease patients in a manner that will permit--

(A) the preparation of the annual report to the Congress required under subsection (g);

(B) an identification of the economic impact, cost-effectiveness, and medical efficacy of alternative modalities of treatment;

(C) an evaluation with respect to the most appropriate allocation of resources for the treatment and research into the cause of end stage renal disease;

(D) the determination of patient mortality and morbidity rates, and trends in such rates, and other indices of quality of care; and

(E) such other analyses relating to the treatment and management of end stage renal disease as will assist the Congress in evaluating the end stage renal disease program under this section.

The Secretary shall provide for such coordination of data collection activities, and such consolidation of existing end stage renal disease data systems, as is necessary to achieve the purpose of such registry, shall determine the appropriate location of the registry, and shall provide for the appointment of a professional advisory group to assist the Secretary in the formulation of policies and procedures relevant to the management of such registry.

(8) The provisions of sections 1157 and 1160 [*42 USCS §§ 1320c-6* and *1320c-9*] shall apply with respect to network administrative organizations (including such organizations as medical review boards) with which the Secretary has entered into agreements under this subsection.

(d) Donors of kidney for transplant surgery. Notwithstanding any provision to the contrary in section 226 [*42 USCS § 426*] any individual who donates a kidney for transplant surgery shall be entitled to benefits under parts A and B of this *title [42 USCS §§ 1395c* et seq. and *1395j* et seq.] with respect to such donation. Reimbursement for the reasonable

expenses incurred by such an individual with respect to a kidney donation shall be made (without regard to the deductible, premium, and coinsurance provisions of this *title [42 USCS §§ 1395* et seq.]), in such manner as may be prescribed by the Secretary in regulations, for all reasonable preparatory, operation, and postoperation recovery expenses associated with such donation, including but not limited to the expenses for which payment could be made if he were an eligible individual for purposes of parts A and B of this *title [42 USCS §§ 1395c* et seq. and *1395j* et seq.] without regard to this subsection. Payments for postoperation recovery expenses shall be limited to the actual period of recovery.

(e) Reimbursement of providers, facilities, and nonprofit entities for costs of artificial kidney and automated dialysis peritoneal machines for home dialysis.

(1) Notwithstanding any other provision of this *title [42 USCS §§ 1395* et seq.], the Secretary may, pursuant to agreements with approved providers of services, renal dialysis facilities, and nonprofit entities which the Secretary finds can furnish equipment economically and efficiently, reimburse such providers, facilities, and nonprofit entities (without regard to the deductible and coinsurance provisions of this *title [42 USCS §§ 1395* et seq.]) for the reasonable cost of the purchase, installation, maintenance and reconditioning for subsequent use of artificial kidney and automated dialysis peritoneal machines (including supportive equipment) which are to be used exclusively by entitled individuals dialyzing at home.

(2) An agreement under this subsection shall require that the provider, facility, or entity will--

(A) make the equipment available for use only by entitled individuals dialyzing at home;

(B) recondition the equipment, as needed, for reuse by such individuals throughout the useful life of the equipment, including modification of the equipment consistent with advances in research and technology;

(C) provide for full access for the Secretary to all records and information relating to the purchase, maintenance, and use of the equipment; and

(D) submit such reports, data, and information as the Secretary may require with respect to the cost, management, and use of the equipment.

(3) For purposes of this section, the term "supportive equipment" includes blood pumps, heparin pumps, bubble detectors, other alarm systems, and such other items as the Secretary may determine are medically necessary.

(f) Experiments, studies, and pilot projects.

(1) The Secretary shall initiate and carry out, at selected locations in the United States, pilot projects under which financial assistance in the purchase of new or used durable medical equipment for renal dialysis is provided to individuals suffering from end stage renal disease at the time home dialysis is begun, with provision for a trial period to assure successful adaptation to home dialysis before the actual purchase of such equipment.

(2) The Secretary shall conduct experiments to evaluate methods for reducing the costs of the end stage renal disease program. Such experiments shall include (without being limited to) reimbursement for nurses and dialysis technicians to assist with home dialysis, and reimbursement to family members assisting with home dialysis.

(3) The Secretary shall conduct experiments to evaluate methods of dietary control for reducing the costs of the end stage renal disease program, including (without being limited to) the use of protein-controlled products to delay the necessity for, or reduce the frequency of, dialysis in the treatment of end stage renal disease.

(4) The Secretary shall conduct a comprehensive study of methods for increasing public participation in kidney donation and other organ donation programs.

(5) The Secretary shall conduct a full and complete study of the reimbursement of physicians for services furnished to patients with end stage renal disease under this *title [42 USCS §§ 1395* et seq.], giving particular attention to the range of payments to physicians for such services, the average amounts of such payments, and the number of hours devoted to furnishing such services to patients at home, in renal disease facilities, in hospitals, and elsewhere.

(6) The Secretary shall conduct a study of the number of patients with end stage renal disease who are not eligible for benefits with respect to such disease under this *title [42 USCS §§ 1395* et seq.] (by reason of this section or otherwise), and of the economic impact of such noneligibility of such individuals. Such study shall include consideration of mechanisms whereby governmental and other health plans might be instituted or modified to permit the purchase of actuarially sound coverage for the costs of end stage renal disease.

(7) (A) The Secretary shall establish protocols on standards and conditions for the reuse of dialyzer filters for those facilities and providers which voluntarily elect to reuse such filters.

(B) With respect to dialysis services furnished on or after January 1, 1988 (or July 1, 1988, with respect to protocols that relate to the reuse of bloodlines), no dialysis facility may reuse dialysis supplies (other than dialyzer filters) unless the Secretary has established a protocol with respect to the reuse of such supplies and the facility follows the protocol so established.

(C) The Secretary shall incorporate protocols established under this paragraph, and the requirement of subparagraph (B), into the requirements for facilities prescribed under subsection (b)(1)(A) and failure to follow such a protocol or requirement subjects such a facility to denial of participation in the program established under this section and to denial of payment for dialysis treatment not furnished in compliance with such a protocol or in violation of such requirement.

(8) The Secretary shall submit to the Congress no later than October 1, 1979, a full report on the experiments conducted under paragraphs (1), (2), (3), and (7), and the studies under paragraphs (4), (5), (6), and (7). Such report shall include any recommendations for legislative changes which the Secretary finds necessary or desirable as a result of such experiments and studies.

(g) Conditional approval of dialysis facilities; restriction-of-payments; notice to public and facility; notice and hearing; judicial review.

(1) In any case where the Secretary--

(A) finds that a renal dialysis facility is not in substantial compliance with requirements for such facilities prescribed under subsection (b)(1)(A),

(B) finds that the facility's deficiencies do not immediately jeopardize the health and safety of patients, and

(C) has given the facility a reasonable opportunity to correct its deficiencies,

the Secretary may, in lieu of terminating approval of the facility, determine that pay+ment under this *title [42 USCS §§ 1395* et seq.] shall be made to the facility only for services furnished to individuals who were patients of the facility before the effective date of the notice.

(2) The Secretary's decision to restrict payments under this subsection shall be made effective only after such notice to the public and to the facility as may be prescribed in regulations, and shall remain in effect until (A) the Secretary finds that the facility is in substantial compliance with the requirements under subsection (b)(1)(A), or (B) the Secretary terminates the agreement under this *title [42 USCS §§ 1395* et seq.] with the facility.

(3) A facility dissatisfied with a determination by the Secretary under paragraph (1) shall be entitled to a hearing thereon by the Secretary (after reasonable notice) to the same extent as is provided in section 205(b) [*42 USCS § 405(b)*], and to judicial review of the Secretary's final decision after such hearing as is provided in section 205(g) [*42 USCS § 405(g)*], except that, in so applying such sections and in applying section 205(l) [*42 USCS § 405(l)*] thereto, any reference therein to the Commissioner of Social Security or the Social Security Administration shall be considered a reference to the Secretary or the Department of Health and Human Services, respectively.

(h) Quality incentives in the end-stage renal disease program.

(1) Quality incentives.

(A) In general. With respect to renal dialysis services (as defined in subsection (b)(14)(B)) furnished on or after January 1, 2012, in the case of a provider of services or a renal dialysis facility that does not meet the requirement described in subparagraph (B) with respect to the year, payments otherwise made to such provider or facility under the system under subsection (b)(14) for such services shall be reduced by up to 2.0 percent, as determined appropriate by the Secretary.

(B) Requirement. The requirement described in this subparagraph is that the provider or facility meets (or exceeds) the total performance score under paragraph (3) with respect to performance standards established by the Secretary with respect to measures specified in paragraph (2).

(C) No effect in subsequent years. The reduction under subparagraph (A) shall apply only with respect to the year involved, and the Secretary shall not take into account such reduction in computing the single payment amount under the system under paragraph (14) in a subsequent year.

(2) Measures.

(A) In general. The measures specified under this paragraph with respect to the year involved shall include--

(i) measures on anemia management that reflect the labeling approved by the Food and Drug Administration for such management and measures on dialysis adequacy;

(ii) to the extent feasible, such measure (or measures) of patient satisfaction as the Secretary shall specify; and

(iii) such other measures as the Secretary specifies, including, to the extent feasible, measures on--

(I) iron management;

(II) bone mineral metabolism; and

(III) vascular access, including for maximizing the placement of arterial venous fistula.

(B) Use of endorsed measures.

(i) In general. Subject to clause (ii), any measure specified by the Secretary under subparagraph (A)(iii) must have been endorsed by the entity with a contract under section 1890(a) [*42 USCS § 1395aaa(a)*].

(ii) Exception. In the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a) [*42 USCS §*

1395aaa(a)], the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary.

(C) Updating measures. The Secretary shall establish a process for updating the measures specified under subparagraph (A) in consultation with interested parties.

(D) Consideration. In specifying measures under subparagraph (A), the Secretary shall consider the availability of measures that address the unique treatment needs of children and young adults with kidney failure.

(3) Performance scores.

(A) Total performance score.

(i) In general. Subject to clause (ii), the Secretary shall develop a methodology for assessing the total performance of each provider of services and renal dialysis facility based on performance standards with respect to the measures selected under paragraph (2) for a performance period established under paragraph (4)(D) (in this subsection referred to as the "total performance score").

(ii) Application. For providers of services and renal dialysis facilities that do not meet (or exceed) the total performance score established by the Secretary, the Secretary shall ensure that the application of the methodology developed under clause (i) results in an appropriate distribution of reductions in payment under paragraph (1) among providers and facilities achieving different levels of total performance scores, with providers and facilities achieving the lowest total performance scores receiving the largest reduction in payment under paragraph (1)(A).

(iii) Weighting of measures. In calculating the total performance score, the Secretary shall weight the scores with respect to individual measures calculated under subparagraph (B) to reflect priorities for quality improvement, such as weighting scores to ensure that providers of services and renal dialysis facilities have strong incentives to meet or exceed anemia management and dialysis adequacy performance standards, as determined appropriate by the Secretary.

(B) Performance score with respect to individual measures. The Secretary shall also calculate separate performance scores for each measure, including for dialysis adequacy and anemia management.

(4) Performance standards.

(A) Establishment. Subject to subparagraph (E), the Secretary shall establish performance standards with respect to measures selected under paragraph (2) for a performance period with respect to a year (as established under subparagraph (D)).

(B) Achievement and improvement. The performance standards established under subparagraph (A) shall include levels of achievement and improvement, as determined appropriate by the Secretary.

(C) Timing. The Secretary shall establish the performance standards under subparagraph (A) prior to the beginning of the performance period for the year involved.

(D) Performance period. The Secretary shall establish the performance period with respect to a year. Such performance period shall occur prior to the beginning of such year.

(E) Special rule. The Secretary shall initially use as the performance standard for the measures specified under paragraph (2)(A)(i) for a provider of services or a renal dialysis facility the lesser of--

(i) the performance of such provider or facility for such measures in the year selected by the Secretary under the second sentence of subsection (b)(14)(A)(ii); or

(ii) a performance standard based on the national performance rates for such measures in a period determined by the Secretary.

(5) Limitation on review. There shall be no administrative or judicial review under section 1869 [*42 USCS § 1395ff*], section 1878 [*42 USCS § 1395oo*], or otherwise of the following:

(A) The determination of the amount of the payment reduction under paragraph (1).

(B) The establishment of the performance standards and the performance period under paragraph (4).

(C) The specification of measures under paragraph (2).

(D) The methodology developed under paragraph (3) that is used to calculate total performance scores and performance scores for individual measures.

(6) Public reporting.

(A) In general. The Secretary shall establish procedures for making information regarding performance under this subsection available to the public, including--

(i) the total performance score achieved by the provider of services or renal dialysis facility under paragraph (3) and appropriate comparisons of providers of services and renal dialysis facilities to the national average with respect to such scores; and

(ii) the performance score achieved by the provider or facility with respect to individual measures.

(B) Opportunity to review. The procedures established under subparagraph (A) shall ensure that a provider of services and a renal dialysis facility has the opportunity to review the information that is to be made public with respect to the provider or facility prior to such data being made public.

(C) Certificates.

(i) In general. The Secretary shall provide certificates to providers of services and renal dialysis facilities who furnish renal dialysis services under this section to display in patient areas. The certificate shall indicate the total performance score achieved by the provider or facility under paragraph (3).

(ii) Display. Each facility or provider receiving a certificate under clause (i) shall prominently display the certificate at the provider or facility.

(D) Web-based list. The Secretary shall establish a list of providers of services and renal dialysis facilities who furnish renal dialysis services under this section that indicates the total performance score and the performance score for individual measures achieved by the provider and facility under paragraph (3). Such information shall be posted on the Internet website of the Centers for Medicare & Medicaid Services in an easily understandable format.

HISTORY:

(Aug. 14, 1935, ch 531, Title XVIII, Part E[D][C], § 1881, as added June 13, 1978, P.L. 95-292, § 2, 92 Stat. 308; Dec. 5, 1980, P.L. 96-499, Title IX, Part B, Subpart II, § 957, 94 Stat. 2648; Aug. 13, 1981, P.L. 97-35, Title XXI, Subtitle B, Ch 3, § 2145(a), 95 Stat. 799; April 20, 1983, P.L. 98-21, Title VI, § 602(i), 97 Stat. 165; July 18, 1984, P.L. 98-369, Division B, Title III, Subtitle A, Part I, § 2323(c), Part II, §§ 2352(a), 2354(b)(41), 98 Stat. 1086, 1099, 1100; Nov. 8, 1984, P.L. 98-617, § 3(b)(8), 98 Stat. 3296; Oct. 21, 1986, P.L. 99-509, Title IX, Subtitle D, Part 3, § 9335(a)(2), (d)(1), (e)-(i)(1), (j)(1), (k)(1), 100 Stat. 2028-2032; Aug. 18, 1987, P.L. 100-93, § 12, 101 Stat. 697; Dec. 22, 1987, P.L. 100-203, Title IV, Subtitle A, Part 2, Subpt. C, § 4036(b), (c)(2), (d)(5), Part 3, Subpt. B, § 4065(b), 101 Stat. 1330-79, 1330-80, 1330-112; Dec. 19, 1989, P.L. 101-239, Title VI, Subtitle A, Part 2, Subpart A, § 6102(e)(8), Part 3, Subpart A, § 6203(b)(1), (2), Subpart B, § 6219(a), (b), 103 Stat. 2188, 2235, 2254; Nov. 5, 1990, P.L. 101-508, Title IV, Subtitle A, Part 2, § 4201(c)(1), (d)(2), 104 Stat. 1388-103; Aug. 10, 1993, P.L. 103-66, Title XIII, Ch 2, Subch A, Part III, § 13566(a), 107 Stat. 607; Aug. 15, 1994, P.L. 103-296, Title I, § 108(c)(5), 108 Stat. 1495; Oct. 31, 1994, P.L. 103-432, Title I, Subtitle C, § 160(d)(3), 108 Stat. 4444; Aug. 5, 1997, P.L. 105-33, Title IV, Subtitle A, Ch 1, Subch A, § 4001, 111 Stat. 275; Nov. 29, 1999, P.L. 106-113, Div B, § 1000(a)(6), 113 Stat. 1536; Dec. 21, 2000, P.L. 106-554, § 1(a)(6), 114 Stat. 2763; Dec. 8, 2003, P.L. 108-173, Title I, § 101(a)(1), Title VI, Subtitle C, § 623(a), (b)(2), (d), 117 Stat. 2071, 2312, 2313; Feb. 8, 2006, P.L. 109-171, Title V, Subtitle B, Ch. 1, § 5106, 120 Stat. 42; Dec. 20, 2006, P.L. 109-432, Div B, Title I, § 103(a), 120 Stat. 2981; July 15, 2008, P.L. 110-275, Title I, Subtitle C, Part II, § 153(a), (b)(1), (3)(A), (c), 122 Stat. 2553, 2556.)

§ 1395ss. Certification of Medicare supplemental health insurance policies

(a) Submission of policy by insurer.

(1) The Secretary shall establish a procedure whereby medicare supplemental policies (as defined in subsection (g)(1)) may be certified by the Secretary as meeting minimum standards and requirements set forth in subsection (c). Such procedure shall provide an opportunity for any insurer to submit any such policy, and such additional data as the Secretary finds necessary, to the Secretary for his examination and for his certification thereof as meeting the standards and requirements set forth in subsection (c). Subject to subsections (k)(3), (m), and (n), such certification shall remain in effect if the insurer files a notarized statement with the Secretary no later than June 30 of each year stating that the policy continues to meet such standards and requirements and if the insurer submits such additional data as the Secretary finds necessary to independently verify the accuracy of such notarized statement. Where the Secretary determines such a policy meets (or continues to meet) such standards and requirements, he shall authorize the insurer to have printed on such policy (but only in accordance with such requirements and conditions as the Secretary may prescribe) an emblem which the Secretary shall cause to be designed for use as an indication that a policy has received the Secretary's certification. The Secretary shall provide each State commissioner or superintendent of insurance with a list of all the policies which have received his certification.

(2) No medicare supplemental policy may be issued in a State on or after the date specified in subsection (p)(1)(c) unless--

(A) the State's regulatory program under subsection (b)(1) provides for the application and enforcement of the standards and requirements set forth in such subsection (including the 1991 NAIC Model Regulation or 1991 Federal Regulation (as the case may be)) by the date specified in subsection (p)(1)(c); or

(B) if the State's program does not provide for the application and enforcement of such standards and requirements, the policy has been certified by the Secretary under paragraph (1) as meeting the standards and requirements set forth in subsection (c) (including such applicable standards) by such date.

Any person who issues a medicare supplemental policy, on and after the effective date specified in subsection (p)(1)(C), in violation of this paragraph is subject to a civil money penalty of not to exceed $ 25,000 for each such violation. The provisions of section 1128A [*42 USCS § 1320a-7a*] (other than the first sentence of subsection (a) and

other than subsection (b)) shall apply to a civil money penalty under the previous sentence in the same manner as such provisions apply to a penalty or proceeding under section 1128A(a) *[42 USCS § 132a-7a*(a)].

(b) Standards and requirements; periodic review by Secretary.

(1) **[Caution: For application and termination of Nov. 5, 1990 amendment of this section, see § 4358(c) of Act Nov. 5, 1990, P.L. 101-508, which appears as a note to this section.]** Any medicare supplemental policy issued in any State which the Secretary determines has established under State law a regulatory program that--

(A) **[Caution: For application and termination of 1990 amendment, see § 4358(c) of Act Nov. 4, 1990, P.L. 101-508, which appears as a note to this section.]** provides for the application and enforcement of standards with respect to such policies equal to or more stringent than the NAIC Model Standards (as defined in subsection (g)(2)(A)), except as otherwise provided by subparagraph (H);

(B) includes requirements equal to or more stringent than the requirements described in paragraphs (2) through (5) of subsection (c);

(C) provides that--

(i) information with respect to the actual ratio of benefits provided to premiums collected under such policies will be reported to the State on forms conforming to those developed by the National Association of Insurance Commissioners for such purpose, or

(ii) such ratios will be monitored under the program in an alternative manner approved by the Secretary, and that a copy of each such policy, the most recent premium for each such policy, and a listing of the ratio of benefits provided to premiums collected for the most recent 3-year period for each such policy issued or sold in the State is maintained and made available to interested persons;

(D) provides for application and enforcement of the standards and requirements described in subparagraphs (A), (B), and (C) to all medicare supplemental policies (as defined in subsection (g)(1)) issued in such State,

(E) provides the Secretary periodically (but at least annually) with a list containing the name and address of the issuer of each such policy and the name and number of each such policy (including an indication of policies that have been previously approved, newly approved, or withdrawn from approval since the previous list was provided),

(F) reports to the Secretary on the implementation and enforcement of standards and requirements of this paragraph at intervals established by the Secretary,

(G) provides for a process for approving or disapproving proposed premium increases with respect to such policies, and establishes a policy for the holding of public hearings prior to approval of a premium increase, and

(H) **[Caution: For application and termination of this subparagraph, see § 4358(c) of Act Nov. 4, 1990, P.L. 101-508, which appears as a note to this section.]** in the case of a policy that meets the standards under subparagraph (A) except that benefits under the policy are limited to items and services furnished by certain entities (or reduced benefits are provided when items or services are furnished by other entities), provides for the application of requirements equal to or more stringent than the requirements under subsection (t),

shall be deemed (subject to subsections (k)(3), (m), and (n), for so long as the Secretary finds that such State regulatory program continues to meet the standards and requirements of this paragraph) to meet the standards and requirements set forth in subsection (c). Each report required under subparagraph (F) shall include information on loss ratios of policies sold in the State, frequency and types of instances in which policies approved by the State fail to meet the standards and requirements of this paragraph, actions taken by the State to bring such policies into compliance, information regarding State programs implementing consumer protection provisions, and such further information as the Secretary in consultation with the National Association of Insurance Commissioners may specify.

(2) The Secretary periodically shall review State regulatory programs to determine if they continue to meet the standards and requirements specified in paragraph (1). If the Secretary finds that a State regulatory program no longer meets the standards and requirements, before making a final determination, the Secretary shall provide the State an opportunity to adopt such a plan of correction as would permit the State regulatory program to continue to meet such standards and requirements. If the Secretary makes a final determination that the State regulatory program, after such an opportunity, fails to meet such standards and requirements, the program shall no longer be considered to have in operation a program meeting such standards and requirements.

(3) Notwithstanding paragraph (1), a medicare supplemental policy offered in a State shall not be deemed to meet the standards and requirements set forth in subsection (c), with respect to an advertisement (whether through written, radio, or television medium) used (or, at a State's option, to be used) for the policy in the State, unless the entity issuing the policy provides a copy of each advertisement to the Commissioner of Insurance (or comparable officer identified by the Secretary) of that State for review or approval to the extent it may be required under State law.

(c) Requisite findings. The Secretary shall certify under this section any medicare supplemental policy, or continue certification of such a policy, only if he finds that such policy (or, with respect to paragraph (3) or the requirement described in subsection (s), the issuer of the policy)--

(1) **[Caution: For application and termination of Nov. 5, 1990 amendment of this section, see § 4358(c) of Act Nov. 5, 1990, P.L. 101-508, which appears as a note to this section.]** meets or exceeds (either in a single policy or, in the case of nonprofit hospital and medical service associations, in one or more policies issued in conjunction with one another) the NAIC Model Standards (except as otherwise provided by subsection (t));

(2) meets the requirements of subsection (r);

(3) (A) accepts a notice under section 1842(h)(3)(B) [*42 USCS § 1395u(h)(3)(B)*] as a claim form for benefits under such policy in lieu of any claim form otherwise required and agrees to make a payment determination on the basis of the information contained in such notice;

(B) where such a notice is received--

(i) provides notice to such physician or supplier and the beneficiary of the payment determination under the policy, and

(ii) provides any payment covered by such policy directly to the participating physician or supplier involved;

(C) provides each enrollee at the time of enrollment a card listing the policy name and number and a single mailing address to which notices under section 1842(h)(3)(B) [*42 USCS § 1395u(h)(3)(B)*] respecting the policy are to be sent;

(D) agrees to pay any user fees established under section 1842(h)(3)(B) [*42 USCS § 1395u(h)(3)(B)*] with respect to information transmitted to the issuer of the policy; and

(E) provides to the Secretary at least annually, for transmittal to carriers, a single mailing address to which notices under section 1842(h)(3)(B) [*42 USCS § 1395u(h)(3)(B)*] respecting the policy are to be sent;

(4) may, during a period of not less than 30 days after the policy is issued, be returned for a full refund of any premiums paid (without regard to the manner in which the purchase of the policy was solicited); and

(5) meets the applicable requirements of subsections (o) through (t).

(d) Criminal penalties; civil penalties for certain violations.

(1) Whoever knowingly and willfully makes or causes to be made or induces or seeks to induce the making of any false statement or representation of a material fact with respect to the compliance of any policy with the standards and requirements set forth in subsection (c) or in regulations promulgated pursuant to such subsection, or with respect to the use of the emblem designed by the Secretary under subsection (a), shall be fined under title 18, United States Code, or imprisoned not more than 5 years, or both, and, in addition to or in lieu of such a criminal penalty, is subject to a civil money penalty of not to exceed $ 5,000 for each such prohibited act.

(2) Whoever falsely assumes or pretends to be acting, or misrepresents in any way that he is acting, under the authority of or in association with, the program of health insurance established by this *title [42 USCS §§ 1395* et seq.], or any Federal agency, for the purpose of selling or attempting to sell insurance, or in such pretended character demands, or obtains money, paper, documents, or anything of value, shall be fined under title 18, United States Code, or imprisoned not more than 5 years, or both, and, in addition to or in lieu of such a criminal penalty, is subject to a civil money penalty of not to exceed $ 5,000 for each such prohibited act.

(3) (A) (i) It is unlawful for a person to sell or issue to an individual entitled to benefits under part A [*42 USCS §§ 1395c* et seq.] or enrolled under part B of this *title [42 USCS §§ 1395j* et seq.] (including an individual electing a Medicare + Choice plan under section 1851)--

(I) a health insurance policy with knowledge that the policy duplicates health benefits to which the individual is otherwise entitled under this title or title XIX [*42 USCS §§ 1395* et seq. or *1396* et seq.],

(II) in the case of an individual not electing a Medicare + Choice plan, a medicare supplemental policy with knowledge that the individual is entitled to benefits under another medicare supplemental policy or in the case of an individual electing a Medicare + Choice plan, a medicare supplemental policy with knowledge that the policy duplicates health benefits to which the individual is otherwise entitled under the Medicare + Choice plan or under another medicare supplemental policy, or

(III) a health insurance policy (other than a medicare supplemental policy) with knowledge that the policy duplicates health benefits to which the individual is otherwise entitled, other than benefits to which the individual is entitled under a requirement of State or Federal law.

(ii) Whoever violates clause (i) shall be fined under title 18, United States Code, or imprisoned not more than 5 years, or both, and, in addition to or in lieu of such a criminal penalty, is subject to a civil money penalty of not to exceed $ 25,000 (or $ 15,000 in the case of a person other than the issuer of the policy) for each such prohibited act.

(iii) A seller (who is not the issuer of a health insurance policy) shall not be considered to violate clause (i)(II) with respect to the sale of a medicare supplemental policy if the policy is sold in compliance with subparagraph (B).

(iv) For purposes of this subparagraph, a health insurance policy (other than a Medicare supplemental policy) providing for benefits which are payable to or on behalf of an individual without regard to other health benefit coverage of such individual is not considered to "duplicate" any health benefits under this *title [42 USCS §§ 1395* et seq.], under title XIX [*42 USCS §§ 1396* et seq.], or under a health insurance policy, and subclauses (I) and (III) of clause (i) do not apply to such a policy.

(v) For purposes of this subparagraph, a health insurance policy (or a rider to an insurance contract which is not a health insurance policy) is not considered to "duplicate" health benefits under this title or under another health insurance policy if it--

(I) provides health care benefits only for long-term care, nursing home care, home health care, or community-based care, or any combination thereof,

(II) coordinates against or excludes items and services available or paid for under this title or under another health insurance policy, and

(III) for policies sold or issued on or after the end of the 90-day period beginning on the date of enactment of the Health Insurance Portability and Accountability Act of 1996 [enacted Aug. 21, 1996] discloses such coordination or exclusion in the policy's outline of coverage.

For purposes of this clause, the terms "coordinates" and "coordination" mean, with respect to a policy in relation to health benefits under this title or under another health insurance policy, that the policy under its terms is secondary to, or excludes from payment, items and services to the extent available or paid for under this *title [42 USCS §§ 1395* et seq.] or under another health insurance policy.

(vi) (I) An individual entitled to benefits under part A [*42 USCS §§ 1395c* et seq.] or enrolled under part B of this *title [42 USCS §§ 1395j* et seq.] who is applying for a health insurance policy (other than a policy described in subclause (III)) shall be furnished a disclosure statement described in clause (vii) for the type of policy being applied for. Such statement shall be furnished as a part of (or together with) the application for such policy.

(II) Whoever issues or sells a health insurance policy (other than a policy described in subclause (III)) to an individual described in subclause (I) and fails to furnish the appropriate disclosure statement as required under such subclause shall be fined under title 18, United States Code, or imprisoned not more than 5 years, or both, and, in addition to or in lieu of such a criminal penalty, is subject to a civil money penalty of not to exceed $ 25,000 (or $ 15,000 in the case of a person other than the issuer of the policy) for each such violation.

(III) A policy described in this subclause (to which subclauses (I) and (II) do not apply) is a Medicare supplemental policy, a policy described in clause (v), or a health insurance policy identified under *60 Federal Register 30880* (June 12, 1995) as a policy not required to have a disclosure statement.

(IV) Any reference in this section to the revised NAIC model regulation (referred to in subsection (m)(1)(A)) is deemed a reference to such regulation as revised by section 171(m)(2) of the Social Security Act Amendments of 1994 (Public Law 103-432) and as modified by substituting, for the disclosure required under section 16D(2), disclosure under subclause (I) of an appropriate disclosure statement under clause (vii).

(vii) The disclosure statement described in this clause for a type of policy is the statement specified under subparagraph (D) of this paragraph (as in effect before the date of the enactment of the Health Insurance Portability and Accountability Act of 1996 [enacted Aug. 21, 1996]) for that type of policy, as revised as follows:

(I) In each statement, amend the second line to read as follows:

"**THIS IS NOT MEDICARE SUPPLEMENT INSURANCE**".

(II) In each statement, strike the third line and insert the following: "**Some health care services paid for by Medicare may also trigger the payment of benefits under this policy.**".

(III) In each statement not described in subclause (V), strike the boldface matter that begins "**This insurance**" and all that follows up to the next paragraph that begins "**Medicare**".

(IV) In each statement not described in subclause (V), insert before the boxed matter (that states "**Before You Buy This Insurance**") the following: "**This policy must pay benefits without regard to other health benefit coverage to which you may be entitled under Medicare or other insurance.**".

(V) In a statement relating to policies providing both nursing home and non-institutional coverage, to policies providing nursing home benefits only, or policies providing home care benefits only, amend the sentence that begins "Federal law" to read as follows: "Federal law requires us to inform you that in certain situations this insurance may pay for some care also covered by Medicare.".

(viii) (I) Subject to subclause (II), nothing in this subparagraph shall restrict or preclude a State's ability to regulate health insurance policies, including any health insurance policy that is described in clause (iv), (v), or (vi)(III).

(II) A State may not declare or specify, in statute, regulation, or otherwise, that a health insurance policy (other than a Medicare supplemental policy) or rider to an insurance contract which is not a health insurance policy, that is described in clause (iv), (v), or (vi)(III) and that is sold, issued, or renewed to an individual entitled to benefits under

part A [*42 USCS §§ 1395c* et seq.] or enrolled under part B [*42 USCS §§ 1395j* et seq.] "duplicates" health benefits under this *title [42 USCS §§ 1395* et seq.] or under a Medicare supplemental policy.

(B)

(i) It is unlawful for a person to issue or sell a medicare supplemental policy to an individual entitled to benefits under part A [*42 USCS §§ 1395c* et seq.] or enrolled under part B [*42 USCS §§ 1395j* et seq.], whether directly, through the mail, or otherwise, unless--

(I) the person obtains from the individual, as part of the application for the issuance or purchase and on a form described in clause ii, a written statement signed by the individual stating, to the best of the individual's knowledge, what health insurance policies (including any Medicare + Choice plan) the individual has, from what source, and whether the individual is entitled to any medical assistance under title XIX [*42 USCS §§ 1396* et seq.], whether as a qualified medicare beneficiary or otherwise, and

(II) the written statement is accompanied by a written acknowledgment, signed by the seller of the policy, of the request for and receipt of such statement.

(ii) The statement required by clause (i) shall be made on a form that--

(I) states in substance that a medicare-eligible individual does not need more than one medicare supplemental policy,

(II) states in substance that individuals may be eligible for benefits under the State medicaid program under title XIX [*42 USCS §§ 1396* et seq.] and that such individuals who are entitled to benefits under that program usually do not need a medicare supplemental policy and that benefits and premiums under any such policy shall be suspended upon request of the policyholder during the period (of not longer than 24 months) of entitlement to benefits under such *title [42 USCS §§ 1396* et seq.] and may be reinstituted upon loss of such entitlement, and

(III) states that counseling services may be available in the State to provide advice concerning the purchase of medicare supplemental policies and enrollment under the medicaid program and may provide the telephone number for such services.

(iii)

(I) Except as provided in subclauses (II) and (III), if the statement required by clause (i) is not obtained or indicates that the individual has a medicare supplemental policy or indicates that the individual is entitled to any medical assistance under title XIX [*42 USCS §§ 1396* et seq.], the sale of a medicare supplemental policy shall be considered to be a violation of subparagraph (A).

(II) Subclause (I) shall not apply in the case of an individual who has a medicare supplemental policy, if the individual indicates in writing, as part of the application for purchase, that the policy being purchased replaces such other policy and indicates an intent to terminate the policy being replaced when the new policy becomes effective and the issuer or seller certifies in writing that such policy will not, to the best of the issuer's or seller's knowledge, duplicate coverage (taking into account any such replacement).

(III) If the statement required by clause (i) is obtained and indicates that the individual is entitled to any medical assistance under title XIX [*42 USCS §§ 1396* et seq.], the sale of the policy is not in violation of clause (i) (insofar as such clause relates to such medical assistance), if (aa) a State medicaid plan under such title pays the premiums for the policy, (bb) in the case of a qualified medicare beneficiary described in section 1905(p)(1) [*42 USCS § 1396d(p)(1)*], the policy provides for coverage of outpatient prescription drugs, or (cc) the only medical assistance to which the individual is entitled under the State plan is medicare cost sharing described in section 1905(p)(3)(A)(ii) [*42 USCS § 1396d(p)(3)(A)*].

(iv) Whoever issues or sells a medicare supplemental policy in violation of this subparagraph shall be fined under title 18, United States Code, or imprisoned not more than 5 years, or both, and, in addition to or in lieu of such a criminal penalty, is subject to a civil money penalty of not to exceed $ 25,000 (or $ 15,000 in the case of a seller who is not the issuer of a policy) for each such violation.

(C) Subparagraph (A) shall not apply with respect to the sale or issuance of a group policy or plan of one or more employers or labor organizations, or of the trustees of a fund established by one or more employers or labor organizations (or combination thereof), for employees or former employees (or combination thereof) or for members or former members (or combination thereof) of the labor organizations.

(4)

(A) Whoever knowingly, directly or through his agent, mails or causes to be mailed any matter for a prohibited purpose (as determined under subparagraph (B)) shall be fined under title 18, United States Code, or imprisoned not more than 5 years, or both, and, in addition to or in lieu of such a criminal penalty, is subject to a civil money penalty of not to exceed $ 5,000 for each such prohibited act.

(B) For purposes of subparagraph (A), a prohibited purpose means the advertising, solicitation, or offer for sale of a medicare supplemental policy, or the delivery of such a policy, in or into any State in which such policy has not been approved by the State commissioner or superintendent of insurance.

(C) Subparagraph (A) shall not apply in the case of a person who mails or causes to be mailed a medicare supplemental policy into a State if such person has ascertained that the party insured under such policy to whom (or on whose behalf) such policy is mailed is located in such State on a temporary basis.

(D) Subparagraph (A) shall not apply in the case of a person who mails or causes to be mailed a duplicate copy of a medicare supplemental policy previously issued to the party to whom (or on whose behalf) such duplicate copy is mailed.

(E) Subparagraph (A) shall not apply in the case of an issuer who mails or causes to be mailed a policy, certificate, or other matter solely to comply with the requirements of subsection (q).

(5) The provisions of section 1128A [*42 USCS § 1320a-7a*] (other than subsections (a) and (b)) shall apply to civil money penalties under paragraphs (1), (2), (3)(A), and (4)(A) in the same manner as such provisions apply to penalties and proceedings under section 1128A(a) [*42 USCS § 1320a-7a(a)*].

(e) Dissemination of information.

(1) The Secretary shall provide to all individuals entitled to benefits under this *title [42 USCS §§ 1395* et seq.] (and, to the extent feasible, to individuals about to become so entitled) such information as will permit such individuals to evaluate the value of medicare supplemental policies to them and the relationship of any such policies to benefits provided under this *title [42 USCS §§ 1395* et seq.].

(2) The Secretary shall--

(A) inform all individuals entitled to benefits under this *title [42 USCS §§ 1395* et seq.] (and, to the extent feasible, individuals about to become so entitled) of--

(i) the actions and practices that are subject to sanctions under subsection (d), and

(ii) the manner in which they may report any such action or practice to an appropriate official of the Department of Health and Human Services (or to an appropriate State official), and

(B) publish the toll-free telephone number for individuals to report suspected violations of the provisions of such subsection.

(3) The Secretary shall provide individuals entitled to benefits under this *title [42 USCS §§ 1395* et seq.] and, to the extent feasible, individuals about to become so entitled) with a listing of the addresses and telephone numbers of State and Federal agencies and offices that provide information and assistance to individuals with respect to the selection of medicare supplemental policies.

(f) Study and evaluation of comparative effectiveness of various State approaches to regulating medicare supplemental policies; report to Congress no later than January 1, 1982; periodic evaluations.

(1) (A) The Secretary shall, in consultation with Federal and State regulatory agencies, the National Association of Insurance Commissioners, private insurers, and organizations representing consumers and the aged, conduct a comprehensive study and evaluation of the comparative effectiveness of various State approaches to the regulation of medicare supplemental policies in (i) limiting marketing and agent abuse, (ii) assuring the dissemination of such information to individuals entitled to benefits under this *title [42 USCS §§ 1395* et seq.] (and to other consumers) as is necessary to permit informed choice, (iii) promoting policies which provide reasonable economic benefits for such individuals, (iv) reducing the purchase of unnecessary duplicative coverage, (v) improving price competition, and (vi) establishing effective approved State regulatory programs described in subsection (b).

(B) Such study shall also address the need for standards or certification of health insurance policies, other than medicare supplemental policies, sold to individuals eligible for benefits under this *title [42 USCS §§ 1395* et seq.].

(C) The Secretary shall, no later than January 1, 1982, submit a report to the Congress on the results of such study and evaluation, accompanied by such recommendations as the Secretary finds warranted by such results with respect to the need for legislative or administrative changes to accomplish the objectives set forth in subparagraphs (A) and (B), including the need for a mandatory Federal regulatory program to assure the marketing of appropriate types of medicare supplemental policies, and such other means as he finds may be appropriate to enhance effective State regulation of such policies.

(2) The Secretary shall submit to the Congress no later than July 1, 1982, and periodically as may be appropriate thereafter (but not less often than once every 2 years), a report evaluating the effectiveness of the certification procedure and the criminal penalties established under this section, and shall include in such reports an analysis of--

(A) the impact of such procedure and penalties on the types, market share, value, and cost to individuals entitled to benefits under this *title [42 USCS §§ 1395* et seq.] of medicare supplemental policies which have been certified by the Secretary;

(B) the need for any change in the certification procedure to improve its administration or effectiveness; and

(C) whether the certification program and criminal penalties should be continued.

(3) The Secretary shall provide information via a toll-free telephone number on medicare supplemental policies (including the relationship of State programs under title XIX [*42 USCS §§ 1396* et seq.] to such policies).

(g) Definitions.

(1) For purposes of this section, a medicare supplemental policy is a health insurance policy or other health benefit plan offered by a private entity to individuals who are entitled to have payment made under this *title [42 USCS §§ 1395* et seq.], which provides reimbursement for expenses incurred for services and items for which payment may be made under this *title [42 USCS §§ 1395* et seq.] but which are not reimbursable by reason of the applicability of deductibles, coinsurance amounts, or other limitations imposed pursuant to this *title [42 USCS §§ 1395* et seq.]; but does not include a prescription drug plan under part D [*42 USCS §§ 1395w-101* et seq.] or a Medicare + Choice plan or any such policy or plan of one or more employers or labor organizations, or of the trustees of a fund established by one or more employers or labor organizations (or combination thereof), for employees or former employees (or combination thereof) or for members or former members (or combination thereof) of the labor organizations and does not include a policy or plan of an eligible organization (as defined in section 1876(b) [*42 USCS § 1395mm(b)*]) if the policy or plan provides benefits pursuant to a contract under section 1876 [*42 USCS § 1395mm*] or an approved demonstration project described in section 603(c) of the Social Security Amendments of 1983 [unclassified], section 2355 of the Deficit Reduction Act of 1984 [unclassified], or section 9412(b) of the Omnibus Budget Reconciliation Act of 1986 [unclassified], or a policy or plan of an organization if the policy or plan provides benefits pursuant to an agreement under section 1833(a)(1)(A) [*42 USCS § 1395l(a)(1)(A)*]. For purposes of this section, the term "policy" includes a certificate issued under such policy.

(2) For purposes of this section:

(A) The term "NAIC Model Standards" means the "NAIC Model Regulation to Implement the Individual Accident and Sickness Insurance Minimum Standards Act", adopted by the National Association of Insurance Commissioners on June 6, 1979, as it applies to medicare supplemental policies.

(B) The term "State with an approved regulatory program" means a State for which the Secretary has made a determination under subsection (b)(1).

(C) The State in which a policy is issued means--

(i) in the case of an individual policy, the State in which the policyholder resides; and

(ii) in the case of a group policy, the State in which the holder of the master policy resides.

(h) Rules and regulations. The Secretary shall prescribe such regulations as may be necessary for the effective, efficient, and equitable administration of the certification procedure established under this section. The Secretary shall first issue final regulations to implement the certification procedure established under subsection (a) not later than March 1, 1981.

(i) Commencement of certification program.

(1) No medicare supplemental policy shall be certified and no such policy may be issued bearing the emblem authorized by the Secretary under subsection (a) until July 1, 1982. On and after such date policies certified by the Secretary may bear such emblem, including policies which were issued prior to such date and were subsequently certified, and insurers may notify holders of such certified policies issued prior to such date using such emblem in the notification.

(2) (A) The Secretary shall not implement the certification program established under subsection (a) with respect to policies issued in a State unless the Panel makes a finding that such State cannot be expected to have established, by July 1, 1982, an approved State regulatory program meeting the standards and requirements of subsection (b)(1). If the Panel makes such a finding, the Secretary shall implement such program under subsection (a) with respect to medicare supplemental policies issued in such State, until such time as the Panel determines that such State has a program that meets the standards and requirements of subsection (b)(1).

(B) Any finding by the Panel under subparagraph (A) shall be transmitted in writing, not later than January 1, 1982, to the Committee on Finance of the Senate and to the Committee on Interstate and Foreign Commerce [Committee on Energy and Commerce] and the Committee on Ways and Means of the House of Representatives and shall not become effective until 60 days after the date of its transmittal to the Committees of the Congress under this subparagraph. In counting such days, days on which either House is not in session because of an adjournment sine die or an adjournment of more than three days to a day certain are excluded in the computation.

(j) State regulation of policies issued in other States. Nothing in this section shall be construed so as to affect the right of any State to regulate medicare supplemental policies which, under the provisions of this section, are considered to be issued in another State.

(k) Amended NAIC Model Regulation or Federal model standards applicable; effective date; medicare supplemental policy and State regulatory program meeting applicable standards.

(1) (A) If, within the 90-day period beginning on the date of the enactment of this subsection [enacted July 1, 1988] the National Association of Insurance Commissioners (in this subsection referred to as the "Association") amends the NAIC Model Regulation adopted on June 6, 1979 (as it relates to medicare supplemental policies), with respect to matters such as minimum benefit standards, loss ratios, disclosure requirements, and replacement requirements and provisions otherwise necessary to reflect the changes in law made by the Medicare Catastrophic Coverage Act of 1988, except as provided in subsection (m), subsection (g)(2)(A) shall be applied in a State, effective on and after the date specified in subparagraph (B), as if the reference to the Model Regulation adopted on June 6, 1979, were a reference to the Model Regulation as amended by the Association in accordance with this paragraph (in this subsection and subsection (l) referred to as the "amended NAIC Model Regulation").

(B) The date specified in this subparagraph for a State is the earlier of the date the State adopts standards equal to or more stringent than the amended NAIC Model Regulation or 1 year after the date the Association first adopts such amended Regulation.

(2) (A) If the Association does not amend the NAIC Model Regulation within the 90-day period specified in paragraph (1)(A), the Secretary shall promulgate, not later than 60 days after the end of such period, Federal model standards (in this subsection and subsection (l) referred to as "Federal model standards") for medicare supplemental policies to reflect the changes in law made by the Medicare Catastrophic Coverage Act of 1988, and subsection (g)(2)(A) shall be applied in a State, effective on and after the date specified in subparagraph (B), as if the reference to the Model Regulation adopted on June 6, 1979, were a reference to Federal model standards.

(B) The date specified in this subparagraph for a State is the earlier of the date the State adopts standards equal to or more stringent than the Federal model standards or 1 year after the date the Secretary first promulgates such standards.

(3) Notwithstanding any other provision of this section (except as provided in subsections (l), (m), and (n))--

(A) no medicare supplemental policy may be certified by the Secretary pursuant to subsection (a),

(B) no certification made pursuant to subsection (a) shall remain in effect, and

(C) no State regulatory program shall be found to meet (or to continue to meet) the requirements of subsection (b)(1)(A),

unless such policy meets (or such program provides for the application of standards equal to or more stringent than) the standards set forth in the amended NAIC Model Regulation or the Federal model standards (as the case may be) by the date specified in paragraph (1)(B) or (2)(B) (as the case may be).

(l) Transitional compliance with NAIC Model Transition Regulation; "qualifying medicare supplement policy" and "NAIC Model Transition Regulation" defined; report to Congress respecting State action in adopting equal or more stringent standards.

(1) Until the date specified in paragraph (3), in the case of a qualifying medicare supplemental policy described in paragraph (2) issued--

(A) before January 1, 1989, the policy is deemed to remain in compliance with this section if the insurer issuing the policy complies with the NAIC Model Transition Regulation (including giving notices to subscribers and filing for premium adjustments with the State as described in section 5.B. of such Regulation) by January 1, 1989; or

(B) on or after January 1, 1989, the policy is deemed to be in compliance with this section if the insurer issuing the policy complies with the NAIC Model Transition Regulation before the date of the sale of the policy.

(2) In paragraph (1), the term "qualifying medicare supplemental policy" means a medicare supplemental policy--

(A) issued in a State which--

(i) has not adopted standards equal to or more stringent than the NAIC Model Transition Regulation by January 1, 1989, and

(ii) has not adopted standards equal to or more stringent than the amended NAIC Model Regulation (or Federal model standards) by January 1, 1989; and

(B) which has been issued in compliance with this section (as in effect on June 1, 1988).

(3) (A) The date specified in this paragraph is the earlier of--

(i) the first date a State adopts, after January 1, 1989, standards equal to or more stringent than the NAIC Model Transition Regulation or equal to or more stringent than the amended NAIC Model Regulation (or Federal model standards), as the case may be, or

(ii) the later of (I) the date specified in subsection (k)(1)(B) or (k)(2)(B) (as the case may be), or (II) the date specified in subparagraph (B).

(B) In the case of a State which the Secretary identifies as--

(i) requiring State legislation (other than legislation appropriating funds) in order for medicare supplemental policies to meet standards described in subparagraph (A)(i), but

(ii) having a legislature which is not scheduled to meet in 1989 in a legislative session in which such legislation may be considered,

the date specified in this subparagraph is the first day of the first calendar quarter beginning after the close of the first legislative session of the State legislature that begins on or after January 1, 1989, and in which legislation described in clause (i) may be considered. For purposes of the previous sentence, in the case of a State that has a 2-year legislative session, each year of such session shall be deemed to be a separate regular session of the State legislature.

(4) In the case of a medicare supplemental policy in effect on January 1, 1989, and offered in a State which, as of such date--

(A) has adopted standards equal to or more stringent than the amended NAIC Model Regulation (or Federal model standards), but

(B) does not have in effect standards equal to or more stringent than the NAIC Model Transition Regulation (or otherwise requiring notice substantially the same as the notice required in section 5.B. of such Regulation),

the policy shall not be deemed to meet the standards in subsection (c) unless each individual who is entitled to benefits under this *title [42 USCS §§ 1395* et seq.] and is a policyholder under such policy on January 1, 1989, is sent such a notice in any appropriate form by not later than January 31, 1989, that explains--

(A) the improved benefits under this *title [42 USCS §§ 1395* et seq.] contained in the Medicare Catastrophic Coverage Act of 1988, and

(B) how these improvements affect the benefits contained in the policies and the premium for the policy.

(5) In this subsection, the term "NAIC Model Transition Regulation" refers to the standards contained in the "Model Regulation to Implement Transitional Requirements for the Conversion of Medicare Supplement Insurance Benefits and Premiums to Conform to Medicare Program Revisions" (as adopted by the National Association of Insurance Commissioners in September 1987).

(m) Revision of amended NAIC Model Regulation and amended Federal model standards; effective dates; medicare supplemental policy and State regulatory program meeting applicable standards.

(1) (A) If, within the 90-day period beginning on the date of the enactment of this subsection [enacted Dec. 13, 1989], the National Association of Insurance Commissioners (in this subsection and subsection (n) referred to as the "Association") revises the amended NAIC Model Regulation (referred to in subsection (k)(1)(A) and adopted on September 20, 1988) to improve such regulation and otherwise to reflect the changes in law made by the Medicare Catastrophic Coverage Repeal Act of 1989, subsection (g)(2)(A) shall be applied in a State, effective on and after the date specified in subparagraph (B), as if the reference to the Model Regulation adopted on June 6, 1979, were a reference to the amended NAIC Model Regulation (referred to in subsection (k)(1)(A)) as revised by the Association in accordance with this paragraph (in this subsection and subsection (n) referred to as the "revised NAIC Model Regulation").

(B) The date specified in this subparagraph for a State is the earlier of the date the State adopts standards equal to or more stringent than the revised NAIC Model Regulation or 1 year after the date the Association first adopts such revised Regulation.

(2) (A) If the Association does not revise the amended NAIC Model Regulation, within the 90-day period specified in paragraph (1)(A), the Secretary shall promulgate, not later than 60 days after the end of such period, revised Federal model standards (in this subsection and subsection (n) referred to as "revised Federal model standards") for medicare supplemental policies to improve such standards and otherwise to reflect the changes in law made by the Medicare Catastrophic Coverage Repeal Act of 1989, subsection (g)(2)(A) shall be applied in a State, effective on and after the date specified in subparagraph (B), as if the reference to the Model Regulation adopted on June 6, 1979, were a reference to the revised Federal model standards.

(B) The date specified in this subparagraph for a State is the earlier of the date the State adopts standards equal to or more stringent than the revised Federal model standards or 1 year after the date the Secretary first promulgates such standards.

(3) Notwithstanding any other provision of this section (except as provided in subsection (n))--

(A) no medicare supplemental policy may be certified by the Secretary pursuant to subsection (a),

(B) no certification made pursuant to subsection (a) shall remain in effect, and

(C) no State regulatory program shall be found to meet (or to continue to meet) the requirements of subsection (b)(1)(A),

unless such policy meets (or such program provides for the application of standards equal to or more stringent than) the standards set forth in the revised NAIC Model Regulation or the revised Federal model standards (as the case may be) by the date specified in paragraph (1)(B) or (2)(B) (as the case may be).

(n) Transition compliance with revision of NAIC Model Regulation and Federal model standards.

(1) Until the date specified in paragraph (4), in the case of a qualifying medicare supplemental policy described in paragraph (3) issued in a State--

(A) before the transition deadline, the policy is deemed to remain in compliance with the standards described in subsection (b)(1)(A) only if the insurer issuing the policy complies with the transition provision described in paragraph (2), or

(B) on or after the transition deadline, the policy is deemed to be in compliance with the standards described in subsection (b)(1)(A) only if the insurer issuing the policy complies with the revised NAIC Model Regulation or the revised Federal model standards (as the case may be) before the date of the sale of the policy.

In this paragraph, the term "transition deadline" means 1 year after the date the Association adopts the revised NAIC Model Regulation or 1 year after the date the Secretary promulgates revised Federal model standards (as the case may be).

(2) The transition provision described in this paragraph is--

(A) such transition provision as the Association provides, by not later than December 15, 1989, so as to provide for an appropriate transition (i) to restore benefit provisions which are no longer duplicative as a result of the changes in benefits under this *title [42 USCS §§ 1395* et seq.] made by the Medicare Catastrophic Coverage Repeal Act of 1989 and (ii) to eliminate the requirement of payment for the first 8 days of coinsurance for extended care services, or

(B) if the Association does not provide for a transition provision by the date described in subparagraph (A), such transition provision as the Secretary shall provide, by January 1, 1990, so as to provide for an appropriate transition described in subparagraph (A).

(3) In paragraph (1), the term "qualifying medicare supplemental policy" means a medicare supplemental policy which has been issued in compliance with this section as in effect on the date before the date of the enactment of this subsection [enacted Dec. 13, 1989].

(4) (A) The date specified in this paragraph for a policy issued in a State is--

(i) the first date a State adopts, after the date of the enactment of this subsection, standards equal to or more stringent than the revised NAIC Model Regulation (or revised Federal model standards), as the case may be, or

(ii) the date specified in subparagraph (B), whichever is earlier.

(B) In the case of a State which the Secretary identifies, in consultation with the Association, as--

(i) requiring State legislation (other than legislation appropriating funds) in order for medicare supplemental policies to meet standards described in subparagraph (A)(i), but

(ii) having a legislature which is not scheduled to meet in 1990 in a legislative session in which such legislation may be considered,

the date specified in this subparagraph is the first day of the first calendar quarter beginning after the close of the first legislative session of the State legislature that begins on or after January 1, 1990. For purposes of the previous sentence, in the case of a State that has a 2-year legislative session, each year of such session shall be deemed to be a separate regular session of the State legislature.

(5) In the case of a medicare supplemental policy in effect on January 1, 1990, the policy shall not be deemed to meet the standards in subsection (c) unless each individual who is entitled to benefits under this *title [42 USCS §§ 1395* et seq.] and is a policyholder or certificate holder under such policy on such date is sent a notice in an appropriate form by not later than January 31, 1990, that explains--

(A) the changes in benefits under this *title [42 USCS §§ 1395* et seq.] effected by the Medicare Catastrophic Coverage Repeal Act of 1989, and

(B) how these changes may affect the benefits contained in such policy and the premium for the policy.

(6) (A) Except as provided in subparagraph (B), in the case of an individual who had in effect, as of December 31, 1988, a medicare supplemental policy with an insurer (as a policyholder or, in the case of a group policy, as a certificate holder) and the individual terminated coverage under such policy before the date of the enactment of this subsection [enacted Dec. 13, 1989], no medicare supplemental policy of the insurer shall be deemed to meet the standards in subsection (c) unless the insurer--

(i) provides written notice, no earlier than December 15, 1989, and no later than January 30, 1990, to the policyholder or certificate holder (at the most recent available address) of the offer described in clause (ii), and

(ii) offers the individual, during a period of at least 60 days beginning not later than February 1, 1990, reinstitution of coverage (with coverage effective as of January 1, 1990), under the terms which (I) do not provide for any waiting period with respect to treatment of pre-existing conditions, (II) provides for coverage which is substantially equivalent

to coverage in effect before the date of such termination, and (III) provides for classification of premiums on which terms are at least as favorable to the policyholder or certificate holder as the premium classification terms that would have applied to the policyholder or certificate holder had the coverage never terminated.

(B) An insurer is not required to make the offer under subparagraph (A)(ii) in the case of an individual who is a policyholder or certificate holder in another medicare supplemental policy as of the date of the enactment of this subsection, if (as of January 1, 1990) the individual is not subject to a waiting period with respect to treatment of a pre-existing condition under such other policy.

(o) Requirements of group benefits; core group benefits; uniform outline of coverage. The requirements of this subsection are as follows:

(1) Each medicare supplemental policy shall provide for coverage of a group of benefits consistent with subsections (p), (v), and (w).

(2) If the medicare supplemental policy provides for coverage of a group of benefits other than the core group of basic benefits described in subsection (p)(2)(B), the issuer of the policy must make available to the individual a medicare supplemental policy with only such core group of basic benefits.

(3) The issuer of the policy has provided, before the sale of the policy, an outline of coverage that uses uniform language and format (including layout and print size) that facilitates comparison among medicare supplemental policies and comparison with medicare benefits.

(4) **[Caution: This paragraph is applicable for policy years beginning on or after 5/21/2009, as provided by § 104(c) of Act May 21, 2008, P.L. 110-233, which appears as a note to this section.]** The issuer of the medicare supplemental policy complies with subsection (s)(2)(E) and subsection (x).

(5) In addition to the requirement under paragraph (2), the issuer of the policy must make available to the individual at least Medicare supplemental policies with benefit packages classified as "C" or "F".

(p) Standards for group benefits.

(1)

(A) If, within 9 months after the date of the enactment of this subsection [enacted Nov. 5, 1990], the National Association of Insurance Commissioners (in this subsection referred to as the "Association") changes the revised NAIC Model Regulation (described in subsection (m)) to incorporate--

(i) limitations on the groups or packages of benefits that may be offered under a medicare supplemental policy consistent with paragraphs (2) and (3) of this subsection,

(ii) uniform language and definitions to be used with respect to such benefits,

(iii) uniform format to be used in the policy with respect to such benefits, and

(iv) other standards to meet the additional requirements imposed by the amendments made by the Omnibus Budget Reconciliation Act of 1990,

subsection (g)(2)(A) shall be applied in each State, effective for policies issued to policyholders on and after the date specified in subparagraph (C), as if the reference to the Model Regulation adopted on June 6, 1979, were a reference to the revised NAIC Model Regulation as changed under this subparagraph (such changed regulation referred to in this section as the "1991 NAIC Model Regulation").

(B) If the Association does not make the changes in the revised NAIC Model Regulation within the 9-month period specified in subparagraph (A), the Secretary shall promulgate, not later than 9 months after the end of such period, a regulation and subsection (g)(2)(A) shall be applied in each State, effective for policies issued to policyholders on and after the date specified in subparagraph (C), as if the reference to the Model Regulation adopted on June 6, 1979, were a reference to the revised NAIC Model Regulation as changed by the Secretary under this subparagraph (such changed regulation referred to in this section as the "1991 Federal Regulation").

(C) (i) Subject to clause (ii), the date specified in this subparagraph for a State is the date the State adopts the 1991 NAIC Model Regulation or 1991 Federal Regulation or 1 year after the date the Association or the Secretary first adopts such standards, whichever is earlier.

(ii) In the case of a State which the Secretary identifies, in consultation with the Association, as--

(I) requiring State legislation (other than legislation appropriating funds) in order for medicare supplemental policies to meet the 1991 NAIC Model Regulation or 1991 Federal Regulation, but

(II) having a legislature which is not scheduled to meet in 1992 in a legislative session in which such legislation may be considered,

the date specified in this subparagraph is the first day of the first calendar quarter beginning after the close of the first legislative session of the State legislature that begins on or after January 1, 1992. For purposes of the previous sentence, in the case of a State that has a 2-year legislative session, each year of such session shall be deemed to be a separate regular session of the State legislature.

(D) In promulgating standards under this paragraph, the Association or Secretary shall consult with a working group composed of representatives of issuers of medicare supplemental policies, consumer groups, medicare beneficiaries, and other qualified individuals. Such representatives shall be selected in a manner so as to assure balanced representation among the interested groups.

(E) If benefits (including deductibles and coinsurance) under this *title [42 USCS §§ 1395* et seq.] are changed and the Secretary determines, in consultation with the Association, that changes in the 1991 NAIC Model Regulation or 1991 Federal Regulation are needed to reflect such changes, the preceding provisions of this paragraph shall apply to the modification of standards previously established in the same manner as they applied to the original establishment of such standards.

(2) The benefits under the 1991 NAIC Model Regulation or 1991 Federal Regulation shall provide--

(A) for such groups or packages of benefits as may be appropriate taking into account the considerations specified in paragraph (3) and the requirements of the succeeding subparagraphs;

(B) for identification of a core group of basic benefits common to all policies; and

(C) that, subject to paragraph (4)(B), the total number of different benefit packages (counting the core group of basic benefits described in subparagraph (B) and each other combination of benefits that may be offered as a separate benefit package) that may be established in all the States and by all issuers shall not exceed 10 plus the 2 plans described in paragraph (11)(A).

(3) The benefits under paragraph (2) shall, to the extent possible--

(A) provide for benefits that offer consumers the ability to purchase the benefits that are available in the market as of the date of the enactment of this subsection; and

(B) balance the objectives of (i) simplifying the market to facilitate comparisons among policies, (ii) avoiding adverse selection, (iii) providing consumer choice, (iv) providing market stability, and (v) promoting competition.

(4) (A) (i) Except as provided in subparagraph (B) or paragraph (6), no State with a regulatory program approved under subsection (b)(1) may provide for or permit the grouping of benefits (or language or format with respect to such benefits) under a medicare supplemental policy unless such grouping meets the applicable 1991 NAIC Model Regulation or 1991 Federal Regulation.

(ii) Except as provided in subparagraph (B), the Secretary may not provide for or permit the grouping of benefits (or language or format with respect to such benefits) under a medicare supplemental policy seeking approval by the Secretary unless such grouping meets the applicable 1991 NAIC Model Regulation or 1991 Federal Regulation.

(B) With the approval of the State (in the case of a policy issued in a State with an approved regulatory program) or the Secretary (in the case of any other policy), the issuer of a medicare supplemental policy may offer new or innovative benefits in addition to the benefits provided in a policy that otherwise complies with the applicable 1991 NAIC Model Regulation or 1991 Federal Regulation. Any such new or innovative benefits may include benefits that are not otherwise available and are cost-effective and shall be offered in a manner which is consistent with the goal of simplification of medicare supplemental policies.

(5) (A) Except as provided in subparagraph (B), this subsection shall not be construed as preventing a State from restricting the groups of benefits that may be offered in medicare supplemental policies in the State.

(B) A State with a regulatory program approved under subsection (b)(1) may not restrict under subparagraph (A) the offering of a medicare supplemental policy consisting only of the core group of benefits described in paragraph (2)(B).

(6) The Secretary may waive the application of standards described in clauses (i) through (iii) of paragraph (1)(A) in those States that on the date of enactment of this subsection had in place an alternative simplification program.

(7) This subsection shall not be construed as preventing an issuer of a medicare supplemental policy who otherwise meets the requirements of this section from providing, through an arrangement with a vendor, for discounts from that vendor to policyholders or certificateholders for the purchase of items or services not covered under its medicare supplemental policies.

(8) Any person who sells or issues a medicare supplemental policy, on and after the effective date specified in paragraph (1)(C) (but subject to paragraph (10)), in violation of the applicable 1991 NAIC Model Regulation or 1991 Federal Regulation insofar as such regulation relates to the requirements of subsection (o) or (q) or clause (i), (ii), or (iii) of paragraph (1)(A) is subject to a civil money penalty of not to exceed $ 25,000 (or $ 15,000 in the case of a seller who is not an issuer of a policy) for each such violation. The provisions of section 1128A [*42 USCS § 1320a-7a*] (other than the first sentence of subsection (a) and other than subsection (b)) shall apply to a civil money penalty under the previous sentence in the same manner as such provisions apply to a penalty or proceeding under section 1128A(a) [*42 USCS § 1320a-7a(a)*].

(9) (A) Anyone who sells a medicare supplemental policy to an individual shall make available for sale to the individual a medicare supplemental policy with only the core group of basic benefits (described in paragraph (2)(B)).

(B) Anyone who sells a medicare supplemental policy to an individual shall provide the individual, before the sale of the policy, an outline of coverage which describes the benefits under the policy. Such outline shall be on a standard

form approved by the State regulatory program or the Secretary (as the case may be) consistent with the 1991 NAIC Model Regulation or 1991 Federal Regulation under this subsection.

(C) Whoever sells a medicare supplemental policy in violation of this paragraph is subject to a civil money penalty of not to exceed $ 25,000 (or $ 15,000 in the case of a seller who is not the issuer of the policy) for each such violation. The provisions of section 1128A [*42 USCS § 1320a-7a*] (other than the first sentence of subsection (a) and other than subsection (b)) shall apply to a civil money penalty under the previous sentence in the same manner as such provisions apply to a penalty or proceeding under section 1128A(a) [*42 USCS § 1320a-7a(a)*].

(D) Subject to paragraph (10), this paragraph shall apply to sales of policies occurring on or after the effective date specified in paragraph (1)(C).

(10) No penalty may be imposed under paragraph (8) or (9) in the case of a seller who is not the issuer of a policy until the Secretary has published a list of the groups of benefit packages that may be sold or issued consistent with paragraph (1)(A)(i).

(11) (A) For purposes of paragraph (2), the benefit packages described in this subparagraph are as follows:

(i) The benefit package classified as "F" under the standards established by such paragraph, except that it has a high deductible feature.

(ii) The benefit package classified as "J" under the standards established by such paragraph, except that it has a high deductible feature.

(B) For purposes of subparagraph (A), a high deductible feature is one which--

(i) requires the beneficiary of the policy to pay annual out-of-pocket expenses (other than premiums) in the amount specified in subparagraph (C) before the policy begins payment of benefits, and

(ii) covers 100 percent of covered out-of-pocket expenses once such deductible has been satisfied in a year.

(C) The amount specified in this subparagraph--

(i) for 1998 and 1999 is $ 1,500, and

(ii) for a subsequent year, is the amount specified in this subparagraph for the previous year increased by the percentage increase in the Consumer Price Index for all urban consumers (all items; U.S. city average) for the 12-month period ending with August of the preceding year. If any amount determined under clause (ii) is not a multiple of $ 10, it shall be rounded to the nearest multiple of $ 10.

(q) Requirements. The requirements of this subsection are as follows:

(1) Each medicare supplemental policy shall be guaranteed renewable and--

(A) the issuer may not cancel or nonrenew the policy solely on the ground of health status of the individual; and

(B) the issuer shall not cancel or nonrenew the policy for any reason other than nonpayment of premium or material misrepresentation.

(2) If the medicare supplemental policy is terminated by the group policyholder and is not replaced as provided under paragraph (4), the issuer shall offer certificateholders an individual medicare supplemental policy which (at the option of the certificateholder)--

(A) provides for continuation of the benefits contained in the group policy, or

(B) provides for such benefits as otherwise meets [meet] the requirements of this section.

(3) If an individual is a certificateholder in a group medicare supplemental policy and the individual terminates membership in the group, the issuer shall--

(A) offer the certificateholder the conversion opportunity described in paragraph (2), or

(B) at the option of the group policyholder, offer the certificateholder continuation of coverage under the group policy.

(4) If a group medicare supplemental policy is replaced by another group medicare supplemental policy purchased by the same policyholder, [the] issuer of the replacement policy shall offer coverage to all persons covered under the old group policy on its date of termination. Coverage under the new group policy shall not result in any exclusion for preexisting conditions that would have been covered under the group policy being replaced.

(5) (A) Each medicare supplemental policy shall provide that benefits and premiums under the policy shall be suspended at the request of the policyholder for the period (not to exceed 24 months) in which the policyholder has applied for and is determined to be entitled to medical assistance under title XIX [*42 USCS §§ 1396* et seq.], but only if the policyholder notifies the issuer of such policy within 90 days after the date the individual becomes entitled to such assistance. If such suspension occurs and if the policyholder or certificate holder loses entitlement to such medical assistance, such policy shall be automatically reinstituted (effective as of the date of termination of such entitlement) under terms described in subsection (n)(6)(A)(ii) as of the termination of such entitlement if the policyholder provides notice of loss of such entitlement within 90 days after the date of such loss.

(B) Nothing in this section shall be construed as affecting the authority of a State, under title XIX [*42 USCS §§ 1396* et seq.], to purchase a medicare supplemental policy for an individual otherwise entitled to assistance under such title.

(C) Any person who issues a medicare supplemental policy and fails to comply with the requirements of this paragraph or paragraph (6) is subject to a civil money penalty of not to exceed $ 25,000 for each such violation. The provisions of section 1128A [*42 USCS § 1320a-7a*] (other than the first sentence of subsection (a) and other than subsection (b)) shall apply to a civil money penalty under the previous sentence in the same manner as such provisions apply to a penalty or proceeding under section 1128A(a) [*42 USCS § 1320a-7a(a)*].

(6) Each medicare supplemental policy shall provide that benefits and premiums under the policy shall be suspended at the request of the policyholder if the policyholder is entitled to benefits under section 226(b) [*42 USCS § 426(b)*] and is covered under a group health plan (as defined in section 1862(b)(1)(A)(v) [*42 USCS § 1395y(b)(1)(A)(v)*]). If such suspension occurs and if the policyholder or certificate holder loses coverage under the group health plan, such policy shall be automatically reinstituted (effective as of the date of such loss of coverage) under terms described in subsection (n)(6)(A)(ii) as of the loss of such coverage if the policyholder provides notice of loss of such coverage within 90 days after the date of such loss.

(r) Loss ratio of aggregate benefits to aggregate premiums.

(1) A medicare supplemental policy may not be issued or renewed (or otherwise provide coverage after the date described in subsection (p)(1)(C)) in any State unless--

(A) the policy can be expected for periods after the effective date of these provisions (as estimated for the entire period for which rates are computed to provide coverage, on the basis of incurred claims experience and earned premiums for such periods and in accordance with a uniform methodology, including uniform reporting standards, developed by the National Association of Insurance Commissioners) to return to policyholders in the form of aggregate benefits provided under the policy, at least 75 percent of the aggregate amount of premiums collected in the case of group policies and at least 65 percent in the case of individual policies; and

(B) the issuer of the policy provides for the issuance of a proportional refund, or a credit against future premiums of a proportional amount, based on the premium paid and in accordance with paragraph (2), of the amount of premiums received necessary to assure that the ratio of aggregate benefits provided to the aggregate premiums collected (net of such refunds or credits) complies with the expectation required under subparagraph (A), treating policies of the same type as a single policy for each standard package.

For purposes of applying subparagraph (A) only, policies issued as a result of solicitations of individuals through the mails or by mass media advertising (including both print and broadcast advertising) shall be deemed to be individual policies. For the purpose of calculating the refund or credit required under paragraph (1)(B) for a policy issued before the date specified in subsection (p)(1)(C), the refund or credit calculation shall be based on the aggregate benefits provided and premiums collected under all such policies issued by an insurer in a State (separated as to individual and group policies) and shall be based only on aggregate benefits provided and premiums collected under such policies after the date specified in section 171(m)(4) of the Social Security Act Amendments of 1994 [note to this section].

(2) (A) Paragraph (1)(B) shall be applied with respect to each type of policy by standard package. Paragraph (1)(B) shall not apply to a policy until 12 months following issue. The Comptroller General, in consultation with the National Association of Insurance Commissioners, shall submit to Congress a report containing recommendations on adjustments in the percentages under paragraph (1)(A) that may be appropriate. In the case of a policy issued before the date specified in subsection (p)(1)(C), paragraph (1)(B) shall not apply until 1 year after the date specified in section 171(m)(4) of the Social Security Act Amendments of 1994 [note to this section].

(B) A refund or credit required under paragraph (1)(B) shall be made to each policyholder insured under the applicable policy as of the last day of the year involved.

(C) Such a refund or credit shall include interest from the end of the calendar year involved until the date of the refund or credit at a rate as specified by the Secretary for this purpose from time to time which is not less than the average rate of interest for 13-week Treasury notes.

(D) For purposes of this paragraph and paragraph (1)(B), refunds or credits against premiums due shall be made, with respect to a calendar year, not later than the third quarter of the succeeding calendar year.

(3) The provisions of this subsection do not preempt a State from requiring a higher percentage than that specified in paragraph (1)(A).

(4) The Secretary shall submit in October of each year (beginning with 1993) a report to the Committees on Energy and Commerce and Ways and Means of the House of Representatives and the Committee on Finance of the Senate on loss ratios under medicare supplemental policies and the use of sanctions, such as a required rebate or credit or the disallowance of premium increases, for policies that fail to meet the requirements of this subsection (relating to loss ratios). Such report shall include a list of the policies that failed to comply with such loss ratio requirements or other requirements of this section.

(5) The Secretary may perform audits with respect to the compliance of medicare supplemental policies with the loss ratio requirements of this subsection and shall report the results of such audits to the State involved and to the Secretary.

(6)

(A) A person who fails to provide refunds or credits as required in paragraph (1)(B) is subject to a civil money penalty of not to exceed $ 25,000 for each policy issued for which such failure occurred. The provisions of section 1128A [*42 USCS § 1320a-7a*] (other than the first sentence of subsection (a) and other than subsection (b)) shall apply to a civil money penalty under the previous sentence in the same manner as such provisions apply to a penalty or proceeding under section 1128A(a) [*42 USCS § 1320a-7a(a)*].

(B) Each issuer of a policy subject to the requirements of paragraph (1)(B) shall be liable to the policyholder or, in the case of a group policy, to the certificate holder for credits required under such paragraph.

(s) Coverage for pre-existing conditions.

(1) If a medicare supplemental policy replaces another medicare supplemental policy, the issuer of the replacing policy shall waive any time periods applicable to preexisting conditions, waiting period, elimination periods and probationary periods in the new medicare supplemental policy for similar benefits to the extent such time was spent under the original policy.

(2)

(A) The issuer of a medicare supplemental policy may not deny or condition the issuance or effectiveness of a medicare supplemental policy, or discriminate in, the pricing of the policy, because of health status, claims experience, receipt of health care, or medical condition in the case of an individual for whom an application is submitted prior to or during the 6 month period beginning with the first month as of the first day on which the individual is 65 years of age or older and is enrolled for benefits under part B [*42 USCS §§ 1395j* et seq.].

(B) Subject to subparagraphs (C) and (D), subparagraph (A) shall not be construed as preventing the exclusion of benefits under a policy, during its first 6 months, based on a pre-existing condition for which the policyholder received treatment or was otherwise diagnosed during the 6 months before the policy became effective.

(C) If a medicare supplemental policy or certificate replaces another such policy or certificate which has been in effect for 6 months or longer, the replacing policy may not provide any time period applicable to pre-existing conditions, waiting periods, elimination periods, and probationary periods in the new policy or certificate for similar benefits.

(D) In the case of a policy issued during the 6-month period described in subparagraph (A) to an individual who is 65 years of age or older as of the date of issuance and who as of the date of the application for enrollment has a continuous period of creditable coverage (as defined in section 2701(c) of the Public Health Service Act [*42 USCS § 300gg*]) of--

(i) at least 6 months, the policy may not exclude benefits based on a pre-existing condition; or

(ii) less than 6 months, if the policy excludes benefits based on a preexisting condition, the policy shall reduce the period of any preexisting condition exclusion by the aggregate of the periods of creditable coverage (if any, as so defined) applicable to the individual as of the enrollment date.

The Secretary shall specify the manner of the reduction under clause (ii), based upon the rules used by the Secretary in carrying out section 2701(a)(3) of such Act [*42 USCS § 300gg(a)(3)*].

(E) **[Caution: This subparagraph is applicable for policy years beginning on or after 5/21/2009, as provided by § 104(c) of Act May 21, 2008, P.L. 110-233, which appears as a note to this section.]** An issuer of a medicare supplemental policy shall not deny or condition the issuance or effectiveness of the policy (including the imposition of any exclusion of benefits under the policy based on a pre-existing condition) and shall not discriminate in the pricing of the policy (including the adjustment of premium rates) of an individual on the basis of the genetic information with respect to such individual.

(F) **[Caution: This subparagraph is applicable for policy years beginning on or after 5/21/2009, as provided by § 104(c) of Act May 21, 2008, P.L. 110-233, which appears as a note to this section.]** Rule of construction. Nothing in subparagraph (E) or in subparagraphs (A) or (B) of subsection (x)(2) shall be construed to limit the ability of an issuer of a medicare supplemental policy from, to the extent otherwise permitted under this title

(i) denying or conditioning the issuance or effectiveness of the policy or increasing the premium for an employer based on the manifestation of a disease or disorder of an individual who is covered under the policy; or

(ii) increasing the premium for any policy issued to an individual based on the manifestation of a disease or disorder of an individual who is covered under the policy (in such case, the manifestation of a disease or disorder in one individual cannot also be used as genetic information about other group members and to further increase the premium for the employer).

(3)

(A) The issuer of a medicare supplemental policy--

(i) may not deny or condition the issuance or effectiveness of a medicare supplemental policy described in subparagraph (C) that is offered and is available for issuance to new enrollees by such issuer;

(ii) may not discriminate in the pricing of such policy, because of health status, claims experience, receipt of health care, or medical condition; and

(iii) may not impose an exclusion of benefits based on a preexisting condition under such policy,

in the case of an individual described in subparagraph (B) who seeks to enroll under the policy during the period specified in subparagraph (E) and who submits evidence of the date of termination or disenrollment along with the application for such medicare supplemental policy.

(B) An individual described in this subparagraph is an individual described in any of the following clauses:

(i) The individual is enrolled under an employee welfare benefit plan that provides health benefits that supplement the benefits under this *title [42 USCS §§ 1395* et seq.] and the plan terminates or ceases to provide all such supplemental health benefits to the individual.

(ii) The individual is enrolled with a Medicare + Choice organization under a Medicare + Choice plan under part C [*42 USCS §§ 1395w-21* et seq.], and there are circumstances permitting discontinuance of the individual's election of the plan under the first sentence of section 1851(e)(4) [*42 USCS § 1395w-21(e)(4)*] or the individual is 65 years of age or older and is enrolled with a PACE provider under section 1894 [*42 USCS § 1395eee*], and there are circumstances that would permit the discontinuance of the individual's enrollment with such provider under circumstances that are similar to the circumstances that would permit discontinuance of the individual's election under the first sentence of such section if such individual were enrolled in a Medicare + Choice plan.

(iii) The individual is enrolled with an eligible organization under a contract under section 1876 [*42 USCS § 1395mm*], a similar organization operating under demonstration project authority, effective for periods before April 1, 1999, with an organization under an agreement under section 1833(a)(1)(A) [*42 USCS § 1395l(a)(1)(A)*], or with an organization under a policy described in subsection (t), and such enrollment ceases under the same circumstances that would permit discontinuance of an individual's election of coverage under the first sentence of section 1851(e)(4) [*42 USCS § 1395w-21(e)(4)*] and, in the case of a policy described in subsection (t), there is no provision under applicable State law for the continuation or conversion of coverage under such policy.

(iv) The individual is enrolled under a medicare supplemental policy under this section and such enrollment ceases because--

(I) of the bankruptcy or insolvency of the issuer or because of other involuntary termination of coverage or enrollment under such policy and there is no provision under applicable State law for the continuation or conversion of such coverage;

(II) the issuer of the policy substantially violated a material provision of the policy; or

(III) the issuer (or an agent or other entity acting on the issuer's behalf) materially misrepresented the policy's provisions in marketing the policy to the individual.

(v) The individual--

(I) was enrolled under a medicare supplemental policy under this section,

(II) subsequently terminates such enrollment and enrolls, for the first time, with any Medicare + Choice organization under a Medicare + Choice plan under part C [*42 USCS §§ 1395w-21* et seq.], any eligible organization under a contract under section 1876 [*42 USCS § 1395mm*], any similar organization operating under demonstration project authority, any PACE provider under section 1894 [*42 USCS § 1395eee*], or any policy described in subsection (t), and

(III) the subsequent enrollment under subclause (II) is terminated by the enrollee during any period within the first 12 months of such enrollment (during which the enrollee is permitted to terminate such subsequent enrollment under section 1851(e) [*42 USCS § 1395w-21(e)*]).

(vi) The individual, upon first becoming eligible for benefits under part A [*42 USCS §§ 1395c* et seq.] at age 65, enrolls in a Medicare + Choice plan under part C [*42 USCS §§ 1395w-21* et seq.] or in a PACE program under section 1894 [*42 USCS § 1395eee*], and disenrolls from such plan or such program by not later than 12 months after the effective date of such enrollment.

(C)

(i) Subject to clauses (ii) and (iii), a medicare supplemental policy described in this subparagraph is a medicare supplemental policy which has a benefit package classified as "A", "B", "C", or "F" under the standards established under subsection (p)(2).

(ii) (I) Subject to subclause (II), only for purposes of an individual described in subparagraph (B)(v), a medicare supplemental policy described in this subparagraph is the same medicare supplemental policy referred to in such subparagraph in which the individual was most recently previously enrolled, if available from the same issuer, or, if not so available, a policy described in clause (i).

(II) If the medicare supplemental policy referred to in subparagraph (B)(v) was a medigap Rx policy (as defined in subsection (v)(6)(A)), a medicare supplemental policy described in this subparagraph is such policy in which the

individual was most recently enrolled as modified under subsection (v)(2)(C)(i) or, at the election of the individual, a policy referred to in subsection (v)(3)(A)(i).

(iii) Only for purposes of an individual described in subparagraph (B)(vi) and subject to subsection (v)(1), a medicare supplemental policy described in this subparagraph shall include any medicare supplemental policy.

(iv) For purposes of applying this paragraph in the case of a State that provides for offering of benefit packages other than under the classification referred to in clause (i), the references to benefit packages in such clause are deemed references to comparable benefit packages offered in such State.

(D) At the time of an event described in subparagraph (B) because of which an individual ceases enrollment or loses coverage or benefits under a contract or agreement, policy, or plan, the organization that offers the contract or agreement, the insurer offering the policy, or the administrator of the plan, respectively, shall notify the individual of the rights of the individual under this paragraph, and obligations of issuers of medicare supplemental policies, under subparagraph (A).

(E) For purposes of subparagraph (A), the time period specified in this subparagraph is--

(i) in the case of an individual described in subparagraph (B)(i), the period beginning on the date the individual receives a notice of termination or cessation of all supplemental health benefits (or, if no such notice is received, notice that a claim has been denied because of such a termination or cessation) and ending on the date that is 63 days after the applicable notice;

(ii) in the case of an individual described in clause (ii), (iii), (v), or (vi) of subparagraph (B) whose enrollment is terminated involuntarily, the period beginning on the date that the individual receives a notice of termination and ending on the date that is 63 days after the date the applicable coverage is terminated;

(iii) in the case of an individual described in subparagraph (B)(iv)(I), the period beginning on the earlier of (I) the date that the individual receives a notice of termination, a notice of the issuer's bankruptcy or insolvency, or other such similar notice, if any, and (II) the date that the applicable coverage is terminated, and ending on the date that is 63 days after the date the coverage is terminated;

(iv) in the case of an individual described in clause (ii), (iii), (iv)(II), (iv)(III), (v), or (vi) of subparagraph (B) who disenrolls voluntarily, the period beginning on the date that is 60 days before the effective date of the disenrollment and ending on the date that is 63 days after such effective date; and

(v) in the case of an individual described in subparagraph (B) but not described in the preceding provisions of this subparagraph, the period beginning on the effective date of the disenrollment and ending on the date that is 63 days after such effective date.

(F) (i) Subject to clause (ii), for purposes of this paragraph--

(I) in the case of an individual described in subparagraph (B)(v) (or deemed to be so described, pursuant to this subparagraph) whose enrollment with an organization or provider described in subclause (II) of such subparagraph is involuntarily terminated within the first 12 months of such enrollment, and who, without an intervening enrollment, enrolls with another such organization or provider, such subsequent enrollment shall be deemed to be an initial enrollment described in such subparagraph; and

(II) in the case of an individual described in clause (vi) of subparagraph (B) (or deemed to be so described, pursuant to this subparagraph) whose enrollment with a plan or in a program described in such clause is involuntarily terminated within the first 12 months of such enrollment, and who, without an intervening enrollment, enrolls in another such plan or program, such subsequent enrollment shall be deemed to be an initial enrollment described in such clause.

(ii) For purposes of clauses (v) and (vi) of subparagraph (B), no enrollment of an individual with an organization or provider described in clause (v)(II), or with a plan or in a program described in clause (vi), may be deemed to be an initial enrollment under this clause after the 2-year period beginning on the date on which the individual first enrolled with such an organization, provider, plan, or program.

(4) Any issuer of a medicare supplemental policy that fails to meet the requirements of this subsection is subject to a civil money penalty of not to exceed $ 5,000 for each such failure. The provisions of section 1128A [*42 USCS § 1320a-7a*] (other than the first sentence of subsection (a) and other than subsection (b)) shall apply to a civil money penalty under the previous sentence in the same manner as such provisions apply to a penalty or proceeding under section 1128A(a) [*42 USCS § 1320a-7a(a)*].

(t) Medicare select policies [Caution: For application and termination of this subsection, see § 4358(c) of Act Nov. 5, 1990, P.L. 101-508, which appears as a note to this section.].

(1) If a medicare supplemental policy meets the 1991 NAIC Model Regulation or 1991 Federal Regulation and otherwise complies with the requirements of this section except that benefits under the policy are restricted to items and services furnished by certain entities (or reduced benefits are provided when items or services are furnished by other entities), the policy shall nevertheless be treated as meeting those standards if--

(A) full benefits are provided for items and services furnished through a network of entities which have entered into contracts or agreements with the issuer of the policy;

(B) full benefits are provided for items and services furnished by other entities if the services are medically necessary and immediately required because of an unforeseen illness, injury, or condition and it is not reasonable given the circumstances to obtain the services through the network;

(C) the network offers sufficient access;

(D) the issuer of the policy has arrangements for an ongoing quality assurance program for items and services furnished through the network;

(E) (i) the issuer of the policy provides to each enrollee at the time of enrollment an explanation of (I) the restrictions on payment under the policy for services furnished other than by or through the network, (II) out of area coverage under the policy, (III) the policy's coverage of emergency services and urgently needed care, and (IV) the availability of a policy through the entity that meets the standards in the 1991 NAIC Model Regulation or 1991 Federal Regulation without reference to this subsection and the premium charged for such policy, and

(ii) each enrollee prior to enrollment acknowledges receipt of the explanation provided under clause (i); and

(F) the issuer of the policy makes available to individuals, in addition to the policy described in this subsection, any policy (otherwise offered by the issuer to individuals in the State) that meets the standards in the 1991 NAIC Model Regulation or 1991 Federal Regulation and other requirements of this section without reference to this subsection.

(2) If the Secretary determines that an issuer of a policy approved under paragraph (1)--

(A) fails substantially to provide medically necessary items and services to enrollees seeking such items and services through the issuer's network, if the failure has adversely affected (or has substantial likelihood of adversely affecting) the individual,

(B) imposes premiums on enrollees in excess of the premiums approved by the State,

(C) acts to expel an enrollee for reasons other than nonpayment of premiums, or

(D) does not provide the explanation required under paragraph (1)(E)(i) or does not obtain the acknowledgment required under paragraph (1)(E)(ii),

the issuer is subject to a civil money penalty in an amount not to exceed $ 25,000 for each such violation. The provisions of section 1128A [*42 USCS § 1320a-7a*] (other than the first sentence of subsection (a) and other than subsection (b)) shall apply to a civil money penalty under the previous sentence in the same manner as such provisions apply to a penalty or proceeding under section 1128A(a) [*42 USCS § 1320a-7a(a)*].

(3) The Secretary may enter into a contract with an entity whose policy has been certified under paragraph (1) or has been approved by a State under subsection (b)(1)(H) to determine whether items and services (furnished to individuals entitled to benefits under this *title [42 USCS §§ 1395* et seq.] and under that policy) are not allowable under section 1862(a)(1) [*42 USCS § 1395y(a)(1)*]. Payments to the entity shall be in such amounts as the Secretary may determine, taking into account estimated savings under contracts with carriers and fiscal intermediaries and other factors that the Secretary finds appropriate. Paragraph (1), the first sentence of paragraph (2)(A), paragraph (2)(B), paragraph (3)(C), paragraph (3)(D), and paragraph (3)(E) of section 1842(b) [*42 USCS § 1395u(b)*] shall apply to the entity.

(u) Additional rules relating to MSA plans and private fee-for-service plans.

(1) It is unlawful for a person to sell or issue a policy described in paragraph (2) to an individual with knowledge that the individual has in effect under section 1851 [*42 USCS § 1395w-21*] an election of an MSA plan or a Medicare + Choice private fee-for-service plan.

(2) (A) A policy described in this subparagraph is a health insurance policy (other than a policy described in subparagraph (B)) that provides for coverage of expenses that are otherwise required to be counted toward meeting the annual deductible amount provided under the MSA plan.

(B) A policy described in this subparagraph is any of the following:

(i) A policy that provides coverage (whether through insurance or otherwise) for accidents, disability, dental care, vision care, or long-term care.

(ii) A policy of insurance to which substantially all of the coverage relates to--

(I) liabilities incurred under workers' compensation laws,

(II) tort liabilities,

(III) liabilities relating to ownership or use of property, or

(IV) such other similar liabilities as the Secretary may specify by regulations.

(iii) A policy of insurance that provides coverage for a specified disease or illness.

(iv) A policy of insurance that pays a fixed amount per day (or other period) of hospitalization.

(v) Rules relating to medigap policies that provide prescription drug coverage.

(1) Prohibition on sale, issuance, and renewal of new policies that provide prescription drug coverage.

(A) In general. Notwithstanding any other provision of law, on or after January 1, 2006, a medigap Rx policy (as defined in paragraph (6)(A)) may not be sold, issued, or renewed under this section--

(i) to an individual who is a part D enrollee (as defined in paragraph (6)(B)); or

(ii) except as provided in subparagraph (B), to an individual who is not a part D enrollee.

(B) Continuation permitted for non-part D enrollees. Subparagraph (A)(ii) shall not apply to the renewal of a medigap Rx policy that was issued before January 1, 2006.

(C) Construction. Nothing in this subsection shall be construed as preventing the offering on and after January 1, 2006, of "H", "I", and "J" policies described in paragraph (2)(D)(i) if the benefit packages are modified in accordance with paragraph (2)(C).

(2) Elimination of duplicative coverage upon part D enrollment.

(A) In general. In the case of an individual who is covered under a medigap Rx policy and enrolls under a part D plan--

(i) before the end of the initial part D enrollment period, the individual may--

(I) enroll in a medicare supplemental policy without prescription drug coverage under paragraph (3); or

(II) continue the policy in effect subject to the modification described in subparagraph (C)(i); or

(ii) after the end of such period, the individual may continue the policy in effect subject to such modification.

(B) Notice required to be provided to current policyholders with medigap Rx policy. No medicare supplemental policy of an issuer shall be deemed to meet the standards in subsection (c) unless the issuer provides written notice (in accordance with standards of the Secretary established in consultation with the National Association of Insurance Commissioners) during the 60-day period immediately preceding the initial part D enrollment period, to each individual who is a policyholder or certificate holder of a medigap Rx policy (at the most recent available address of that individual) of the following:

(i) If the individual enrolls in a plan under part D [*42 USCS §§ 1395w-101* et seq.] during the initial enrollment period under section 1860D-1(b)(2)(A) [*42 USCS § 1395w-101(b)(2)(A)*], the individual has the option of--

(I) continuing enrollment in the individual's current plan, but the plan's coverage of prescription drugs will be modified under subparagraph (C)(i); or

(II) enrolling in another medicare supplemental policy pursuant to paragraph (3).

(ii) If the individual does not enroll in a plan under part D [*42 USCS §§ 1395w-101* et seq.] during such period, the individual may continue enrollment in the individual's current plan without change, but--

(I) the individual will not be guaranteed the option of enrollment in another medicare supplemental policy pursuant to paragraph (3); and

(II) if the current plan does not provide creditable prescription drug coverage (as defined in section 1860D-13(b)(4) [*42 USCS § 1395w-113(b)(4)*]), notice of such fact and that there are limitations on the periods in a year in which the individual may enroll under a part D plan and any such enrollment is subject to a late enrollment penalty.

(iii) Such other information as the Secretary may specify (in consultation with the National Association of Insurance Commissioners), including the potential impact of such election on premiums for medicare supplemental policies.

(C) Modification.

(i) In general. The policy modification described in this subparagraph is the elimination of prescription coverage for expenses of prescription drugs incurred after the effective date of the individual's coverage under a part D plan and the appropriate adjustment of premiums to reflect such elimination of coverage.

(ii) Continuation of renewability and application of modification. No medicare supplemental policy of an issuer shall be deemed to meet the standards in subsection (c) unless the issuer--

(I) continues renewability of medigap Rx policies that it has issued, subject to subclause (II); and

(II) applies the policy modification described in clause (i) in the cases described in clauses (i)(II) and (ii) of subparagraph (A).

(D) References to Rx policies.

(i) H, I, and J policies. Any reference to a benefit package classified as "H", "I", or "J" (including the benefit package classified as "J" with a high deductible feature, as described in subsection (p)(11)) under the standards established under subsection (p)(2) shall be construed as including a reference to such a package as modified under subparagraph (C) and such packages as modified shall not be counted as a separate benefit package under such subsection.

(ii) Application in waivered States. Except for the modification provided under subparagraph (C), the waivers previously in effect under subsection (p)(2) shall continue in effect.

(3) Availability of substitute policies with guaranteed issue.

(A) In general. The issuer of a medicare supplemental policy--

(i) may not deny or condition the issuance or effectiveness of a medicare supplemental policy that has a benefit package classified as "A", "B", "C", or "F" (including the benefit package classified as "F" with a high deductible feature, as described in subsection (p)(11)), under the standards established under subsection (p)(2), or a benefit package described in subparagraph (A) or (B) of subsection (w)(2) and that is offered and is available for issuance to new enrollees by such issuer;

(ii) may not discriminate in the pricing of such policy, because of health status, claims experience, receipt of health care, or medical condition; and

(iii) may not impose an exclusion of benefits based on a pre-existing condition under such policy,

in the case of an individual described in subparagraph (B) who seeks to enroll under the policy not later than 63 days after the effective date of the individual's coverage under a part D plan.

(B) Individual covered. An individual described in this subparagraph with respect to the issuer of a medicare supplemental policy is an individual who--

(i) enrolls in a part D plan during the initial part D enrollment period;

(ii) at the time of such enrollment was enrolled in a medigap Rx policy issued by such issuer; and

(iii) terminates enrollment in such policy and submits evidence of such termination along with the application for the policy under subparagraph (A).

(C) Special rule for waivered States. For purposes of applying this paragraph in the case of a State that provides for offering of benefit packages other than under the classification referred to in subparagraph (A)(i), the references to benefit packages in such subparagraph are deemed references to comparable benefit packages offered in such State.

(4) Enforcement.

(A) Penalties for duplication. The penalties described in subsection (d)(3)(A)(ii) shall apply with respect to a violation of paragraph (1)(A).

(B) Guaranteed issue. The provisions of paragraph (4) of subsection (s) shall apply with respect to the requirements of paragraph (3) in the same manner as they apply to the requirements of such subsection.

(5) Construction. Any provision in this section or in a medicare supplemental policy relating to guaranteed renewability of coverage shall be deemed to have been met with respect to a part D enrollee through the continuation of the policy subject to modification under paragraph (2)(C) or the offering of a substitute policy under paragraph (3). The previous sentence shall not be construed to affect the guaranteed renewability of such a modified or substitute policy.

(6) Definitions. For purposes of this subsection:

(A) Medigap Rx policy. The term "medigap Rx policy" means a medicare supplemental policy--

(i) which has a benefit package classified as "H", "I", or "J" (including the benefit package classified as "J" with a high deductible feature, as described in subsection (p)(11)) under the standards established under subsection (p)(2), without regard to this subsection; and

(ii) to which such standards do not apply (or to which such standards have been waived under subsection (p)(6)) but which provides benefits for prescription drugs.

Such term does not include a policy with a benefit package as classified under clause (i) which has been modified under paragraph (2)(C)(i).

(B) Part D enrollee. The term "part D enrollee" means an individual who is enrolled in a part D plan.

(C) Part D plan. The term "part D plan" means a prescription drug plan or an MA-PD plan (as defined for purposes of part D [*42 USCS §§ 1395w-101* et seq.]).

(D) Initial part D enrollment period. The term "initial part D enrollment period" means the initial enrollment period described in section 1860D-1(b)(2)(A) [*42 USCS § 1395w-101(b)(2)(A)*].

(w) Development of new standards for medicare supplemental policies.

(1) In general. The Secretary shall request the National Association of Insurance Commissioners to review and revise the standards for benefit packages under subsection (p)(1), taking into account the changes in benefits resulting from enactment of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 and to otherwise update standards to reflect other changes in law included in such Act. Such revision shall incorporate the inclusion of the 2 benefit packages described in paragraph (2). Such revisions shall be made consistent with the rules applicable under subsection (p)(1)(E) with the reference to the "1991 NAIC Model Regulation" deemed a reference to the NAIC Model Regulation as published in the Federal Register on December 4, 1998, and as subsequently updated by the National Association of Insurance Commissioners to reflect previous changes in law (and subsection (v)) and the reference to "date of enactment of this subsection" deemed a reference to the date of enactment of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 [enacted Dec. 8, 2003]. To the extent practicable, such revision shall provide for the implementation of revised standards for benefit packages as of January 1, 2006.

(2) New benefit packages. The benefit packages described in this paragraph are the following (notwithstanding any other provision of this section relating to a core benefit package):

(A) First new benefit package. A benefit package consisting of the following:

(i) Subject to clause (ii), coverage of 50 percent of the cost-sharing otherwise applicable under parts A and B, except there shall be no coverage of the part B deductible and coverage of 100 percent of any cost-sharing otherwise applicable for preventive benefits.

(ii) Coverage for all hospital inpatient coinsurance and 365 extra lifetime days of coverage of inpatient hospital services (as in the current core benefit package).

(iii) A limitation on annual out-of-pocket expenditures under parts A and B to $ 4,000 in 2006 (or, in a subsequent year, to such limitation for the previous year increased by an appropriate inflation adjustment specified by the Secretary).

(B) Second new benefit package. A benefit package consisting of the benefit package described in subparagraph (A), except as follows:

(i) Substitute "75 percent" for "50 percent" in clause (i) of such subparagraph.

(ii) Substitute "$ 2,000" for "$ 4,000" in clause (iii) of such subparagraph.

(x) Limitations on genetic testing and information [Caution: This subsection is applicable for policy years beginning on or after 5/21/2009, as provided by § 104(c) of Act May 21, 2008, P.L. 110-233, which appears as a note to this section.].

(1) Genetic testing.

(A) Limitation on requesting or requiring genetic testing. An issuer of a medicare supplemental policy shall not request or require an individual or a family member of such individual to undergo a genetic test.

(B) Rule of construction. Subparagraph (A) shall not be construed to limit the authority of a health care professional who is providing health care services to an individual to request that such individual undergo a genetic test.

(C) Rule of construction regarding payment.

(i) In general. Nothing in subparagraph (A) shall be construed to preclude an issuer of a medicare supplemental policy from obtaining and using the results of a genetic test in making a determination regarding payment (as such term is defined for the purposes of applying the regulations promulgated by the Secretary under part C of title XI [*42 USCS §§ 1320d* et seq.] and *section 264* of the Health Insurance Portability and Accountability Act of 1996 [*42 USCS § 1320d-2* note], as may be revised from time to time) consistent with subsection (s)(2)(E).

(ii) Limitation. For purposes of clause (i), an issuer of a medicare supplemental policy may request only the minimum amount of information necessary to accomplish the intended purpose.

(D) Research exception. Notwithstanding subparagraph (A), an issuer of a medicare supplemental policy may request, but not require, that an individual or a family member of such individual undergo a genetic test if each of the following conditions is met:

(i) The request is made pursuant to research that complies with part 46 of title 45, Code of Federal Regulations, or equivalent Federal regulations, and any applicable State or local law or regulations for the protection of human subjects in research.

(ii) The issuer clearly indicates to each individual, or in the case of a minor child, to the legal guardian of such child, to whom the request is made that--

(I) compliance with the request is voluntary; and

(II) non-compliance will have no effect on enrollment status or premium or contribution amounts.

(iii) No genetic information collected or acquired under this subparagraph shall be used for underwriting, determination of eligibility to enroll or maintain enrollment status, premium rating, or the creation, renewal, or replacement of a plan, contract, or coverage for health insurance or health benefits.

(iv) The issuer notifies the Secretary in writing that the issuer is conducting activities pursuant to the exception provided for under this subparagraph, including a description of the activities conducted.

(v) The issuer complies with such other conditions as the Secretary may by regulation require for activities conducted under this subparagraph.

(2) Prohibition on collection of genetic information.

(A) In general. An issuer of a medicare supplemental policy shall not request, require, or purchase genetic information for underwriting purposes (as defined in paragraph (3)).

(B) Prohibition on collection of genetic information prior to enrollment. An issuer of a medicare supplemental policy shall not request, require, or purchase genetic information with respect to any individual prior to such individual's enrollment under the policy in connection with such enrollment.

(C) Incidental collection. If an issuer of a medicare supplemental policy obtains genetic information incidental to the requesting, requiring, or purchasing of other information concerning any individual, such request, requirement, or purchase shall not be considered a violation of subparagraph (B) if such request, requirement, or purchase is not in violation of subparagraph (A).

(3) Definitions. In this subsection:

(A) Family member. The term "family member" means with respect to an individual, any other individual who is a first-degree, second-degree, third-degree, or fourth-degree relative of such individual.

(B) Genetic information.

(i) In general. The term "genetic information" means, with respect to any individual, information about--

(I) such individual's genetic tests,

(II) the genetic tests of family members of such individual, and

(III) subject to clause (iv), the manifestation of a disease or disorder in family members of such individual.

(ii) Inclusion of genetic services and participation in genetic research. Such term includes, with respect to any individual, any request for, or receipt of, genetic services, or participation in clinical research which includes genetic services, by such individual or any family member of such individual.

(iii) Exclusions. The term "genetic information" shall not include information about the sex or age of any individual.

(C) Genetic test.

(i) In general. The term "genetic test" means an analysis of human DNA, RNA, chromosomes, proteins, or metabolites, that detects genotypes, mutations, or chromosomal changes.

(ii) Exceptions. The term "genetic test" does not mean--

(I) an analysis of proteins or metabolites that does not detect genotypes, mutations, or chromosomal changes; or

(II) an analysis of proteins or metabolites that is directly related to a manifested disease, disorder, or pathological condition that could reasonably be detected by a health care professional with appropriate training and expertise in the field of medicine involved.

(D) Genetic services. The term "genetic services" means--

(i) a genetic test;

(ii) genetic counseling (including obtaining, interpreting, or assessing genetic information); or

(iii) genetic education.

(E) Underwriting purposes. The term "underwriting purposes" means, with respect to a medicare supplemental policy--

(i) rules for, or determination of, eligibility (including enrollment and continued eligibility) for benefits under the policy;

(ii) the computation of premium or contribution amounts under the policy;

(iii) the application of any pre-existing condition exclusion under the policy; and

(iv) other activities related to the creation, renewal, or replacement of a contract of health insurance or health benefits.

(F) Issuer of a medicare supplemental policy. The term "issuer of a medicare supplemental policy" includes a third-party administrator or other person acting for or on behalf of such issuer.

(4) Genetic information of a fetus or embryo. Any reference in this section to genetic information concerning an individual or family member of an individual shall--

(A) with respect to such an individual or family member of an individual who is a pregnant woman, include genetic information of any fetus carried by such pregnant woman; and

(B) with respect to an individual or family member utilizing an assisted reproductive technology, include genetic information of any embryo legally held by the individual or family member.

HISTORY:

(Aug. 14, 1935, ch 531, Title XVIII, Part E[D][C], § 1882, as added June 9, 1980, P.L. 96-265, Title V, § 507(a), 94 Stat. 476; Aug. 18, 1987, P.L. 100-93, § 13, 101 Stat. 697; Dec. 22, 1987, P.L. 100-203, Title IV, Subtitle A, Part 3, Subpt. D, § 4081(b), 101 Stat. 1330-126; July 1, 1988, P.L. 100-360, Title II, Subtitle C, § 221(a)-(f) Title IV, Subtitle B, § 411(i)(1)(B), (C), Subtitle C, § 428(b), 102 Stat. 742, 788, 817; Dec. 13, 1989, P.L. 101-234, Title II, § 203(a), 103 Stat. 1981; Nov. 5, 1990, P.L. 101-508, Title IV, Subtitle B, Part 4, § 4207(k)(1), Part 5, §§ 4351-4353(d)(1), 4354(a), (b), 4355(a)-(c), 4356(a), 4357(a), 4358(a), (b)(1), (2), 104 Stat. 1388-124, 1388-125-1388-137; Oct. 31, 1994, P.L. 103-432, Title I, Subtitle C, § 160(d)(4), Subtitle D, § 171(a)-(d)(3)(B), (4), (e)(1), (2), (f)(1), (g), (h)(1), (j)(2), (k), 108 Stat. 4444, 4448, 4449, 4451; Aug. 21, 1996, P.L. 104-191, Title II, Subtitle G, § 271(a), (b), 110 Stat. 2034; Aug. 5, 1997, P.L. 105-33, Title IV, Subtitle A, Ch 1, Subch A, §§ 4001, 4002(j)(2), 4003, Ch 4, §§ 4031(a)-(c), 4032(a), 111 Stat. 275, 330, 355, 359; Nov. 10, 1998, P.L. 105-362, Title VI, § 601(b)(6), 112 Stat. 3286; Nov. 29, 1999, P.L. 106-113, Div B, § 1000(a)(6), 113 Stat. 1536; Dec. 17, 1999, P.L. 106-170, Title II, § 205(a), 113 Stat. 1899; Dec. 21, 2000, P.L. 106-554, § 1(a)(6), 114 Stat. 2763; Dec. 8, 2003, P.L. 108-173, Title I, §§ 101(a)(1), 104(a), (b), Title VII, Subtitle D, § 736(e), 117 Stat. 2071, 2161, 2357; Dec. 26, 2007, P.L. 110-161, Div H, Title I, § 1502(f), 121 Stat. 2250; May 21, 2008, P.L. 110-233, Title I, § 104(a), (b), 122 Stat. 899; July 15, 2008, P.L. 110-275, Title I, Subtitle A, Part I, § 104(b), 122 Stat. 2502.)

§ 1395ss-1. Applicability of section 1882 [42 USCS § 1395ss]

Any health insurance policy that provides reimbursement for expenses incurred for items and services for which payment may be made under title XVIII of the Social Security Act [*42 USCS §§ 1395* et seq.] but which are not reimbursable by reason of the applicability of deductibles, coinsurance, copayments or other limitations imposed by a Medicare Advantage plan (including a Medicare Advantage private fee-for-service plan) under part C of such *title [42 USCS §§ 1395w-21* et seq.] shall comply with the requirements of section 1882(o) of [the] such Act (*42 U.S.C. 1395ss(o)*).

HISTORY:

(July 15, 2008, P.L. 110-275, Title I, Subtitle A, Part I, § 104(c), 122 Stat. 2502.)

§ 1395tt. Hospital providers of extended care services

(a) Hospital facility agreements; reasonable costs of services.

(1) Any hospital which has an agreement under section 1866 [*42 USCS § 1395cc*] may (subject to subsection (b)) enter into an agreement with the Secretary under which its inpatient hospital facilities may be used for the furnishing of services of the type which, if furnished by a skilled nursing facility, would constitute extended care services.

(2) (A) Notwithstanding any other provision of this *title [42 USCS §§ 1395* et seq.], payment to any hospital (other than a critical access hospital) for services furnished under an agreement entered into under this section shall be based upon the reasonable cost of the services as determined under subparagraph (B).

(B) (i) The reasonable cost of the services consists of the reasonable cost of routine services (determined under clause (ii)) and the reasonable cost of ancillary services (determined under clause (iii)).

(ii) The reasonable cost of routine services furnished during any calendar year by a hospital under an agreement under this section is equal to the product of--

(I) the number of patient-days during the year for which the services were furnished, and

(II) the average reasonable cost per patient-day, such average reasonable cost per patient-day being the average rate per patient-day paid for routine services during the most recent year for which cost reporting data are available with respect to such services (increased in a compounded manner by the applicable increase for payments for routine service costs of skilled nursing facilities under subsections (a) through (d) of section 1888 [*42 USCS § 1395yy(a)*-(d)] for subsequent cost reporting periods and up to and including such calendar year) under this *title [42 USCS §§ 1395* et seq.] to freestanding skilled nursing facilities in the region (as defined in section 1886(d)(2)(D) [*42 USCS § 1395ww(d)(2)(D)*]) in which the facility is located.

(iii) The reasonable cost of ancillary services shall be determined in the same manner as the reasonable cost of ancillary services provided for inpatient hospital services.

(3) Notwithstanding any other provision of this title, a critical access hospital shall be paid for covered skilled nursing facility services furnished under an agreement entered into under this section on the basis of [equal to] 101 percent of the reasonable costs of such services (as determined under section 1861(v) [*42 USCS § 1395x(v)*]).

(b) Eligible facilities. The Secretary may not enter into an agreement under this section with any hospital unless, except as provided under subsection (g), the hospital is located in a rural area and has less than 100 beds.

(c) Terms and conditions of facility agreements. An agreement with a hospital under this section shall, except as otherwise provided under regulations of the Secretary, be of the same duration and subject to termination on the same conditions as are agreements with skilled nursing facilities under section 1866 [*42 USCS § 1395cc*] and shall, where not inconsistent with any provision of this section, impose the same duties, responsibilities, conditions, and limitations, as those imposed under such agreements entered into under section 1866 [*42 USCS § 1395cc*]; except that no such agreement with any hospital shall be in effect for any period during which the hospital does not have in effect an agreement under section 1866 [*42 USCS § 1395cc*]. A hospital with respect to which an agreement under this section has been terminated shall not be eligible to enter into a new agreement until a two-year period has elapsed from the termination date.

(d) Post-hospital extended care services. Any agreement with a hospital under this section shall provide that payment for services will be made only for services for which payment would be made as post-hospital extended care services if those services had been furnished by a skilled nursing facility under an agreement entered into under section 1866 [*42 USCS § 1395cc*]; and any individual who is furnished services, for which payment may be made under an agreement under this section, shall, for purposes of this *title [42 USCS §§ 1395* et seq.] (other than this section), be deemed to have

received post-hospital extended care services in like manner and to the same extent as if the services furnished to him had been post-hospital extended care services furnished by a skilled nursing facility under an agreement under section 1866 [*42 USCS § 1395cc*].

(e) Reimbursement for routine hospital services. During a period for which a hospital has in effect an agreement under this section, in order to allocate routine costs between hospital and long-term care services for purposes of determining payment for inpatient hospital services, the total reimbursement due for routine services from all classes of long-term care patients (including title XVIII, title XIX [*42 USCS §§ 1395* et seq., *1396* et seq.], and private pay patients) shall be subtracted from the hospital's total routine costs before calculations are made to determine title XVIII [*42 USCS §§ 1395* et seq.] reimbursement for routine hospital services.

(f) Conditions applicable to skilled nursing facilities. A hospital which enters into an agreement with the Secretary under this section shall be required to meet those conditions applicable to skilled nursing facilities relating to discharge planning and the social services function (and staffing requirements to satisfy it) which are promulgated by the Secretary under section 1819 [*42 USCS § 1395i-3*]. Services furnished by such a hospital which would otherwise constitute post-hospital extended care services if furnished by a skilled nursing facility shall be subject to the same requirements applicable to such services when furnished by a skilled nursing facility except for those requirements the Secretary determines are inappropriate in the case of these services being furnished by a hospital under this section.

(g) Agreements on demonstration basis. The Secretary may enter into an agreement under this section on a demonstration basis with any hospital which does not meet the requirement of subsection (b)(1), if the hospital otherwise meets the requirements of this section.

HISTORY:

(Act Aug. 14, 1935, ch 531, Title XVIII, Part E[D][C], § 1883, as added Dec. 5, 1980, P.L. 96-499, Title IX, Part A, Subpart I, § 904(a), 94 Stat. 2615; Dec. 22, 1987, P.L. 100-203, Title IV, Subtitle A, Part 1, § 4005(b)(1), (2), Subtitle C, Part 2, § 4201(d)(3) 101 Stat. 1330-48; July 1, 1988, P.L. 100-360, Title I, Subtitle A, § 104(d), Title IV, Subtitle B, § 411(b)(4)(D), (l)(1)(C) 102 Stat. 689, 770; Oct. 13, 1988, P.L. 100-485, Title VI, § 608(d)(27)(B), 102 Stat. 2422; Dec. 13, 1989, P.L. 101-234, Title I, § 101(a)(1), 103 Stat. 1979; Nov. 5, 1990, P.L. 101-508, Title IV, Subtitle A, Part 1, § 4008(j)(1), 104 Stat. 1388-51; Aug. 5, 1997, P.L. 105-33, Title IV, Subtitle A, Ch 1, Subch A, § 4001, Subtitle D, Ch 3, § 4432(b)(5)(G), 111 Stat. 275, 422; Nov. 29, 1999, P.L. 106-113, Div B, § 1000(a)(6), 113 Stat. 1536; Dec. 21, 2000, P.L. 106-554, § 1(a)(6), 114 Stat. 2763; Dec. 8, 2003, P.L. 108-173, Title I, § 101(a)(1), Title IV, Subtitle A, § 405(a)(1), 117 Stat. 2071, 2266.)

§ 1395uu. Payments to promote closing or conversion of underutilized hospital facilities

(a) Transitional allowances; procedures applicable. Any hospital may file an application with the Secretary (in such form and including such data and information as the Secretary may require) for establishment of a transitional allowance under this *title [42 USCS §§ 1395* et seq.] with respect to the closing or conversion of an underutilized hospital facility. The Secretary also may establish procedures, consistent with this section, by which a hospital, before undergoing an actual closure or conversion of a hospital facility, can have a determination made as to whether or not it will be eligible for a transitional allowance under this section with respect to such closure or conversion.

(b) Allowable costs as transitional allowances; findings and determinations. If the Secretary finds, after consideration of an application under subsection (a), that--

(1) the hospital's closure or conversion--

(A) is formally initiated after September 30, 1981,

(B) is expected to benefit the program under this *title [42 USCS §§ 1395* et seq.] by (i) eliminating excess bed capacity, (ii) discontinuing an underutilized service for which there are adequate alternative sources, or (iii) substituting for the underutilized service some other service which is needed in the area, and

(C) is consistent with the findings of an appropriate health planning agency and with any applicable State program for reduction in the number of hospital beds in the State, and

(2) in the case of a complete closure of a hospital--

(A) the hospital is a private nonprofit hospital or a local governmental hospital, and

(B) the closure is not for replacement of the hospital,

the Secretary may include as an allowable cost in the hospital's reasonable cost (for the purpose of making payments to the hospital under this *title [42 USCS §§ 1395* et seq.]) an amount (in this section referred to as a "transitional allowance"), as provided in subsection (c).

(c) Factors determinative of transitional allowance.

(1) Each transitional allowance established shall be reasonably related to the prior or prospective use of the facility involved under this *title [42 USCS §§ 1395* et seq.] and shall recognize--

(A) in the case of a facility conversion or closure (other than a complete closure of a hospital)--

(i) in the case of a private nonprofit or local governmental hospital, that portion of the hospital's costs attributable to capital assets of the facility which have been taken into account in determining reasonable cost for purposes of determining the amount of payment of the hospital under this *title [42 USCS §§ 1395* et seq.], and

(ii) in the case of any hospital, transitional operating cost increases related to the conversion or closure to the extent that such operating costs exceed amounts ordinarily reimbursable under this *title [42 USCS §§ 1395* et seq.]; and

(B) in the case of complete closure of a hospital, the outstanding portion of actual debt obligations previously recognized as reasonable for purposes of reimbursement under this *title [42 USCS §§ 1395* et seq.], less any salvage value of the hospital.

(2) A transitional allowance shall be for a period (not to exceed 20 years) specified by the Secretary, except that, in the case of a complete closure described in paragraph (1)(B), the Secretary may provide for a lump-sum allowance where the Secretary determines that such a one-time allowance is more efficient and economical.

(3) A transitional allowance shall take effect on a date established by the Secretary, but not earlier than the date of completion of the closure or conversion concerned.

(4) A transitional allowance shall not be considered in applying the limits to costs recognized as reasonable pursuant to the third sentence of subparagraph (A) and subparagraph (L)(i) of section 1861(v)(1) of this Act [*42 USCS § 1395x(v)(1)*], or in determining whether the reasonable cost exceeds the customary charges for a service for purposes of determining the amount to be paid to a provider pursuant to sections 1814(b) and 1833(a)(2) of this Act [*42 USCS §§ 1395f(b)* and *1395l(a)(2)*].

(d) Hearing to review determination. A hospital dissatisfied with a determination of the Secretary on its application under this section may obtain an informal or formal hearing, at the discretion of the Secretary, by filing (in such form and within such time period as the Secretary establishes) a request for such a hearing. The Secretary shall make a final determination on such application within 30 days after the last day of such hearing.

HISTORY:

(Act Aug. 14, 1935, ch 531, Title XVIII, Part E[D][C], § 1884, as added Aug. 13, 1981, P.L. 97-35, Title XXI, Subtitle A, Ch 1, § 2101(a)(1), 95 Stat. 785; Sept. 3, 1982, P.L. 97-248, Title I, Subtitle A, Part III, § 128(a)(6), 96 Stat. 366; Aug. 5, 1997, P.L. 105-33, Title IV, Subtitle A, Ch 1, Subch A, § 4001, 111 Stat. 275.)

§ 1395vv. Withholding payments from certain medicaid providers

(a) Adjustments by Secretary. The Secretary may adjust, in accordance with this section, payments under parts A and B [*42 USCS §§ 1395c* et seq. and *1395j* et seq.] to any institution which has in effect an agreement with the Secretary under section 1866 [*42 USCS § 1395cc*], and any person who has accepted payment on the basis of an assignment under section 1842(b)(3)(B)(ii) [*42 USCS § 1395u(b)(3)(B)(ii)*] where such institution or person--

(1) has (or previously had) in effect an agreement with a State agency to furnish medical care and services under a State plan approved under title XIX [*42 USCS §§ 1396* et seq.], and

(2) from which (or from whom) such State agency (A) has been unable to recover overpayments made under the State plan, or (B) has been unable to collect the information necessary to enable it to determine the amount (if any) of the overpayments made to such institution or person under the State plan.

(b) Implementing regulations; notice, opportunity to be heard, etc. The Secretary shall by regulation provide procedures for implementation of this section, which procedures shall--

(1) assure that the authority under this section is exercised only on behalf of a State agency which demonstrates to the Secretary's satisfaction that it has provided adequate notice of a determination or of a need for information, and an opportunity to appeal such determination or to provide such information,

(2) determine the amount of the payment to which the institution or person would otherwise be entitled under this *title [42 USCS §§ 1395* et seq.] which shall be treated as a setoff against overpayments under title XIX [*42 USCS §§ 1396* et seq.], and

(3) assure the restoration to the institution or person of amounts withheld under this section which are ultimately determined to be in excess of overpayments under title XIX [*42 USCS §§ 1396* et seq.] and to which the institution or person would otherwise be entitled under this *title [42 USCS §§ 1395* et seq.].

(c) Payment to States of amounts recovered. Notwithstanding any other provision of this Act, from the trust funds established under sections 1817 and 1841 [*42 USCS §§ 1395i* and *1395t*], as appropriate, the Secretary shall pay to the appropriate State agency amounts recovered under this section to offset the State agency's overpayment under title XIX [*42 USCS §§ 1395* et seq.]. Such payments shall be accounted for by the State agency as recoveries of overpayments under the State plan.

HISTORY:

(Aug. 14, 1935, ch 531, Title XVIII, Part E[D][C], § 1885, as added Aug. 13, 1981, P.L. 97-35, Title XXI, Subtitle A, Ch 1, § 2104, 95 Stat. 788; Aug. 5, 1997, P.L. 105-33, Title IV, Subtitle A, Ch 1, Subch A, § 4001, 111 Stat. 275; Dec. 8, 2003, P.L. 108-173, Title I, § 101(a)(1), 117 Stat. 2071.)

§ 1395ww. Payments to hospitals for inpatient hospital services

(a) Determination of costs for inpatient hospital services; limitations; exemptions; "operating costs of inpatient hospital services" defined.

(1) (A) (i) The Secretary, in determining the amount of the payments that may be made under this *title [42 USCS §§ 1395* et seq.] with respect to operating costs of inpatient hospital services (as defined in paragraph (4)) shall not recognize as reasonable (in the efficient delivery of health services) costs for the provision of such services by a hospital for a cost reporting period to the extent such costs exceed the applicable percentage (as determined under clause (ii)) of the average of such costs for all hospitals in the same grouping as such hospital for comparable time periods.

(ii) For purposes of clause (i), the applicable percentage for hospital cost reporting periods beginning--

(I) on or after October 1, 1982, and before October 1, 1983, is 120 percent;

(II) on or after October 1, 1983, and before October 1, 1984, is 115 percent; and

(III) on or after October 1, 1984, is 110 percent.

(B) (i) For purposes of subparagraph (A) the Secretary shall establish case mix indexes for all short-term hospitals, and shall set limits for each hospital based upon the general mix of types of medical cases with respect to which such hospital provides services for which payment may be made under this *title [42 USCS §§ 1395* et seq.].

(ii) The Secretary shall set such limits for a cost reporting period of a hospital--

(I) by updating available data for a previous period to the immediate preceding cost reporting period by the estimated average rate of change of hospital costs industry-wide, and

(II) by projecting for the cost reporting period by the applicable percentage increase (as defined in subsection (b)(3)(B)).

(C) The limitation established under subparagraph (A) for any hospital shall in no event be lower than the allowable operating costs of inpatient hospital services (as defined in paragraph (4)) recognized under this *title [42 USCS §§ 1395* et seq.] for such hospital for such hospital's last cost reporting period prior to the hospital's first cost reporting period for which this section is in effect.

(D) Subparagraph (A) shall not apply to cost reporting periods beginning on or after October 1, 1983.

(2) The Secretary shall provide for such exemptions from, and exceptions and adjustments to, the limitation established under paragraph (1)(A) as he deems appropriate, including those which he deems necessary to take into account--

(A) the special needs of sole community hospitals, of new hospitals, of risk based health maintenance organizations, and of hospitals which provide atypical services or essential community services, and to take into account extraordinary circumstances beyond the hospital's control, medical and paramedical education costs, significantly fluctuating population in the service area of the hospital, and unusual labor costs,

(B) the special needs of psychiatric hospitals and of public or other hospitals that serve a significantly disproportionate number of patients who have low income or are entitled to benefits under part A of this *title [42 USCS §§ 1395c* et seq.], and

(C) a decrease in the inpatient hospital services that a hospital provides and that are customarily provided directly by similar hospitals which results in a significant distortion in the operating costs of inpatient hospital services.

(3) The limitation established under paragraph (1)(A) shall not apply with respect to any hospital which--

(A) is located outside of a standard metropolitan statistical area, and

(B) (i) has less than 50 beds, and

(ii) was in operation and had less than 50 beds on the date of the enactment of this section [enacted Sept. 3, 1982].

(4) For purposes of this section, the term "operating costs of inpatient hospital services" includes all routine operating costs, ancillary service operating costs, and special care unit operating costs with respect to inpatient hospital services as such costs are determined on an average per admission or per discharge basis (as determined by the Secretary), and includes the costs of all services for which payment may be made under this *title [42 USCS §§ 1395* et seq.] that are provided by the hospital (or by an entity wholly owned or operated by the hospital) to the patient during the 3 days (or, in the case of a hospital that is not a subsection (d) hospital, during the 1 day) immediately preceding the date of the patient's admission if such services are diagnostic services (including clinical diagnostic laboratory tests) or are other services related to the admission (as defined by the Secretary). Such term does not include costs of approved educational activities, a return on equity capital, other capital-related costs (as defined by the Secretary for periods before October 1, 1987), or costs with respect to administering blood clotting factors to individuals with hemophilia.

(b) Computation of payment; definition; exemptions; adjustments.

(1) Notwithstanding section 1814(b) [*42 USCS § 1395f(b)*] but subject to the provisions of section 1813 [*42 USCS § 1395e*], if the operating costs of inpatient hospital services (as defined in subsection (a)(4)) of a hospital (other than a subsection (d) hospital, as defined in subsection (d)(1)(B) and other than a rehabilitation facility described in subsection (j)(1)) for a cost reporting period subject to this paragraph--

(A) are less than or equal to the target amount (as defined in paragraph (3)) for that hospital for that period, the amount of the payment with respect to such operating costs payable under part A [*42 USCS §§ 1395c* et seq.] on a per discharge or per admission basis (as the case may be) shall be equal to the amount of such operating costs, plus--

(i) 15 percent of the amount by which the target amount exceeds the amount of the operating costs, or

(ii) 2 percent of the target amount,

whichever is less;

(B) are greater than the target amount but do not exceed 110 percent of the target amount, the amount of the payment with respect to those operating costs payable under part A [*42 USCS §§ 1395c* et seq.] on a per discharge basis shall equal the target amount; or

(C) are greater than 110 percent of the target amount, the amount of the payment with respect to such operating costs payable under part A [*42 USCS §§ 1395c* et seq.] on a per discharge or per admission basis (as the case may be) shall be equal to (i) the target amount, plus (ii) in the case of cost reporting periods beginning on or after October 1, 1991, an additional amount equal to 50 percent of the amount by which the operating costs exceed 110 percent of the target amount (except that such additional amount may not exceed 10 percent of the target amount) after any exceptions or adjustments are made to such target amount for the cost reporting period;

plus the amount, if any, provided under paragraph (2), except that in no case may the amount payable under this *title [42 USCS §§ 1395* et seq.] (other than on the basis of a DRG prospective payment rate determined under subsection (d)) with respect to operating costs of inpatient hospital services exceed the maximum amount payable with respect to such costs pursuant to subsection (a).

(2) (A) Except as provided in subparagraph (E), in addition to the payment computed under paragraph (1), in the case of an eligible hospital (described in subparagraph (B)) for a cost reporting period beginning on or after October 1, 1997, the amount of payment on a per discharge basis under paragraph (1) shall be increased by the lesser of--

(i) 50 percent of the amount by which the operating costs are less than the expected costs (as defined in subparagraph (D)) for the period; or

(ii) 1 percent of the target amount for the period.

(B) For purposes of this paragraph, an "eligible hospital" means with respect to a cost reporting period, a hospital--

(i) that has received payments under this subsection for at least 3 full cost reporting periods before that cost reporting period, and

(ii) whose operating costs for the period are less than the least of its target amount, its trended costs (as defined in subparagraph (C)), or its expected costs (as defined in subparagraph (D)) for the period.

(C) For purposes of subparagraph (B)(ii), the term "trended costs" means for a hospital cost reporting period ending in a fiscal year--

(i) in the case of a hospital for which its cost reporting period ending in fiscal year 1996 was its third or subsequent full cost reporting period for which it receives payments under this subsection, the lesser of the operating costs or target amount for that hospital for its cost reporting period ending in fiscal year 1996, or

(ii) in the case of any other hospital, the operating costs for that hospital for its third full cost reporting period for which it receives payments under this subsection,

increased (in a compounded manner) for each succeeding fiscal year (through the fiscal year involved) by the market basket percentage increase for the fiscal year.

(D) For purposes of this paragraph, the term "expected costs", with respect to the cost reporting period ending in a fiscal year, means the lesser of the operating costs of inpatient hospital services or target amount per discharge for the

previous cost reporting period updated by the market basket percentage increase (as defined in paragraph (3)(B)(iii)) for the fiscal year.

(E)

(i) In the case of an eligible hospital that is a hospital or unit that is within a class of hospital described in clause (ii) with a 12-month cost reporting period beginning before the enactment of this subparagraph [enacted Nov. 29, 1999], in determining the amount of the increase under subparagraph (A), the Secretary shall substitute for the percentage of the target amount applicable under subparagraph (A)(ii)--

(I) for a cost reporting period beginning on or after October 1, 2000, and before September 30, 2001, 1.5 percent; and

(II) for a cost reporting period beginning on or after October 1, 2001, and before September 30, 2002, 2 percent.

(ii) For purposes of clause (i), each of the following shall be treated as a separate class of hospital:

(I) Hospitals described in clause (i) of subsection (d)(1)(B) and psychiatric units described in the matter following clause (v) of such subsection.

(II) Hospitals described in clause (iv) of such subsection.

(3)

(A) Except as provided in subparagraph (C) and succeeding subparagraphs, and in paragraph (7)(A)(ii), for purposes of this subsection, the term "target amount" means, with respect to a hospital for a particular 12-month cost reporting period--

(i) in the case of the first such reporting period for which this subsection is in effect, the allowable operating costs of inpatient hospital services (as defined in subsection (a)(4)) recognized under this *title [42 USCS §§ 1395* et seq.] for such hospital for the preceding 12-month cost reporting period, and

(ii) in the case of a later reporting period, the target amount for the preceding 12-month cost reporting period, increased by the applicable percentage increase under subparagraph (B) for that particular cost reporting period.

(B) (i) For purposes of subsection (d) and subsection (j) for discharges occurring during a fiscal year, the "applicable percentage increase" shall be--

(I) for fiscal year 1986, 1/2 percent,

(II) for fiscal year 1987, 1.15 percent, and

(III) for fiscal year 1988, 3.0 percent for hospitals located in a rural area, 1.5 percent for hospitals located in a large urban area (as defined in subsection (d)(2)(D)), and 1.0 percent for hospitals located in other urban areas.

(IV) for fiscal year 1989, the market basket percentage increase minus 1.5 percentage points for hospitals located in a rural area, the market basket percentage increase minus 2.0 percentage points for hospitals located in a large urban area, and the market basket percentage increase minus 2.5 percentage points for hospitals located in other urban areas,

(V) for fiscal year 1990, the market basket percentage increase plus 4.22 percentage points for hospitals located in a rural area, the market basket percentage increase plus 0.12 percentage points for hospitals located in a large urban area, and the market basket percentage increase minus 0.53 percentage points for hospitals located in other urban areas,

(VI) for fiscal year 1991, the market basket percentage increase minus 2.0 percentage points for hospitals in a large urban or other urban area, and the market basket percentage increase minus 0.7 percentage point for hospitals located in a rural area,

(VII) for fiscal year 1992, the market basket percentage increase minus 1.6 percentage points for hospitals in a large urban or other urban area, and the market basket percentage increase minus 0.6 percentage point for hospitals located in a rural area,

(VIII) for fiscal year 1993, the market basket percentage increase minus 1.55 percentage point for hospitals in a large urban or other urban area, and the market basket percentage increase minus 0.55 [percentage point] for hospitals located in a rural area,

(IX) for fiscal year 1994, the market basket percentage increase minus 2.5 percentage points for hospitals located in a large urban or other urban area, and the market basket percentage increase minus 1.0 percentage point for hospitals located in a rural area,

(X) for fiscal year 1995, the market basket percentage increase minus 2.5 percentage points for hospitals located in a large urban or other urban area, and such percentage increase for hospitals located in a rural area as will provide for the average standardized amount determined under subsection (d)(3)(A) for hospitals located in a rural area being equal to such average standardized amount for hospitals located in an urban area (other than a large urban area),

(XI) for fiscal year 1996, the market basket percentage increase minus 2.0 percentage points for hospitals in all areas,

(XII) for fiscal year 1997, the market basket percentage increase minus 0.5 percentage point for hospitals in all areas,

(XIII) for fiscal year 1998, 0 percent,

(XIV) for fiscal year 1999, the market basket percentage increase minus 1.9 percentage points for hospitals in all areas,

(XV) for fiscal year 2000, the market basket percentage increase minus 1.8 percentage points for hospitals in all areas,

(XVI) for fiscal year 2001, the market basket percentage increase for hospitals in all areas,

(XVII) for fiscal year 2002, the market basket percentage increase minus 0.55 percentage points for hospitals in all areas,

(XVIII) for fiscal year 2003, the market basket percentage increase minus 0.55 percentage points for hospitals in all areas,

(XIX) for each of fiscal years 2004 through 2006, subject to clause (vii), the market basket percentage increase for hospitals in all areas;[,] and

(XX) for each subsequent fiscal year, subject to clause (viii), the market basket percentage increase for hospitals in all areas.

(ii) For purposes of subparagraphs (A) and (E), the "applicable percentage increase" for 12-month cost reporting periods beginning during--

(I) fiscal year 1986, is 0.5 percent,

(II) fiscal year 1987, is 1.15 percent,

(III) fiscal year 1988, is the market basket percentage increase minus 2.0 percentage points,

(IV) a subsequent fiscal year ending on or before September 30, 1993, is the market basket percentage increase,

(V) fiscal years 1994 through 1997, is the market basket percentage increase minus the applicable reduction (as defined in clause (v)(II)), or in the case of a hospital for a fiscal year for which the hospital's update adjustment percentage (as defined in clause (v)(I)) is at least 10 percent, the market basket percentage increase,

(VI) [for] fiscal year 1998, is 0 percent,

(VII) [for] fiscal years 1999 through 2002, is the applicable update factor specified under clause (vi) for the fiscal year, and

(VIII) subsequent fiscal years is the market basket percentage increase.

(iii) For purposes of this subparagraph, the term "market basket percentage increase" means, with respect to cost reporting periods and discharges occurring in a fiscal year, the percentage, estimated by the Secretary before the beginning of the period or fiscal year, by which the cost of the mix of goods and services (including personnel costs but excluding nonoperating costs) comprising routine, ancillary, and special care unit inpatient hospital services, based on an index of appropriately weighted indicators of changes in wages and prices which are representative of the mix of goods and services included in such inpatient hospital services, for the period or fiscal year will exceed the cost of such mix of goods and services for the preceding 12-month cost reporting period or fiscal year.

(iv) For purposes of subparagraphs (C) and (D), the "applicable percentage increase" is--

(I) for 12-month cost reporting periods beginning during fiscal years 1986 through 1993, the applicable percentage increase specified in clause (ii),

(II) for fiscal year 1994, the market basket percentage increase minus 2.3 percentage points (adjusted to exclude any portion of a cost reporting period beginning during fiscal year 1993 for which the applicable percentage increase is determined under subparagraph (I)),

(III) for fiscal year 1995, the market basket percentage increase minus 2.2 percentage points, and

(IV) for fiscal year 1996 and each subsequent fiscal year, the applicable percentage increase under clause (i).

(v) For purposes of clause (ii)(V)--

(I) a hospital's "update adjustment percentage" for a fiscal year is the percentage by which the hospital's allowable operating costs of inpatient hospital services recognized under this *title [42 USCS §§ 1395* et seq.] for the cost reporting period beginning in fiscal year 1990 exceeds the hospital's target amount (as determined under subparagraph (A)) for such cost reporting period, increased for each fiscal year (beginning with fiscal year 1994) by the sum of any of the hospital's applicable reductions under subclause (V) for previous fiscal years; and

(II) the "applicable reduction" with respect to a hospital for a fiscal year is the lesser of 1 percentage point or the percentage point difference between 10 percent and the hospital's update adjustment percentage for the fiscal year.

(vi) For purposes of clause (ii)(VII) for a fiscal year, if a hospital's allowable operating costs of inpatient hospital services recognized under this *title [42 USCS §§ 1395* et seq.] for the most recent cost reporting period for which information is available--

(I) is equal to, or exceeds, 110 percent of the hospital's target amount (as determined under subparagraph (A)) for such cost reporting period, the applicable update factor specified under this clause is the market basket percentage;

(II) exceeds 100 percent, but is less than 110 percent, of such target amount for the hospital, the applicable update factor specified under this clause is 0 percent or, if greater, the market basket percentage minus 0.25 percentage

points for each percentage point by which such allowable operating costs (expressed as a percentage of such target amount) is less than 110 percent of such target amount;

(III) is equal to, or less than 100 percent, but exceeds 2/3 of such target amount for the hospital, the applicable update factor specified under this clause is 0 percent or, if greater, the market basket percentage minus 2.5 percentage points; or

(IV) does not exceed 2/3 of such target amount for the hospital, the applicable update factor specified under this clause is 0 percent.

(vii) (I) For purposes of clause (i)(XIX) for fiscal years 2005 and 2006, in a case of a subsection (d) hospital that does not submit data to the Secretary in accordance with subclause (II) with respect to such a fiscal year, the applicable percentage increase under such clause for such fiscal year shall be reduced by 0.4 percentage points. Such reduction shall apply only with respect to the fiscal year involved, and the Secretary shall not take into account such reduction in computing the applicable percentage increase under clause (i)(XIX) for a subsequent fiscal year.

(II) For fiscal years 2005 and 2006, each subsection (d) hospital shall submit to the Secretary quality data (for a set of 10 indicators established by the Secretary as of November 1, 2003) that relate to the quality of care furnished by the hospital in inpatient settings in a form and manner, and at a time, specified by the Secretary for purposes of this clause, but with respect to fiscal year 2005, the Secretary shall provide for a 30-day grace period for the submission of data by a hospital.

(viii) (I) For purposes of clause (i) for fiscal year 2007 and each subsequent fiscal year, in the case of a subsection (d) hospital that does not submit, to the Secretary in accordance with this clause, data required to be submitted on measures selected under this clause with respect to such a fiscal year, the applicable percentage increase under clause (i) for such fiscal year shall be reduced by 2.0 percentage points. Such reduction shall apply only with respect to the fiscal year involved and the Secretary shall not take into account such reduction in computing the applicable percentage increase under clause (i) for a subsequent fiscal year, and the Secretary and the Medicare Payment Advisory Commission shall carry out the requirements under section 5001(b) of the Deficit Reduction Act of 2005 [note to this section].

(II) Each subsection (d) hospital shall submit data on measures selected under this clause to the Secretary in a form and manner, and at a time, specified by the Secretary for purposes of this clause.

(III) The Secretary shall expand, beyond the measures specified under clause (vii)(II) and consistent with the succeeding subclauses, the set of measures that the Secretary determines to be appropriate for the measurement of the quality of care (including medication errors) furnished by hospitals in inpatient settings.

(IV) Effective for payments beginning with fiscal year 2007, in expanding the number of measures under subclause (III), the Secretary shall begin to adopt the baseline set of performance measures as set forth in the November 2005 report by the Institute of Medicine of the National Academy of Sciences under section 238(b) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 [*42 USCS § 1395ll* note].

(V) Effective for payments beginning with fiscal year 2008, the Secretary shall add other measures that reflect consensus among affected parties and, to the extent feasible and practicable, shall include measures set forth by one or more national consensus building entities.

(VI) For purposes of this clause and clause (vii), the Secretary may replace any measures or indicators in appropriate cases, such as where all hospitals are effectively in compliance or the measures or indicators have been subsequently shown not to represent the best clinical practice.

(VII) The Secretary shall establish procedures for making data submitted under this clause available to the public. Such procedures shall ensure that a hospital has the opportunity to review the data that are to be made public with respect to the hospital prior to such data being made public. The Secretary shall report quality measures of process, structure, outcome, patients' perspectives on care, efficiency, and costs of care that relate to services furnished in inpatient settings in hospitals on the Internet website of the Centers for Medicare & Medicaid Services.

(C) In the case of a hospital that is a sole community hospital (as defined in subsection (d)(5)(D)(iii)), subject to subparagraphs (I) and (L), the term "target amount" means--

(i) with respect to the first 12-month cost reporting period in which this subparagraph is applied to the hospital--

(I) the allowable operating costs of inpatient hospital services (as defined in subsection (a)(4)) recognized under this *title [42 USCS §§ 1395* et seq.] for the hospital for the 12-month cost reporting period (in this subparagraph referred to as the "base cost reporting period") preceding the first cost reporting period for which this subsection was in effect with respect to such hospital, increased (in a compounded manner) by--

(II) the applicable percentage increases applied to such hospital under this paragraph for cost reporting periods after the base cost reporting period and up to and including such first 12-month cost reporting period,

(ii) with respect to a later cost reporting period beginning before fiscal year 1994, the target amount for the preceding 12-month cost reporting period, increased by the applicable percentage increase under subparagraph (B)(iv) for discharges occurring in the fiscal year in which that later cost reporting period begins,

(iii) with respect to discharges occurring in fiscal year 1994, the target amount for the cost reporting period beginning in fiscal year 1993 increased by the applicable percentage increase under subparagraph (B)(iv), or

(iv) with respect to discharges occurring in fiscal year 1995 and each subsequent fiscal year, the target amount for the preceding year increased by the applicable percentage increase under subparagraph (B)(iv).

There shall be substituted for the base cost reporting period described in clause (i) a hospital's cost reporting period (if any) beginning during fiscal year 1987 if such substitution results in an increase in the target amount for the hospital.

(D) For cost reporting periods ending on or before September 30, 1994, and for discharges occurring on or after October 1, 1997, and before October 1, 2011, in the case of a hospital that is a medicare-dependent, small rural hospital (as defined in subsection (d)(5)(G)), subject to subparagraph (K), the term "target amount" means--

(i) with respect to the first 12-month cost reporting period in which this subparagraph is applied to the hospital--

(I) the allowable operating costs of inpatient hospital services (as defined in subsection (a)(4)) recognized under this *title [42 USCS §§ 1395* et seq.] for the hospital for the 12-month cost reporting period (in this subparagraph referred to as the "base cost reporting period") preceding the first cost reporting period for which this subsection was in effect with respect to such hospital, increased (in a compounded manner) by--

(II) the applicable percentage increases applied to such hospital under this paragraph for cost reporting periods after the base cost reporting period and up to and including such first 12-month cost reporting period, or

(ii) with respect to a later cost reporting period beginning before fiscal year 1994, the target amount for the preceding 12-month cost reporting period, increased by the applicable percentage increase under subparagraph (B)(iv) for discharges occurring in the fiscal year in which that later cost reporting period begins,

(iii) with respect to discharges occurring in fiscal year 1994, the target amount for the cost reporting period beginning in fiscal year 1993 increased by the applicable percentage increase under subparagraph (B)(iv), and

(iv) with respect to discharges occurring during fiscal year 1998 through fiscal year 2011, the target amount for the preceding year increased by the applicable percentage increase under subparagraph (B)(iv).

There shall be substituted for the base cost reporting period described in clause (i) a hospital's cost reporting period (if any) beginning during fiscal year 1987 if such substitution results in an increase in the target amount for the hospital.

(E) In the case of a hospital described in clause (v) of subsection (d)(1)(B), the term "target amount" means--

(i) with respect to the first 12-month cost reporting period in which this subparagraph is applied to the hospital--

(I) the allowable operating costs of inpatient hospital services (as defined in subsection (a)(4)) recognized under this *title [42 USCS §§ 1395* et seq.] for the hospital for the 12-month cost reporting period (in this subparagraph referred to as the "base cost reporting period") preceding the first cost reporting period for which this subsection was in effect with respect to such hospital, increased (in a compounded manner) by--

(II) the sum of the applicable percentage increases applied to such hospital under this paragraph for cost reporting periods after the base cost reporting period and up to and including such first 12-month cost reporting period, or

(ii) with respect to a later cost reporting period, the target amount for the preceding 12-month cost reporting period, increased by the applicable percentage increase under subparagraph (B)(ii) for that later cost reporting period.

There shall be substituted for the base cost reporting period described in clause (i) a hospital's cost reporting period (if any) beginning during fiscal year 1987 if such substitution results in an increase in the target amount for the hospital.

(F) (i) In the case of a hospital (or unit described in the matter following clause (v) of subsection (d)(1)(B)) that received payment under this subsection for inpatient hospital services furnished during cost reporting periods beginning before October 1, 1990, that is within a class of hospital described in clause (iii), and that elects (in a form and manner determined by the Secretary) this subparagraph to apply to the hospital, the target amount for the hospital's 12-month cost reporting period beginning during fiscal year 1998 is equal to the average described in clause (ii).

(ii) The average described in this clause for a hospital or unit shall be determined by the Secretary as follows:

(I) The Secretary shall determine the allowable operating costs for inpatient hospital services for the hospital or unit for each of the 5 cost reporting periods for which the Secretary has the most recent settled cost reports as of the date of the enactment of this subparagraph [enacted Aug. 5, 1997].

(II) The Secretary shall increase the amount determined under subclause (I) for each cost reporting period by the applicable percentage increase under subparagraph (B)(ii) for each subsequent cost reporting period up to the cost reporting period described in clause (i).

(III) The Secretary shall identify among such 5 cost reporting periods the cost reporting periods for which the amount determined under subclause (II) is the highest, and the lowest.

(IV) The Secretary shall compute the averages of the amounts determined under subclause (II) for the 3 cost reporting periods not identified under subclause (III).

(iii) For purposes of this subparagraph, each of the following shall be treated as a separate class of hospital:

(I) Hospitals described in clause (i) of subsection (d)(1)(B) and psychiatric units described in the matter following clause (v) of such subsection.

(II) Hospitals described in clause (ii) of such subsection and rehabilitation units described in the matter following clause (v) of such subsection.

(III) Hospitals described in clause (iii) of such subsection.

(IV) Hospitals described in clause (iv) of such subsection.

(V) Hospitals described in clause (v) of such subsection.

(G) (i) In the case of a qualified long-term care hospital (as defined in clause (ii)) that elects (in a form and manner determined by the Secretary) this subparagraph to apply to the hospital, the target amount for the hospital's 12-month cost reporting period beginning during fiscal year 1998 is equal to the allowable operating costs of inpatient hospital services (as defined in subsection (a)(4)) recognized under this *title [42 USCS §§ 1395* et seq.] for the hospital for the 12-month cost reporting period beginning during fiscal year 1996, increased by the applicable percentage increase for the cost reporting period beginning during fiscal year 1997.

(ii) In clause (i), a "qualified long-term care hospital" means, with respect to a cost reporting period, a hospital described in clause (iv) of subsection (d)(1)(B) during each of the 2 cost reporting periods for which the Secretary has the most recent settled cost reports as of the date of the enactment of this subparagraph [enacted Aug. 5, 1997] for each of which--

(I) the hospital's allowable operating costs of inpatient hospital services recognized under this *title [42 USCS §§ 1395* et seq.] exceeded 115 percent of the hospital's target amount, and

(II) the hospital would have a disproportionate patient percentage of at least 70 percent (as determined by the Secretary under subsection (d)(5)(F)(vi)) if the hospital were a subsection (d) hospital.

(H) (i) In the case of a hospital or unit that is within a class of hospital described in clause (iv), for a cost reporting period beginning during fiscal years 1998 through 2002, the target amount for such a hospital or unit may not exceed the amount as updated up to or for such cost reporting period under clause (ii).

(ii) (I) In the case of a hospital or unit that is within a class of hospital described in clause (iv), the Secretary shall estimate the 75th percentile of the target amounts for such hospitals within such class for cost reporting periods ending during fiscal year 1996, as adjusted under clause (iii).

(II) The Secretary shall update the amount determined under subclause (I), for each cost reporting period after the cost reporting period described in such subclause and up to the first cost reporting period beginning on or after October 1, 1997, by a factor equal to the market basket percentage increase.

(III) For cost reporting periods beginning during each of fiscal years 1999 through 2002, subject to subparagraph (J), the Secretary shall update such amount by a factor equal to the market basket percentage increase.

(iii) In applying clause (ii)(I) in the case of a hospital or unit, the Secretary shall provide for an appropriate adjustment to the labor-related portion of the amount determined under such subparagraph to take into account differences between average wage-related costs in the area of the hospital and the national average of such costs within the same class of hospital.

(iv) For purposes of this subparagraph, each of the following shall be treated as a separate class of hospital:

(I) Hospitals described in clause (i) of subsection (d)(1)(B) and psychiatric units described in the matter following clause (v) of such subsection.

(II) Hospitals described in clause (ii) of such subsection and rehabilitation units described in the matter following clause (v) of such subsection.

(III) Hospitals described in clause (iv) of such subsection.

(I) (i) Subject to subparagraph (L), for cost reporting periods beginning on or after October 1, 2000, in the case of a sole community hospital there shall be substituted for the amount otherwise determined under subsection (d)(5)(D)(i), if such substitution results in a greater amount of payment under this section for the hospital--

(I) with respect to discharges occurring in fiscal year 2001, 75 percent of the amount otherwise applicable to the hospital under subsection (d)(5)(D)(i) (referred to in this clause as the "subsection (d)(5)(D)(i) amount") and 25 percent of the rebased target amount (as defined in clause (ii));

(II) with respect to discharges occurring in fiscal year 2002, 50 percent of the subsection (d)(5)(D)(i) amount and 50 percent of the rebased target amount;

(III) with respect to discharges occurring in fiscal year 2003, 25 percent of the subsection (d)(5)(D)(i) amount and 75 percent of the rebased target amount; and

(IV) with respect to discharges occurring after fiscal year 2003, 100 percent of the rebased target amount.

(ii) For purposes of this subparagraph, the "rebased target amount" has the meaning given the term "target amount" in subparagraph (C) except that--

(I) there shall be substituted for the base cost reporting period the 12-month cost reporting period beginning during fiscal year 1996;

(II) any reference in subparagraph (C)(i) to the "first cost reporting period" described in such subparagraph is deemed a reference to the first cost reporting period beginning on or after October 1, 2000; and

(III) applicable increase percentage shall only be applied under subparagraph (C)(iv) for discharges occurring in fiscal years beginning with fiscal year 2002.

(iii) In no case shall a hospital be denied treatment as a sole community hospital or payment (on the basis of a target rate as such as a hospital) because data are unavailable for any cost reporting period due to changes in ownership, changes in fiscal intermediaries, or other extraordinary circumstances, so long as data for at least one applicable base cost reporting period is available.

(J) For cost reporting periods beginning during fiscal year 2001, for a hospital described in subsection (d)(1)(B)(iv)--

(i) the limiting or cap amount otherwise determined under subparagraph (H) shall be increased by 2 percent; and

(ii) the target amount otherwise determined under subparagraph (A) shall be increased by 25 percent (subject to the limiting or cap amount determined under subparagraph (H), as increased by clause (i)).

(K) (i) With respect to discharges occurring on or after October 1, 2006, in the case of a medicare-dependent, small rural hospital, for purposes of applying subparagraph (D)--

(I) there shall be substituted for the base cost reporting period described in subparagraph (D)(i) the 12-month cost reporting period beginning during fiscal year 2002; and

(II) any reference in such subparagraph to the "first cost reporting period" described in such subparagraph is deemed a reference to the first cost reporting period beginning on or after October 1, 2006.

(ii) This subparagraph shall only apply to a hospital if the substitution described in clause (i)(I) results in an increase in the target amount under subparagraph (D) for the hospital.

(L) (i) For cost reporting periods beginning on or after January 1, 2009, in the case of a sole community hospital there shall be substituted for the amount otherwise determined under subsection (d)(5)(D)(i) of this section, if such substitution results in a greater amount of payment under this section for the hospital, the subparagraph (L) rebased target amount.

(ii) For purposes of this subparagraph, the term "subparagraph (L) rebased target amount" has the meaning given the term "target amount" in subparagraph (C), except that--

(I) there shall be substituted for the base cost reporting period the 12-month cost reporting period beginning during fiscal year 2006;

(II) any reference in subparagraph (C)(i) to the "first cost reporting period" described in such subparagraph is deemed a reference to the first cost reporting period beginning on or after January 1, 2009; and

(III) the applicable percentage increase shall only be applied under subparagraph (C)(iv) for discharges occurring on or after January 1, 2009.

(4)

(A) (i) The Secretary shall provide for an exception and adjustment to (and in the case of a hospital described in subsection (d)(1)(B)(iii), may provide an exemption from) the method under this subsection for determining the amount of payment to a hospital where events beyond the hospital's control or extraordinary circumstances, including changes in the case mix of such hospital, create a distortion in the increase in costs for a cost reporting period (including any distortion in the costs for the base period against which such increase is measured). The Secretary may provide for such other exemptions from, and exceptions and adjustments to, such method as the Secretary deems appropriate, including the assignment of a new base period which is more representative, as determined by the Secretary, of the reasonable and necessary cost of inpatient services and including those which he deems necessary to take into account a decrease in the inpatient hospital services that a hospital provides and that are customarily provided directly by similar hospitals which results in a significant distortion in the operating costs of inpatient hospital services. The Secretary shall announce a decision on any request for an exemption, exception, or adjustment under this paragraph not later than 180 days after receiving a completed application from the intermediary for such exemption, exception, or adjustment, and shall include in such decision a detailed explanation of the grounds on which such request was approved or denied.

(ii) The payment reductions under paragraph (3)(B)(ii)(V) shall not be considered by the Secretary in making adjustments pursuant to clause (i). In making such reductions, the Secretary shall treat the applicable update factor described in paragraph (3)(B)(vi) for a fiscal year as being equal to the market basket percentage for that year.

(B) In determining under subparagraph (A) whether to assign a new base period which is more representative of the reasonable and necessary cost to a hospital of providing inpatient services, the Secretary shall take into consideration--

(i) changes in applicable technologies and medical practices, or differences in the severity of illness among patients, that increase the hospital's costs;

(ii) whether increases in wages and wage-related costs for hospitals located in the geographic area in which the hospital is located exceed the average of the increases in such costs paid by hospitals in the United States; and

(iii) such other factors as the Secretary considers appropriate in determining increases in the hospital's costs of providing inpatient services.

(C) Paragraph (1) shall not apply to payment of hospitals which is otherwise determined under paragraph (3) of section 1814(b) [*42 USCS § 1395f(b)(3)*].

(5) In the case of any hospital having any cost reporting period of other than a 12-month period, the Secretary shall determine the 12-month period which shall be used for purposes of this section.

(6) In the case of any hospital which becomes subject to the taxes under *section 3111 of the Internal Revenue Code of 1954* [1986] [*26 USCS § 3111*], with respect to any or all of its employees, for part or all of a cost reporting period, and was not subject to such taxes with respect to any or all of its employees for all or part of the 12-month base cost reporting period referred to in subsection (b)(3)(A)(i), the Secretary shall provide for an adjustment by increasing the base period amount described in such subsection for such hospital by an amount equal to the amount of such taxes which would have been paid or accrued by such hospital for such base period if such hospital had been subject to such taxes for all of such base period with respect to all its employees, minus the amount of any such taxes actually paid or accrued for such base period.

(7)

(A) Notwithstanding paragraph (1), in the case of a hospital or unit that is within a class of hospital described in subparagraph (B) which first receives payments under this section on or after October 1, 1997--

(i) for each of the first 2 cost reporting periods for which the hospital has a settled cost report, the amount of the payment with respect to operating costs described in paragraph (1) under part A on a per discharge or per admission basis (as the case may be) is equal to the lesser of--

(I) the amount of operating costs for such respective period, or

(II) 110 percent of the national median (as estimated by the Secretary) of the target amount for hospitals in the same class as the hospital for cost reporting periods ending during fiscal year 1996, updated by the hospital market basket increase percentage to the fiscal year in which the hospital first received payments under this section, as adjusted under subparagraph (C); and

(ii) for purposes of computing the target amount for the subsequent cost reporting period, the target amount for the preceding cost reporting period is equal to the amount determined under clause (i) for such preceding period.

(B) For purposes of this paragraph, each of the following shall be treated as a separate class of hospital:

(i) Hospitals described in clause (i) of subsection (d)(1)(B) and psychiatric units described in the matter following clause (v) of such subsection.

(ii) Hospitals described in clause (ii) of such subsection and rehabilitation units described in the matter following clause (v) of such subsection.

(iii) Hospitals described in clause (iv) of such subsection.

(C) In applying subparagraph (A)(i)(II) in the case of a hospital or unit, the Secretary shall provide for an appropriate adjustment to the labor-related portion of the amount determined under such subparagraph to take into account differences between average wage-related costs in the area of the hospital and the national average of such costs within the same class of hospital.

(c) Payment in accordance with State hospital reimbursement control system; amount of payment; discontinuance of payments.

(1) The Secretary may provide, in his discretion, that payment with respect to services provided by a hospital in a State may be made in accordance with a hospital reimbursement control system in a State, rather than in accordance with the other provisions of this *title [42 USCS §§ 1395* et seq.], if the chief executive officer of the State requests such treatment and if--

(A) the Secretary determines that the system, if approved under this subsection, will apply (i) to substantially all non-Federal acute care hospitals (as defined by the Secretary) in the State and (ii) to the review of at least 75 percent of all revenues or expenses in the State for inpatient hospital services and of revenues or expenses for inpatient hospital services provided under the State's plan approved under title XIX [*42 USCS §§ 1396* et seq.];

(B) the Secretary has been provided satisfactory assurances as to the equitable treatment under the system of all entities (including Federal and State programs) that pay hospitals for inpatient hospital services, of hospital employees, and of hospital patients;

(C) the Secretary has been provided satisfactory assurances that under the system, over 36-month periods (the first such period beginning with the first month in which this subsection applies to that system in the State), the amount of payments made under this *title [42 USCS §§ 1395* et seq.] under such system will not exceed the amount of payments which would otherwise have been made under this title not using such system;

(D) the Secretary determines that the system will not preclude an eligible organization (as defined in section 1876(b) [*42 USCS § 1395mm(b)*]) from negotiating directly with hospitals with respect to the organization's rate of payment for inpatient hospital services; and

(E) the Secretary determines that the system requires hospitals to meet the requirement of section 1866(a)(1)(G) [*42 USCS § 1395cc(a)(1)(G)*] and the system provides for the exclusion of certain costs in accordance with section 1862(a)(14) [*42 USCS § 1395y(a)(14)*] (except for such waivers thereof as the Secretary provides by regulation).

The Secretary cannot deny the application of a State under this subsection on the ground that the State's hospital reimbursement control system is based on a payment methodology other than on the basis of a diagnosis-related group or on the ground that the amount of payments made under this *title [42 USCS §§ 1395* et seq.] under such system must be less than the amount of payments which would otherwise have been made under this *title [42 USCS §§ 1395* et seq.] not using such system. If the Secretary determines that the conditions described in subparagraph (C) are based on maintaining payment amounts at no more than a specified percentage increase above the payment amounts in a base period, the State has the option of applying such test (for inpatient hospital services under part A [*42 USCS §§ 1395c* et seq.]) on an aggregate payment basis or on the basis of the amount of payment per inpatient discharge or admission. If the Secretary determines that the conditions described in subparagraph (C) are based on maintaining aggregate payment amounts below a national average percentage increase in total payments under part A [*42 USCS §§ 1395c* et seq.] for inpatient hospital services, the Secretary cannot deny the application of a State under this subsection on the ground that the State's rate of increase in such payments for such services must be less than such national average rate of increase.

(2) In determining under paragraph (1)(C) the amount of payment which would otherwise have been made under this *title [42 USCS §§ 1395* et seq.] for a State, the Secretary may provide for appropriate adjustment of such amount to take into account previous reductions effected in the amount of payments made under this *title [42 USCS §§ 1395* et seq.] in the State due to the operation of the hospital reimbursement control system in the State if the system has resulted in an aggregate rate of increase in operating costs of inpatient hospital services (as defined in subsection (a)(4)) under this *title [42 USCS §§ 1395* et seq.] for hospitals in the State which is less than the aggregate rate of increase in such costs under this *title [42 USCS §§ 1395* et seq.] for hospitals in the United States.

(3) The Secretary shall discontinue payments under a system described in paragraph (1) if the Secretary--

(A) determines that the system no longer meets the requirements of subparagraphs (A), (D), and (E) of paragraph (1) and, if applicable, the requirements of paragraph (5), or

(B) has reason to believe that the assurances described in subparagraph (B) or (C) of paragraph (1) (or, if applicable, in paragraph (5)) are not being (or will not be) met.

(4) The Secretary shall approve the request of a State under paragraph (1) with respect to a hospital reimbursement control system if--

(A) the requirements of subparagraphs (A), (B), (C), (D), and (E) of paragraph (1) have been met with respect to the system, and

(B) with respect to that system a waiver of certain requirements of title XVIII of the Social Security Act [*42 USCS §§ 1395* et seq.] has been approved on or before (and which is in effect as of) the date of the enactment of the Social Security Amendments of 1983 [enacted April 20, 1983], pursuant to section 402(a) of the Social Security Amendments of 1967 [*42 USCS § 1395b-1(a)*] or section 222(a) of the Social Security Amendments of 1972 [*42 USCS § 1395b-1* note].

With respect to a State system described in this paragraph, the Secretary shall judge the effectiveness of such system on the basis of its rate of increase or inflation in inpatient hospital payments for individuals under this *title [42 USCS §§ 1395* et seq.], as compared to the national rate of increase or inflation for such payments, with the State retaining the option to have the test applied on the basis of the aggregate payments under the State system as compared to aggregate payments which would have been made under the national system since October 1, 1984, to the most recent date for which annual data are available.

(5) The Secretary shall approve the request of a State under paragraph (1) with respect to a hospital reimbursement control system if--

(A) the requirements of subparagraphs (A), (B), (C), (D), and (E) of paragraph (1) have been met with respect to the system;

(B) the Secretary determines that the system--

(i) is operated directly by the State or by an entity designated pursuant to State law,

(ii) provides for payment of hospitals covered under the system under a methodology (which sets forth exceptions and adjustments, as well as any method for changes in the methodology) by which rates or amounts to be paid for hospital services during a specified period are established under the system prior to the defined rate period, and

(iii) hospitals covered under the system will make such reports (in lieu of cost and other reports, identified by the Secretary, otherwise required under this *title [42 USCS §§ 1395* et seq.]) as the Secretary may require in order to properly monitor assurances provided under this subsection;

(C) the State has provided the Secretary with satisfactory assurances that operation of the system will not result in any change in hospital admission practices which result in--

(i) a significant reduction in the proportion of patients (receiving hospital services covered under the system) who have no third-party coverage and who are unable to pay for hospital services,

(ii) a significant reduction in the proportion of individuals admitted to hospitals for inpatient hospital services for which payment is (or is likely to be) less than the anticipated charges for or costs of such services,

(iii) the refusal to admit patients who would be expected to require unusually costly or prolonged treatment for reasons other than those related to the appropriateness of the care available at the hospital, or

(iv) the refusal to provide emergency services to any person who is in need of emergency services if the hospital provides such services;

(D) any change by the State in the system which has the effect of materially reducing payments to hospitals can only take effect upon 60 days notice to the Secretary and to the hospitals the payment to which is likely to be materially affected by the change; and

(E) the State has provided the Secretary with satisfactory assurances that in the development of the system the State has consulted with local governmental officials concerning the impact of the system on public hospitals.

The Secretary shall respond to requests of States under this paragraph within 60 days of the date the request is submitted to the Secretary.

(6) If the Secretary determines that the assurances described in paragraph (1)(C) have not been met with respect to any 36-month period, the Secretary may reduce payments under this *title [42 USCS §§ 1395* et seq.] to hospitals under the system in an amount equal to the amount by which the payment under this *title [42 USCS §§ 1395* et seq.] under such system for such period exceeded the amount of payments which would otherwise have been made under this *title [42 USCS §§ 1395* et seq.] not using such system.

(7) In the case of a State which made a request under paragraph (5) before December 31, 1984, for the approval of a State hospital reimbursement control system and which request was approved--

(A) in applying paragraphs (1)(C) and (6), a reference to a "36-month period" is deemed a reference to a "48-month period", and

(B) in order to allow the State the opportunity to provide the assurances described in paragraph (1)(C) for a 48-month period, the Secretary may not discontinue payments under the system, under the authority of paragraph (3)(A) because the Secretary has reason to believe that such assurances are not being (or will not be) met, before July 1, 1986.

(d) Inpatient hospital service payments on basis of prospective rates; Medicare Geographical Classification Review Board.

(1)

(A) Notwithstanding section 1814(b) [*42 USCS § 1395f(b)*] but subject to the provisions of section 1813 [*42 USCS § 1395e*], the amount of the payment with respect to the operating costs of inpatient hospital services (as defined in subsection (a)(4)) of a subsection (d) hospital (as defined in subparagraph (B)) for inpatient hospital discharges in a cost reporting period or in a fiscal year--

(i) beginning on or after October 1, 1983, and before October 1, 1984, is equal to the sum of--

(I) the target percentage (as defined in subparagraph (C)) of the hospital's target amount for the cost reporting period (as defined in subsection (b)(3)(A), but determined without the application of subsection (a)), and

(II) the DRG percentage (as defined in subparagraph (C)) of the regional adjusted DRG prospective payment rate determined under paragraph (2) for such discharges;

(ii) beginning on or after October 1, 1984, and before October 1, 1987, is equal to the sum of--

(I) the target percentage (as defined in subparagraph (C)) of the hospital's target amount for the cost reporting period (as defined in subsection (b)(3)(A), but determined without the application of subsection (a)), and

(II) the DRG percentage (as defined in subparagraph (C)) of the applicable combined adjusted DRG prospective payment rate determined under subparagraph (D) for such discharges; or

(iii) beginning on or after April 1, 1988, is equal to--

(I) the national adjusted DRG prospective payment rate determined under paragraph (3) for such discharges, or

(II) for discharges occurring during a fiscal year ending on or before September 30, 1996, the sum of 85 percent of the national adjusted DRG prospective payment rate determined under paragraph (3) for such discharges and 15 percent of the regional adjusted DRG prospective payment rate determined under such paragraph, but only if the average standardized amount (described in clause (i)(I) or clause (ii)(I) of paragraph (3)(D)) for hospitals within the region of, and in the same large urban or other area (or, for discharges occurring during a fiscal year ending on or before September 30, 1994, the same large urban or other area) as, the hospital is greater than the average standardized amount (described in the respective clause) for hospitals within the United States in that type of area for discharges occurring during such fiscal year.

(B) As used in this section, the term "subsection (d) hospital" means a hospital located in one of the fifty States or the District of Columbia other than--

(i) a psychiatric hospital (as defined in section 1861(f)) [*42 USCS § 1395x(f)*],

(ii) a rehabilitation hospital (as defined by the Secretary),

(iii) a hospital whose inpatients are predominantly individuals under 18 years of age,

(iv) (I) a hospital which has an average inpatient length of stay (as determined by the Secretary) of greater than 25 days, or

(II) a hospital that first received payment under this subsection in 1986 which has an average inpatient length of stay (as determined by the Secretary) of greater than 20 days and that has 80 percent or more of its annual medicare inpatient discharges with a principal diagnosis that reflects a finding of neoplastic disease in the 12-month cost reporting period ending in fiscal year 1997, or

(v) (I) a hospital that the Secretary has classified, at any time on or before December 31, 1990[,] (or, in the case of a hospital that, as of the date of the enactment of this clause, is located in a State operating a demonstration project under section 1814(b) [*42 USCS § 1395f(b)*], on or before December 31, 1991) for purposes of applying exceptions and adjustments to payment amounts under this subsection, as a hospital involved extensively in treatment for or research on cancer,

(II) a hospital that was recognized as a comprehensive cancer center or clinical cancer research center by the National Cancer Institute of the National Institutes of Health as of April 20, 1983, that is located in a State which, as of December 19, 1989, was not operating a demonstration project under section 1814(b) [*42 USCS § 1395f(b)*], that applied and was denied, on or before December 31, 1990, for classification as a hospital involved extensively in treatment for or research on cancer under this clause (as in effect on the day before the date of the enactment of this subclause), that as of the date of the enactment of this subclause, is licensed for less than 50 acute care beds, and that demonstrates for the 4-year period ending on December 31, 1996, that at least 50 percent of its total discharges have a principal finding of neoplastic disease, as defined in subparagraph (E), or

(III) a hospital that was recognized as a clinical cancer research center by the National Cancer Institute of the National Institutes of Health as of February 18, 1998, that has never been reimbursed for inpatient hospital services pursuant to a reimbursement system under a demonstration project under section 1814(b) [*42 USCS § 1395f(b)*], that is a freestanding facility organized primarily for treatment of and research on cancer and is not a unit of another hospital, that as of the date of the enactment of this subclause, is licensed for 162 acute care beds, and that demonstrates for the 4-year period ending on June 30, 1999, that at least 50 percent of its total discharges have a principal finding of neoplastic disease, as defined in subparagraph (E);

and, in accordance with regulations of the Secretary, does not include a psychiatric or rehabilitation unit of the hospital which is a distinct part of the hospital (as defined by the Secretary). A hospital that was classified by the Secretary on or before September 30, 1995, as a hospital described in clause (iv) shall continue to be so classified notwithstanding that it is located in the same building as, or on the same campus as, another hospital.

(C) For purposes of this subsection, for cost reporting periods beginning--

(i) on or after October 1, 1983, and before October 1, 1984, the "target percentage" is 75 percent and the "DRG percentage" is 25 percent;

(ii) on or after October 1, 1984, and before October 1, 1985, the "target percentage" is 50 percent and the "DRG percentage" is 50 percent;

(iii) on or after October 1, 1985, and before October 1, 1986, the "target percentage" is 45 percent and the "DRG percentage" is 55 percent; and

(iv) on or after October 1, 1986, and before October 1, 1987, the "target percentage" is 25 percent and the "DRG percentage" is 75 percent.

(D) For purposes of subparagraph (A)(ii)(II), the "applicable combined adjusted DRG prospective payment rate" for discharges occurring--

(i) on or after October 1, 1984, and before October 1, 1986, is a combined rate consisting of 25 percent of the national adjusted DRG prospective payment rate, and 75 percent of the regional adjusted DRG prospective payment rate, determined under paragraph (3) for such discharges; and

(ii) on or after October 1, 1986, and before October 1, 1987, is a combined rate consisting of 50 percent of the national adjusted DRG prospective payment rate, and 50 percent of the regional adjusted DRG prospective payment rate, determined under paragraph (3) for such discharges.

(E) For purposes of subclauses (II) and (III) of subparagraph (B)(v) only, the term "principal finding of neoplastic disease" means the condition established after study to be chiefly responsible for occasioning the admission of a patient to a hospital, except that only discharges with ICD-9-CM principal diagnosis codes of 140 through 239, V58.0, V58.1, V66.1, V66.2, or 990 will be considered to reflect such a principal diagnosis.

(2) The Secretary shall determine a national adjusted DRG prospective payment rate, for each inpatient hospital discharge in fiscal year 1984 involving inpatient hospital services of a subsection (d) hospital in the United States, and shall determine a regional adjusted DRG prospective payment rate for such discharges in each region, for which payment may be made under part A of this *title [42 USCS §§ 1395c* et seq.]. Each such rate shall be determined for hospitals located in urban or rural areas within the United States or within each such region, respectively, as follows:

(A) The Secretary shall determine the allowable operating costs per discharge of inpatient hospital services for the hospital for the most recent cost reporting period for which data are available.

(B) The Secretary shall update each amount determined under subparagraph (A) for fiscal year 1984 by--

(i) updating for fiscal year 1983 by the estimated average rate of change of hospital costs industry-wide between the cost reporting period used under such subparagraph and fiscal year 1983 and the most recent case-mix data available, and

(ii) projecting for fiscal year 1984 by the applicable percentage increase (as defined in subsection (b)(3)(B)) for fiscal year 1984.

(C) The Secretary shall standardize the amount updated under subparagraph (B) for each hospital by--

(i) excluding an estimate of indirect medical education costs (taking into account, for discharges occurring after September 30, 1986, the amendments made by section 9104(a) of the Medicare and Medicaid Budget Reconciliation Amendments of 1985), except that the Secretary shall not take into account any reduction in the amount of additional payments under paragraph (5)(B)(ii) resulting from the amendment made by section 4621(a)(1) of the Balanced Budget Act of 1997 or any additional payments under such paragraph resulting from the application of section 111 of the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999, of section 302 of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000, or the Medicare Prescription Drug, Improvement, and Modernization Act of 2003,

(ii) adjusting for variations among hospitals by area in the average hospital wage level,

(iii) adjusting for variations in case mix among hospitals, and

(iv) for discharges occurring on or after October 1, 1986, excluding an estimate of the additional payments to certain hospitals to be made under paragraph (5)(F), except that the Secretary shall not exclude additional payments under such paragraph made as a result of the enactment of section 6003(c) of the Omnibus Budget Reconciliation Act of 1989 or the enactment of section 4002(b) of the Omnibus Budget Reconciliation Act of 1990, the enactment of section 303 of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000, or the enactment of section 402(a)(1) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003.

(D) The Secretary shall compute an average of the standardized amounts determined under subparagraph (C) for the United States and for each region--

(i) for all subsection (d) hospitals located in an urban area within the United States or that region, respectively, and

(ii) for all subsection (d) hospitals located in a rural area within the United States or that region, respectively.

For purposes of this subsection, the term "region" means one of the nine census divisions, comprising the fifty States and the District of Columbia, established by the Bureau of the Census for statistical and reporting purposes; the term "urban area" means an area within a Metropolitan Statistical Area (as defined by the Office of Management and Budget) or within such similar area as the Secretary has recognized under subsection (a) by regulation; the term "large urban area" means, with respect to a fiscal year, such an urban area which the Secretary determines (in the publications described in subsection (e)(5) before the fiscal year) has a population of more than 1,000,000 (as determined by the Secretary based on the most recent available population data published by the Bureau of the Census); and the term "rural area" means any area outside such an area or similar area. A hospital located in a Metropolitan Statistical Area shall be deemed to be located in the region in which the largest number of the hospitals in the same Metropolitan Statistical Area are located, or, at the option of the Secretary, the region in which the majority of the inpatient discharges (with respect to which payments are made under this *title [42 USCS §§ 1395* et seq.]) from hospitals in the same Metropolitan Statistical Area are made.

(E) The Secretary shall reduce each of the average standardized amounts determined under subparagraph (D) by a proportion equal to the proportion (estimated by the Secretary) of the amount of payments under this subsection based on DRG prospective payment rates which are additional payments described in paragraph (5)(A) (relating to outlier payments).

(F) The Secretary shall adjust each of such average standardized amounts as may be required under subsection (e)(1)(B) for that fiscal year.

(G) For each discharge classified within a diagnosis-related group, the Secretary shall establish a national DRG prospective payment rate and shall establish a regional DRG prospective payment rate for each region, each of which is equal--

(i) for hospitals located in an urban area in the United States or that region (respectively), to the product of--

(I) the average standardized amount (computed under subparagraph (D), reduced under subparagraph (E), and adjusted under subparagraph (F)) for hospitals located in an urban area in the United States or that region, and

(II) the weighting factor (determined under paragraph (4)(B)) for that diagnosis-related group; and

(ii) for hospitals located in a rural area in the United States or that region (respectively), to the product of--

(I) the average standardized amount (computed under subparagraph (D), reduced under subparagraph (E), and adjusted under subparagraph (F)) for hospitals located in a rural area in the United States or that region, and

(II) the weighting factor (determined under paragraph (4)(B)) for that diagnosis-related group.

(H) The Secretary shall adjust the proportion, (as estimated by the Secretary from time to time) of hospitals' costs which are attributable to wages and wage-related costs, of the national and regional DRG prospective payment rates computed under subparagraph (G) for area differences in hospital wage levels by a factor (established by the Secretary) reflecting the relative hospital wage level in the geographic area of the hospital compared to the national average hospital wage level.

(3) The Secretary shall determine a national adjusted DRG prospective payment rate, for each inpatient hospital discharge in a fiscal year after fiscal year 1984 involving inpatient hospital services of a subsection (d) hospital in the United States, and shall determine, for fiscal years before fiscal year 1997, a regional adjusted DRG prospective payment rate for such discharges in each region for which payment may be made under part A of this *title [42 USCS §§ 1395c* et seq.]. Each such rate shall be determined for hospitals located in large urban, other urban, or rural areas within the United States and within each such region, respectively, as follows:

(A) Updating previous standardized amounts.

(i) For discharges occurring in a fiscal year beginning before October 1, 1987, the Secretary shall compute an average standardized amount for hospitals located in an urban area and for hospitals located in a rural area within the United States and for hospitals located in an urban area and for hospitals located in a rural area within each region, equal to the respective average standardized amount computed for the previous fiscal year under paragraph (2)(D) or under this subparagraph, increased for the fiscal year involved by the applicable percentage increase under subsection (b)(3)(B). With respect to discharges occurring on or after October 1, 1987, the Secretary shall compute urban and rural averages on the basis of discharge weighting rather than hospital weighting, making appropriate adjustments to ensure that computation on such basis does not result in total payments under this section that are greater or less than the total payments that would have been made under this section but for this sentence, and making appropriate changes in the manner of determining the reductions under subparagraph (C)(ii).

(ii) For discharges occurring in a fiscal year beginning on or after October 1, 1987, and ending on or before September 30, 1994, the Secretary shall compute an average standardized amount for hospitals located in a large urban area, for hospitals located in a rural area, and for hospitals located in other urban areas, within the United States and within each region, equal to the respective average standardized amount computed for the previous fiscal year under this subparagraph increased by the applicable percentage increase under subsection (b)(3)(B)(i) with respect to hospitals located in the respective areas for the fiscal year involved.

(iii) For discharges occurring in the fiscal year beginning on October 1, 1994, the average standardized amount for hospitals located in a rural area shall be equal to the average standardized amount for hospitals located in an urban area. For discharges occurring on or after October 1, 1994, the Secretary shall adjust the ratio of the labor portion to non-labor portion of each average standardized amount to equal such ratio for the national average of all standardized amounts.

(iv) (I) Subject to subclause (II), for discharges occurring in a fiscal year beginning on or after October 1, 1995, the Secretary shall compute an average standardized amount for hospitals located in a large urban area and for hospitals located in other areas within the United States and within each region equal to the respective average standardized amount computed for the previous fiscal year under this subparagraph increased by the applicable percentage increase under subsection (b)(3)(B)(i) with respect to hospitals located in the respective areas for the fiscal year involved.

(II) For discharges occurring in a fiscal year (beginning with fiscal year 2004), the Secretary shall compute a standardized amount for hospitals located in any area within the United States and within each region equal to the standardized amount computed for the previous fiscal year under this subparagraph for hospitals located in a large urban area (or, beginning with fiscal year 2005, for all hospitals in the previous fiscal year) increased by the applicable percentage increase under subsection (b)(3)(B)(i) for the fiscal year involved.

(v) Average standardized amounts computed under this paragraph shall be adjusted to reflect the most recent case-mix data available.

(vi) Insofar as the Secretary determines that the adjustments under paragraph (4)(C)(i) for a previous fiscal year (or estimates that such adjustments for a future fiscal year) did (or are likely to) result in a change in aggregate payments under this subsection during the fiscal year that are a result of changes in the coding or classification of discharges that do not reflect real changes in case mix, the Secretary may adjust the average standardized amounts computed under this paragraph for subsequent fiscal years so as to eliminate the effect of such coding or classification changes.

(B) The Secretary shall reduce each of the average standardized amounts determined under subparagraph (A) by a factor equal to the proportion of payments under this subsection (as estimated by the Secretary) based on DRG prospective payment amounts which are additional payments described in paragraph (5)(A) (relating to outlier payments).

(C) (i) For discharges occurring in fiscal year 1985, the Secretary shall adjust each of such average standardized amounts as may be required under subsection (e)(1)(B) for that fiscal year.

(ii) For discharges occurring after September 30, 1986, the Secretary shall further reduce each of the average standardized amounts (in a proportion which takes into account the differing effects of the standardization effected under paragraph (2)(C)(i)) so as to provide for a reduction in the total of the payments (attributable to this paragraph) made for discharges occurring on or after October 1, 1986, of an amount equal to the estimated reduction in the payment amounts under paragraph (5)(B) that would have resulted from the enactment of the amendments made by section 9104 of the Medicare and Medicaid Budget Reconciliation Amendments of 1985 and by section 4003(a)(1) of the Omnibus Budget Reconciliation Act of 1987 if the factor described in clause (ii)(II) of paragraph (5)(B) (determined without regard to amendments made by the Omnibus Budget Reconciliation Act of 1990) were applied for discharges occurring on or after such date instead of the factor described in clause (ii) of that paragraph.

(D) For each discharge classified within a diagnosis-related group, the Secretary shall establish for the fiscal year a national DRG prospective payment rate and shall establish, for fiscal years before fiscal year 1997, a regional DRG prospective payment rate for each region which is equal--

(i) for fiscal years before fiscal year 2004, for hospitals located in a large urban area in the United States or that region (respectively), to the product of--

(I) the average standardized amount (computed under subparagraph (A), reduced under subparagraph (B), and adjusted or reduced under subparagraph (C)) for the fiscal year for hospitals located in such a large urban area in the United States or that region, and

(II) the weighting factor (determined under paragraph (4)(B)) for that diagnosis-related group;

(ii) for fiscal years before fiscal year 2004, for hospitals located in other areas in the United States or that region (respectively), to the product of--

(I) the average standardized amount (computed under subparagraph (A), reduced under subparagraph (B), and adjusted or reduced under subparagraph (C)) for the fiscal year for hospitals located in other areas in the United States or that region, and

(II) the weighting factor (determined under paragraph (4)(B)) for that diagnosis-related group; and

(iii) for a fiscal year beginning after fiscal year 2003, for hospitals located in all areas, to the product of--

(I) the applicable standardized amount (computed under subparagraph (A)), reduced under subparagraph (B), and adjusted or reduced under subparagraph (C) for the fiscal year; and

(II) the weighting factor (determined under paragraph (4)(B)) for that diagnosis-related group.

(E) Wage levels.

(i) In general. Except as provided in clause (ii), the Secretary shall adjust the proportion, (as estimated by the Secretary from time to time) of hospitals' costs which are attributable to wages and wage-related costs, of the DRG prospective payment rates computed under subparagraph (D) for area differences in hospital wage levels by a factor (established by the Secretary) reflecting the relative hospital wage level in the geographic area of the hospital compared to the national average hospital wage level. Not later than October 1, 1990, and October 1, 1993 (and at least every 12 months thereafter), the Secretary shall update the factor under the preceding sentence on the basis of a survey conducted by the Secretary (and updated as appropriate) of the wages and wage-related costs of subsection (d) hospitals in the United States. Not less often than once every 3 years the Secretary (through such survey or otherwise) shall measure the earnings and paid hours of employment by occupational category and shall exclude data with respect to the wages and wage-related costs incurred in furnishing skilled nursing facility services. Any adjustments or updates made under this subparagraph for a fiscal year (beginning with fiscal year 1991) shall be made in a manner that assures that the aggregate payments under this subsection in the fiscal year are not greater or less than those that would have been made in the year without such adjustment. The Secretary shall apply the previous sentence for any period as if the amendments made by section 403(a)(1) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 had not been enacted.

(ii) Alternative proportion to be adjusted beginning in fiscal year 2005. For discharges occurring on or after October 1, 2004, the Secretary shall substitute "62 percent" for the proportion described in the first sentence of clause (i), unless the application of this clause would result in lower payments to a hospital than would otherwise be made.

(4)

(A) The Secretary shall establish a classification of inpatient hospital discharges by diagnosis-related groups and a methodology for classifying specific hospital discharges within these groups.

(B) For each such diagnosis-related group the Secretary shall assign an appropriate weighting factor which reflects the relative hospital resources used with respect to discharges classified within that group compared to discharges classified within other groups.

(C)

(i) The Secretary shall adjust the classifications and weighting factors established under subparagraphs (A) and (B), for discharges in fiscal year 1988 and at least annually, to reflect changes in treatment patterns, technology

(including a new medical service or technology under paragraph (5)(K)), and other factors which may change the relative use of hospital resources.

(ii) For discharges in fiscal year 1990, the Secretary shall reduce the weighting factor for each diagnosis-related group by 1.22 percent.

(iii) Any such adjustment under clause (i) for discharges in a fiscal year (beginning with fiscal year 1991) shall be made in a manner that assures that the aggregate payments under this subsection for discharges in the fiscal year are not greater or less than those that would have been made for discharges in the year without such adjustment.

(iv) [Deleted]

(D) (i) For discharges occurring on or after October 1, 2008, the diagnosis-related group to be assigned under this paragraph for a discharge described in clause (ii) shall be a diagnosis-related group that does not result in higher payment based on the presence of a secondary diagnosis code described in clause (iv).

(ii) A discharge described in this clause is a discharge which meets the following requirements:

(I) The discharge includes a condition identified by a diagnosis code selected under clause (iv) as a secondary diagnosis.

(II) But for clause (i), the discharge would have been classified to a diagnosis-related group that results in a higher payment based on the presence of a secondary diagnosis code selected under clause (iv).

(III) At the time of admission, no code selected under clause (iv) was present.

(iii) As part of the information required to be reported by a hospital with respect to a discharge of an individual in order for payment to be made under this subsection, for discharges occurring on or after October 1, 2007, the information shall include the secondary diagnosis of the individual at admission.

(iv) By not later than October 1, 2007, the Secretary shall select diagnosis codes associated with at least two conditions, each of which codes meets all of the following requirements (as determined by the Secretary):

(I) Cases described by such code have a high cost or high volume, or both, under this title.

(II) The code results in the assignment of a case to a diagnosis-related group that has a higher payment when the code is present as a secondary diagnosis.

(III) The code describes such conditions that could reasonably have been prevented through the application of evidence-based guidelines.

The Secretary may from time to time revise (through addition or deletion of codes) the diagnosis codes selected under this clause so long as there are diagnosis codes associated with at least two conditions selected for discharges occurring during any fiscal year.

(v) In selecting and revising diagnosis codes under clause (iv), the Secretary shall consult with the Centers for Disease Control and Prevention and other appropriate entities.

(vi) Any change resulting from the application of this subparagraph shall not be taken into account in adjusting the weighting factors under subparagraph (C)(i) or in applying budget neutrality under subparagraph (C)(iii).

(5)

(A) (i) For discharges occurring during fiscal years ending on or before September 30, 1997, the Secretary shall provide for an additional payment for a subsection (d) hospital for any discharge in a diagnosis-related group, the length of stay of which exceeds the mean length of stay for discharges within that group by a fixed number of days, or exceeds such mean length of stay by some fixed number of standard deviations, whichever is the fewer number of days.

(ii) For cases which are not included in clause (i), a subsection (d) hospital may request additional payments in any case where charges, adjusted to cost, exceed a fixed multiple of the applicable DRG prospective payment rate, or exceed such other fixed dollar amount, whichever is greater, or, for discharges in fiscal years beginning on or after October 1, 1994, exceed the sum of the applicable DRG prospective payment rate plus any amounts payable under subparagraphs (B) and (F) plus a fixed dollar amount determined by the Secretary.

(iii) The amount of such additional payment under clauses (i) and (ii) shall be determined by the Secretary and shall (except as payments under clause (i) are required to be reduced to take into account the requirements of clause (v)) approximate the marginal cost of care beyond the cutoff point applicable under clause (i) or (ii).

(iv) The total amount of the additional payments made under this subparagraph for discharges in a fiscal year may not be less than 5 percent nor more than 6 percent of the total payments projected or estimated to be made based on DRG prospective payment rates for discharges in that year.

(v) The Secretary shall provide that--

(I) the day outlier percentage for fiscal year 1995 shall be 75 percent of the day outlier percentage for fiscal year 1994;

(II) the day outlier percentage for fiscal year 1996 shall be 50 percent of the day outlier percentage for fiscal year 1994; and

(III) the day outlier percentage for fiscal year 1997 shall be 25 percent of the day outlier percentage for fiscal year 1994.

(vi) For purposes of this subparagraph, the term "day outlier percentage" means, for a fiscal year, the percentage of the total additional payments made by the Secretary under this subparagraph for discharges in that fiscal year which are additional payments under clause (i).

(B) The Secretary shall provide for an additional payment amount for subsection (d) hospitals with indirect costs of medical education, in an amount computed in the same manner as the adjustment for such costs under regulations (in effect as of January 1, 1983) under subsection (a)(2), except as follows:

(i) The amount of such additional payment shall be determined by multiplying (I) the sum of the amount determined under paragraph (1)(A)(ii)(II) (or, if applicable, the amount determined under paragraph (1)(A)(iii)) and, for cases qualifying for additional payment under subparagraph (A)(i), the amount paid to the hospital under subparagraph (A), by (II) the indirect teaching adjustment factor described in clause (ii).

(ii) For purposes of clause (i)(II), the indirect teaching adjustment factor is equal to c x A (((1 + r) to the nth power) - 1), where "r" is the ratio of the hospital's full-time equivalent interns and residents to beds and "n" equals .405. Subject to clause (ix), for discharges occurring--

(I) on or after October 1, 1988, and before October 1, 1997, "c" is equal to 1.89;

(II) during fiscal year 1998, "c" is equal to 1.72;

(III) during fiscal year 1999, "c" is equal to 1.6;

(IV) during fiscal year 2000, "c" is equal to 1.47;

(V) during fiscal year 2001, "c" is equal to 1.54;

(VI) during fiscal year 2002, "c" is equal to 1.6;

(VII) on or after October 1, 2002, and before April 1, 2004, "c" is equal to 1.35;

(VIII) on or after April 1, 2004, and before October 1, 2004, "c" is equal to 1.47;

(IX) during fiscal year 2005, "c" is equal to 1.42;

(X) during fiscal year 2006, "c" is equal to 1.37;

(XI) during fiscal year 2007, "c" is equal to 1.32; and

(XII) on or after October 1, 2007, "c" is equal to 1.35.

(iii) In determining such adjustment the Secretary shall not distinguish between those interns and residents who are employees of a hospital and those interns and residents who furnish services to a hospital but are not employees of such hospital.

(iv) Effective for discharges occurring on or after October 1, 1997, all the time spent by an intern or resident in patient care activities under an approved medical residency training program at an entity in a nonhospital setting shall be counted towards the determination of full-time equivalency if the hospital incurs all, or substantially all, of the costs for the training program in that setting.

(v) In determining the adjustment with respect to a hospital for discharges occurring on or after October 1, 1997, the total number of full-time equivalent interns and residents in the fields of allopathic and osteopathic medicine in either a hospital or nonhospital setting may not exceed the number (or, 130 percent of such number in the case of a hospital located in a rural area) of such full-time equivalent interns and residents in the hospital with respect to the hospital's most recent cost reporting period ending on or before December 31, 1996. Rules similar to the rules of subsection (h)(4)(F)(ii) shall apply for purposes of this clause. The provisions of subsection (h)(7) shall apply with respect to the first sentence of this clause in the same manner as it applies with respect to subsection (h)(4)(F)(i).

(vi) For purposes of clause (ii)--

(I) "r" may not exceed the ratio of the number of interns and residents, subject to the limit under clause (v), with respect to the hospital for its most recent cost reporting period to the hospital's available beds (as defined by the Secretary) during that cost reporting period, and

(II) for the hospital's cost reporting periods beginning on or after October 1, 1997, subject to the limits described in clauses (iv) and (v), the total number of full-time equivalent residents for payment purposes shall equal the average of the actual full-time equivalent resident count for the cost reporting period and the preceding two cost reporting periods.

In the case of the first cost reporting period beginning on or after October 1, 1997, subclause (II) shall be applied by using the average for such period and the preceding cost reporting period.

(vii) If any cost reporting period beginning on or after October 1, 1997, is not equal to twelve months, the Secretary shall make appropriate modifications to ensure that the average full-time equivalent residency count pursuant to subclause (II) of clause (vi) is based on the equivalent of full twelve-month cost reporting periods.

(viii) Rules similar to the rules of subsection (h)(4)(H) shall apply for purposes of clauses (v) and (vi).

(ix) For discharges occurring on or after July 1, 2005, insofar as an additional payment amount under this subparagraph is attributable to resident positions redistributed to a hospital under subsection (h)(7)(B), in computing the indirect teaching adjustment factor under clause (ii) the adjustment shall be computed in a manner as if "c" were equal to 0.66 with respect to such resident positions.

(C)

(i) The Secretary shall provide for such exceptions and adjustments to the payment amounts established under this subsection (other than under paragraph (9)) as the Secretary deems appropriate to take into account the special needs of regional and national referral centers (including those hospitals of 275 or more beds located in rural areas). A hospital which is classified as a rural hospital may appeal to the Secretary to be classified as a rural referral center under this clause on the basis of criteria (established by the Secretary) which shall allow the hospital to demonstrate that it should be so reclassified by reason of certain of its operating characteristics being similar to those of a typical urban hospital located in the same census region and which shall not require a rural osteopathic hospital to have more than 3,000 discharges in a year in order to be classified as a rural referral center. Such characteristics may include wages, scope of services, service area, and the mix of medical specialties. The Secretary shall publish the criteria not later than August 17, 1984, for implementation by October 1, 1984. An appeal allowed under this clause must be submitted to the Secretary (in such form and manner as the Secretary may prescribe) during the quarter before the first quarter of the hospital's cost reporting period (or, in the case of a cost reporting period beginning during October 1984, during the first quarter of that period), and the Secretary must make a final determination with respect to such appeal within 60 days after the date the appeal was submitted. Any payment adjustments necessitated by a reclassification based upon the appeal shall be effective at the beginning of such cost reporting period.

(ii) The Secretary shall provide, under clause (i), for the classification of a rural hospital as a regional referral center if the hospital has a case mix index equal to or greater than the median case mix index for hospitals (other than hospitals with approved teaching programs) located in an urban area in the same region (as defined in paragraph (2)(D)), has at least 5,000 discharges a year or, if less, the median number of discharges in urban hospitals in the region in which the hospital is located (or, in the case of a rural osteopathic hospital, meets the criterion established by the Secretary under clause (i) with respect to the annual number of discharges for such hospitals), and meets any other criteria established by the Secretary under clause (i).

(D) (i) For any cost reporting period beginning on or after April 1, 1990, with respect to a subsection (d) hospital which is a sole community hospital, payment under paragraph (1)(A) shall be--

(I) an amount based on 100 percent of the hospital's target amount for the cost reporting period, as defined in subsection (b)(3)(C), or

(II) the amount determined under paragraph (1)(A)(iii),

whichever results in greater payment to the hospital.

(ii) In the case of a sole community hospital that experiences, in a cost reporting period compared to the previous cost reporting period, a decrease of more than 5 percent in its total number of inpatient cases due to circumstances beyond its control, the Secretary shall provide for such adjustment to the payment amounts under this subsection (other than under paragraph (9)) as may be necessary to fully compensate the hospital for the fixed costs it incurs in the period in providing inpatient hospital services, including the reasonable cost of maintaining necessary core staff and services.

(iii) For purposes of this *title [42 USCS §§ 1395* et seq.], the term "sole community hospital" means any hospital--

(I) that the Secretary determines is located more than 35 road miles from another hospital,

(II) that, by reason of factors such as the time required for an individual to travel to the nearest alternative source of appropriate inpatient care (in accordance with standards promulgated by the Secretary), location, weather conditions, travel conditions, or absence of other like hospitals (as determined by the Secretary), is the sole source of inpatient hospital services reasonably available to individuals in a geographic area who are entitled to benefits under part A [*42 USCS §§ 1395c* et seq.], or

(III) that is located in a rural area and designated by the Secretary as an essential access community hospital under section 1820(i)(1) [*42 USCS § 1395i-4(i)(1)*] as in effect on September 30, 1997.

(iv) The Secretary shall promulgate a standard for determining whether a hospital meets the criteria for classification as a sole community hospital under clause (iii)(II) because of the time required for an individual to travel to the nearest alternative source of appropriate inpatient care.

(v) If the Secretary determines that, in the case of a hospital located in a rural area and designated by the Secretary as an essential access community hospital under section 1820(i)(1) [*42 USCS § 1395i-4(i)(1)*] as in effect on September 30, 1997, the hospital has incurred increases in reasonable costs during a cost reporting period as a result of becoming a member of a rural health network (as defined in section 1820(d) [*42 USCS § 1395i-4(d)*]) in the State in which it is located, and in incurring such increases, the hospital will increase its costs for subsequent cost reporting periods, the Secretary shall increase the hospital's target amount under subsection (b)(3)(C) to account for such incurred increases.

(E) (i) The Secretary shall estimate the amount of reimbursement made for services described in section 1862(a)(14) [*42 USCS § 1395y(a)(14)*] with respect to which payment was made under part B [*42 USCS §§ 1395j* et seq.] in the base reporting periods referred to in paragraph (2)(A) and with respect to which payment is no longer being made.

(ii) The Secretary shall provide for an adjustment to the payment for subsection (d) hospitals in each fiscal year so as appropriately to reflect the net amount described in clause (i).

(F)

(i) For discharges occurring on or after May 1, 1986, the Secretary shall provide, in accordance with this subparagraph, for an additional payment amount for each subsection (d) hospital which--

(I) serves a significantly disproportionate number of low-income patients (as defined in clause (v)), or

(II) is located in an urban area, has 100 or more beds, and can demonstrate that its net inpatient care revenues (excluding any of such revenues attributable to this title or State plans approved under title XIX [*42 USCS §§ 1396* et seq.]), during the cost reporting period in which the discharges occur, for indigent care from State and local government sources exceed 30 percent of its total of such net inpatient care revenues during the period.

(ii) Subject to clause (ix), the amount of such payment for each discharge shall be determined by multiplying (I) the sum of the amount determined under paragraph (1)(A)(ii)(II) (or, if applicable, the amount determined under paragraph (1)(A)(iii)) and, for cases qualifying for additional payment under subparagraph (A)(i), the amount paid to the hospital under subparagraph (A) for that discharge, by (II) the disproportionate share adjustment percentage established under clause (iii) or (iv) for the cost reporting period in which the discharge occurs.

(iii) The disproportionate share adjustment percentage for a cost reporting period for a hospital described in clause (i)(II) is equal to 35 percent.

(iv) The disproportionate share adjustment percentage for a cost reporting period for a hospital that is not described in clause (i)(II) and that--

(I) is located in an urban area and has 100 or more beds or is described in the second sentence of clause (v), is equal to the percent determined in accordance with the applicable formula described in clause (vii);

(II) is located in an urban area and has less than 100 beds, is equal to 5 percent or, subject to clause (xiv) and for discharges occurring on or after April 1, 2001, is equal to the percent determined in accordance with clause (xiii);

(III) is located in a rural area and is not described in subclause (IV) or (V) or in the second sentence of clause (v), is equal to 4 percent or, subject to clause (xiv) and for discharges occurring on or after April 1, 2001, is equal to the percent determined in accordance with clause (xii);

(IV) is located in a rural area, is classified as a rural referral center under subparagraph (C), and is classified as a sole community hospital under subparagraph (D), is equal to 10 percent or, if greater, the percent determined in accordance with the applicable formula described in clause (viii) or, subject to clause (xiv) and for discharges occurring on or after April 1, 2001, the greater of the percentages determined under clause (x) or (xi);

(V) is located in a rural area, is classified as a rural referral center under subparagraph (C), and is not classified as a sole community hospital under subparagraph (D), is equal to the percent determined in accordance with the applicable formula described in clause (viii) or, subject to clause (xiv) and for discharges occurring on or after April 1, 2001, is equal to the percent determined in accordance with clause (xi); or

(VI) is located in a rural area, is classified as a sole community hospital under subparagraph (D), and is not classified as a rural referral center under subparagraph (C), is 10 percent or, subject to clause (xiv) and for discharges occurring on or after April 1, 2001, is equal to the percent determined in accordance with clause (x).

(v) In this subparagraph, a hospital "serves a significantly disproportionate number of low income patients" for a cost reporting period if the hospital has a disproportionate patient percentage (as defined in clause (vi)) for that period which equals, or exceeds--

(I) 15 percent, if the hospital is located in an urban area and has 100 or more beds,

(II) 30 percent (or 15 percent, for discharges occurring on or after April 1, 2001), if the hospital is located in a rural area and has more than 100 beds, or is located in a rural area and is classified as a sole community hospital under subparagraph (D),

(III) 40 percent (or 15 percent, for discharges occurring on or after April 1, 2001), if the hospital is located in an urban area and has less than 100 beds, or

(IV) 45 percent (or 15 percent, for discharges occurring on or after April 1, 2001), if the hospital is located in a rural area and is not described in subclause (II).

A hospital located in a rural area and with 500 or more beds also "serves a significantly disproportionate number of low income patients" for a cost reporting period if the hospital has a disproportionate patient percentage (as defined in clause (vi)) for that period which equals or exceeds a percentage specified by the Secretary.

(vi) In this subparagraph, the term "disproportionate patient percentage" means, with respect to a cost reporting period of a hospital, the sum of--

(I) the fraction (expressed as a percentage), the numerator of which is the number of such hospital's patient days for such period which were made up of patients who (for such days) were entitled to benefits under part A of this *title [42 USCS §§ 1395c* et seq.] and were entitled to supplemental security income benefits (excluding any State supplementation) under title XVI of this Act [*42 USCS §§ 1381* et seq.], and the denominator of which is the number of such hospital's patient days for such period which were made up of patients who (for such days) were entitled to benefits under part A of this *title [42 USCS §§ 1395c* et seq.], and

(II) the fraction (expressed as a percentage), the numerator of which is the number of the hospital's patient days for such period which consist of patients who (for such days) were eligible for medical assistance under a State plan approved under title XIX [*42 USCS §§ 1396* et seq.], but who were not entitled to benefits under part A of this *title [42 USCS §§ 1395c* et seq.], and the denominator of which is the total number of the hospital's patient days for such period.

In determining under subclause (II) the number of the hospital's patient days for such period which consist of patients who (for such days) were eligible for medical assistance under a State plan approved under title XIX [*42 USCS §§ 1396* et seq.], the Secretary may, to the extent and for the period the Secretary determines appropriate, include patient days of patients not so eligible but who are regarded as such because they receive benefits under a demonstration project approved under title XI [*42 USCS §§ 1301* et seq.].

(vii) The formula used to determine the disproportionate share adjustment percentage for a cost reporting period for a hospital described in clause (iv)(I) is--

(I) in the case of such a hospital with a disproportionate patient percentage (as defined in clause (vi)) greater than 20.2--

(a) for discharges occurring on or after April 1, 1990, and on or before December 31, 1990, (P - 20.2)(.65) + 5.62,

(b) for discharges occurring on or after January 1, 1991, and on or before September 30, 1993, (P - 20.2)(.7) + 5.62,

(c) for discharges occurring on or after October 1, 1993, and on or before September 30, 1994, (P - 20.2)(.8) + 5.88, and

(d) for discharges occurring on or after October 1, 1994, (P - 20.2)(.825) + 5.88; or

(II) in the case of any other such hospital--

(a) for discharges occurring on or after April 1, 1990, and on or before December 31, 1990, (P - 15)(.6) + 2.5,

(b) for discharges occurring on or after January 1, 1991, and on or before September 30, 1993, (P - 15)(.6) + 2.5, [and]

(c) for discharges occurring on or after October 1, 1993, (P - 15)(.65) + 2.5,

where "P" is the hospital's disproportionate patient percentage (as defined in clause (vi)).

(viii) Subject to clause (xiv), the formula used to determine the disproportionate share adjustment percentage for a cost reporting period for a hospital described in clause (iv)(IV) or (iv)(V) is the percentage determined in accordance with the following formula: (P - 30)(.6) + 4.0, where "P" is the hospital's disproportionate patient percentage (as defined in clause (vi)).

(ix) In the case of discharges occurring--

(I) during fiscal year 1998, the additional payment amount otherwise determined under clause (ii) shall be reduced by 1 percent;

(II) during fiscal year 1999, such additional payment amount shall be reduced by 2 percent;

(III) during fiscal years 2000 and 2001, such additional payment amount shall be reduced by 3 percent and 2 percent, respectively;

(IV) during fiscal year 2002, such additional payment amount shall be reduced by 3 percent; and

(V) during fiscal year 2003 and each subsequent fiscal year, such additional payment amount shall be reduced by 0 percent.

(x) Subject to clause (xiv), for purposes of clause (iv)(VI) (relating to sole community hospitals), in the case of a hospital for a cost reporting period with a disproportionate patient percentage (as defined in clause (vi)) that--

(I) is less than 19.3, the disproportionate share adjustment percentage is determined in accordance with the following formula: (P - 15)(.65) + 2.5;

(II) is equal to or exceeds 19.3, but is less than 30.0, such adjustment percentage is equal to 5.25 percent; or

(III) is equal to or exceeds 30, such adjustment percentage is equal to 10 percent,

where "P" is the hospital's disproportionate patient percentage (as defined in clause (vi)).

(xi) Subject to clause (xiv), for purposes of clause (iv)(V) (relating to rural referral centers), in the case of a hospital for a cost reporting period with a disproportionate patient percentage (as defined in clause (vi)) that--

(I) is less than 19.3, the disproportionate share adjustment percentage is determined in accordance with the following formula: (P - 15)(.65) + 2.5;

(II) is equal to or exceeds 19.3, but is less than 30.0, such adjustment percentage is equal to 5.25 percent; or

(III) is equal to or exceeds 30, such adjustment percentage is determined in accordance with the following formula: (P - 30)(.6) + 5.25,

where "P" is the hospital's disproportionate patient percentage (as defined in clause (vi)).

(xii) Subject to clause (xiv), for purposes of clause (iv)(III) (relating to small rural hospitals generally), in the case of a hospital for a cost reporting period with a disproportionate patient percentage (as defined in clause (vi)) that--

(I) is less than 19.3, the disproportionate share adjustment percentage is determined in accordance with the following formula: (P - 15)(.65) + 2.5; or

(II) is equal to or exceeds 19.3, such adjustment percentage is equal to 5.25 percent,

where "P" is the hospital's disproportionate patient percentage (as defined in clause (vi)).

(xiii) Subject to clause (xiv), for purposes of clause (iv)(II) (relating to urban hospitals with less than 100 beds), in the case of a hospital for a cost reporting period with a disproportionate patient percentage (as defined in clause (vi)) that--

(I) is less than 19.3, the disproportionate share adjustment percentage is determined in accordance with the following formula: (P - 15)(.65) + 2.5; or

(II) is equal to or exceeds 19.3, such adjustment percentage is equal to 5.25 percent,

where "P" is the hospital's disproportionate patient percentage (as defined in clause (vi)).

(xiv) (I) In the case of discharges occurring on or after April 1, 2004, subject to subclause (II), there shall be substituted for the disproportionate share adjustment percentage otherwise determined under clause (iv) (other than subclause (I)) or under clause (viii), (x), (xi), (xii), or (xiii), the disproportionate share adjustment percentage determined under clause (vii) (relating to large, urban hospitals).

(II) Under subclause (I), the disproportionate share adjustment percentage shall not exceed 12 percent for a hospital that is not classified as a rural referral center under subparagraph (C) or, in the case of discharges occurring on or after October 1, 2006, as a medicare-dependent, small rural hospital under subparagraph (G)(iv).

(G) (i) For any cost reporting period beginning on or after April 1, 1990, and before October 1, 1994, or discharges occurring on or after October 1, 1997, and before October 1, 2011, in the case of a subsection (d) hospital which is a medicare-dependent, small rural hospital, payment under paragraph (1)(A) shall be equal to the sum of the amount determined under clause (ii) and the amount determined under paragraph (1)(A)(iii).

(ii) The amount determined under this clause is--

(I) for discharges occurring during the 36-month period beginning with the first day of the cost reporting period that begins on or after April 1, 1990, the amount by which the hospital's target amount for the cost reporting period (as defined in subsection (b)(3)(D)) exceeds the amount determined under paragraph (1)(A)(iii); and

(II) for discharges occurring during any subsequent cost reporting period (or portion thereof) and before October 1, 1994, or discharges occurring on or after October 1, 1997, and before October 1, 2011, 50 percent (or 75 percent in the case of discharges occurring on or after October 1, 2006) of the amount by which the hospital's target amount for the cost reporting period or for discharges in the fiscal year (as defined in subsection (b)(3)(D)) exceeds the amount determined under paragraph (1)(A)(iii).

(iii) In the case of a medicare dependent, small rural hospital that experiences, in a cost reporting period compared to the previous cost reporting period, a decrease of more than 5 percent in its total number of inpatient cases due to circumstances beyond its control, the Secretary shall provide for such adjustment to the payment amounts under this subsection (other than under paragraph (9)) as may be necessary to fully compensate the hospital for the fixed costs it incurs in the period in providing inpatient hospital services, including the reasonable cost of maintaining necessary core staff and services.

(iv) The term "medicare-dependent, small rural hospital" means, with respect to any cost reporting period to which clause (i) applies, any hospital--

(I) located in a rural area,

(II) that has not more than 100 beds,

(III) that is not classified as a sole community hospital under subparagraph (D), and

(IV) for which not less than 60 percent of its inpatient days or discharges during the cost reporting period beginning in fiscal year 1987, or two of the three most recently audited cost reporting periods for which the Secretary has a settled cost report, were attributable to inpatients entitled to benefits under part A [*42 USCS §§ 1395c* et seq.].

(H) The Secretary may provide for such adjustments to the payment amounts under this subsection as the Secretary deems appropriate to take into account the unique circumstances of hospitals located in Alaska and Hawaii.

(I) (i) The Secretary shall provide by regulation for such other exceptions and adjustments to such payment amounts under this subsection as the Secretary deems appropriate.

(ii) In making adjustments under clause (i) for transfer cases (as defined by the Secretary) in a fiscal year, not taking in account the effect of subparagraph (J), the Secretary may make adjustments to each of the average standardized amounts determined under paragraph (3) to assure that the aggregate payments made under this subsection for such fiscal year are not greater or lesser than those that would have otherwise been made in such fiscal year.

(J) (i) The Secretary shall treat the term "transfer case" (as defined in subparagraph (I)(ii)) as including the case of a qualified discharge (as defined in clause (ii)), which is classified within a diagnosis-related group described in clause (iii), and which occurs on or after October 1, 1998. In the case of a qualified discharge for which a substantial portion of

the costs of care are incurred in the early days of the inpatient stay (as defined by the Secretary), in no case may the payment amount otherwise provided under this subsection exceed an amount equal to the sum of--

(I) 50 percent of the amount of payment under this subsection for transfer cases (as established under subparagraph (I)(i)), and

(II) 50 percent of the amount of payment which would have been made under this subsection with respect to the qualified discharge if no transfer were involved.

(ii) For purposes of clause (i), subject to clause (iii), the term "qualified discharge" means a discharge classified with a diagnosis-related group (described in clause (iii)) of an individual from a subsection (d) hospital, if upon such discharge the individual--

(I) is admitted as an inpatient to a hospital or hospital unit that is not a subsection (d) hospital for the provision of inpatient hospital services;

(II) is admitted to a skilled nursing facility;

(III) is provided home health services from a home health agency, if such services relate to the condition or diagnosis for which such individual received inpatient hospital services from the subsection (d) hospital, and if such services are provided within an appropriate period (as determined by the Secretary); or

(IV) for discharges occurring on or after October 1, 2000, the individual receives post discharge services described in clause (iv)(I).

(iii) Subject to clause (iv), a diagnosis-related group described in this clause is--

(I) 1 of 10 diagnosis-related groups selected by the Secretary based upon a high volume of discharges classified within such groups and a disproportionate use of post discharge services described in clause (ii); and

(II) a diagnosis-related group specified by the Secretary under clause (iv)(II).

(iv) The Secretary shall include in the proposed rule published under subsection (e)(5)(A) for fiscal year 2001, a description of the effect of this subparagraph. The Secretary may include in the proposed rule (and in the final rule published under paragraph (6)) for fiscal year 2001 or a subsequent fiscal year, a description of--

(I) post-discharge services not described in subclauses (I), (II), and (III) of clause (ii), the receipt of which results in a qualified discharge; and

(II) diagnosis-related groups described in clause (iii)(I) in addition to the 10 selected under such clause.

(K) (i) Effective for discharges beginning on or after October 1, 2001, the Secretary shall establish a mechanism to recognize the costs of new medical services and technologies under the payment system established under this subsection. Such mechanism shall be established after notice and opportunity for public comment (in the publications required by subsection (e)(5) for a fiscal year or otherwise). Such mechanism shall be modified to meet the requirements of clause (viii).

(ii) The mechanism established pursuant to clause (i) shall--

(I) apply to a new medical service or technology if, based on the estimated costs incurred with respect to discharges involving such service or technology, the DRG prospective payment rate otherwise applicable to such discharges under this subsection is inadequate (applying a threshold specified by the Secretary that is the lesser of 75 percent of the standardized amount (increased to reflect the difference between cost and charges) or 75 percent of one standard deviation for the diagnosis-related group involved);

(II) provide for the collection of data with respect to the costs of a new medical service or technology described in subclause (I) for a period of not less than two years and not more than three years beginning on the date on which an inpatient hospital code is issued with respect to the service or technology;

(III) provide for additional payment to be made under this subsection with respect to discharges involving a new medical service or technology described in subclause (I) that occur during the period described in subclause (II) in an amount that adequately reflects the estimated average cost of such service or technology; and

(IV) provide that discharges involving such a service or technology that occur after the close of the period described in subclause (II) will be classified within a new or existing diagnosis-related group with a weighting factor under paragraph (4)(B) that is derived from cost data collected with respect to discharges occurring during such period.

(iii) For purposes of clause (ii)(II), the term "inpatient hospital code" means any code that is used with respect to inpatient hospital services for which payment may be made under this subsection and includes an alphanumeric code issued under the International Classification of Diseases, 9th Revision, Clinical Modification ("ICD-9-CM") and its subsequent revisions.

(iv) For purposes of clause (ii)(III), the term "additional payment" means, with respect to a discharge for a new medical service or technology described in clause (ii)(I), an amount that exceeds the prospective payment rate otherwise applicable under this subsection to discharges involving such service or technology that would be made but for this subparagraph.

(v) The requirement under clause (ii)(III) for an additional payment may be satisfied by means of a new-technology group (described in subparagraph (L)), an add-on payment, a payment adjustment, or any other similar

mechanism for increasing the amount otherwise payable with respect to a discharge under this subsection. The Secretary may not establish a separate fee schedule for such additional payment for such services and technologies, by utilizing a methodology established under subsection (a) or (h) of section 1834 [*42 USCS § 1395m*] to determine the amount of such additional payment, or by other similar mechanisms or methodologies.

(vi) For purposes of this subparagraph and subparagraph (L), a medical service or technology will be considered a "new medical service or technology" if the service or technology meets criteria established by the Secretary after notice and an opportunity for public comment.

(vii) Under the mechanism under this subparagraph, the Secretary shall provide for the addition of new diagnosis and procedure codes in April 1 of each year, but the addition of such codes shall not require the Secretary to adjust the payment (or diagnosis-related group classification) under this subsection until the fiscal year that begins after such date.

(viii) The mechanism established pursuant to clause (i) shall be adjusted to provide, before publication of a proposed rule, for public input regarding whether a new service or technology represents an advance in medical technology that substantially improves the diagnosis or treatment of individuals entitled to benefits under part A [*42 USCS §§ 1395c* et seq.] as follows:

(I) The Secretary shall make public and periodically update a list of all the services and technologies for which an application for additional payment under this subparagraph is pending.

(II) The Secretary shall accept comments, recommendations, and data from the public regarding whether the service or technology represents a substantial improvement.

(III) The Secretary shall provide for a meeting at which organizations representing hospitals, physicians, such individuals, manufacturers, and any other interested party may present comments, recommendations, and data to the clinical staff of the Centers for Medicare & Medicaid Services before publication of a notice of proposed rulemaking regarding whether service or technology represents a substantial improvement.

(ix) Before establishing any add-on payment under this subparagraph with respect to a new technology, the Secretary shall seek to identify one or more diagnosis-related groups associated with such technology, based on similar clinical or anatomical characteristics and the cost of the technology. Within such groups the Secretary shall assign an eligible new technology into a diagnosis-related group where the average costs of care most closely approximate the costs of care of using the new technology. No add-on payment under this subparagraph shall be made with respect to such new technology and this clause shall not affect the application of paragraph (4)(C)(iii).

(L)

(i) In establishing the mechanism under subparagraph (K), the Secretary may establish new-technology groups into which a new medical service or technology will be classified if, based on the estimated average costs incurred with respect to discharges involving such service or technology, the DRG prospective payment rate otherwise applicable to such discharges under this subsection is inadequate.

(ii) Such groups--

(I) shall not be based on the costs associated with a specific new medical service or technology; but

(II) shall, in combination with the applicable standardized amounts and the weighting factors assigned to such groups under paragraph (4)(B), reflect such cost cohorts as the Secretary determines are appropriate for all new medical services and technologies that are likely to be provided as inpatient hospital services in a fiscal year.

(iii) The methodology for classifying specific hospital discharges within a diagnosis-related group under paragraph (4)(A) or a new-technology group shall provide that a specific hospital discharge may not be classified within both a diagnosis-related group and a new-technology group.

(6) The Secretary shall provide for publication in the Federal Register, on or before the August 1 before each fiscal year (beginning with fiscal year 1984), of a description of the methodology and data used in computing the adjusted DRG prospective payment rates under this subsection, including any adjustments required under subsection (e)(1)(B).

(7) There shall be no administrative or judicial review under section 1878 [*42 USCS § 1395oo*] or otherwise of--

(A) the determination of the requirement, or the proportional amount, of any adjustment effected pursuant to subsection (e)(1) or the determination of the applicable percentage increase under paragraph (12)(A)(ii), and

(B) the establishment of diagnosis-related groups, of the methodology for the classification of discharges within such groups, and of the appropriate weighting factors thereof under paragraph (4), including the selection and revision of codes under paragraph (4)(D).

(8) (A) In the case of any hospital which is located in an area which is, at any time after April 20, 1983, reclassified from an urban to a rural area, payments to such hospital for the first two cost reporting periods for which such reclassification is effective shall be made as follows:

(i) For the first such cost reporting period, payment shall be equal to the amount payable to such hospital for such reporting period on the basis of the rural classification, plus an amount equal to two-thirds of the amount (if any) by which--

(I) the amount which would have been payable to such hospital for such reporting period on the basis of an urban classification, exceeds

(II) the amount payable to such hospital for such reporting period on the basis of the rural classification.

(ii) For the second such cost reporting period, payment shall be equal to the amount payable to such hospital for such reporting period on the basis of the rural classification, plus an amount equal to one-third of the amount (if any) by which--

(I) the amount which would have been payable to such hospital for such reporting period on the basis of an urban classification, exceeds

(II) the amount payable to such hospital for such reporting period on the basis of the rural classification.

(B) (i) For purposes of this subsection, the Secretary shall treat a hospital located in a rural county adjacent to one or more urban areas as being located in the urban metropolitan statistical area to which the greatest number of workers in the county commute, if the rural county would otherwise be considered part of an urban area, under the standards for designating Metropolitan Statistical Areas (and for designating New England County Metropolitan Areas) described in clause (ii), if the commuting rates used in determining outlying counties (or, for New England, similar recognized areas) were determined on the basis of the aggregate number of resident workers who commute to (and, if applicable under the standards, from) the central county or counties of all contiguous Metropolitan Statistical Areas (or New England County Metropolitan Areas).

(ii) The standards described in this clause for cost reporting periods beginning in a fiscal year--

(I) before fiscal year 2003, are the standards published in the Federal Register on January 3, 1980, or, at the election of the hospital with respect to fiscal years 2001 and 2002, standards so published on March 30, 1990; and

(II) after fiscal year 2002, are the standards published in the Federal Register by the Director of the Office of Management and Budget based on the most recent available decennial population data.

Subparagraphs (C) and (D) shall not apply with respect to the application of subclause (I).

(C) (i) If the application of subparagraph (B) or a decision of the Medicare Geographic Classification Review Board or the Secretary under paragraph (10), by treating hospitals located in a rural county or counties as being located in an urban area, or by treating hospitals located in one urban area as being located in another urban area--

(I) reduces the wage index for that urban area (as applied under this subsection) by 1 percentage point or less, the Secretary, in calculating such wage index under this subsection, shall exclude those hospitals so treated, or

(II) reduces the wage index for that urban area by more than 1 percentage point (as applied under this subsection), the Secretary shall calculate and apply such wage index under this subsection separately to hospitals located in such urban area (excluding all the hospitals so treated) and to the hospitals so treated (as if such hospitals were located in such urban area).

(ii) If the application of subparagraph (B) or a decision of the Medicare Geographic Classification Review Board or the Secretary under paragraph (10), by treating hospitals located in a rural county or counties as not being located in the rural area in a State, reduces the wage index for that rural area (as applied under this subsection), the Secretary shall calculate and apply such wage index under this subsection as if the hospitals so treated had not been excluded from calculation of the wage index for that rural area.

(iii) The application of subparagraph (B) or a decision of the Medicare Geographic Classification Review Board or the Secretary under paragraph (10) may not result in the reduction of any county's wage index to a level below the wage index for rural areas in the State in which the county is located.

(iv) The application of subparagraph (B) or a decision of the Medicare Geographic Classification Review Board or of the Secretary under paragraph (10) may not result in a reduction in an urban area's wage index if--

(I) the urban area has a wage index below the wage index for rural areas in the State in which it is located; or

(II) the urban area is located in a State that is composed of a single urban area.

(v) This subparagraph shall apply with respect to discharges occurring in a fiscal year only if the Secretary uses a method for making adjustments to the DRG prospective payment rate for area differences in hospital wage levels under paragraph (3)(E) for the fiscal year that is based on the use of Metropolitan Statistical Area classifications.

(D) The Secretary shall make a proportional adjustment in the standardized amounts determined under paragraph (3) to assure that the provisions of subparagraphs (B) and (C) or a decision of the Medicare Geographic Classification Review Board or the Secretary under paragraph (10) do not result in aggregate payments under this section that are greater or less than those that would otherwise be made.

(E)

(i) For purposes of this subsection, not later than 60 days after the receipt of an application (in a form and manner determined by the Secretary) from a subsection (d) hospital described in clause (ii), the Secretary shall treat the hospital as being located in the rural area (as defined in paragraph (2)(D)) of the State in which the hospital is located.

(ii) For purposes of clause (i), a subsection (d) hospital described in this clause is a subsection (d) hospital that is located in an urban area (as defined in paragraph (2)(D)) and satisfies any of the following criteria:

(I) The hospital is located in a rural census tract of a metropolitan statistical area (as determined under the most recent modification of the Goldsmith Modification, originally published in the Federal Register on February 27, 1992 *(57 Fed. Reg. 6725))*.

(II) The hospital is located in an area designated by any law or regulation of such State as a rural area (or is designated by such State as a rural hospital).

(III) The hospital would qualify as a rural, regional, or national referral center under paragraph (5)(C) or as a sole community hospital under paragraph (5)(D) if the hospital were located in a rural area.

(IV) The hospital meets such other criteria as the Secretary may specify.

(9) (A) Notwithstanding section 1814(b) [*42 USCS § 1395f(b)*] but subject to the provisions of section 1813 [*42 USCS § 1395e*], the amount of the payment with respect to the operating costs of inpatient hospital services of a subsection (d) Puerto Rico hospital for inpatient hospital discharges is equal to the sum of--

(i) the applicable Puerto Rico percentage (specified in subparagraph (E)) of the Puerto Rico adjusted DRG prospective payment rate (determined under subparagraph (B) or (C)) for such discharges,

(ii) the applicable Federal percentage (specified in subparagraph (E)) of--

(I) for discharges beginning in a fiscal year beginning on or after October 1, 1997, and before October 1, 2003, the discharge-weighted average of--

(aa) the national adjusted DRG prospective payment rate (determined under paragraph (3)(D)) for hospitals located in a large urban area,

(bb) such rate for hospitals located in other urban areas, and

(cc) such rate for hospitals located in a rural area,

for such discharges, adjusted in the manner provided in paragraph (3)(E) for different area wage levels; and

(II) for discharges in a fiscal year beginning on or after October 1, 2003, the national DRG prospective payment rate determined under paragraph (3)(D)(iii) for hospitals located in any area for such discharges, adjusted in the manner provided in paragraph (3)(E) for different area wage levels.

As used in this section, the term "subsection (d) Puerto Rico hospital" means a hospital that is located in Puerto Rico and that would be a subsection (d) hospital (as defined in paragraph (1)(B)) if it were located in one of the 50 States.

(B) The Secretary shall determine a Puerto Rico adjusted DRG prospective payment rate, for each inpatient hospital discharge in fiscal year 1988 involving inpatient hospital services of a subsection (d) Puerto Rico hospital for which payment may be made under part A of this *title [42 USCS §§ 1395c* et seq.]. Such rate shall be determined for such hospitals located in urban or rural areas within Puerto Rico, as follows:

(i) The Secretary shall determine the target amount (as defined in subsection (b)(3)(A)) for the hospital for the cost reporting period beginning in fiscal year 1987 and increase such amount by prorating the applicable percentage increase (as defined in subsection (b)(3)(B)) to update the amount to the midpoint in fiscal year 1988.

(ii) The Secretary shall standardize the amount determined under clause (i) for each hospital by--

(I) excluding an estimate of indirect medical education costs,

(II) adjusting for variations among hospitals by area in the average hospital wage level,

(III) adjusting for variations in case mix among hospitals, and

(IV) excluding an estimate of the additional payments to certain subsection (d) Puerto Rico hospitals to be made under subparagraph (D)(iii) (relating to disproportionate share payments).

(iii) The Secretary shall compute a discharge weighted average of the standardized amounts determined under clause (ii) for all hospitals located in an urban area and for all hospitals located in a rural area (as such terms are defined in paragraph (2)(D)).

(iv) The Secretary shall reduce the average standardized amount by a proportion equal to the proportion (estimated by the Secretary) of the amount of payments under this paragraph which are additional payments described in subparagraph (D)(i) (relating to outlier payments).

(v) For each discharge classified within a diagnosis-related group for hospitals located in an urban or rural area, respectively, the Secretary shall establish a Puerto Rico DRG prospective payment rate equal to the product of--

(I) the average standardized amount (computed under clause (iii) and reduced under clause (iv)) for hospitals located in an urban or rural area, respectively, and

(II) the weighting factor (determined under paragraph (4)(B)) for that diagnosis-related group.

(vi) The Secretary shall adjust the proportion (as estimated by the Secretary from time to time) of hospitals' costs which are attributable to wages and wage-related costs, of the Puerto Rico DRG prospective payment rate computed under clause (v) for area differences in hospital wage levels by a factor (established by the Secretary) reflecting the relative hospital wage level in the geographic area of the hospital compared to the Puerto Rican average hospital wage level.

(C) The Secretary shall determine a Puerto Rico adjusted DRG prospective payment rate, for each inpatient hospital discharge after fiscal year 1988 involving inpatient hospital services of a subsection (d) Puerto Rico hospital for which

payment may be made under part A of this *title [42 USCS §§ 1395c* et seq.]. Such rate shall be determined for hospitals located in urban or rural areas within Puerto Rico as follows:

(i) (I) For discharges in a fiscal year after fiscal year 1988 and before fiscal year 2004, the Secretary shall compute an average standardized amount for hospitals located in an urban area and for hospitals located in a rural area equal to the respective average standardized amount computed for the previous fiscal year under subparagraph (B)(iii) or under this clause, increased for fiscal year 1989 by the applicable percentage increase under subsection (b)(3)(B), and adjusted for subsequent fiscal years in accordance with the final determination of the Secretary under subsection (e)(4), and adjusted to reflect the most recent case-mix data available.

(II) For discharges occurring in a fiscal year (beginning with fiscal year 2004), the Secretary shall compute an average standardized amount for hospitals located in any area of Puerto Rico that is equal to the average standardized amount computed under subclause (I) for fiscal year 2003 for hospitals in a large urban area (or, beginning with fiscal year 2005, for all hospitals in the previous fiscal year) increased by the applicable percentage increase under subsection (b)(3)(B) for the fiscal year involved.

(ii) The Secretary shall reduce each of the average standardized amounts (or for fiscal year 2004 and thereafter, the average standardized amount) by a proportion equal to the proportion (estimated by the Secretary) of the amount of payments under this paragraph which are additional payments described in subparagraph (D)(i) (relating to outlier payments).

(iii) For each discharge classified within a diagnosis-related group for hospitals located in an urban or rural area, respectively, the Secretary shall establish a Puerto Rico DRG prospective payment rate equal to the product of--

(I) the average standardized amount (computed under clause (i) and reduced under clause (ii)), and

(II) the weighting factor (determined under paragraph (4)(B)) for that diagnosis-related group.

(iv) (I) The Secretary shall adjust the proportion (as estimated by the Secretary from time to time) of hospitals' costs which are attributable to wages and wage-related costs, of the Puerto Rico DRG prospective payment rate computed under clause (iii) for area differences in hospital wage levels by a factor (established by the Secretary) reflecting the relative hospital wage level in the geographic area of the hospital compared to the Puerto Rico average hospital wage level. The second and third sentences of paragraph (3)(E)(i) shall apply to subsection (d) Puerto Rico hospitals under this clause in the same manner as they apply to subsection (d) hospitals under such paragraph and, for purposes of this clause, any reference in such paragraph to a subsection (d) hospital is deemed a reference to a subsection (d) Puerto Rico hospital.

(II) For discharges occurring on or after October 1, 2004, the Secretary shall substitute "62 percent" for the proportion described in the first sentence of clause (i), unless the application of this subclause would result in lower payments to a hospital than would otherwise be made.

(D) The following provisions of paragraph (5) shall apply to subsection (d) Puerto Rico hospitals receiving payment under this paragraph in the same manner and to the extent as they apply to subsection (d) hospitals receiving payment under this subsection:

(i) Subparagraph (A) (relating to outlier payments).

(ii) Subparagraph (B) (relating to payments for indirect medical education costs), except that for this purpose the sum of the amount determined under subparagraph (A) of this paragraph and the amount paid to the hospital under clause (i) of this subparagraph shall be substituted for the sum referred to in paragraph (5)(B)(i)(I).

(iii) Subparagraph (F) (relating to disproportionate share payments), except that for this purpose the sum described in clause (ii) of this subparagraph shall be substituted for the sum referred to in paragraph (5)(F)(ii)(I).

(iv) Subparagraph (H) (relating to exceptions and adjustments).

(E) For purposes of subparagraph (A), for discharges occurring--

(i) on or after October 1, 1987, and before October 1, 1997, the applicable Puerto Rico percentage is 75 percent and the applicable Federal percentage is 25 percent;

(ii) on or after October 1, 1997, and before April 1, 2004, the applicable Puerto Rico percentage is 50 percent and the applicable Federal percentage is 50 percent;

(iii) on or after April 1, 2004, and before October 1, 2004, the applicable Puerto Rico percentage is 37.5 percent and the applicable Federal percentage is 62.5 percent; and

(iv) on or after October 1, 2004, the applicable Puerto Rico percentage is 25 percent and the applicable Federal percentage is 75 percent.

(10)

(A) There is hereby established the Medicare Geographic Classification Review Board (hereinafter in this paragraph referred to as the "Board").

(B) (i) The Board shall be composed of 5 members appointed by the Secretary without regard to the provisions of title 5, United States Code, governing appointments in the competitive service. Two of such members shall be

representative of subsection (d) hospitals located in a rural area under paragraph (2)(D). At least 1 member shall be knowledgeable in the field of analyzing costs with respect to the provision of inpatient hospital services.

(ii) The Secretary shall make initial appointments to the Board as provided in this paragraph within 180 days after the date of the enactment of this paragraph.

(C) (i) The Board shall consider the application of any subsection (d) hospital requesting that the Secretary change the hospital's geographic classification for purposes of determining for a fiscal year--

(I) the hospital's average standardized amount under paragraph (2)(D), or

(II) the factor used to adjust the DRG prospective payment rate for area differences in hospital wage levels that applies to such hospital under paragraph (3)(E).

(ii) A hospital requesting a change in geographic classification under clause (i) for a fiscal year shall submit its application to the Board not later than the first day of the 13-month period ending on September 30 of the preceding fiscal year.

(iii) (I) The Board shall render a decision on an application submitted under clause (i) not later than 180 days after the deadline referred to in clause (ii).

(II) Appeal of decisions of the Board shall be subject to the provisions of section 557b [557(b)] of title 5, United States Code. The Secretary shall issue a decision on such an appeal not later than 90 days after the date on which the appeal is filed. The decision of the Secretary shall be final and shall not be subject to judicial review.

(D) (i) The Secretary shall publish guidelines to be utilized by the Board in rendering decisions on applications submitted under this paragraph, and shall include in such guidelines the following:

(I) Guidelines for comparing wages, taking into account (to the extent the Secretary determines appropriate) occupational mix, in the area in which the hospital is classified and the area in which the hospital is applying to be classified.

(II) Guidelines for determining whether the county in which the hospital is located should be treated as being a part of a particular Metropolitan Statistical Area.

(III) Guidelines for considering information provided by an applicant with respect to the effects of the hospital's geographic classification on access to inpatient hospital services by medicare beneficiaries.

(IV) Guidelines for considering the appropriateness of the criteria used to define New England County Metropolitan Areas.

(ii) Notwithstanding clause (i), if the Secretary uses a method for making adjustments to the DRG prospective payment rate for area differences in hospital wage levels under paragraph (3)(E) that is not based on the use of Metropolitan Statistical Area classifications, the Secretary may revise the guidelines published under clause (i) to the extent such guidelines are used to determine the appropriateness of the geographic area in which the hospital is determined to be located for purposes of making such adjustments.

(iii) Under the guidelines published by the Secretary under clause (i), in the case of a hospital which has ever been classified by the Secretary as a rural referral center under paragraph (5)(C), the Board may not reject the application of the hospital under this paragraph on the basis of any comparison between the average hourly wage of the hospital and the average hourly wage of hospitals in the area in which it is located.

(iv) The Secretary shall publish the guidelines described in clause (i) by July 1, 1990.

(v) Any decision of the Board to reclassify a subsection (d) hospital for purposes of the adjustment factor described in subparagraph (C)(i)(II) for fiscal year 2001 or any fiscal year thereafter shall be effective for a period of 3 fiscal years, except that the Secretary shall establish procedures under which a subsection (d) hospital may elect to terminate such reclassification before the end of such period.

(vi) Such guidelines shall provide that, in making decisions on applications for reclassification for the purposes described in clause (v) for fiscal year 2003 and any succeeding fiscal year, the Board shall base any comparison of the average hourly wage for the hospital with the average hourly wage for hospitals in an area on--

(I) an average of the average hourly wage amount for the hospital from the most recently published hospital wage survey data of the Secretary (as of the date on which the hospital applies for reclassification) and such amount from each of the two immediately preceding surveys; and

(II) an average of the average hourly wage amount for hospitals in such area from the most recently published hospital wage survey data of the Secretary (as of the date on which the hospital applies for reclassification) and such amount from each of the two immediately preceding surveys.

(E) (i) The Board shall have full power and authority to make rules and establish procedures, not inconsistent with the provisions of this *title [42 USCS §§ 1395* et seq.] or regulations of the Secretary, which are necessary or appropriate to carry out the provisions of this paragraph. In the course of any hearing the Board may administer oaths and affirmations. The provisions of subsections (d) and (e) of section 205 [*42 USCS § 405*] with respect to subpenas shall apply to the Board to the same extent as such provisions apply to the Secretary with respect to title II [*42 USCS §§ 401* et seq.].

(ii) The Board is authorized to engage such technical assistance and to receive such information as may be required to carry out its functions, and the Secretary shall, in addition, make available to the Board such secretarial, clerical, and other assistance as the Board may require to carry out its functions.

(F) (i) Each member of the Board who is not an officer or employee of the Federal Government shall be compensated at a rate equal to the daily equivalent of the annual rate of basic pay prescribed for grade GS-18 of the General Schedule under *section 5332 of title 5, United States Code*, for each day (including travel time) during which such member is engaged in the performance of the duties of the Board. Each member of the Board who is an officer or employee of the United States shall serve without compensation in addition to that received for service as an officer or employee of the United States.

(ii) Members of the Board shall be allowed travel expenses, including per diem in lieu of subsistence, at rates authorized for employees of agencies under subchapter I of chapter 57 of title 5, United States Code [*5 USCS §§ 5701* et seq.], while away from their homes or regular places of business in the performance of services for the Board.

(11) Additional payments for managed care enrollees.

(A) In general. For portions of cost reporting periods occurring on or after January 1, 1998, the Secretary shall provide for an additional payment amount for each applicable discharge of any subsection (d) hospital that has an approved medical residency training program.

(B) Applicable discharge. For purposes of this paragraph, the term "applicable discharge" means the discharge of any individual who is enrolled under a risk-sharing contract with an eligible organization under section 1876 [*42 USCS § 1395mm*] and who is entitled to benefits under part A [*42 USCS §§ 1395c* et seq.] or any individual who is enrolled with a Medicare + Choice organization under part C [*42 USCS §§ 1395w-21* et seq.].

(C) Determination of amount. The amount of the payment under this paragraph with respect to any applicable discharge shall be equal to the applicable percentage (as defined in subsection (h)(3)(D)(ii)) of the estimated average per discharge amount that would otherwise have been paid under paragraph (5)(B) if the individuals had not been enrolled as described in subparagraph (B).

(D) Special rule for hospitals under reimbursement system. The Secretary shall establish rules for the application of this paragraph to a hospital reimbursed under a reimbursement system authorized under section 1814(b)(3) [*42 USCS § 1395f(b)(3)*] in the same manner as it would apply to the hospital if it were not reimbursed under such section.

(12) Payment adjustment for low-volume hospitals.

(A) In general. In addition to any payments calculated under this section for a subsection (d) hospital, for discharges occurring during a fiscal year (beginning with fiscal year 2005), the Secretary shall provide for an additional payment amount to each low-volume hospital (as defined in subparagraph (C)(i)) for discharges occurring during that fiscal year that is equal to the applicable percentage increase (determined under subparagraph (B) for the hospital involved) in the amount paid to such hospital under this section for such discharges (determined without regard to this paragraph).

(B) Applicable percentage increase. The Secretary shall determine an applicable percentage increase for purposes of subparagraph (A) as follows:

(i) The Secretary shall determine the empirical relationship for subsection (d) hospitals between the standardized cost-per-case for such hospitals and the total number of discharges of such hospitals and the amount of the additional incremental costs (if any) that are associated with such number of discharges.

(ii) The applicable percentage increase shall be determined based upon such relationship in a manner that reflects, based upon the number of such discharges for a subsection (d) hospital, such additional incremental costs.

(iii) In no case shall the applicable percentage increase exceed 25 percent.

(C) Definitions.

(i) Low-volume hospital. For purposes of this paragraph, the term "low-volume hospital" means, for a fiscal year, a subsection (d) hospital (as defined in paragraph (1)(B)) that the Secretary determines is located more than 25 road miles from another subsection (d) hospital and has less than 800 discharges during the fiscal year.

(ii) Discharge. For purposes of subparagraph (B) and clause (i), the term "discharge" means an inpatient acute care discharge of an individual regardless of whether the individual is entitled to benefits under part A [*42 USCS §§ 1395c* et seq.].

(13) (A) In order to recognize commuting patterns among geographic areas, the Secretary shall establish a process through application or otherwise for an increase of the wage index applied under paragraph (3)(E) for subsection (d) hospitals located in a qualifying county described in subparagraph (B) in the amount computed under subparagraph (D) based on out-migration of hospital employees who reside in that county to any higher wage index area.

(B) The Secretary shall establish criteria for a qualifying county under this subparagraph based on the out-migration referred to in subparagraph (A) and differences in the area wage indices. Under such criteria the Secretary shall, utilizing such data as the Secretary determines to be appropriate, establish--

(i) a threshold percentage, established by the Secretary, of the weighted average of the area wage index or indices for the higher wage index areas involved;

(ii) a threshold (of not less than 10 percent) for minimum out-migration to a higher wage index area or areas; and

(iii) a requirement that the average hourly wage of the hospitals in the qualifying county equals or exceeds the average hourly wage of all the hospitals in the area in which the qualifying county is located.

(C) For purposes of this paragraph, the term "higher wage index area" means, with respect to a county, an area with a wage index that exceeds that of the county.

(D) The increase in the wage index under subparagraph (A) for a qualifying county shall be equal to the percentage of the hospital employees residing in the qualifying county who are employed in any higher wage index area multiplied by the sum of the products, for each higher wage index area of--

(i) the difference between--

(I) the wage index for such higher wage index area, and

(II) the wage index of the qualifying county; and

(ii) the number of hospital employees residing in the qualifying county who are employed in such higher wage index area divided by the total number of hospital employees residing in the qualifying county who are employed in any higher wage index area.

(E) The process under this paragraph may be based upon the process used by the Medicare Geographic Classification Review Board under paragraph (10). As the Secretary determines to be appropriate to carry out such process, the Secretary may require hospitals (including subsection (d) hospitals and other hospitals) and critical access hospitals, as required under section 1866(a)(1)(T) [*42 USCS § 1395cc(a)(1)(T)*], to submit data regarding the location of residence, or the Secretary may use data from other sources.

(F) A wage index increase under this paragraph shall be effective for a period of 3 fiscal years, except that the Secretary shall establish procedures under which a subsection (d) hospital may elect to waive the application of such wage index increase.

(G) A hospital in a county that has a wage index increase under this paragraph for a period and that has not waived the application of such an increase under subparagraph (F) is not eligible for reclassification under paragraph (8) or (10) during that period.

(H) Any increase in a wage index under this paragraph for a county shall not be taken into account for purposes of--

(i) computing the wage index for portions of the wage index area (not including the county) in which the county is located; or

(ii) applying any budget neutrality adjustment with respect to such index under paragraph (8)(D).

(I) The thresholds described in subparagraph (B), data on hospital employees used under this paragraph, and any determination of the Secretary under the process described in subparagraph (E) shall be final and shall not be subject to judicial review.

(e) Proportional adjustments in applicable percentage increases; Prospective Payment Assessment Commission [Medicare Payment Advisory Commission].

(1)

(A) For cost reporting periods of hospitals beginning in fiscal year 1984 or fiscal year 1985, the Secretary shall provide for such proportional adjustment in the applicable percentage increase (otherwise applicable to the periods under subsection (b)(3)(B)) as may be necessary to assure that--

(i) the aggregate payment amounts otherwise provided under subsection (d)(1)(A)(i)(I) for that fiscal year for operating costs of inpatient hospital services of hospitals (excluding payments made under section 1866(a)(1)(F)) [*42 USCS § 1395cc(a)(1)(F)*],

are not greater or less than--

(ii) the target percentage (as defined in subsection (d)(1)(C)) of the payment amounts which would have been payable for such services for those same hospitals for that fiscal year under this section under the law as in effect before the date of the enactment of the Social Security Amendments of 1983 [enacted April 20, 1983] (excluding payments made under section 1866(a)(1)(F) [*42 USCS § 1395cc(a)(1)(F)*]);

except that the adjustment made under this subparagraph shall apply only to subsection (d) hospitals and shall not apply for purposes of making computations under subsection (d)(2)(B)(ii) or subsection (d)(3)(A).

(B) For discharges occurring in fiscal year 1984 or fiscal year 1985, the Secretary shall provide under subsections (d)(2)(F) and (d)(3)(C) for such equal proportional adjustment in each of the average standardized amounts otherwise computed for that fiscal year as may be necessary to assure that--

(i) the aggregate payment amounts otherwise provided under subsection (d)(1)(A)(i)(II) and (d)(5) for that fiscal year for operating costs of inpatient hospital services of hospitals (excluding payments made under section 1866(a)(1)(F) [*42 USCS § 1395cc(a)(1)(F)*]),

are not greater or less than--

(ii) the DRG percentage (as defined in subsection (d)(1)(C)) of the payment amounts which would have been payable for such services for those same hospitals for that fiscal year under this section under the law as in effect before the date of the enactment of the Social Security Amendments of 1983 [enacted April 20, 1983] (excluding payments made under section 1866(a)(1)(F) [*42 USCS § 1395cc(a)(1)(F)*]).

(C) For discharges occurring in fiscal year 1988, the Secretary shall provide for such equal proportional adjustment in each of the average standardized amounts otherwise computed under subsection (d)(3) for that fiscal year as may be necessary to assure that--

(i) the aggregate payment amounts otherwise provided under subsections (d)(1)(A)(iii), (d)(5), and (d)(9) for that fiscal year for operating costs of inpatient hospital services of subsection (d) hospitals and subsection (d) Puerto Rico hospitals,

are not greater or less than--

(ii) the payment amounts that would have been payable for such services for those same hospitals for that fiscal year but for the enactment of the amendments made by section 9304 of the Omnibus Budget Reconciliation Act of 1986 [enacted Oct. 21, 1986].

(2) [Deleted]

(3) [Deleted]

(4)

(A) Taking into consideration the recommendations of the Commission, the Secretary shall recommend for each fiscal year (beginning with fiscal year 1988) an appropriate change factor for inpatient hospital services for discharges in that fiscal year which will take into account amounts necessary for the efficient and effective delivery of medically appropriate and necessary care of high quality. The appropriate change factor may be different for all large urban subsection (d) hospitals, other urban subsection (d) hospitals, urban subsection (d) Puerto Rico hospitals, rural subsection (d) hospitals, and rural subsection (d) Puerto Rico hospitals, and all other hospitals and units not paid under subsection (d), and may vary among such other hospitals and units.

(B) In addition to the recommendation made under subparagraph (A), the Secretary shall, taking into consideration the recommendations of the Commission under paragraph (2)(B), recommend for each fiscal year (beginning with fiscal year 1992) other appropriate changes in each existing reimbursement policy under this *title [42 USCS §§ 1395* et seq.] under which payments to an institution are based upon prospectively determined rates.

(5) The Secretary shall cause to have published in the Federal Register, not later than--

(A) the April 1 before each fiscal year (beginning with fiscal year 1986), the Secretary's proposed recommendation under paragraph (4) for that fiscal year for public comment, and

(B) the August 1 before such fiscal year after such consideration of public comment on the proposal as is feasible in the time available, the Secretary's final recommendation under such paragraph for that year.

The Secretary shall include in the publication referred to in subparagraph (A) for a fiscal year the report of the Commission's recommendations submitted under paragraph (3) for that fiscal year. To the extent that the Secretary's recommendations under paragraph (4) differ from the Commission's recommendations for that fiscal year, the Secretary shall include in the publication referred to in subparagraph (A) an explanation of the Secretary's grounds for not following the Commission's recommendations.

(f) Reporting of costs of hospitals receiving payments on basis of prospective rates.

(1) (A) The Secretary shall maintain a system for the reporting of costs of hospitals receiving payments computed under subsection (d).

(B) (i) Subject to clause (ii), the Secretary shall place into effect a standardized electronic cost reporting format for hospitals under this *title [42 USCS §§ 1395* et seq.].

(ii) The Secretary may delay or waive the implementation of such format in particular instances where such implementation would result in financial hardship (in particular with respect to hospitals with a small percentage of inpatients entitled to benefits under this *title [42 USCS §§ 1395* et seq.]).

(2) If the Secretary determines, based upon information supplied by a utilization and quality control peer review organization under part B of title XI [*42 USCS §§ 1320c* et seq.], that a hospital, in order to circumvent the payment method established under subsection (b) or (d) of this section, has taken an action that results in the admission of individuals entitled to benefits under part A [*42 USCS §§ 1395c* et seq.] unnecessarily, unnecessary multiple admissions of the same such individuals, or other inappropriate medical or other practices with respect to such individuals, the Secretary may--

(A) deny payment (in whole or in part) under part A [*42 USCS §§ 1395c* et seq.] with respect to inpatient hospital services provided with respect to such an unnecessary admission (or subsequent admission of the same individual), or

(B) require the hospital to take other corrective action necessary to prevent or correct the inappropriate practice.

(3) The provisions of subsections (c) through (g) of section 1128 [*42 USCS § 1320a-7(c)*-(g)] shall apply to determinations made under paragraph (2) in the same manner as they apply to exclusions effected under section 1128(b)(13) [*42 USCS § 1320a-7(b)(13)*].

(g) Prospective payment of capital-related costs; return on equity capital for hospital.

(1)

(A) Notwithstanding section 1861(v) [*42 USCS § 1395x(v)*], instead of any amounts that are otherwise payable under this *title [42 USCS §§ 1395* et seq.] with respect to the reasonable costs of subsection (d) hospitals and subsection (d) Puerto Rico hospitals for capital-related costs of inpatient hospital services, the Secretary shall, for hospital cost reporting periods beginning on or after October 1, 1991, provide for payments for such costs in accordance with a prospective payment system established by the Secretary. Aggregate payments made under subsection (d) and this subsection during fiscal years 1992 through 1995 shall be reduced in a manner that results in a reduction (as estimated by the Secretary) in the amount of such payments equal to a 10 percent reduction in the amount of payments attributable to capital-related costs that would otherwise have been made during such fiscal year had the amount of such payments been based on reasonable costs (as defined in section 1861(v) [*42 USCS § 1395x(v)*]). For discharges occurring after September 30, 1993, the Secretary shall reduce by 7.4 percent the unadjusted standard Federal capital payment rate (as described in *42 CFR 412.308(c)*, as in effect on the date of the enactment of the Omnibus Budget Reconciliation Act of 1993 [enacted Aug. 10, 1993]) and shall (for hospital cost reporting periods beginning on or after October 1, 1993) redetermine which payment methodology is applied to the hospital under such system to take into account such reduction. In addition to the reduction described in the preceding sentence, for discharges occurring on or after October 1, 1997, the Secretary shall apply the budget neutrality adjustment factor used to determine the Federal capital payment rate in effect on September 30, 1995 (as described in *section 412.352 of title 42 of the Code of Federal R*egulations), to (i) the unadjusted standard Federal capital payment rate (as described in section 412.308(c) of that title, as in effect on September 30, 1997), and (ii) the unadjusted hospital-specific rate (as described in section 412.328(e)(1) of that title, as in effect on September 30, 1997), and, for discharges occurring on or after October 1, 1997, and before October 1, 2002, reduce the rates described in clauses (i) and (ii) by 2.1 percent.

(B) Such system--

(i) shall provide for (I) a payment on a per discharge basis, and (II) an appropriate weighting of such payment amount as relates to the classification of the discharge;

(ii) may provide for an adjustment to take into account variations in the relative costs of capital and construction for the different types of facilities or areas in which they are located;

(iii) may provide for such exceptions (including appropriate exceptions to reflect capital obligations) as the Secretary determines to be appropriate, and

(iv) may provide for suitable adjustment to reflect hospital occupancy rate.

(C) In this paragraph, the term "capital-related costs" has the meaning given such term by the Secretary under subsection (a)(4) as of September 30, 1987, and does not include a return on equity capital.

(2) (A) The Secretary shall provide that the amount which is allowable, with respect to reasonable costs of inpatient hospital services for which payment may be made under this *title [42 USCS §§ 1395* et seq.], for a return on equity capital for hospitals shall, for cost reporting periods beginning on or after the date of the enactment of this subsection [enacted April 20, 1983], be equal to amounts otherwise allowable under regulations in effect on March 1, 1983, except that the rate of return to be recognized shall be equal to the applicable percentage (described in subparagraph (B)) of the average of the rates of interest, for each of the months any part of which is included in the reporting period, on obligations issued for purchase by the Federal Hospital Insurance Trust Fund.

(B) In this paragraph, the "applicable percentage" is--

(i) 75 percent, for cost reporting periods beginning during fiscal year 1987,

(ii) 50 percent, for cost reporting periods beginning during fiscal year 1988,

(iii) 25 percent, for cost reporting periods beginning during fiscal year 1989, and

(iv) 0 percent, for cost reporting periods beginning on or after October 1, 1989.

(3)

(A) Except as provided in subparagraph (B), in determining the amount of the payments that may be made under this title with respect to all the capital-related costs of inpatient hospital services of a subsection (d) hospital and a subsection (d) Puerto Rico hospital, the Secretary shall reduce the amounts of such payments otherwise established under this *title [42 USCS §§ 1395* et seq.] by--

(i) 3.5 percent for payments attributable to portions of cost reporting periods occurring during fiscal year 1987,

(ii) 7 percent for payments attributable to portions of cost reporting periods or discharges (as the case may be) occurring during fiscal year 1988 on or after October 1, 1987, and before January 1, 1988,

(iii) 12 percent for payments attributable to portions of cost reporting periods or discharges (as the case may be) in fiscal year 1988, occurring on or after January 1, 1988,

(iv) 15 percent for payments attributable to portions of cost reporting periods or discharges (as the case may be) occurring during fiscal year 1989, and

(v) 15 percent for payments attributable to portions of cost reporting periods or discharges (as the case may be) occurring during the period beginning January 1, 1990, and ending September 30, 1991.

(B) Subparagraph (A) shall not apply to payments with respect to the capital-related costs of any hospital that is a sole community hospital (as defined in subsection (d)(5)(D)(iii)) or a critical access hospital (as defined in section 1861(mm)(1) [*42 USCS § 1395x(mm)(1)*]).

(4) In determining the amount of the payments that are attributable to portions of cost reporting periods occurring during fiscal years 1998 through 2002 and that may be made under this *title [42 USCS §§ 1395* et seq.] with respect to capital-related costs of inpatient hospital services of a hospital which is described in clause (i), (ii), or (iv) of subsection (d)(1)(B) or a unit described in the matter after clause (v) of such subsection, the Secretary shall reduce the amounts of such payments otherwise determined under this *title [42 USCS §§ 1395* et seq.] by 15 percent.

(h) Payments for direct graduate medical education costs.

(1) Substitution of special payment rules. Notwithstanding section 1861(v) [*42 USCS §§ 1395x(v)*], instead of any amounts that are otherwise payable under this *title [42 USCS §§ 1395* et seq.] with respect to the reasonable costs of hospitals for direct graduate medical education costs, the Secretary shall provide for payments for such costs in accordance with paragraph (3) of this subsection. In providing for such payments, the Secretary shall provide for an allocation of such payments between part A and part B [*42 USCS §§ 1395c* et seq. and *1395j* et seq.] (and the trust funds established under the respective parts) as reasonably reflects the proportion of direct graduate medical education costs of hospitals associated with the provision of services under each respective part.

(2) Determination of hospital-specific approved FTE resident amounts. The Secretary shall determine, for each hospital with an approved medical residency training program, an approved FTE resident amount for each cost reporting period beginning on or after July 1, 1985, as follows:

(A) Determining allowable average cost per FTE resident in a hospital's base period. The Secretary shall determine, for the hospital's cost reporting period that began during fiscal year 1984, the average amount recognized as reasonable under this title for direct graduate medical education costs of the hospital for each full-time-equivalent resident.

(B) Updating to the first cost reporting period.

(i) In general. The Secretary shall update each average amount determined under subparagraph (A) by the percentage increase in the consumer price index during the 12-month cost reporting period described in such subparagraph.

(ii) Exception. The Secretary shall not perform an update under clause (i) in the case of a hospital if the hospital's reporting period, described in subparagraph (A), began on or after July 1, 1984, and before October 1, 1984.

(C) Amount for first cost reporting period. For the first cost reporting period of the hospital beginning on or after July 1, 1985, the approved FTE resident amount for the hospital is equal to the amount determined under subparagraph (B) increased by 1 percent.

(D) Amount for subsequent cost reporting periods.

(i) In general. Except as provided in a subsequent clause, for each subsequent cost reporting period, the approved FTE resident amount for the hospital is equal to the approved FTE resident amount determined under this paragraph for the previous cost reporting period updated, through the midpoint of the period, by projecting the estimated percentage change in the consumer price index during the 12-month period ending at that midpoint, with appropriate adjustments to reflect previous under- or over-estimations under this subparagraph in the projected percentage change in the consumer price index.

(ii) Freeze in update for fiscal years 1994 and 1995. For cost reporting periods beginning during fiscal year 1994 or fiscal year 1995, the approved FTE resident amount for a hospital shall not be updated under clause (i) for a resident who is not a primary care resident (as defined in paragraph (5)(H)) or a resident enrolled in an approved medical residency training program in obstetrics and gynecology.

(iii) Floor for locality adjusted national average per resident amount. The approved FTE resident amount for a hospital for the cost reporting period beginning during fiscal year 2001 shall not be less than 70 percent, and for the cost reporting period beginning during fiscal year 2002 shall not be less than 85 percent, of the locality adjusted national average per resident amount computed under subparagraph (E) for the hospital and period.

(iv) Adjustment in rate of increase for hospitals with FTE approved amount above 140 percent of locality adjusted national average per resident amount.

(I) Freeze for fiscal years 2001 and 2002 and 2004 through 2013. For a cost reporting period beginning during fiscal year 2001 or fiscal year 2002 or during the period beginning with fiscal year 2004 and ending with fiscal year

2013, if the approved FTE resident amount for a hospital for the preceding cost reporting period exceeds 140 percent of the locality adjusted national average per resident amount computed under subparagraph (E) for that hospital and period, subject to subclause (III), the approved FTE resident amount for the period involved shall be the same as the approved FTE resident amount for the hospital for such preceding cost reporting period.

(II) 2 percent decrease in update for fiscal years 2003, 2004, and 2005 [fiscal year 2003]. For the cost reporting period beginning during fiscal year 2003, if the approved FTE resident amount for a hospital for the preceding cost reporting period exceeds 140 percent of the locality adjusted national average per resident amount computed under subparagraph (E) for that hospital and preceding period, the approved FTE resident amount for the period involved shall be updated in the manner described in subparagraph (D)(i) except that, subject to subclause (III), the consumer price index applied for a 12-month period shall be reduced (but not below zero) by 2 percentage points.

(III) No adjustment below 140 percent. In no case shall subclause (I) or (II) reduce an approved FTE resident amount for a hospital for a cost reporting period below 140 percent of the locality adjusted national average per resident amount computed under subparagraph (E) for such hospital and period.

(E) Determination of locality adjusted national average per resident amount. The Secretary shall determine a locality adjusted national average per resident amount with respect to a cost reporting period of a hospital beginning during a fiscal year as follows:

(i) Determining hospital single per resident amount. The Secretary shall compute for each hospital operating an approved graduate medical education program a single per resident amount equal to the average (weighted by number of full-time equivalent residents, as determined under paragraph (4)) of the primary care per resident amount and the non-primary care per resident amount computed under paragraph (2) for cost reporting periods ending during fiscal year 1997.

(ii) Standardizing per resident amounts. The Secretary shall compute a standardized per resident amount for each such hospital by dividing the single per resident amount computed under clause (i) by an average of the 3 geographic index values (weighted by the national average weight for each of the work, practice expense, and malpractice components) as applied under section 1848(e) for 1999 for the fee schedule area in which the hospital is located.

(iii) Computing of weighted average. The Secretary shall compute the average of the standardized per resident amounts computed under clause (ii) for such hospitals, with the amount for each hospital weighted by the average number of full-time equivalent residents at such hospital (as determined under paragraph (4)).

(iv) Computing national average per resident amount. The Secretary shall compute the national average per resident amount, for a hospital's cost reporting period that begins during fiscal year 2001, equal to the weighted average computed under clause (iii) increased by the estimated percentage increase in the consumer price index for all urban consumers during the period beginning with the month that represents the midpoint of the cost reporting periods described in clause (i) and ending with the midpoint of the hospital's cost reporting period that begins during fiscal year 2001.

(v) Adjusting for locality. The Secretary shall compute the product of--

(I) the national average per resident amount computed under clause (iv) for the hospital, and

(II) the geographic index value average (described and applied under clause (ii)) for the fee schedule area in which the hospital is located.

(vi) Computing locality adjusted amount. The locality adjusted national per resident amount for a hospital for--

(I) the cost reporting period beginning during fiscal year 2001 is the product computed under clause (v); or

(II) each subsequent cost reporting period is equal to the locality adjusted national per resident amount for the hospital for the previous cost reporting period (as determined under this clause) updated, through the midpoint of the period, by projecting the estimated percentage change in the consumer price index for all urban consumers during the 12-month period ending at that midpoint.

(F) Treatment of certain hospitals. In the case of a hospital that did not have an approved medical residency training program or was not participating in the program under this *title [42 USCS §§ 1395* et seq.] for a cost reporting period beginning during fiscal year 1984, the Secretary shall, for the first such period for which it has such a residency training program and is participating under this *title [42 USCS §§ 1395* et seq.], provide for such approved FTE resident amount as the Secretary determines to be appropriate, based on approved FTE resident amounts for comparable programs.

(3) Hospital payment amount per resident.

(A) In general. The payment amount, for a hospital cost reporting period beginning on or after July 1, 1985, is equal to the product of--

(i) the aggregate approved amount (as defined in subparagraph (B)) for that period, and

(ii) the hospital's medicare patient load (as defined in subparagraph (C)) for that period.

(B) Aggregate approved amount. As used in subparagraph (A), the term "aggregate approved amount" means, for a hospital cost reporting period, the product of--

(i) the hospital's approved FTE resident amount (determined under paragraph (2)) for that period, and

(ii) the weighted average number of full-time-equivalent residents (as determined under paragraph (4)) in the hospital's approved medical residency training programs in that period.

The Secretary shall reduce the aggregate approved amount to the extent payment is made under subsection (k) for residents included in the hospital's count of full-time equivalent residents.

(C) Medicare patient load. As used in subparagraph (A), the term "medicare patient load" means, with respect to a hospital's cost reporting period, the fraction of the total number of inpatient-bed-days (as established by the Secretary) during the period which are attributable to patients with respect to whom payment may be made under part A [*42 USCS §§ 1395c* et seq.].

(D) Payment for managed care enrollees.

(i) In general. For portions of cost reporting periods occurring on or after January 1, 1998, the Secretary shall provide for an additional payment amount under this subsection for services furnished to individuals who are enrolled under a risk-sharing contract with an eligible organization under section 1876 [*42 USCS § 1395mm*] and who are entitled to part A [*42 USCS §§ 1395c* et seq.] or with a Medicare + Choice organization under part C [*42 USCS §§ 1395w-21* et seq.]. The amount of such a payment shall equal, subject to clause (iii), the applicable percentage of the product of--

(I) the aggregate approved amount (as defined in subparagraph (B)) for that period; and

(II) the fraction of the total number of inpatient-bed days (as established by the Secretary) during the period which are attributable to such enrolled individuals.

(ii) Applicable percentage. For purposes of clause (i), the applicable percentage is--

(I) 20 percent in 1998,

(II) 40 percent in 1999,

(III) 60 percent in 2000,

(IV) 80 percent in 2001, and

(V) 100 percent in 2002 and subsequent years.

(iii) Proportional reduction for nursing and allied health education. The Secretary shall estimate a proportional adjustment in payments to all hospitals determined under clauses (i) and (ii) for portions of cost reporting periods beginning in a year (beginning with 2000) such that the proportional adjustment reduces payments in an amount for such year equal to the total additional payment amounts for nursing and allied health education determined under subsection (l) for portions of cost reporting periods occurring in that year.

(iv) Special rule for hospitals under reimbursement system. The Secretary shall establish rules for the application of this subparagraph to a hospital reimbursed under a reimbursement system authorized under section 1814(b)(3) [*42 USCS § 1395f(b)(3)*] in the same manner as it would apply to the hospital if it were not reimbursed under such section.

(4) Determination of full-time-equivalent residents.

(A) Rules. The Secretary shall establish rules consistent with this paragraph for the computation of the number of full-time-equivalent residents in an approved medical residency training program.

(B) Adjustment for part-year or part-time residents. Such rules shall take into account individuals who serve as residents for only a portion of a period with a hospital or simultaneously with more than one hospital.

(C) Weighting factors for certain residents. Subject to subparagraph (D), such rules shall provide, in calculating the number of full-time-equivalent residents in an approved residency program--

(i) before July 1, 1986, for each resident the weighting factor is 1.00,

(ii) on or after July 1, 1986, for a resident who is in the resident's initial residency period (as defined in paragraph (5)(F)), the weighting factor is 1.00,

(iii) on or after July 1, 1986, and before July 1, 1987, for a resident who is not in the resident's initial residency period (as defined in paragraph (5)(F)), the weighting factor is .75, and

(iv) on or after July 1, 1987, for a resident who is not in the resident's initial residency period (as defined in paragraph (5)(F)), the weighting factor is .50.

(D) Foreign medical graduates required to pass FMGEMS examination.

(i) In general. Except as provided in clause (ii), such rules shall provide that, in the case of an individual who is a foreign medical graduate (as defined in paragraph (5)(D)), the individual shall not be counted as a resident on or after July 1, 1986, unless--

(I) the individual has passed the FMGEMS examination (as defined in paragraph (5)(E)), or

(II) the individual has previously received certification from, or has previously passed the examination of, the Educational Commission for Foreign Medical Graduates.

(ii) Transition for current FMGS. On or after July 1, 1986, but before July 1, 1987, in the case of a foreign medical graduate who--

(I) has served as a resident before July 1, 1986, and is serving as a resident after that date, but

(II) has not passed the FMGEMS examination or a previous examination of the Educational Commission for Foreign Medical Graduates before July 1, 1986,

the individual shall be counted as a resident at a rate equal to one-half of the rate at which the individual would otherwise be counted.

(E) Counting time spent in outpatient settings. Such rules shall provide that only time spent in activities relating to patient care shall be counted and that all the time so spent by a resident under an approved medical residency training program shall be counted towards the determination of full-time equivalency, without regard to the setting in which the activities are performed, if the hospital incurs all, or substantially all, of the costs for the training program in that setting.

(F) Limitation on number of residents in allopathic and osteopathic medicine.

(i) In general. Such rules shall provide that for purposes of a cost reporting period beginning on or after October 1, 1997, subject to paragraph (7), the total number of full-time equivalent residents before application of weighting factors (as determined under this paragraph) with respect to a hospital's approved medical residency training program in the fields of allopathic medicine and osteopathic medicine may not exceed the number (or, 130 percent of such number in the case of a hospital located in a rural area) of such full-time equivalent residents for the hospital's most recent cost reporting period ending on or before December 31, 1996.

(ii) Counting primary care residents on certain approved leaves of absence in base year FTE count.

(I) In general. In determining the number of such full-time equivalent residents for a hospital's most recent cost reporting period ending on or before December 31, 1996, for purposes of clause (i), the Secretary shall count an individual to the extent that the individual would have been counted as a primary care resident for such period but for the fact that the individual, as determined by the Secretary, was on maternity or disability leave or a similar approved leave of absence.

(II) Limitation to 3 FTE residents for any hospital. The total number of individuals counted under subclause (I) for a hospital may not exceed 3 full-time equivalent residents.

(G) Counting interns and residents for FY 1998 and subsequent years.

(i) In general. For cost reporting periods beginning during fiscal years beginning on or after October 1, 1997, subject to the limit described in subparagraph (F), the total number of full-time equivalent residents for determining a hospital's graduate medical education payment shall equal the average of the actual full-time equivalent resident counts for the cost reporting period and the preceding two cost reporting periods.

(ii) Adjustment for short periods. If any cost reporting period beginning on or after October 1, 1997, is not equal to twelve months, the Secretary shall make appropriate modifications to ensure that the average full-time equivalent resident counts pursuant to clause (i) are based on the equivalent of full twelve-month cost reporting periods.

(iii) Transition rule for 1998. In the case of a hospital's first cost reporting period beginning on or after October 1, 1997, clause (i) shall be applied by using the average for such period and the preceding cost reporting period.

(H) Special rules for application of subparagraphs (f) and (g).

(i) New facilities. The Secretary shall, consistent with the principles of subparagraphs (F) and (G) and subject to paragraph (7), prescribe rules for the application of such subparagraphs in the case of medical residency training programs established on or after January 1, 1995. In promulgating such rules for purposes of subparagraph (F), the Secretary shall give special consideration to facilities that meet the needs of underserved rural areas.

(ii) Aggregation. The Secretary may prescribe rules which allow institutions which are members of the same affiliated group (as defined by the Secretary) to elect to apply the limitation of subparagraph (F) on an aggregate basis.

(iii) Data collection. The Secretary may require any entity that operates a medical residency training program and to which subparagraphs (F) and (G) apply to submit to the Secretary such additional information as the Secretary considers necessary to carry out such subparagraphs.

(iv) Nonrural hospitals operating training programs in rural areas. In the case of a hospital that is not located in a rural area but establishes separately accredited approved medical residency training programs (or rural tracks) in an rural area or has an accredited training program with an integrated rural track, the Secretary shall adjust the limitation under subparagraph (F) in an appropriate manner insofar as it applies to such programs in such rural areas in order to encourage the training of physicians in rural areas.

(v) Special provider agreement. If an entity enters into a provider agreement pursuant to section 1866(a) [*42 USCS § 1395cc(a)*] to provide hospital services on the same physical site previously used by Medicare Provider No. 05-0578--

(I) the limitation on the number of total full time equivalent residents under subparagraph (F) and clauses (v) and (vi)(I) of subsection (d)(5)(B) applicable to such provider shall be equal to the limitation applicable under such provisions to Provider No. 05-0578 for its cost reporting period ending on June 30, 2006; and

(II) the provisions of subparagraph (G) and subsection (d)(5)(B)(vi)(II) shall not be applicable to such provider for the first three cost reporting years in which such provider trains residents under any approved medical residency training program.

(5) Definitions and special rules. As used in this subsection:

(A) Approved medical residency training program. The term "approved medical residency training program" means a residency or other postgraduate medical training program participation in which may be counted toward certification in a specialty or subspecialty and includes formal postgraduate training programs in geriatric medicine approved by the Secretary.

(B) Consumer price index. The term "consumer price index" refers to the Consumer Price Index for All Urban Consumers (United States city average), as published by the Secretary of Commerce.

(C) Direct graduate medical education costs. The term "direct graduate medical education costs" means direct costs of approved educational activities for approved medical residency training programs.

(D) Foreign medical graduate. The term "foreign medical graduate" means a resident who is not a graduate of--

(i) a school of medicine accredited by the Liaison Committee on Medical Education of the American Medical Association and the Association of American Medical Colleges (or approved by such Committee as meeting the standards necessary for such accreditation),

(ii) a school of osteopathy accredited by the American Osteopathic Association, or approved by such Association as meeting the standards necessary for such accreditation, or

(iii) a school of dentistry or podiatry which is accredited (or meets the standards for accreditation) by an organization recognized by the Secretary for such purpose.

(E) FMGEMS examination. The term "FMGEMS examination" means parts I and II of the Foreign Medical Graduate Examination in the Medical Sciences or any successor examination recognized by the Secretary for this purpose.

(F) Initial residency period. The term "initial residency period" means the period of board eligibility, except that--

(i) except as provided in clause (ii), in no case shall the initial period of residency exceed an aggregate period of formal training of more than five years for any individual, and

(ii) a period, of not more than two years, during which an individual is in a geriatric residency or fellowship program or a preventive medicine residency or fellowship program which meets such criteria as the Secretary may establish, shall be treated as part of the initial residency period, but shall not be counted against any limitation on the initial residency period.

Subject to subparagraph (G)(v), the initial residency period shall be determined, with respect to a resident, as of the time the resident enters the residency training program.

(G) Period of board eligibility.

(i) General rule. Subject to clauses (ii), (iii), (iv), and (v), the term "period of board eligibility" means, for a resident, the minimum number of years of formal training necessary to satisfy the requirements for initial board eligibility in the particular specialty for which the resident is training.

(ii) Application of 1985-1986 directory. Except as provided in clause (iii), the period of board eligibility shall be such period specified in the 1985-1986 Directory of Residency Training Programs published by the Accreditation Council on Graduate-Medical Education.

(iii) Changes in period of board eligibility. On or after July 1, 1989, if the Accreditation Council on Graduate Medical Education, in its Directory of Residency Training Programs--

(I) increases the minimum number of years of formal training necessary to satisfy the requirements for a specialty, above the period specified in its 1985-1986 Directory, the Secretary may increase the period of board eligibility for that specialty, but not to exceed the period of board eligibility specified in that later Directory, or

(II) decreases the minimum number of years of formal training necessary to satisfy the requirements for a specialty, below the period specified in its 1985-1986 Directory, the Secretary may decrease the period of board eligibility for that specialty, but not below the period of board eligibility specified in that later Directory.

(iv) Special rule for certain primary care combined residency programs.

(I) In the case of a resident enrolled in a combined medical residency training program in which all of the individual programs (that are combined) are for training a primary care resident (as defined in subparagraph (H)), the period of board eligibility shall be the minimum number of years of formal training required to satisfy the requirements for initial board eligibility in the longest of the individual programs plus one additional year.

(II) A resident enrolled in a combined medical residency training program that includes an obstetrics and gynecology program shall qualify for the period of board eligibility under subclause (I) if the other programs such resident combines with such obstetrics and gynecology program are for training a primary care resident.

(v) Child neurology training programs. In the case of a resident enrolled in a child neurology residency training program, the period of board eligibility and the initial residency period shall be the period of board eligibility for pediatrics plus 2 years.

(H) Primary care resident. The term "primary care resident" means a resident enrolled in an approved medical residency training program in family medicine, general internal medicine, general pediatrics, preventive medicine, geriatric medicine, or osteopathic general practice.

(I) Resident. The term "resident" includes an intern or other participant in an approved medical residency training program.

(J) Adjustments for certain family practice residency programs.

(i) In general. In the case of an approved medical residency training program (meeting the requirements of clause (ii)) of a hospital which received funds from the United States, a State, or a political subdivision of a State or an instrumentality of such a State or political subdivision (other than payments under this title or a State plan under title XIX [*42 USCS §§ 1396* et seq.]) for the program during the cost reporting period that began during fiscal year 1984, the Secretary shall--

(I) provide for an average amount under paragraph (2)(A) that takes into account the Secretary's estimate of the amount that would have been recognized as reasonable under this title if the hospital had not received such funds, and

(II) reduce the payment amount otherwise provided under this subsection in an amount equal to the proportion of such program funds received during the cost reporting period involved that is allocable to this *title [42 USCS §§ 1395* et seq.].

(ii) Additional requirements. A hospital's approved medical residency program meets the requirements of this clause if--

(I) the program is limited to training for family and community medicine;

(II) the program is the only approved medical residency program of the hospital; and

(III) the average amount determined under paragraph (2)(A) for the hospital (as determined without regard to the increase in such amount described in clause (i)(I)) does not exceed $ 10,000.

(6) Incentive payment under plans for voluntary reduction in number of residents.

(A) In general. In the case of a voluntary residency reduction plan for which an application is approved under subparagraph (B), subject to subparagraph (F), each hospital which is part of the qualifying entity submitting the plan shall be paid an applicable hold harmless percentage (as specified in subparagraph (E)) of the sum of--

(i) the amount (if any) by which--

(I) the amount of payment which would have been made under this subsection if there had been a 5-percent reduction in the number of full-time equivalent residents in the approved medical education training programs of the hospital as of June 30, 1997, exceeds

(II) the amount of payment which is made under this subsection, taking into account the reduction in such number effected under the reduction plan; and

(ii) the amount of the reduction in payment under subsection (d)(5)(B) for the hospital that is attributable to the reduction in number of residents effected under the plan below 95 percent of the number of full-time equivalent residents in such programs of the hospital as of June 30, 1997.

The determination of the amounts under clauses (i) and (ii) for any year shall be made on the basis of the provisions of this *title [42 USCS §§ 1395* et seq.] in effect on the application deadline date for the first calendar year to which the reduction plan applies.

(B) Approval of plan applications. The Secretary may not approve the application of an qualifying entity unless--

(i) the application is submitted in a form and manner specified by the Secretary and by not later than November 1, 1999,[;]

(ii) the application provides for the operation of a plan for the reduction in the number of full-time equivalent residents in the approved medical residency training programs of the entity consistent with the requirements of subparagraph (D);

(iii) the entity elects in the application the period of residency training years (not greater than 5) over which the reduction will occur;

(iv) the entity will not reduce the proportion of its residents in primary care (to the total number of residents) below such proportion as in effect as of the applicable time described in subparagraph (D)(v); and

(v) the Secretary determines that the application and the entity and such plan meet such other requirements as the Secretary specifies in regulations.

(C) Qualifying entity. For purposes of this paragraph, any of the following may be a qualifying entity:

(i) Individual hospitals operating one or more approved medical residency training programs.

(ii) Two or more hospitals that operate such programs and apply for treatment under this paragraph as a single qualifying entity.

(iii) A qualifying consortium (as described in section 4628 of the Balanced Budget Act of 1997 [note to this section]).

(D) Residency reduction requirements.

(i) Individual hospital applicants. In the case of a qualifying entity described in subparagraph (C)(i), the number of full-time equivalent residents in all the approved medical residency training programs operated by or through the entity shall be reduced as follows:

(I) If the base number of residents exceeds 750 residents, by a number equal to at least 20 percent of such base number.

(II) Subject to subclause (IV), if the base number of residents exceeds 600 but is less than 750 residents, by 150 residents.

(III) Subject to subclause (IV), if the base number of residents does not exceed 600 residents, by a number equal to at least 25 percent of such base number.

(IV) In the case of a qualifying entity which is described in clause (v) and which elects treatment under this subclause, by a number equal to at least 20 percent of the base number.

(ii) Joint applicants. In the case of a qualifying entity described in subparagraph (C)(ii), the number of full-time equivalent residents in the aggregate for all the approved medical residency training programs operated by or through the entity shall be reduced as follows:

(I) Subject to subclause (II), by a number equal to at least 25 percent of the base number.

(II) In the case of such a qualifying entity which is described in clause (v) and which elects treatment under this subclause, by a number equal to at least 20 percent of the base number.

(iii) Consortia. In the case of a qualifying entity described in subparagraph (C)(iii), the number of full-time equivalent residents in the aggregate for all the approved medical residency training programs operated by or through the entity shall be reduced by a number equal to at least 20 percent of the base number.

(iv) Manner of reduction. The reductions specified under the preceding provisions of this subparagraph for a qualifying entity shall be below the base number of residents for that entity and shall be fully effective not later than the 5th residency training year in which the application under subparagraph (B) is effective.

(v) Entities providing assurance of increase in primary care residents. An entity is described in this clause if--

(I) the base number of residents for the entity is less than 750 or the entity is described in subparagraph (C)(ii); and

(II) the entity represents in its application under subparagraph (B) that it will increase the number of full-time equivalent residents in primary care by at least 20 percent (from such number included in the base number of residents) by not later than the 5th residency training year in which the application under subparagraph (B) is effective.

If a qualifying entity fails to comply with the representation described in subclause (II) by the end of such 5th residency training year, the entity shall be subject to repayment of all amounts paid under this paragraph, in accordance with procedures established to carry out subparagraph (F).

(vi) Base number of residents defined. For purposes of this paragraph, the term "base number of residents" means, with respect to a qualifying entity (or its participating hospitals) operating approved medical residency training programs, the number of full-time equivalent residents in such programs (before application of weighting factors) of the entity as of the most recent residency training year ending before June 30, 1997, or, if less, for any subsequent residency training year that ends before the date the entity makes application under this paragraph.

(E) Applicable hold harmless percentage. For purposes of subparagraph (A), the "applicable hold harmless percentage" for the--

(i) first and second residency training years in which the reduction plan is in effect, 100 percent,

(ii) third such year, 75 percent,

(iii) fourth such year, 50 percent, and

(iv) fifth such year, 25 percent.

(F) Penalty for noncompliance.

(i) In general. No payment may be made under this paragraph to a hospital for a residency training year if the hospital has failed to reduce the number of full-time equivalent residents (in the manner required under subparagraph (D)) to the number agreed to by the Secretary and the qualifying entity in approving the application under this paragraph with respect to such year.

(ii) Increase in number of residents in subsequent years. If payments are made under this paragraph to a hospital, and if the hospital increases the number of full-time equivalent residents above the number of such residents permitted under the reduction plan as of the completion of the plan, then, as specified by the Secretary, the entity is liable for repayment to the Secretary of the total amounts paid under this paragraph to the entity.

(G) Treatment of rotating residents. In applying this paragraph, the Secretary shall establish rules regarding the counting of residents who are assigned to institutions the medical residency training programs in which are not covered under approved applications under this paragraph.

(7) Redistribution of unused resident positions.

(A) Reduction in limit based on unused positions.

(i) Programs subject to reduction.

(I) In general. Except as provided in subclause (II), if a hospital's reference resident level (specified in clause (ii)) is less than the otherwise applicable resident limit (as defined in subparagraph (C)(ii)), effective for portions of cost

reporting periods occurring on or after July 1, 2005, the otherwise applicable resident limit shall be reduced by 75 percent of the difference between such otherwise applicable resident limit and such reference resident level.

(II) Exception for small rural hospitals. This subparagraph shall not apply to a hospital located in a rural area (as defined in subsection (d)(2)(D)(ii)) with fewer than 250 acute care inpatient beds.

(ii) Reference resident level.

(I) In general. Except as otherwise provided in subclauses (II) and (III), the reference resident level specified in this clause for a hospital is the resident level for the most recent cost reporting period of the hospital ending on or before September 30, 2002, for which a cost report has been settled (or, if not, submitted (subject to audit)), as determined by the Secretary.

(II) Use of most recent accounting period to recognize expansion of existing programs. If a hospital submits a timely request to increase its resident level due to an expansion of an existing residency training program that is not reflected on the most recent settled cost report, after audit and subject to the discretion of the Secretary, the reference resident level for such hospital is the resident level for the cost reporting period that includes July 1, 2003, as determined by the Secretary.

(III) Expansions under newly approved programs. Upon the timely request of a hospital, the Secretary shall adjust the reference resident level specified under subclause (I) or (II) to include the number of medical residents that were approved in an application for a medical residency training program that was approved by an appropriate accrediting organization (as determined by the Secretary) before January 1, 2002, but which was not in operation during the cost reporting period used under subclause (I) or (II), as the case may be, as determined by the Secretary.

(iii) Affiliation. The provisions of clause (i) shall be applied to hospitals which are members of the same affiliated group (as defined by the Secretary under paragraph (4)(H)(ii)) as of July 1, 2003.

(B) Redistribution.

(i) In general. The Secretary is authorized to increase the otherwise applicable resident limit for each qualifying hospital that submits a timely application under this subparagraph by such number as the Secretary may approve for portions of cost reporting periods occurring on or after July 1, 2005. The aggregate number of increases in the otherwise applicable resident limits under this subparagraph may not exceed the Secretary's estimate of the aggregate reduction in such limits attributable to subparagraph (A).

(ii) Considerations in redistribution. In determining for which hospitals the increase in the otherwise applicable resident limit is provided under clause (i), the Secretary shall take into account the demonstrated likelihood of the hospital filling the positions within the first 3 cost reporting periods beginning on or after July 1, 2005, made available under this subparagraph, as determined by the Secretary.

(iii) Priority for rural and small urban areas. In determining for which hospitals and residency training programs an increase in the otherwise applicable resident limit is provided under clause (i), the Secretary shall distribute the increase to programs of hospitals located in the following priority order:

(I) First, to hospitals located in rural areas (as defined in subsection (d)(2)(D)(ii)).

(II) Second, to hospitals located in urban areas that are not large urban areas (as defined for purposes of subsection (d)).

(III) Third, to other hospitals in a State if the residency training program involved is in a specialty for which there are not other residency training programs in the State.

Increases of residency limits within the same priority category under this clause shall be determined by the Secretary.

(iv) Limitation. In no case shall more than 25 full-time equivalent additional residency positions be made available under this subparagraph with respect to any hospital.

(v) Application of locality adjusted national average per resident amount. With respect to additional residency positions in a hospital attributable to the increase provided under this subparagraph, notwithstanding any other provision of this subsection, the approved FTE resident amount is deemed to be equal to the locality adjusted national average per resident amount computed under paragraph (4)(E) for that hospital.

(vi) Construction. Nothing in this subparagraph shall be construed as permitting the redistribution of reductions in residency positions attributable to voluntary reduction programs under paragraph (6), under a demonstration project approved as of October 31, 2003, under the authority of section 402 of Public Law 90-248, or as affecting the ability of a hospital to establish new medical residency training programs under paragraph (4)(H).

(C) Resident level and limit defined. In this paragraph:

(i) Resident level. The term "resident level" means, with respect to a hospital, the total number of full-time equivalent residents, before the application of weighting factors (as determined under paragraph (4)), in the fields of allopathic and osteopathic medicine for the hospital.

(ii) Otherwise applicable resident limit. The term "otherwise applicable resident limit" means, with respect to a hospital, the limit otherwise applicable under subparagraphs (F)(i) and (H) of paragraph (4) on the resident level for the hospital determined without regard to this paragraph.

(D) Adjustment based on settled cost report. In the case of a hospital with a dual accredited osteopathic and allopathic family practice program for which--

(i) the otherwise applicable resident limit was reduced under subparagraph (A)(i)(I); and

(ii) such reduction was based on a reference resident level that was determined using a cost report and where a revised or corrected notice of program reimbursement was issued for such cost report between September 1, 2006 and September 15, 2006, whether as a result of an appeal or otherwise, and the reference resident level under such settled cost report is higher than the level used for the reduction under subparagraph (A)(i)(I);

the Secretary shall apply subparagraph (A)(i)(I) using the higher resident reference level and make any necessary adjustments to such reduction. Any such necessary adjustments shall be effective for portions of cost reporting periods occurring on or after July 1, 2005.

(E) Judicial review. There shall be no administrative or judicial review under section 1869 [*42 USCS § 1395ff*], 1878 [*42 USCS § 1395oo*], or otherwise, with respect to determinations made under this paragraph.

(i) Avoiding duplicative payments to hospitals participating in rural demonstration programs. The Secretary shall reduce any payment amounts otherwise determined under this section to the extent necessary to avoid duplication of any payment made under section 4005(e) of the Omnibus Budget Reconciliation Act of 1987 [note to this section].

(j) Prospective payment for inpatient rehabilitation services.

(1) Payment during transition period.

(A) In general. Notwithstanding section 1814(b) [*42 USCS § 1395f(b)*], but subject to the provisions of section 1813 [*42 USCS § 1395e*], the amount of the payment with respect to the operating and capital costs of inpatient hospital services of a rehabilitation hospital or a rehabilitation unit (in this subsection referred to as a "rehabilitation facility"), other than a facility making an election under subparagraph (F) in a cost reporting period beginning on or after October 1, 2000, and before October 1, 2002, is equal to the sum of--

(i) the TEFRA percentage (as defined in subparagraph (C)) of the amount that would have been paid under part A with respect to such costs if this subsection did not apply, and

(ii) the prospective payment percentage (as defined in subparagraph (C)) of the product of (I) the per unit payment rate established under this subsection for the fiscal year in which the payment unit of service occurs, and (II) the number of such payment units occurring in the cost reporting period.

(B) Fully implemented system. Notwithstanding section 1814(b) [*42 USCS § 1395f(b)*], but subject to the provisions of section 1813 [*42 USCS § 1395e*], the amount of the payment with respect to the operating and capital costs of inpatient hospital services of a rehabilitation facility for a payment unit in a cost reporting period beginning on or after October 1, 2002, or, in the case of a facility making an election under subparagraph (F), for any cost reporting period described in such subparagraph, is equal to the per unit payment rate established under this subsection for the fiscal year in which the payment unit of service occurs.

(C) TEFRA and prospective payment percentages specified. For purposes of subparagraph (A), for a cost reporting period beginning--

(i) on or after October 1, 2000, and before October 1, 2001, the "TEFRA percentage" is 66 2/3 percent and the "prospective payment percentage" is 33 1/3 percent; and

(ii) on or after October 1, 2001, and before October 1, 2002, the "TEFRA percentage" is 33 1/3 percent and the "prospective payment percentage" is 66 2/3 percent.

(D) Payment unit. For purposes of this subsection, the term "payment unit" means a discharge.

(E) Construction relating to transfer authority. Nothing in this subsection shall be construed as preventing the Secretary from providing for an adjustment to payments to take into account the early transfer of a patient from a rehabilitation facility to another site of care.

(F) Election to apply full prospective payment system. A rehabilitation facility may elect, not later than 30 days before its first cost reporting period for which the payment methodology under this subsection applies to the facility, to have payment made to the facility under this subsection under the provisions of subparagraph (B) (rather than subparagraph (A)) for each cost reporting period to which such payment methodology applies.

(2) Patient case mix groups.

(A) Establishment. The Secretary shall establish--

(i) classes of patient discharges of rehabilitation facilities by functional-related groups (each in this subsection referred to as a "case mix group"), based on impairment, age, comorbidities, and functional capability of the patient and

such other factors as the Secretary deems appropriate to improve the explanatory power of functional independence measure-function related groups; and

(ii) a method of classifying specific patients in rehabilitation facilities within these groups.

(B) Weighting factors. For each case mix group the Secretary shall assign an appropriate weighting which reflects the relative facility resources used with respect to patients classified within that group compared to patients classified within other groups.

(C) Adjustments for case mix.

(i) In general. The Secretary shall from time to time adjust the classifications and weighting factors established under this paragraph as appropriate to reflect changes in treatment patterns, technology, case mix, number of payment units for which payment is made under this *title [42 USCS §§ 1395* et seq.], and other factors which may affect the relative use of resources. Such adjustments shall be made in a manner so that changes in aggregate payments under the classification system are a result of real changes and are not a result of changes in coding that are unrelated to real changes in case mix.

(ii) Adjustment. Insofar as the Secretary determines that such adjustments for a previous fiscal year (or estimates that such adjustments for a future fiscal year) did (or are likely to) result in a change in aggregate payments under the classification system during the fiscal year that are a result of changes in the coding or classification of patients that do not reflect real changes in case mix, the Secretary shall adjust the per payment unit payment rate for subsequent years so as to eliminate the effect of such coding or classification changes.

(D) Data collection. The Secretary is authorized to require rehabilitation facilities that provide inpatient hospital services to submit such data as the Secretary deems necessary to establish and administer the prospective payment system under this subsection.

(3) Payment rate.

(A) In general. The Secretary shall determine a prospective payment rate for each payment unit for which such rehabilitation facility is entitled to receive payment under this *title [42 USCS §§ 1395* et seq.]. Subject to subparagraph (B), such rate for payment units occurring during a fiscal year shall be based on the average payment per payment unit under this *title [42 USCS §§ 1395* et seq.] for inpatient operating and capital costs of rehabilitation facilities using the most recent data available (as estimated by the Secretary as of the date of establishment of the system) adjusted--

(i) by updating such per-payment-unit amount to the fiscal year involved by the weighted average of the applicable percentage increases provided under subsection (b)(3)(B)(ii) (for cost reporting periods beginning during the fiscal year) covering the period from the midpoint of the period for such data through the midpoint of fiscal year 2000 and by an increase factor (described in subparagraph (C)) specified by the Secretary for subsequent fiscal years up to the fiscal year involved;

(ii) by reducing such rates by a factor equal to the proportion of payments under this subsection (as estimated by the Secretary) based on prospective payment amounts which are additional payments described in paragraph (4) (relating to outlier and related payments);

(iii) for variations among rehabilitation facilities by area under paragraph (6);

(iv) by the weighting factors established under paragraph (2)(B); and

(v) by such other factors as the Secretary determines are necessary to properly reflect variations in necessary costs of treatment among rehabilitation facilities.

(B) Budget neutral rates. The Secretary shall establish the prospective payment amounts under this subsection for payment units during fiscal years 2001 and 2002 at levels such that, in the Secretary's estimation, the amount of total payments under this subsection for such fiscal years (including any payment adjustments pursuant to paragraphs (4) and (6) but not taking into account any payment adjustment resulting from an election permitted under paragraph (1)(F)) shall be equal to 98 percent for fiscal year 2001 and 100 percent for fiscal year 2002 of the amount of payments that would have been made under this *title [42 USCS §§ 1395* et seq.] during the fiscal years for operating and capital costs of rehabilitation facilities had this subsection not been enacted. In establishing such payment amounts, the Secretary shall consider the effects of the prospective payment system established under this subsection on the total number of payment units from rehabilitation facilities and other factors described in subparagraph (A).

(C) Increase factor. For purposes of this subsection for payment units in each fiscal year (beginning with fiscal year 2001), the Secretary shall establish an increase factor. Such factor shall be based on an appropriate percentage increase in a market basket of goods and services comprising services for which payment is made under this subsection, which may be the market basket percentage increase described in subsection (b)(3)(B)(iii). The increase factor to be applied under this subparagraph for each of fiscal years 2008 and 2009 shall be 0 percent.

(4) Outlier and special payments.

(A) Outliers.

(i) In general. The Secretary may provide for an additional payment to a rehabilitation facility for patients in a case mix group, based upon the patient being classified as an outlier based on an unusual length of stay, costs, or other factors specified by the Secretary.

(ii) Payment based on marginal cost of care. The amount of such additional payment under clause (i) shall be determined by the Secretary and shall approximate the marginal cost of care beyond the cutoff point applicable under clause (i).

(iii) Total payments. The total amount of the additional payments made under this subparagraph for payment units in a fiscal year may not exceed 5 percent of the total payments projected or estimated to be made based on prospective payment rates for payment units in that year.

(B) Adjustment. The Secretary may provide for such adjustments to the payment amounts under this subsection as the Secretary deems appropriate to take into account the unique circumstances of rehabilitation facilities located in Alaska and Hawaii.

(5) Publication. The Secretary shall provide for publication in the Federal Register, on or before August 1 before each fiscal year (beginning with fiscal year 2001), of the classification and weighting factors for case mix groups under paragraph (2) for such fiscal year and a description of the methodology and data used in computing the prospective payment rates under this subsection for that fiscal year.

(6) Area wage adjustment. The Secretary shall adjust the proportion (as estimated by the Secretary from time to time) of rehabilitation facilities' costs which are attributable to wages and wage-related costs, of the prospective payment rates computed under paragraph (3) for area differences in wage levels by a factor (established by the Secretary) reflecting the relative hospital wage level in the geographic area of the rehabilitation facility compared to the national average wage level for such facilities. Not later than October 1, 2001 (and at least every 36 months thereafter), the Secretary shall update the factor under the preceding sentence on the basis of information available to the Secretary (and updated as appropriate) of the wages and wage-related costs incurred in furnishing rehabilitation services. Any adjustments or updates made under this paragraph for a fiscal year shall be made in a manner that assures that the aggregated payments under this subsection in the fiscal year are not greater or less than those that would have been made in the year without such adjustment.

(7) Limitation on review. There shall be no administrative or judicial review under section 1869, 1878 [*42 USCS §§ 1395ff, 1395oo*], or otherwise of the establishment of--

(A) case mix groups, of the methodology for the classification of patients within such groups, and of the appropriate weighting factors thereof under paragraph (2),

(B) the prospective payment rates under paragraph (3),

(C) outlier and special payments under paragraph (4), and

(D) area wage adjustments under paragraph (6).

(k) Payment to nonhospital providers.

(1) In general. For cost reporting periods beginning on or after October 1, 1997, the Secretary may establish rules for payment to qualified nonhospital providers for their direct costs of medical education, if those costs are incurred in the operation of an approved medical residency training program described in subsection (h). Such rules shall specify the amounts, form, and manner in which such payments will be made and the portion of such payments that will be made from each of the trust funds under this *title [42 USCS §§ 1395* et seq.].

(2) Qualified nonhospital providers. For purposes of this subsection, the term "qualified nonhospital providers" means-

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(A) a Federally qualified health center, as defined in section 1861(aa)(4) [*42 USCS § 1395x(aa)(4)*];

(B) a rural health clinic, as defined in section 1861(aa)(2) [*42 USCS § 1395x(aa)(2)*] ;

(C) Medicare + Choice organizations; and

(D) such other providers (other than hospitals) as the Secretary determines to be appropriate.

(l) Payment for nursing and allied health education for managed care enrollees.

(1) In general. For portions of cost reporting periods occurring in a year (beginning with 2000), the Secretary shall provide for an additional payment amount for any hospital that receives payments for the costs of approved educational activities for nurse and allied health professional training under section 1861(v)(1) [*42 USCS § 1395x(v)(1)*].

(2) Payment amount. The additional payment amount under this subsection for each hospital for portions of cost reporting periods occurring in a year shall be an amount specified by the Secretary in a manner consistent with the following:

(A) Determination of managed care enrollee payment ratio for graduate medical education payments. The Secretary shall estimate the ratio of payments for all hospitals for portions of cost reporting periods occurring in the year under

subsection (h)(3)(D) to total direct graduate medical education payments estimated for such portions of periods under subsection (h)(3).

(B) Application to fee-for-service nursing and allied health education payments. Such ratio shall be applied to the Secretary's estimate of total payments for nursing and allied health education determined under section 1861(v) [*42 USCS § 1395x(v)*] for portions of cost reporting periods occurring in the year to determine a total amount of additional payments for nursing and allied health education to be distributed to hospitals under this subsection for portions of cost reporting periods occurring in the year; except that in no case shall such total amount exceed $ 60,000,000 in any year.

(C) Application to hospital. The amount of payment under this subsection to a hospital for portions of cost reporting periods occurring in a year is equal to the total amount of payments determined under subparagraph (B) for the year multiplied by the Secretary's estimate of the ratio of--

(i) the product of (I) the Secretary's estimate of the ratio of the amount of payments made under section 1861(v) [*42 USCS § 1395x(v)*] to the hospital for nursing and allied health education activities for the hospital's cost reporting period ending in the second preceding fiscal year, to the hospital's total inpatient days for such period, and (II) the total number of inpatient days (as established by the Secretary) for such period which are attributable to services furnished to individuals who are enrolled under a risk sharing contract with an eligible organization under section 1876 [*42 USCS § 1395mm*] and who are entitled to benefits under part A [*42 USCS §§ 1395c* et seq.] or who are enrolled with a Medicare + Choice organization under part C [*42 USCS § 1395w-21* et seq.]; to

(ii) the sum of the products determined under clause (i) for such cost reporting periods.

(m) Prospective payment for long-term care hospitals.

(1) Reference to establishment and implementation of system. For provisions related to the establishment and implementation of a prospective payment system for payments under this *title [42 USCS §§ 1395* et seq.] for inpatient hospital services furnished by a long-term care hospital described in subsection (d)(1)(B)(iv), see section 123 of the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999 [note to this section] and section 307(b) of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 [note to this section].

(2) Update for rate year 2008. In implementing the system described in paragraph (1) for discharges occurring during the rate year ending in 2008 for a hospital, the base rate for such discharges for the hospital shall be the same as the base rate for discharges for the hospital occurring during the rate year ending in 2007.

HISTORY:

(Aug. 14, 1935, ch 531, Title XVIII, Part E[D][C], 1886, as added Sept. 3, 1982, P.L. 97-248, Title I, Subtitle A, Part I, Subpart A, § 101(a)(1), 96 Stat. 331; Sept. 3, 1982, P.L. 97-248, Title I, Subtitle A, Part I, Subpart A, § 110, 96 Stat. 339; Jan. 12, 1983, P.L. 97-448, Title III, § 309(b)(13)-(15), 96 Stat. 2409; April 20, 1983, P.L. 98-21, Title VI, 601(a)(1), (2), (b)(1)-(8), (9) in part, (c)-(e), 97 Stat. 149-162; July 18, 1984, P.L. 98-369, Division B, Title III, Subtitle A, Part I, §§ 2307(b)(1), 2310(a), 2311(a)-(c), 2312(a), (b), 2313(a), (b), (d), 2315(a)-(c), Part II, § 2354(b)(42)-(44), 98 Stat. 1073, 1075-1080, 1102; Nov. 8, 1984, P.L. 98-617, § 3(b)(9), 98 Stat. 3296; April 7, 1986, P.L. 99-272, Title IX, Subtitle A, Part 1, Subpart A, §§ 9101(b), (c), 9102(a)-(c), 9104(a), (b), 9105(a)-(c), 9106(a), 9107(a), 9109(a), 9111(a), Subpart B 9127(a), Part 2, Subpart A, § 9202(a), 100 Stat. 153-155, 157-162, 170, 171; July 2, 1986, P.L. 99-349, Title II, § 206, 100 Stat. 749; Oct. 21, 1986, P.L. 99-509, Title IX, Subtitle D, Part 1, §§ 9302(a)(1), (2), (b)(1), (c), (d)(1)(A), (e), 9303(a)-(c), § 9306(a)-(c), Part 2, §§ 9314(a), 9320(g), 9321(e)(2), 100 Stat. 1982, 1985, 1995, 2005, 2015, 2017; Oct. 22, 1986, P.L. 99-514, Title XVIII, Subtitle C, Ch 1, § 1895(a), (b)(2)(A) [(C)] 100 Stat. 2932 as amended Oct. 21, 1986, P.L. 99-509, Title IX, Subtitle D, Part 1, §§ 9304(a)-(c), 9307(c)(1), 100 Stat. 1985, 1995 and Dec. 22, 1987, P.L. 100-203, Title IV, Subtitle A, Part 1, § 4009(j)(6)(A)-(C), 101 Stat. 1330-59; Oct. 22, 1986, P.L. 99-514, Title XVIII, Subtitle C, Ch 1, § 1895(b)(3), (9), 100 Stat. 2932, 2933; Aug. 18, 1987, P.L. 100-93, § 8(c)(4), 101 Stat. 693; Dec. 22, 1987, P.L. 100-203, Title IV, Subtitle A, Part 1, §§ 4002(a), (c)(2), (f)(1), 4003(a)-(c), 4004(a), 4005(a)(1), (c)(1), (d)(1)(A), 4006(a), (b)(1), 4007(b)(1), 4009(d)(1), (j)(4), Part 3, Subpart D, § 4083(b)(1), 101 Stat. 1330-42, 1330-46, 1330-47, 1330-49, 1330-52, 1330-53, 1330-57, 1330-129; July 1, 1988, P.L. 100-360, Title IV, Subtitle B, § 411(b)(1)(A)-(H)(i), (3), (4)(A), (B), (5)(A), (B), (8)(B), 102 Stat. 768-772; Oct. 13, 1988, P.L. 100-485, Title VI, § 608(d)(18)(A), (B), 102 Stat. 2418; Nov. 10, 1988, P.L. 100-647, Title VIII, Subtitle E, Part I, §§ 8401, 8403(a) 102 Stat. 3798; Dec. 13, 1989, P.L. 101-234, Title III, § 301(b)(3), (c)(3), 103 Stat. 1985; Dec. 19, 1989, P.L. 101-239, Title VI, Subtitle A, Part 1, Subpart A, §§ 6002, 6003(a)(1), (b), (c)(1)-(3), (e)(1), (2)(B), (f), (g)(2), (4), (h)(1)-(4), (6), 6004(a)(1), (2), (b)(1), Subpart B, §§ 6011(a), 6015(a), 6022, 103 Stat. 2140-2144, 2151, 2154, 2158-2161, 2164, 2167; Oct. 1, 1990, P.L. 101-403, Title I, § 115(b)(1), 104 Stat. 870; Nov. 5, 1990, P.L. 101-508, Title IV, Subtitle A, Part 1, §§ 4001, 4002(a)(1), (b), (c)(1), (2)(A), (B), (e)(1), (g)(1), (2), (h)(1)(A), (2)(B), 4003(a), 4005(a)(1), (c)(1)(B), (2), 4008(f)(1), (m)(2)(A), 104 Stat. 1388-31, 1388-34, 1388-38, 1388-40, 1388-45; Aug. 10, 1993, P.L. 103-66, Title XIII, Ch 2, Subch A, Part I, §§ 13501(a), (b)(1), (c), (e)(1), (f), 13502, 13505, 13506, Part III, § 13563(a), (b)(1), (c)(1), 107 Stat. 572-574, 576, 577, 578, 579, 605, 606; Oct. 31, 1994, P.L. 103-432, Title I, Subtitle A, §§ 101(a)(1), (b), (c),

102(b)(1)(B), 105, 108, 109, 110(a), (c), Subtitle C, § 153(a), 108 Stat. 4400, 4402, 4405, 4407, 4408, 4437; Aug. 5, 1997, P.L. 105-33, Title IV, Subtitle A, Ch 1, Subch A, § 4001, Ch 3, § 4022(b)(1)(A), Subtitle C, §§ 4201(c)(1), (4), 4202(a), 4204(a)(1), (2), Subtitle E, Ch 1, §§ 4401(a), 4402, 4403(a), 4405(a)-(c), 4406, 4407, Ch 2, Subch A, §§ 4411-4414, 4415(a)-(c), 4416, 4417(a)(1), (b)(1), 4418(a), 4419(a)(1), Subch B, § 4421(a), (b), Subtitle G, Ch 2, Subch A, §§ 4621, 4622, Subch B, §§ 4623-4625, 4626(a), 4627(a), Ch 3, § 4644(a)(1), (b)(1), (c)(1), 111 Stat. 275, 354, 373, 374, 375, 397, 398, 400, 403, 406, 407, 408, 409, 410, 475, 483, 488; Nov. 29, 1999, P.L. 106-113, Div B, § 1000(a)(6), 113 Stat. 1536; Dec. 21, 2000, P.L. 106-554, § 1(a)(4), (6), 114 Stat. 2763; Dec. 8, 2003, P.L. 108-173, Title I, § 101(a)(1), Title IV, Subtitle A, §§ 401(a)-(c), 402, 403, 406, 407(a), Subtitle C, § 422(a), (b)(1), Title V, Subtitle A, §§ 501(a), (b), 502(a), (b), 503(a)-(d)(1), 504, 505(a), Title VII, Subtitle B, § 711, Subtitle D, § 736(a)(9), (15), (c)(6), 117 Stat. 2071, 2262, 2264, 2269, 2284, 2289, 2290, 2291, 2292, 2340, 2355, 2356; Feb. 8, 2006, P.L. 109-171, Title V, Subtitle A, §§ 5001(a), (c), 5002(a), 5003(a)(1), (2)(A), (b)-(d), 120 Stat. 28, 30, 32; Dec. 20, 2006, P.L. 109-432, Div B, Title I, §§ 106(c), 109(a)(2), Title II, § 205(b)(1), 120 Stat. 2983, 2985, 2989; Dec. 26, 2007, P.L. 110-161, Div G, Title II, § 225(a), (b)(1), 121 Stat. 2189; Dec. 29, 2007, P.L. 110-173, Title I, §§ 114(e)(1), 115(a)(1), 121 Stat. 2504, 2506; July 15, 2008, P.L. 110-275, Title I, Subtitle B, § 122, 122 Stat. 2514.)

§ 1395xx. Payment of provider-based physicians and payment under certain percentage arrangements

(a) Criteria; amount of payments.

(1) The Secretary shall by regulation determine criteria for distinguishing those services (including inpatient and outpatient services) rendered in hospitals or skilled nursing facilities--

(A) which constitute professional medical services, which are personally rendered for an individual patient by a physician and which contribute to the diagnosis or treatment of an individual patient, and which may be reimbursed as physicians' services under part B [*42 USCS §§ 1395j* et seq.], and

(B) which constitute professional services which are rendered for the general benefit to patients in a hospital or skilled nursing facility and which may be reimbursed only on a reasonable cost basis or on the bases described in section 1886 [*42 USCS § 1395ww*].

(2) (A) For purposes of cost reimbursement, the Secretary shall recognize as a reasonable cost of a hospital or skilled nursing facility only that portion of the costs attributable to services rendered by a physician in such hospital or facility which are services described in paragraph (1)(B), apportioned on the basis of the amount of time actually spent by such physician rendering such services.

(B) In determining the amount of the payments which may be made with respect to services described in paragraph (1)(B), after apportioning costs as required by subparagraph (A), the Secretary may not recognize as reasonable (in the efficient delivery of health services) such portion of the provider's costs for such services to the extent that such costs exceed the reasonable compensation equivalent for such services. The reasonable compensation equivalent for any service shall be established by the Secretary in regulations.

(C) The Secretary may, upon a showing by a hospital or facility that it is unable to recruit or maintain an adequate number of physicians for the hospital or facility on account of the reimbursement limits established under this subsection, grant exceptions to such reimbursement limits as may be necessary to allow such provider to provide a compensation level sufficient to provide adequate physician services in such hospital or facility.

(b) Prohibition of recognition of payments under certain percentage agreements.

(1) Except as provided in paragraph (2), in the case of a provider of services which is paid under this *title [42 USCS §§ 1395* et seq.] on a reasonable cost basis, or other basis related to costs that are reasonable, and which has entered into a contract for the purpose of having services furnished for or on behalf of it, the Secretary may not include any cost incurred by the provider under the contract if the amount payable under the contract by the provider for that cost is determined on the basis of a percentage (or other proportion) of the provider's charges, revenues, or claim for reimbursement.

(2) Paragraph (1) shall not apply--

(A) to services furnished by a physician and described in subsection (a)(1)(B) and covered by regulations in effect under subsection (a), and

(B) under regulations established by the Secretary, where the amount involved under the percentage contract is reasonable and the contract--

(i) is a customary commercial business practice, or

(ii) provides incentives for the efficient and economical operation of the provider of services.

HISTORY:

(Aug. 14, 1935, ch 531, Title XVIII, Part E[D][C], § 1887, as added Sept. 3, 1982, P.L. 97-248, Title I, Subtitle A, Part I, Subpart A, § 108(a)(1), 96 Stat. 337; Sept. 3, 1982, P.L. 97-248, Title I, Subtitle A, Part I, Subpart A, § 109(a)(2), 96 Stat. 338; April 20, 1983, P.L. 98-21, Title VI, § 602(j), 97 Stat. 165; Aug. 5, 1997, P.L. 105-33, Title IV, Subtitle A, Ch 1, Subch A, § 4001, 111 Stat. 275; Dec. 8, 2003, P.L. 108-173, Title I, § 101(a)(1), 117 Stat. 2071.)

§ 1395yy. Payment to skilled nursing facilities for routine service costs

(a) Per diem limitations. The Secretary, in determining the amount of the payments which may be made under this *title [42 USCS §§ 1395* et seq.] with respect to routine service costs of extended care services shall not recognize as reasonable (in the efficient delivery of health services) per diem costs of such services to the extent that such per diem costs exceed the following per diem limits, except as otherwise provided in this section:

(1) With respect to freestanding skilled nursing facilities located in urban areas, the limit shall be equal to 112 percent of the mean per diem routine service costs for freestanding skilled nursing facilities located in urban areas.

(2) With respect to freestanding skilled nursing facilities located in rural areas, the limit shall be equal to 112 percent of the mean per diem routine service costs for freestanding skilled nursing facilities located in rural areas.

(3) With respect to hospital-based skilled nursing facilities located in urban areas, the limit shall be equal to the sum of the limit for freestanding skilled nursing facilities located in urban areas, plus 50 percent of the amount by which 112 percent of the mean per diem routine service costs for hospital-based skilled nursing facilities located in urban areas exceeds the limit for freestanding skilled nursing facilities located in urban areas.

(4) With respect to hospital-based skilled nursing facilities located in rural areas, the limit shall be equal to the sum of the limit for freestanding skilled nursing facilities located in rural areas, plus 50 percent of the amount by which 112 percent of the mean per diem routine service costs for hospital-based skilled nursing facilities located in rural areas exceeds the limit for freestanding skilled nursing facilities located in rural areas.

In applying this subsection the Secretary shall make appropriate adjustments to the labor related portion of the costs based upon an appropriate wage index, and shall, for cost reporting periods beginning on or after October 1, 1992, on or after October 1, 1995, and every 2 years thereafter, provide for an update to the per diem cost limits described in this subsection, except that the limits effective for cost reporting periods beginning on or after October 1, 1997, shall be based on the limits effective for cost reporting periods beginning on or after October 1, 1996.

(b) Exception to limitations for hospital-based skilled nursing facility. With respect to a hospital-based skilled nursing facility, the Secretary may not recognize as reasonable the portion of the cost differences between hospital-based and freestanding skilled nursing facilities attributable to excess overhead allocations.

(c) Adjustments in limitations; publication of data. The Secretary may make adjustments in the limits set forth in subsection (a) with respect to any skilled nursing facility to the extent the Secretary deems appropriate, based upon case mix or circumstances beyond the control of the facility. The Secretary shall publish the data and criteria to be used for purposes of this subsection on an annual basis.

(d) Access to skilled nursing facilities.

(1) Subject to subsection (e), any skilled nursing facility may choose to be paid under this subsection on the basis of a prospective payment for all routine service costs (including the costs of services required to attain or maintain the highest practicable physical, mental, and psychosocial well-being of each resident eligible for benefits under this *title [42 USCS §§ 1395* et seq.]) and capital-related costs of extended care services provided in a cost reporting period if such facility had, in the preceding cost reporting period, fewer than 1,500 patient days with respect to which payments were made under this *title [42 USCS §§ 1395* et seq.]. Such prospective payment shall be in lieu of payments which would otherwise be made for routine service costs pursuant to section 1861(v) [*42 USCS § 1395x(v)*] and subsections (a) through (c) of this section and capital-related costs pursuant to section 1861(v) [*42 USCS § 1395x(v)*]. This subsection shall not apply to a facility for any cost reporting period immediately following a fiscal year in which such facility had 1,500 or more patient days with respect to which payments were made under this *title [42 USCS §§ 1395* et seq.], without regard to whether payments were made under this subsection during such preceding cost reporting period.

(2) (A) The amount of the payment under this section shall be determined on a per diem basis.

(B) Subject to the limitations of subparagraph (C), for skilled nursing facilities located--

(i) in an urban area, the amount shall be equal to 105 percent of the mean of the per diem reasonable routine service and capital-related costs of extended care services for skilled nursing facilities in urban areas within the same region, determined without regard to the limitations of subsection (a) and adjusted for different area wage levels, and

(ii) in a rural area the amount shall be equal to 105 percent of the mean of the per diem reasonable routine service and capital-related costs of extended care services for skilled nursing facilities in rural areas within the same region, determined without regard to the limitations of subsection (a) and adjusted for different area wage levels.

(C) The per diem amounts determined under subparagraph (B) shall not exceed the limit on routine service costs determined under subsection (a) with respect to the facility, adjusted to take into account average capital-related costs with respect to the type and location of the facility.

(3) For purposes of this subsection, urban and rural areas shall be determined in the same manner as for purposes of subsection (a), and the term "region" shall have the same meaning as under section 1886(d)(2)(D) [*42 USCS § 1395ww(d)(2)(D)*].

(4) The Secretary shall establish the prospective payment amounts for cost reporting period beginning in a fiscal year at least 90 days prior to the beginning of such fiscal year, on the basis of the most recent data available for a 12-month period. A skilled nursing facility must notify the Secretary of its intention to be paid pursuant to this subsection for a cost reporting period no later than 30 days before the beginning of that period.

(5) The Secretary shall provide for a simplified cost report to be filed by facilities being paid pursuant to this subsection, which shall require only the cost information necessary for determining prospective payment amounts pursuant to paragraph (2) and reasonable costs of ancillary services.

(6) In lieu of payment on a cost basis for ancillary services provided by a facility which is being paid pursuant to this subsection, the Secretary may pay for such ancillary services on a reasonable charge basis if the Secretary determines that such payment basis will provide an equitable level of reimbursement and will ease the reporting burden of the facility.

(7) In computing the rates of payment to be made under this subsection, there shall be taken into account the costs described in the last sentence of section 1861(v)(1)(E) [*42 USCS § 1395x(v)(1)(E)*] (relating to compliance with nursing facility requirements and of conducting nurse aide training and competency evaluation programs and competency evaluation programs).

(e) Prospective payment.

(1) Payment provision. Notwithstanding any other provision of this *title [42 USCS §§ 1395* et seq.], subject to paragraphs (7), (11), and (12), the amount of the payment for all costs (as defined in paragraph (2)(B)) of covered skilled nursing facility services (as defined in paragraph (2)(A)) for each day of such services furnished--

(A) in a cost reporting period during the transition period (as defined in paragraph (2)(E)), is equal to the sum of--

(i) the non-Federal percentage of the facility-specific per diem rate (computed under paragraph (3)), and

(ii) the Federal percentage of the adjusted Federal per diem rate (determined under paragraph (4)) applicable to the facility; and

(B) after the transition period is equal to the adjusted Federal per diem rate applicable to the facility.

(2) Definitions. For purposes of this subsection:

(A) Covered skilled nursing facility services.

(i) In general. The term "covered skilled nursing facility services"--

(I) means post-hospital extended care services as defined in section 1861(i) [*42 USCS § 1395x(i)*] for which benefits are provided under part A [*42 USCS §§ 1395c* et seq.]; and

(II) includes all items and services (other than items and services described in clauses (ii), (iii), and (iv)) for which payment may be made under part B [*42 USCS §§ 1395j* et seq.] and which are furnished to an individual who is a resident of a skilled nursing facility during the period in which the individual is provided covered post-hospital extended care services.

(ii) Services excluded. Services described in this clause are physicians' services, services described by clauses (i) and (ii) of section 1861(s)(2)(K) [*42 USCS § 1395x(s)(2)(K)*], certified nurse-midwife services, qualified psychologist services, services of a certified registered nurse anesthetist, items and services described in subparagraphs (F) and (O) of section 1861(s)(2) [*42 USCS § 1395x(s)(2)*], telehealth services furnished under section 1834(m)(4)(C)(ii)(VII) [*42 USCS § 1395m(m)(4)(C)(ii)(VII)*], and, only with respect to services furnished during 1998, the transportation costs of electrocardiogram equipment for electrocardiogram test services (HCPCS Code R0076). Services described in this clause do not include any physical, occupational, or speech-language therapy services regardless of whether or not the services are furnished by, or under the supervision of, a physician or other health care professional.

(iii) Exclusion of certain additional items and services. Items and services described in this clause are the following:

(I) Ambulance services furnished to an individual in conjunction with renal dialysis services described in section 1861(s)(2)(F) [*42 USCS § 1395x(s)(2)(F)*].

(II) Chemotherapy items (identified as of July 1, 1999, by HCPCS codes J9000-J9020; J9040-J9151; J9170-J9185; J9200-J9201; J9206-J9208; J9211; J9230-J9245; and J9265-J9600 (and as subsequently modified by the Secretary)) and any additional chemotherapy items identified by the Secretary.

(III) Chemotherapy administration services (identified as of July 1, 1999, by HCPCS codes 36260-36262; 36489; 36530-36535; 36640; 36823; and 96405-96542 (and as subsequently modified by the Secretary)) and any additional chemotherapy administration services identified by the Secretary.

(IV) Radioisotope services (identified as of July 1, 1999, by HCPCS codes 79030-79440 (and as subsequently modified by the Secretary)) and any additional radioisotope services identified by the Secretary.

(V) Customized prosthetic devices (commonly known as artificial limbs or components of artificial limbs) under the following HCPCS codes (as of July 1, 1999 (and as subsequently modified by the Secretary)), and any additional customized prosthetic devices identified by the Secretary, if delivered to an inpatient for use during the stay in the skilled nursing facility and intended to be used by the individual after discharge from the facility: L5050-L5340; L5500-L5611; L5613-L5986; L5988; L6050-L6370; L6400-L6880; L6920-L7274; and L7362-7366.

(iv) Exclusion of certain rural health clinic and federally qualified health center services. Services described in this clause are--

(I) rural health clinic services (as defined in paragraph (1) of section 1861(aa) [*42 USCS § 1395x(aa)*]); and

(II) federally qualified health center services (as defined in paragraph (3) of such section);

that would be described in clause (ii) if such services were furnished by an individual not affiliated with a rural health clinic or a federally qualified health center.

(B) All costs. The term "all costs" means routine service costs, ancillary costs, and capital-related costs of covered skilled nursing facility services, but does not include costs associated with approved educational activities.

(C) Non-Federal percentage; Federal percentage. For--

(i) the first cost reporting period (as defined in subparagraph (D)) of a facility, the "non-Federal percentage" is 75 percent and the "Federal percentage" is 25 percent;

(ii) the next cost reporting period of such facility, the "non-Federal percentage" is 50 percent and the "Federal percentage" is 50 percent; and

(iii) the subsequent cost reporting period of such facility, the "non-Federal percentage" is 25 percent and the "Federal percentage" is 75 percent.

(D) First cost reporting period. The term "first cost reporting period" means, with respect to a skilled nursing facility, the first cost reporting period of the facility beginning on or after July 1, 1998.

(E) Transition period.

(i) In general. The term "transition period" means, with respect to a skilled nursing facility, the 3 cost reporting periods of the facility beginning with the first cost reporting period.

(ii) Treatment of new skilled nursing facilities. In the case of a skilled nursing facility that first received payment for services under this *title [42 USCS §§ 1395* et seq.] on or after October 1, 1995, payment for such services shall be made under this subsection as if all services were furnished after the transition period.

(3) Determination of facility specific per diem rates. The Secretary shall determine a facility-specific per diem rate for each skilled nursing facility not described in paragraph (2)(E)(ii) for a cost reporting period as follows:

(A) Determining base payments. The Secretary shall determine, on a per diem basis, the total of--

(i) the allowable costs of extended care services for the facility for cost reporting periods beginning in fiscal year 1995, including costs associated with facilities described in subsection (d), with appropriate adjustments (as determined by the Secretary) to non-settled cost reports or, in the case of a facility participating in the Nursing Home Case-Mix and Quality Demonstration (RUGS-III), the RUGS-III rate received by the facility during the cost reporting period beginning in 1997, and

(ii) an estimate of the amounts that would be payable under part B (disregarding any applicable deductibles, coinsurance, and copayments) for covered skilled nursing facility services described in paragraph (2)(A)(i)(II) furnished during the applicable cost reporting period described in clause (i) to an individual who is a resident of the facility, regardless of whether or not the payment was made to the facility or to another entity.

In making appropriate adjustments under clause (i), the Secretary shall take into account exceptions and shall take into account exemptions but, with respect to exemptions, only to the extent that routine costs do not exceed 150 percent of the routine cost limits otherwise applicable but for the exemption.

(B) Update to first cost reporting period. The Secretary shall update the amount determined under subparagraph (A), for each cost reporting period after the applicable cost reporting period described in subparagraph (A)(i) and up to the first cost reporting period by a factor equal to the skilled nursing facility market basket percentage increase minus 1.0 percentage point.

(C) Updating to applicable cost reporting period. The Secretary shall update the amount determined under subparagraph (B) for each cost reporting period beginning with the first cost reporting period and up to and including the cost reporting period involved by a factor equal to the facility-specific update factor.

(D) Facility-specific update factor. For purposes of this paragraph, the "facility-specific update factor" for cost reporting periods beginning during--

(i) during each of fiscal years 1998 and 1999, is equal to the skilled nursing facility market basket percentage increase for such fiscal year minus 1 percentage point, and

(ii) during each subsequent fiscal year is equal to the skilled nursing facility market basket percentage increase for such fiscal year.

(4) Federal per diem rate.

(A) Determination of historical per diem for facilities. For each skilled nursing facility that received payments for post-hospital extended care services during a cost reporting period beginning in fiscal year 1995 and that was subject to (and not exempted from) the per diem limits referred to in paragraph (1) or (2) of subsection (a) (and facilities described in subsection (d)), the Secretary shall estimate, on a per diem basis for such cost reporting period, the total of--

(i) the allowable costs of extended care services (excluding exceptions payments) for the facility for cost reporting periods beginning in 1995 with appropriate adjustments (as determined by the Secretary) to non-settled cost reports, and

(ii) an estimate of the amounts that would be payable under part B [*42 USCS §§ 1395j* et seq.] (disregarding any applicable deductibles, coinsurance, and copayments) for covered skilled nursing facility services described in paragraph (2)(A)(i)(II) furnished during such period to an individual who is a resident of the facility, regardless of whether or not the payment was made to the facility or to another entity.

(B) Update to first fiscal year. The Secretary shall update the amount determined under subparagraph (A), for each cost reporting period after the cost reporting period described in subparagraph (A)(i) and up to the first cost reporting period by a factor equal to the skilled nursing facility market basket percentage increase reduced (on an annualized basis) by 1 percentage point.

(C) Computation of standardized per diem rate. The Secretary shall standardize the amount updated under subparagraph (B) for each facility by--

(i) adjusting for variations among facilities by area in the average facility wage level per diem, and

(ii) adjusting for variations in case mix per diem among facilities.

(D) Computation of weighted average per diem rates.

(i) All facilities. The Secretary shall compute a weighted average per diem rate for all facilities by computing an average of the standardized amounts computed under subparagraph (C), weighted for each facility by the number of days of extended care services furnished during the cost reporting period referred to in subparagraph (A).

(ii) Freestanding facilities. The Secretary shall compute a weighted average per diem rate for freestanding facilities by computing an average of the standardized amounts computed under subparagraph (C) only for such facilities, weighted for each facility by the number of days of extended care services furnished during the cost reporting period referred to in subparagraph (A).

(iii) Separate computation. The Secretary may compute and apply such averages separately for facilities located in urban and rural areas (as defined in section 1886(d)(2)(D) [*42 USCS § 1395ww(d)(2)(D)*]).

(E) Updating.

(i) Initial period. For the initial period beginning on July 1, 1998, and ending on September 30, 1999, the Secretary shall compute for skilled nursing facilities an unadjusted Federal per diem rate equal to the average of the weighted average per diem rates computed under clauses (i) and (ii) of subparagraph (D), increased by skilled nursing facility market basket percentage change for such period minus 1 percentage point.

(ii) Subsequent fiscal years. The Secretary shall compute an unadjusted Federal per diem rate equal to the Federal per diem rate computed under this subparagraph--

(I) for fiscal year 2000, the rate computed for the initial period described in clause (i), increased by the skilled nursing facility market basket percentage change for the initial period minus 1 percentage point;

(II) for fiscal year 2001, the rate computed for the previous fiscal year increased by the skilled nursing facility market basket percentage change for the fiscal year;

(III) for each of fiscal years 2002 and 2003, the rate computed for the previous fiscal year increased by the skilled nursing facility market basket percentage change for the fiscal year involved minus 0.5 percentage points; and

(IV) for each subsequent fiscal year, the rate computed for the previous fiscal year increased by the skilled nursing facility market basket percentage change for the fiscal year involved.

(F) Adjustment for case mix creep. Insofar as the Secretary determines that the adjustments under subparagraph (G)(i) for a previous fiscal year (or estimates that such adjustments for a future fiscal year) did (or are likely to) result in a change in aggregate payments under this subsection during the fiscal year that are a result of changes in the coding or

classification of residents that do not reflect real changes in case mix, the Secretary may adjust unadjusted Federal per diem rates for subsequent fiscal years so as to eliminate the effect of such coding or classification changes.

(G) Determination of Federal rate. The Secretary shall compute for each skilled nursing facility for each fiscal year (beginning with the initial period described in subparagraph (E)(i)) an adjusted Federal per diem rate equal to the unadjusted Federal per diem rate determined under subparagraph (E), as adjusted under subparagraph (F), and as further adjusted as follows:

(i) Adjustment for case mix. The Secretary shall provide for an appropriate adjustment to account for case mix. Such adjustment shall be based on a resident classification system, established by the Secretary, that accounts for the relative resource utilization of different patient types. The case mix adjustment shall be based on resident assessment data and other data that the Secretary considers appropriate.

(ii) Adjustment for geographic variations in labor costs. The Secretary shall adjust the portion of such per diem rate attributable to wages and wage-related costs for the area in which the facility is located compared to the national average of such costs using an appropriate wage index as determined by the Secretary. Such adjustment shall be done in a manner that does not result in aggregate payments under this subsection that are greater or less than those that would otherwise be made if such adjustment had not been made.

(iii) Adjustment for exclusion of certain additional items and services. The Secretary shall provide for an appropriate proportional reduction in payments so that beginning with fiscal year 2001, the aggregate amount of such reductions is equal to the aggregate increase in payments attributable to the exclusion effected under clause (iii) of paragraph (2)(A).

(H) Publication of information on per diem rates. The Secretary shall provide for publication in the Federal Register, before May 1, 1998 (with respect to fiscal period described in subparagraph (E)(i)) and before the August 1 preceding each succeeding fiscal year (with respect to that succeeding fiscal year), of--

(i) the unadjusted Federal per diem rates to be applied to days of covered skilled nursing facility services furnished during the fiscal year,

(ii) the case mix classification system to be applied under subparagraph (G)(i) with respect to such services during the fiscal year, and

(iii) the factors to be applied in making the area wage adjustment under subparagraph (G)(ii) with respect to such services.

(5) Skilled nursing facility market basket index and percentage. For purposes of this subsection:

(A) Skilled nursing facility market basket index. The Secretary shall establish a skilled nursing facility market basket index that reflects changes over time in the prices of an appropriate mix of goods and services included in covered skilled nursing facility services.

(B) Skilled nursing facility market basket percentage. The term "skilled nursing facility market basket percentage" means, for a fiscal year or other annual period and as calculated by the Secretary, the percentage change in the skilled nursing facility market basket index (established under subparagraph (A)) from the midpoint of the prior fiscal year (or period) to the midpoint of the fiscal year (or other period) involved.

(6) Submission of resident assessment data. A skilled nursing facility, or a facility described in paragraph (7)(B), shall provide the Secretary, in a manner and within the timeframes prescribed by the Secretary, the resident assessment data necessary to develop and implement the rates under this subsection. For purposes of meeting such requirement, a skilled nursing facility, or a facility described in paragraph (7), may submit the resident assessment data required under section 1819(b)(3) [*42 USCS § 1395i-3(b)(3)*], using the standard instrument designated by the State under section 1819(e)(5) [*42 USCS § 1395i-3(e)(5)*].

(7) Treatment of medicare swing bed hospitals.

(A) Transition. Subject to subparagraph (C), the Secretary shall determine an appropriate manner in which to apply this subsection to the facilities described in subparagraph (B) (other than critical access hospitals), taking into account the purposes of this subsection, and shall provide that at the end of the transition period (as defined in paragraph (2)(E)) such facilities shall be paid only under this subsection. Payment shall not be made under this subsection to such facilities for cost reporting periods beginning before such date (not earlier than July 1, 1999) as the Secretary specifies.

(B) Facilities described. The facilities described in this subparagraph are facilities that have in effect an agreement described in section 1883 [*42 USCS § 1395tt*].

(C) Exemption from PPS of swing-bed services furnished in critical access hospitals. The prospective payment system established under this subsection shall not apply to services furnished by a critical access hospital pursuant to an agreement under section 1883 [*42 USCS § 1395tt*].

(8) Limitation on review. There shall be no administrative or judicial review under section 1869, 1878 [*42 USCS §§ 1395ff, 1395oo*], or otherwise of--

(A) the establishment of Federal per diem rates under paragraph (4), including the computation of the standardized per diem rates under paragraph (4)(C), adjustments and corrections for case mix under paragraphs (4)(F) and (4)(G)(i), adjustments for variations in labor-related costs under paragraph (4)(G)(ii), and adjustments under paragraph (4)(G)(iii);

(B) the establishment of facility specific rates before July 1, 1999 (except any determination of costs paid under part A of this *title [42 USCS §§ 1395c* et seq.]); and

(C) the establishment of transitional amounts under paragraph (7).

(9) Payment for certain services. In the case of an item or service furnished to a resident of a skilled nursing facility or a part of a facility that includes a skilled nursing facility (as determined under regulations) for which payment would (but for this paragraph) be made under part B [*42 USCS §§ 1395j* et seq.] in an amount determined in accordance with section 1833(a)(2)(B) [*42 USCS § 1395l(a)(2)(B)*], the amount of the payment under such part shall be the amount provided under the fee schedule for such item or service. In the case of an item or service described in clause (iii) of paragraph (2)(A) that would be payable under part A [*42 USCS §§ 1395c* et seq.] but for the exclusion of such item or service under such clause, payment shall be made for the item or service, in an amount otherwise determined under part B of this *title [42 USCS §§ 1395j* et seq.] for such item or service, from the Federal Hospital Insurance Trust Fund under section 1817 [*42 USCS § 1395i*] (rather than from the Federal Supplementary Medical Insurance Trust Fund under section 1841 [*42 USCS § 1395t*]).

(10) Required coding. No payment may be made under part B [*42 USCS §§ 1395j* et seq.] for items and services (other than services described in paragraph (2)(A)(ii)) furnished to an individual who is a resident of a skilled nursing facility or of a part of a facility that includes a skilled nursing facility (as determined under regulations), unless the claim for such payment includes a code (or codes) under a uniform coding system specified by the Secretary that identifies the items or services furnished.

(11) Permitting facilities to waive 3-year transition. Notwithstanding paragraph (1)(A), a facility may elect to have the amount of the payment for all costs of covered skilled nursing facility services for each day of such services furnished in cost reporting periods beginning no earlier than 30 days before the date of such election determined pursuant to paragraph (1)(B).

(12) Adjustment for residents with AIDS.

(A) In general. Subject to subparagraph (B), in the case of a resident of a skilled nursing facility who is afflicted with acquired immune deficiency syndrome (AIDS), the per diem amount of payment otherwise applicable (determined without regard to any increase under section 101 of the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999 [unclassified], or under section 314(a) of Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 [unclassified]), shall be increased by 128 percent to reflect increased costs associated with such residents.

(B) Sunset. Subparagraph (A) shall not apply on and after such date as the Secretary certifies that there is an appropriate adjustment in the case mix under paragraph (4)(G)(i) to compensate for the increased costs associated with residents described in such subparagraph.

HISTORY:

(Aug. 14, 1935, ch 531, Title XVIII, Part E[D][C], § 1888, as added July 18, 1984, P.L. 98-369, Division B, Title III, Subtitle A, Part I, § 2319(b), 98 Stat. 1082; April 7, 1986, P.L. 99-272, Title IX, Subtitle A, Part 1, Subpart B, § 9126(a), (b), Part 2, Subpart B, § 9219(b)(1)(C), 100 Stat. 168, 170, 182; Oct. 22, 1986, P.L. 99-514, Title XVIII, Subtitle C, Ch 1, § 1395(b)(7)(A), (B), 100 Stat. 2933; Dec. 22, 1987, P.L. 100-203, Title IV, Subtitle C, Part 1, § 4201(b)(2), 101 Stat. 1330-174; Nov. 5, 1990, P.L. 101-508, Title IV, Subtitle A, Part 1, § 4008(e)(2), (h)(2)(A)(ii), 104 Stat. 1388-45; Aug. 10, 1993, P.L. 103-66, Title XIII, Ch 2, Subch A, Part I, § 13503(a)(2), (3)(A), 107 Stat. 578; Aug. 5, 1997, P.L. 105-33, Title IV, Subtitle A, Ch 1, Subch A, § 4001, Subtitle E, Ch 3, §§ 4431, 4432(a), (b)(3), (5)(H), Subtitle F, Ch 1, Subch B, § 4511(a)(2)(E), 111 Stat. 275, 414, 421, 422, 442; Nov. 29, 1999, P.L. 106-113, Div B, § 1000(a)(6), 113 Stat. 1536; Dec. 21, 2000, P.L. 106-554, § 1(a)(6), 114 Stat. 2763; Dec. 8, 2003, P.L. 108-173, Title I, § 101(a)(1), Title IV, Subtitle A, § 410(a), Title V, Subtitle B, § 511(a), 117 Stat. 2071, 2271, 2298; July 15, 2008, P.L. 110-275, Title I, Subtitle C, Part II, § 149(b), 122 Stat. 2549.)

§ 1395zz. Provider education and technical assistance

(a) Coordination of education funding. The Secretary shall coordinate the educational activities provided through medicare contractors (as defined in subsection (g), including under section 1893 [*42 USCS § 1395ddd*]) in order to maximize the effectiveness of Federal education efforts for providers of services and suppliers.

(b) Enhanced education and training.

(1) Additional resources. There are authorized to be appropriated to the Secretary (in appropriate part from the Federal Hospital Insurance Trust Fund and the Federal Supplementary Medical Insurance Trust Fund) such sums as may be necessary for fiscal years beginning with fiscal year 2005.

(2) Use. The funds made available under paragraph (1) shall be used to increase the conduct by medicare contractors of education and training of providers of services and suppliers regarding billing, coding, and other appropriate items and may also be used to improve the accuracy, consistency, and timeliness of contractor responses.

(c) Tailoring education and training activities for small providers or suppliers.

(1) In general. Insofar as a medicare contractor conducts education and training activities, it shall tailor such activities to meet the special needs of small providers of services or suppliers (as defined in paragraph (2)). Such education and training activities for small providers of services and suppliers may include the provision of technical assistance (such as review of billing systems and internal controls to determine program compliance and to suggest more efficient and effective means of achieving such compliance).

(2) Small provider of services or supplier. In this subsection, the term "small provider of services or supplier" means--

(A) a provider of services with fewer than 25 full-time-equivalent employees; or

(B) a supplier with fewer than 10 full-time-equivalent employees.

(d) Internet websites; FAQs. The Secretary, and each medicare contractor insofar as it provides services (including claims processing) for providers of services or suppliers, shall maintain an Internet website which--

(1) provides answers in an easily accessible format to frequently asked questions, and

(2) includes other published materials of the contractor,that relate to providers of services and suppliers under the programs under this *title [42 USCS §§ 1395* et seq.] (and title XI [*42 USCS §§ 1301* et seq.] insofar as it relates to such programs).

(e) Encouragement of participation in education program activities. A medicare contractor may not use a record of attendance at (or failure to attend) educational activities or other information gathered during an educational program conducted under this section or otherwise by the Secretary to select or track providers of services or suppliers for the purpose of conducting any type of audit or prepayment review.

(f) Construction. Nothing in this section or section 1893(g) [*42 USCS § 1395ddd(g)*] shall be construed as providing for disclosure by a medicare contractor--

(1) of the screens used for identifying claims that will be subject to medical review; or

(2) of information that would compromise pending law enforcement activities or reveal findings of law enforcement-related audits.

(g) Definitions. For purposes of this section, the term "medicare contractor" includes the following:

(1) A medicare administrative contractor with a contract under section 1874A [*42 USCS § 1395kk-1*], including a fiscal intermediary with a contract under section 1816 [*42 USCS § 1395h*] and a carrier with a contract under section 1842 [*42 USCS § 1395u*].

(2) An eligible entity with a contract under section 1893 [*42 USCS § 1395ddd*].

Such term does not include, with respect to activities of a specific provider of services or supplier an entity that has no authority under this title or title IX [*42 USCS §§ 1395* et seq. or *1301* et seq.] with respect to such activities and such provider of services or supplier.

HISTORY:

(Aug. 14, 1935, ch 531, Title XVIII, Part E, § 1889, as added and amended Dec. 8, 2003, P.L. 108-173, Title IX, Subtitle C, § 921(a)(1), (d)(1), (e)(1), (f)(1), 117 Stat. 2388, 2391.)

§ 1395aaa. Contract with a consensus-based entity regarding performance measurement

(a) Contract.

(1) In general. For purposes of activities conducted under this Act [*42 USCS §§ 301* et seq.], the Secretary shall identify and have in effect a contract with a consensus-based entity, such as the National Quality Forum, that meets the requirements described in subsection (c). Such contract shall provide that the entity will perform the duties described in subsection (b).

(2) Timing for first contract. As soon as practicable after the date of the enactment of this subsection [enacted July 15, 2008], the Secretary shall enter into the first contract under paragraph (1).

(3) Period of contract. A contract under paragraph (1) shall be for a period of 4 years (except as may be renewed after a subsequent bidding process).

(4) Competitive procedures. Competitive procedures (as defined in section 4(5) of the Office of Federal Procurement Policy Act (*41 U.S.C. 403(5)*)) shall be used to enter into a contract under paragraph (1).

(b) Duties. The duties described in this subsection are the following:

(1) Priority setting process. The entity shall synthesize evidence and convene key stakeholders to make recommendations, with respect to activities conducted under this Act [*42 USCS §§ 301* et seq.], on an integrated national strategy and priorities for health care performance measurement in all applicable settings. In making such recommendations, the entity shall--

(A) ensure that priority is given to measures--

(i) that address the health care provided to patients with prevalent, high-cost chronic diseases;

(ii) with the greatest potential for improving the quality, efficiency, and patient-centeredness of health care; and

(iii) that may be implemented rapidly due to existing evidence, standards of care, or other reasons; and

(B) take into account measures that--

(i) may assist consumers and patients in making informed health care decisions;

(ii) address health disparities across groups and areas; and

(iii) address the continuum of care a patient receives, including services furnished by multiple health care providers or practitioners and across multiple settings.

(2) Endorsement of measures. The entity shall provide for the endorsement of standardized health care performance measures. The endorsement process under the preceding sentence shall consider whether a measure--

(A) is evidence-based, reliable, valid, verifiable, relevant to enhanced health outcomes, actionable at the caregiver level, feasible to collect and report, and responsive to variations in patient characteristics, such as health status, language capabilities, race or ethnicity, and income level; and

(B) is consistent across types of health care providers, including hospitals and physicians.

(3) Maintenance of measures. The entity shall establish and implement a process to ensure that measures endorsed under paragraph (2) are updated (or retired if obsolete) as new evidence is developed.

(4) Promotion of the development of electronic health records. The entity shall promote the development and use of electronic health records that contain the functionality for automated collection, aggregation, and transmission of performance measurement information.

(5) Annual report to Congress and the Secretary; secretarial publication and comment.

(A) Annual report. By not later than March 1 of each year (beginning with 2009), the entity shall submit to Congress and the Secretary a report containing a description of--

(i) the implementation of quality measurement initiatives under this Act [*42 USCS §§ 301* et seq.] and the coordination of such initiatives with quality initiatives implemented by other payers;

(ii) the recommendations made under paragraph (1); and

(iii) the performance by the entity of the duties required under the contract entered into with the Secretary under subsection (a).

(B) Secretarial review and publication of annual report. Not later than 6 months after receiving a report under subparagraph (A) for a year, the Secretary shall--

(i) review such report; and

(ii) publish such report in the Federal Register, together with any comments of the Secretary on such report.

(c) Requirements described. The requirements described in this subsection are the following:

(1) Private nonprofit. The entity is a private nonprofit entity governed by a board.

(2) Board membership. The members of the board of the entity include--

(A) representatives of health plans and health care providers and practitioners or representatives of groups representing such health plans and health care providers and practitioners;

(B) health care consumers or representatives of groups representing health care consumers; and

(C) representatives of purchasers and employers or representatives of groups representing purchasers or employers.

(3) Entity membership. The membership of the entity includes persons who have experience with--

(A) urban health care issues;

(B) safety net health care issues;

(C) rural and frontier health care issues; and

(D) health care quality and safety issues.

(4) Open and transparent. With respect to matters related to the contract with the Secretary under subsection (a), the entity conducts its business in an open and transparent manner and provides the opportunity for public comment on its activities.

(5) Voluntary consensus standards setting organization. The entity operates as a voluntary consensus standards setting organization as defined for purposes of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (Public Law 104-113) [*15 USCS § 272* note] and Office of Management and Budget Revised Circular A-119 (published in the Federal Register on February 10, 1998).

(6) Experience. The entity has at least 4 years of experience in establishing national consensus standards.

(7) Membership fees. If the entity requires a membership fee for participation in the functions of the entity, such fees shall be reasonable and adjusted based on the capacity of the potential member to pay the fee. In no case shall membership fees pose a barrier to the participation of individuals or groups with low or nominal resources to participate in the functions of the entity.

(d) Funding. For purposes of carrying out this section, the Secretary shall provide for the transfer, from the Federal Hospital Insurance Trust Fund under section 1817 [*42 USCS § 1395i*] and the Federal Supplementary Medical Insurance Trust Fund under section 1841 [*42 USCS § 1395t*] (in such proportion as the Secretary determines appropriate), of $ 10,000,000 to the Centers for Medicare & Medicaid Services Program Management Account for each of fiscal years 2009 through 2012.

HISTORY:

(Aug. 14, 1935, ch 531, Title XVIII, Part E, § 1890, as added July 15, 2008, P.L. 110-275, Title I, Subtitle F, § 183(a)(1), 122 Stat. 2584.)

§ 1395bbb. Conditions of participation for home health agencies; home health quality

(a) Conditions of participation; protection of individual rights; notification of State entities; use of home health aides; medical equipment; individual's plan of care compliance with Federal State, and local laws and regulations. The conditions of participation that a home health agency is required to meet under this subsection are as follows:

(1) The agency protects and promotes the rights of each individual under its care, including each of the following rights:

(A) The right to be fully informed in advance about the care and treatment to be provided by the agency, to be fully informed in advance of any changes in the care or treatment to be provided by the agency that may affect the individual's well-being, and (except with respect to an individual adjudged incompetent) to participate in planning care and treatment or changes in care or treatment.

(B) The right to voice grievances with respect to treatment or care that is (or fails to be) furnished without discrimination or reprisal for voicing grievances.

(C) The right to confidentiality of the clinical records described in section 1861(o)(3) [*42 USCS § 1395x(o)(3)*].

(D) The right to have one's property treated with respect.

(E) The right to be fully informed orally and in writing (in advance of coming under the care of the agency) of--

(i) all items and services furnished by (or under arrangements with) the agency for which payment may be made under this *title [42 USCS §§ 1395* et seq.],

(ii) the coverage available for such items and services under this *title [42 USCS §§ 1395* et seq.], title XIX [*42 USCS §§ 1396* et seq.], and any other Federal program of which the agency is reasonably aware,

(iii) any charges for items and services not covered under this *title [42 USCS §§ 1395* et seq.] and any charges the individual may have to pay with respect to items and services furnished by (or under arrangements with) the agency, and

(iv) any changes in the charges or items and services described in clause (i), (ii), or (iii).

(F) The right to be fully informed in writing (in advance of coming under the care of the agency) of the individual's rights and obligations under this *title [42 USCS §§ 1395* et seq.].

(G) The right to be informed of the availability of the State home health agency hot-line established under section 1864(a) [*42 USCS § 1395aa(a)*].

(2) The agency notifies the State entity responsible for the licensing or certification of the agency of a change in--

(A) the persons with an ownership or control interest (as defined in section 1124(a)(3) [*42 USCS § 1320a-3(a)(3)*]) in the agency,

(B) the persons who are officers, directors, agents, or managing employees (as defined in section 1126(b) [*42 USCS § 1320a-5(b)*]) of the agency, and

(C) the corporation, association, or other company responsible for the management of the agency.

Such notice shall be given at the time of the change and shall include the identity of each new person or company described in the previous sentence.

(3) (A) The agency must not use as a home health aide (on a full-time, temporary, per diem, or other basis), any individual to provide items or services described in section 1861(m) [*42 USCS § 1395x(m)*] on or after January 1, 1990, unless the individual--

(i) has completed a training and competency evaluation program, or a competency evaluation program, that meets the minimum standards established by the Secretary under subparagraph (D), and

(ii) is competent to provide such items and services.

For purposes of clause (i), an individual is not considered to have completed a training and competency evaluation program, or a competency evaluation program if, since the individual's most recent completion of such a program, there has been a continuous period of 24 consecutive months during none of which the individual provided items and services described in section 1861(m) [*42 USCS § 1395x(m)*] for compensation.

(B) (i) The agency must provide, with respect to individuals used as a home health aide by the agency as of July 1, 1989, for a competency evaluation program (as described in subparagraph (A)(i)) and such preparation as may be necessary for the individual to complete such a program by January 1, 1990.

(ii) The agency must provide such regular performance review and regular in-service education as assures that individuals used to provide items and services described in section 1861(m) [*42 USCS § 1395x(m)*] are competent to provide those items and services.

(C) The agency must not permit an individual, other than in a training and competency evaluation program that meets the minimum standards established by the Secretary under subparagraph (D), to provide items or services of a type for which the individual has not demonstrated competency.

(D) (i) The Secretary shall establish minimum standards for the programs described in subparagraph (A) by not later than October 1, 1988.

(ii) Such standards shall include the content of the curriculum, minimum hours of training, qualification of instructors, and procedures for determination of competency.

(iii) Such standards may permit approval of programs offered by or in home health agencies, as well as outside agencies (including employee organizations), and of programs in effect on the date of the enactment of this section [enacted Dec. 22, 1987]; except that they may not provide for the approval of a program offered by or in a home health agency which, within the previous 2 years--

(I) has been determined to be out of compliance with subparagraph (A), (B), or (C);

(II) has been subject to an extended (or partial extended) survey under subsection (c)(2)(D);

(III) has been assessed a civil money penalty described in subsection (f)(2)(A)(i) of not less than $ 5,000; or

(IV) has been subject to the remedies described in subsection (e)(1) or in clauses (ii) or (iii) of subsection (f)(2)(A).

(iv) Such standards shall permit a determination that an individual who has completed (before July 1, 1989) a training and competency evaluation program or a competency evaluation program shall be deemed for purposes of subparagraph (A) to have completed a program that is approved by the Secretary under the standards established under this subparagraph if the Secretary determines that, at the time the program was offered, the program met such standards.

(E) In this paragraph, the term "home health aide" means any individual who provides the items and services described in section 1861(m) [*42 USCS § 1395x(m)*], but does not include an individual--

(i) who is a licensed health professional (as defined in subparagraph (F)), or

(ii) who volunteers to provide such services without monetary compensation.

(F) In this paragraph, the term "licensed health professional" means a physician, physician assistant, nurse practitioner, physical, speech, or occupational therapist, physical or occupational therapy assistant, registered professional nurse, licensed practical nurse, or licensed or certified social worker.

(4) The agency includes an individual's plan of care required under section 1861(m) [*42 USCS § 1395x(m)*] as part of the clinical records described in section 1861(o)(3) [*42 USCS § 1395x(o)(3)*].

(5) The agency operates and provides services in compliance with all applicable Federal, State, and local laws and regulations (including the requirements of section 1124 [*42 USCS § 1320a-3*]) and with accepted professional standards and principles which apply to professionals providing items and services in such an agency.

(6) The agency complies with the requirement of section 1866(f) [*42 USCS § 1395cc(f)*] (relating to maintaining written policies and procedures respecting advance directives).

(b) Duty of Secretary. It is the duty and responsibility of the Secretary to assure that the conditions of participation and requirements specified in or pursuant to section 1861(o) [*42 USCS § 1395x(o)*] and subsection (a) of this section and the enforcement of such conditions and requirements are adequate to protect the health and safety of individuals under the care of a home health agency and to promote the effective and efficient use of public moneys.

(c) Surveys of home health agencies.

(1) Any agreement entered into or renewed by the Secretary pursuant to section 1864 [*42 USCS § 1395aa*] relating to home health agencies shall provide that the appropriate State or local agency shall conduct, without any prior notice, a standard survey of each home health agency. Any individual who notifies (or causes to be notified) a home health agency of the time or date on which such a survey is scheduled to be conducted is subject to a civil money penalty of not to exceed $ 2,000. The provisions of section 1128A [*42 USCS § 1320a-7a*] (other than subsections (a) and (b)) shall apply to a civil money penalty under this paragraph in the same manner as such provisions apply to a penalty or proceeding under section 1128A [*42 USCS § 1320a-7a*]. The Secretary shall review each State's or local agency's procedures for scheduling and conduct of standard surveys to assure that the State or agency has taken all reasonable steps to avoid giving notice of such a survey through the scheduling procedures and the conduct of the surveys themselves.

(2) (A) Except as provided in subparagraph (B), each home health agency shall be subject to a standard survey not later than 36 months after the date of the previous standard survey conducted under this paragraph. The Secretary shall establish a frequency for surveys of home health agencies within this 36- month interval commensurate with the need to assure the delivery of quality home health services.

(B) If not otherwise conducted under subparagraph (A), a standard survey (or an abbreviated standard survey) of an agency--

(i) may be conducted within 2 months of any change of ownership, administration, or management of the agency to determine whether the change has resulted in any decline in the quality of care furnished by the agency, and

(ii) shall be conducted within 2 months of when a significant number of complaints have been reported with respect to the agency to the Secretary, the State, the entity responsible for the licensing of the agency, the State or local agency responsible for maintaining a toll-free hotline and investigative unit (under section 1864(a) [*42 USCS § 1395aa(a)*]), or any other appropriate Federal, State, or local agency.

(C) A standard survey conducted under this paragraph with respect to a home health agency--

(i) shall include (to the extent practicable), for a case-mix stratified sample of individuals furnished items or services by the agency--

(I) visits to the homes of such individuals, but only with the consent of such individuals, for the purpose of evaluating (in accordance with a standardized reproducible assessment instrument (or instruments) approved by the Secretary under subsection (d)) the extent to which the quality and scope of items and services furnished by the agency attained and maintained the highest practicable functional capacity of each such individual as reflected in such individual's written plan of care required under section 1861(m) [*42 USCS § 1395x(m)*] and clinical records required under section 1861(o)(3) [*42 USCS § 1395x(o)(3)*]; and

(II) a survey of the quality of care and services furnished by the agency as measured by indicators of medical, nursing, and rehabilitative care;

(ii) shall be based upon a protocol that is developed, tested, and validated by the Secretary not later than January 1, 1989; and

(iii) shall be conducted by an individual--

(I) who meets minimum qualifications established by the Secretary not later than July 1, 1989,

(II) who is not serving (or has not served within the previous 2 years) as a member of the staff of, or as a consultant to, the home health agency surveyed respecting compliance with the conditions of participation specified in or pursuant to section 1861(o) [*42 USCS § 1395x(o)*] or subsection (a) of this section, and

(III) who has no personal or familial financial interest in the home health agency surveyed.

(D) Each home health agency that is found, under a standard survey, to have provided substandard care shall be subject to an extended survey to review and identify the policies and procedures which produced such substandard care and to determine whether the agency has complied with the conditions of participation specified in or pursuant to section 1861(o) [*42 USCS § 1395x(o)*] or subsection (a) of this section. Any other agency may, at the Secretary's or State's discretion, be subject to such an extended survey (or a partial extended survey). The extended survey shall be conducted immediately after the standard survey (or, if not practical, not later than 2 weeks after the date of completion of the standard survey).

(E) Nothing in this paragraph shall be construed as requiring an extended (or partial extended) survey as a prerequisite to imposing a sanction against an agency under subsection (e) on the basis of the findings of a standard survey.

(d) Assessment process; reports to Congress.

(1) Not later than January 1, 1989, the Secretary shall designate an assessment instrument (or instruments) for use by an agency in complying with subsection (c)(2)(C)(i)(I).

(2)

(A) Not later than January 1, 1992, the Secretary shall--

(i) evaluate the assessment process,

(ii) report to Congress on the results of such evaluation, and

(iii) based on such evaluation, make such modifications in the assessment process as the Secretary determines are appropriate.

(B) The Secretary shall periodically update the evaluation conducted under subparagraph (A), report the results of such update to Congress, and, based on such update, make such modifications in the assessment process as the Secretary determines are appropriate.

(3) The Secretary shall provide for the comprehensive training of State and Federal surveyors in matters relating to the performance of standard and extended surveys under this section, including the use of any assessment instrument (or instruments) designated under paragraph (1).

(e) Enforcement.

(1) If the Secretary determines on the basis of a standard, extended, or partial extended survey or otherwise, that a home health agency that is certified for participation under this *title [42 USCS §§ 1395* et seq.] is no longer in compliance with the requirements specified in or pursuant to section 1861(o) [*42 USCS § 1395x(o)*] or subsection (a) and determines that the deficiencies involved immediately jeopardize the health and safety of the individuals to whom the agency furnishes items and services, the Secretary shall take immediate action to remove the jeopardy and correct the deficiencies through the remedy specified in subsection (f)(2)(A)(iii) or terminate the certification of the agency, and may provide, in addition, for 1 or more of the other remedies described in subsection (f)(2)(A).

(2) If the Secretary determines on the basis of a standard, extended, or partial extended survey or otherwise, that a home health agency that is certified for participation under this *title [42 USCS §§ 1395* et seq.] is no longer in compliance with the requirements specified in or pursuant to section 1861(o) [*42 USCS § 1395x(o)*] or subsection (a) and determines that the deficiencies involved do not immediately jeopardize the health and safety of the individuals to whom the agency furnishes items and services, the Secretary may (for a period not to exceed 6 months) impose intermediate sanctions developed pursuant to subsection (f), in lieu of terminating the certification of the agency. If, after such a period of intermediate sanctions, the agency is still no longer in compliance with the requirements specified in or pursuant to section 1861(o) [*42 USCS § 1395x(o)*] or subsection (a), the Secretary shall terminate the certification of the agency.

(3) If the Secretary determines that a home health agency that is certified for participation under this *title [42 USCS §§ 1395* et seq.] is in compliance with the requirements specified in or pursuant to section 1861(o) [*42 USCS § 1395x(o)*] or subsection (a) but, as of a previous period, did not meet such requirements, the Secretary may provide for a civil money penalty under subsection (f)(2)(A)(i) for the days in which it finds that the agency was not in compliance with such requirements.

(4) The Secretary may continue payments under this *title [42 USCS §§ 1395* et seq.] with respect to a home health agency not in compliance with the requirements specified in or pursuant to section 1861(o) [*42 USCS § 1395x(o)*] or subsection (a) over a period of not longer than 6 months, if--

(A) the State or local survey agency finds that it is more appropriate to take alternative action to assure compliance of the agency with the requirements than to terminate the certification of the agency,

(B) the agency has submitted a plan and timetable for corrective action to the Secretary for approval and the Secretary approves the plan of corrective action, and

(C) the agency agrees to repay to the Federal Government payments received under this subparagraph if the corrective action is not taken in accordance with the approved plan and timetable.

The Secretary shall establish guidelines for approval of corrective actions requested by home health agencies under this subparagraph.

(f) Intermediate sanctions.

(1) The Secretary shall develop and implement, by not later than April 1, 1989--

(A) a range of intermediate sanctions to apply to home health agencies under the conditions described in subsection (e), and

(B) appropriate procedures for appealing determinations relating to the imposition of such sanctions.

(2) (A) The intermediate sanctions developed under paragraph (1) shall include--

(i) civil money penalties in an amount not to exceed $ 10,000 for each day of noncompliance,

(ii) suspension of all or part of the payments to which a home health agency would otherwise be entitled under this *title [42 USCS §§ 1395* et seq.] with respect to items and services furnished by a home health agency on or after the date on which the Secretary determines that intermediate sanctions should be imposed pursuant to subsection (e)(2), and

(iii) the appointment of temporary management to oversee the operation of the home health agency and to protect and assure the health and safety of the individuals under the care of the agency while improvements are made in order to bring the agency into compliance with all the requirements specified in or pursuant to section 1861(o) [*42 USCS § 1395x(o)*] or subsection (a).

The provisions of section 1128A [*42 USCS § 1320a-7a*] (other than subsections (a) and (b)) shall apply to a civil money penalty under clause (i) in the same manner as such provisions apply to a penalty or proceeding under section 1128A(a) [*42 USCS § 1320a-7a(a)*]. The temporary management under clause (iii) shall not be terminated until the Secretary has determined that the agency has the management capability to ensure continued compliance with all the requirements referred to in that clause.

(B) The sanctions specified in subparagraph (A) are in addition to sanctions otherwise available under State or Federal law and shall not be construed as limiting other remedies, including any remedy available to an individual at common law.

(C) A finding to suspend payment under subparagraph (A)(ii) shall terminate when the Secretary finds that the home health agency is in substantial compliance with all the requirements specified in or pursuant to section 1861(o) [*42 USCS § 1395x(o)*] and subsection (a).

(3) The Secretary shall develop and implement, by not later than April 1, 1989, specific procedures with respect to the conditions under which each of the intermediate sanctions developed under paragraph (1) is to be applied, including the amount of any fines and the severity of each of these sanctions. Such procedures shall be designed so as to minimize the time between identification of deficiencies and imposition of these sanctions and shall provide for the imposition of incrementally more severe fines for repeated or uncorrected deficiencies.

(g) Payment on basis of location of service. A home health agency shall submit claims for payment for home health services under this *title [42 USCS §§ 1395* et seq.] only on the basis of the geographic location at which the service is furnished, as determined by the Secretary.

HISTORY:

(Aug. 14, 1935, ch 531, Title XVIII, Part E[D][C], § 1891, as added Dec. 22, 1987, P.L. 100-203, Title IV, Subtitle A, Part 2, Subpart B, § 4021(b), 101 Stat. 1330-67; Dec. 22, 1987, P.L. 100-203, Title IV, Subtitle A, Part 2, Subtitle B, §§ 4022(a), 4023(a), 101 Stat. 1330-69, 1330-71; July 1, 1988, P.L. 100-360, Title IV, Subtitle B, § 411(c)(3)(B)(i), (d)(1)(A), (B)(2), (3)(A), (B), 102 Stat. 772, 773, 774; Oct. 13, 1988, P.L. 100-485, Title VI, § 608(d)(20)(A), 102 Stat. 2419; Nov. 5, 1990, P.L. 101-508, Title IV, Subtitle A, Part 3, §§ 4206(d)(2), 4207(i), 104 Stat. 1388-116, 1388-123; Oct. 31, 1994, P.L. 103-432, Title I, Subtitle C, § 160(d)(4), 108 Stat. 4444; April 26, 1996, P.L. 104-134, Title V, § 516(a), 110 Stat. 1321-246; May 2, 1996, P.L. 104-140, § 1(a), 110 Stat. 1327; Aug. 5, 1997, P.L. 105-33, Title IV, Subtitle A, Ch1, Subch A, § 4001, Subtitle G, Ch 1, Subch A, § 4604(a), 111 Stat. 275, 472; Dec. 8, 2003, P.L. 108-173, Title I, § 101(a)(1), Title VII, Subtitle D, § 736(c)(3), 117 Stat. 2071, 2356.)

§ 1395ccc. Offset of payments to individuals to collect past-due obligations arising from breach of scholarship and loan contract

(a) In general.

(1) (A) Subject to subparagraph (B), the Secretary shall enter into an agreement under this section with any individual who, by reason of a breach of a contract entered into by such individual pursuant to the National Health Service Corps Scholarship Program, the Physician Shortage Area Scholarship Program, or the Health Education Assistance Loan Program, owes a past-due obligation to the United States (as defined in subsection (b)).

(B) The Secretary shall not enter into an agreement with an individual under this section to the extent--

(i) (I) the individual has entered into a contract with the Secretary pursuant to section 204(a)(1) of the Public Health Service Amendments of 1987 [*42 USCS § 254o* note], and

(II) the individual has fulfilled or (as determined by the Secretary) is fulfilling the terms of such contract; or

(ii) the liability of the individual under such section 204(a)(1) [*42 USCS § 254o* note] has otherwise been relieved under such section; or

(iii) the individual is performing such physician's [individual's] service obligation under a forbearance agreement entered into with the Secretary under subpart II of part D of title III of the Public Health Service Act [*42 USCS §§ 254d* et seq.].

(2) The agreement under this section shall provide that--

(A) deductions shall be made from the amounts otherwise payable to the individual under this *title [42 USCS §§ 1395* et seq.], in accordance with a formula and schedule agreed to by the Secretary and the individual, until such past-due obligation (and accrued interest) have been repaid;

(B) payment under this *title [42 USCS §§ 1395* et seq.] for services provided by such individual shall be made only on an assignment-related basis;

(C) if the individual does not provide services, for which payment would otherwise be made under this *title [42 USCS §§ 1395* et seq.], of a sufficient quantity to maintain the offset collection according to the agreed upon formula and schedule--

(i) the Secretary shall immediately inform the Attorney General, and the Attorney General shall immediately commence an action to recover the full amount of the past-due obligation, and

(ii) subject to paragraph (4), the Secretary shall immediately exclude the individual from the program under this *title [42 USCS §§ 1395* et seq.], until such time as the entire past-due obligation has been repaid.

(3) If the individual refuses to enter into an agreement or breaches any provision of the agreement--

(A) the Secretary shall immediately inform the Attorney General, and the Attorney General shall immediately commence an action to recover the full amount of the past-due obligation, and

(B) subject to paragraph (4), the Secretary shall immediately exclude the individual from the program under this *title [42 USCS §§ 1395* et seq.], until such time as the entire past-due obligation has been repaid.

(4) The Secretary shall not exclude an individual pursuant to paragraph (2)(C)(ii) or paragraph (3)(B) if such individual is a sole community individual or sole source of essential specialized services in a community if a State requests that the practitioner not be excluded.

(b) Past-due obligation. For purposes of this section, a past-due obligation is any amount--

(1) owed by an individual to the United States by reason of a breach of a scholarship contract under section 338E of the Public Health Service Act [*42 USCS § 254q*] or under subpart III of part F of title VII of such Act (as in effect before October 1, 1976) and which has not been paid by the deadline established by the Secretary pursuant to such respective section, and has not been canceled, waived, or suspended by the Secretary pursuant to such section; or

(2) owed by an individual to the United States by reason of a loan covered by Federal loan insurance under subpart I of part C of title VII of the Public Health Service Act [*42 USCS §§ 294* et seq.] and payment for which has not been cancelled, waived, or suspended by the Secretary under such subpart.

(c) Collection under this section shall not be exclusive. This section shall not preclude the United States from applying other provisions of law otherwise applicable to the collection of obligations owed to the United States, including (but not limited to) the use of tax refund offsets pursuant to *section 3720A of title 31, United States Code*, and the application of other procedures provided under chapter 37 of title 31, United States Code [*31 USCS §§ 3701* et seq.].

(d) Collection from providers and health maintenance organizations.

(1) In the case of an individual who owes a past-due obligation, and who is an employee of, or affiliated by a medical services agreement with, a provider having an agreement under section 1866 [*42 USCS § 1395cc*] or a health maintenance organization or competitive medical plan having a contract under section 1833 or section 1876 [*42 USCS § 1395l* or *1395mm*], the Secretary shall deduct the amounts of such past-due obligation from amounts otherwise payable under this *title [42 USCS §§ 1395* et seq.] to such provider, organization, or plan.

(2) Deductions shall be in accordance with a formula and schedule agreed to by the Secretary, the individual and the provider, organization, or plan. The deductions shall be made from the amounts otherwise payable to the individual under this *title [42 USCS §§ 1395* et seq.] as long as the individual continues to be employed or affiliated by a medical services agreement.

(3) Such deduction shall not be made until 6 months after the Secretary notifies the provider, organization, or plan of the amount to be deducted and the particular physicians [individuals] to whom the deductions are attributable.

(4) A deduction made under this subsection shall relieve the individual of the obligation (to the extent of the amount collected) to the United States, but the provider, organization, or plan shall have a right of action to collect from such physician the amount deducted pursuant to this subsection (including accumulated interest).

(5) No deduction shall be made under this subsection if, within the 6-month period after notice is given to the provider, organization, or plan, the individual pays the past-due obligation, or ceases to be employed by the provider, organization, or plan.

(6) The Secretary shall also apply the provisions of this subsection in the case of an individual who is a member of a group practice, if such group practice submits bills under this program as a group, rather than by individual physicians.

(e) Transfer from trust funds. Amounts equal to the amounts deducted pursuant to this section shall be transferred from the Trust Fund from which the payment to the individual, provider, or other entity would otherwise have been made, to the general fund in the Treasury, and shall be credited as payment of the past-due obligation of the individual from whom (or with respect to whom) the deduction was made.

HISTORY:

(Aug. 14, 1935, ch 531, Title XVIII, Part E[D][C], § 1892, as added Dec. 22, 1987, P.L. 100-203, Title IV, Subtitle A, Part 3, Subpt. A, § 4052(a), 101 Stat. 1330-95; July 1, 1988, P.L. 100-360, Title IV, Subtitle B, § 411(f)(10)(C)(i), 102 Stat. 780; Oct. 13, 1988, P.L. 100-485, Title VI, § 608(d)(21)(E)-(H), 102 Stat. 2420; Aug. 5, 1997, P.L. 105-33, Title IV, Subtitle A, Ch 1, Subch A, § 4001, 111 Stat. 275; Dec. 8, 2003, P.L. 108-173, Title I, § 101(a)(1), 117 Stat. 2071.)

§ 1395ddd. Medicare Integrity Program

(a) Establishment of Program. There is hereby established the Medicare Integrity Program (in this section referred to as the "Program") under which the Secretary shall promote the integrity of the medicare program by entering into contracts in accordance with this section with eligible entities to carry out the activities described in subsection (b).

(b) Activities described. The activities described in this subsection are as follows:

(1) Review of activities of providers of services or other individuals and entities furnishing items and services for which payment may be made under this *title [42 USCS §§ 1395* et seq.] (including skilled nursing facilities and home health agencies), including medical and utilization review and fraud review (employing similar standards, processes, and technologies used by private health plans, including equipment and software technologies which surpass the capability of the equipment and technologies used in the review of claims under this *title [42 USCS §§ 1395* et seq.] as of the date of the enactment of this section).

(2) Audit of cost reports.

(3) Determinations as to whether payment should not be, or should not have been, made under this *title [42 USCS §§ 1395* et seq.] by reason of section 1862(b) [*42 USCS § 1395y(b)*], and recovery of payments that should not have been made.

(4) Education of providers of services, beneficiaries, and other persons with respect to payment integrity and benefit quality assurance issues.

(5) Developing (and periodically updating) a list of items of durable medical equipment in accordance with section 1834(a)(15) [*42 USCS § 1395m(a)(15)*] which are subject to prior authorization under such section.

(6) The Medicare-Medicaid Data Match Program in accordance with subsection (g).

(c) Eligibility of entities. An entity is eligible to enter into a contract under the Program to carry out any of the activities described in subsection (b) if--

(1) the entity has demonstrated capability to carry out such activities;

(2) in carrying out such activities, the entity agrees to cooperate with the Inspector General of the Department of Health and Human Services, the Attorney General, and other law enforcement agencies, as appropriate, in the investigation and deterrence of fraud and abuse in relation to this *title [42 USCS §§ 1395* et seq.] and in other cases arising out of such activities;

(3) the entity complies with such conflict of interest standards as are generally applicable to Federal acquisition and procurement; and

(4) the entity meets such other requirements as the Secretary may impose.

In the case of the activity described in subsection (b)(5), an entity shall be deemed to be eligible to enter into a contract under the Program to carry out the activity if the entity is a carrier with a contract in effect under section 1842 [*42 USCS § 1395u*].

(d) Process for entering into contracts. The Secretary shall enter into contracts under the Program in accordance with such procedures as the Secretary shall by regulation establish, except that such procedures shall include the following:

(1) Procedures for identifying, evaluating, and resolving organizational conflicts of interest that are generally applicable to Federal acquisition and procurement.

(2) Competitive procedures to be used--

(A) when entering into new contracts under this section;

(B) when entering into contracts that may result in the elimination of responsibilities of an individual fiscal intermediary or carrier under section 202(b) of the Health Insurance Portability and Accountability Act of 1996; and

(C) at any other time considered appropriate by the Secretary,

except that the Secretary may continue to contract with entities that are carrying out the activities described in this section pursuant to agreements under section 1816 [*42 USCS § 1395h*] or contracts under section 1842 [*42 USCS § 1395u*] in effect on the date of the enactment of this section [enacted Aug. 21, 1996].

(3) Procedures under which a contract under this section may be renewed without regard to any provision of law requiring competition if the contractor has met or exceeded the performance requirements established in the current contract.The Secretary may enter into such contracts without regard to final rules having been promulgated.

(e) Limitation on contractor liability. The Secretary shall by regulation provide for the limitation of a contractor's liability for actions taken to carry out a contract under the Program, and such regulation shall, to the extent the Secretary finds appropriate, employ the same or comparable standards and other substantive and procedural provisions as are contained in section 1157 [*42 USCS § 1320c-6*].

(f) Recovery of overpayments.

(1) Use of repayment plans.

(A) In general. If the repayment, within 30 days by a provider of services or supplier, of an overpayment under this *title [42 USCS §§ 1395* et seq.] would constitute a hardship (as described in subparagraph (B)), subject to subparagraph (C), upon request of the provider of services or supplier the Secretary shall enter into a plan with the provider of services or supplier for the repayment (through offset or otherwise) of such overpayment over a period of at least 6 months but not longer than 3 years (or not longer than 5 years in the case of extreme hardship, as determined by the Secretary). Interest shall accrue on the balance through the period of repayment. Such plan shall meet terms and conditions determined to be appropriate by the Secretary.

(B) Hardship.

(i) In general. For purposes of subparagraph (A), the repayment of an overpayment (or overpayments) within 30 days is deemed to constitute a hardship if--

(I) in the case of a provider of services that files cost reports, the aggregate amount of the overpayments exceeds 10 percent of the amount paid under this *title [42 USCS §§ 1395* et seq.] to the provider of services for the cost reporting period covered by the most recently submitted cost report; or

(II) in the case of another provider of services or supplier, the aggregate amount of the overpayments exceeds 10 percent of the amount paid under this *title [42 USCS §§ 1395* et seq.] to the provider of services or supplier for the previous calendar year.

(ii) Rule of application. The Secretary shall establish rules for the application of this subparagraph in the case of a provider of services or supplier that was not paid under this *title [42 USCS §§ 1395* et seq.] during the previous year or was paid under this *title [42 USCS §§ 1395* et seq.] only during a portion of that year.

(iii) Treatment of previous overpayments. If a provider of services or supplier has entered into a repayment plan under subparagraph (A) with respect to a specific overpayment amount, such payment amount under the repayment plan shall not be taken into account under clause (i) with respect to subsequent overpayment amounts.

(C) Exceptions. Subparagraph (A) shall not apply if--

(i) the Secretary has reason to suspect that the provider of services or supplier may file for bankruptcy or otherwise cease to do business or discontinue participation in the program under this *title [42 USCS §§ 1395* et seq.]; or

(ii) there is an indication of fraud or abuse committed against the program.

(D) Immediate collection if violation of repayment plan. If a provider of services or supplier fails to make a payment in accordance with a repayment plan under this paragraph, the Secretary may immediately seek to offset or otherwise recover the total balance outstanding (including applicable interest) under the repayment plan.

(E) Relation to no fault provision. Nothing in this paragraph shall be construed as affecting the application of section 1870(c) [*42 USCS § 1395gg(c)*] (relating to no adjustment in the cases of certain overpayments).

(2) Limitation on recoupment.

(A) In general. In the case of a provider of services or supplier that is determined to have received an overpayment under this *title [42 USCS §§ 1395* et seq.] and that seeks a reconsideration by a qualified independent contractor on such determination under section 1869(b)(1) [*42 USCS § 1395ff(b)(1)*], the Secretary may not take any action (or authorize any other person, including any medicare contractor, as defined in subparagraph (C)) to recoup the overpayment until the date the decision on the reconsideration has been rendered. If the provisions of section 1869(b)(1) [*42 USCS § 1395ff(b)(1)*] (providing for such a reconsideration by a qualified independent contractor) are not in effect, in applying the previous sentence any reference to such a reconsideration shall be treated as a reference to a redetermination by the fiscal intermediary or carrier involved.

(B) Collection with interest. Insofar as the determination on such appeal is against the provider of services or supplier, interest on the overpayment shall accrue on and after the date of the original notice of overpayment. Insofar as

such determination against the provider of services or supplier is later reversed, the Secretary shall provide for repayment of the amount recouped plus interest at the same rate as would apply under the previous sentence for the period in which the amount was recouped.

(C) Medicare contractor defined. For purposes of this subsection, the term "medicare contractor" has the meaning given such term in section 1889(g) [*42 USCS § 1395zz(g)*].

(3) Limitation on use of extrapolation. A medicare contractor may not use extrapolation to determine overpayment amounts to be recovered by recoupment, offset, or otherwise unless the Secretary determines that--

(A) there is a sustained or high level of payment error; or

(B) documented educational intervention has failed to correct the payment error.

There shall be no administrative or judicial review under section 1869 [*42 USCS § 1395ff*], section 1878 [*42 USCS § 1395oo*], or otherwise, of determinations by the Secretary of sustained or high levels of payment errors under this paragraph.

(4) Provision of supporting documentation. In the case of a provider of services or supplier with respect to which amounts were previously overpaid, a medicare contractor may request the periodic production of records or supporting documentation for a limited sample of submitted claims to ensure that the previous practice is not continuing.

(5) Consent settlement reforms.

(A) In general. The Secretary may use a consent settlement (as defined in subparagraph (D)) to settle a projected overpayment.

(B) Opportunity to submit additional information before consent settlement offer. Before offering a provider of services or supplier a consent settlement, the Secretary shall--

(i) communicate to the provider of services or supplier--

(I) that, based on a review of the medical records requested by the Secretary, a preliminary evaluation of those records indicates that there would be an overpayment;

(II) the nature of the problems identified in such evaluation; and

(III) the steps that the provider of services or supplier should take to address the problems; and

(ii) provide for a 45-day period during which the provider of services or supplier may furnish additional information concerning the medical records for the claims that had been reviewed.

(C) Consent settlement offer. The Secretary shall review any additional information furnished by the provider of services or supplier under subparagraph (B)(ii). Taking into consideration such information, the Secretary shall determine if there still appears to be an overpayment. If so, the Secretary--

(i) shall provide notice of such determination to the provider of services or supplier, including an explanation of the reason for such determination; and

(ii) in order to resolve the overpayment, may offer the provider of services or supplier--

(I) the opportunity for a statistically valid random sample; or

(II) a consent settlement.

The opportunity provided under clause (ii)(I) does not waive any appeal rights with respect to the alleged overpayment involved.

(D) Consent settlement defined. For purposes of this paragraph, the term "consent settlement" means an agreement between the Secretary and a provider of services or supplier whereby both parties agree to settle a projected overpayment based on less than a statistically valid sample of claims and the provider of services or supplier agrees not to appeal the claims involved.

(6) Notice of over-utilization of codes. The Secretary shall establish, in consultation with organizations representing the classes of providers of services and suppliers, a process under which the Secretary provides for notice to classes of providers of services and suppliers served by the contractor in cases in which the contractor has identified that particular billing codes may be overutilized by that class of providers of services or suppliers under the programs under this *title [42 USCS §§ 1395* et seq.] (or provisions of title XI [*42 USCS §§ 1301* et seq.] insofar as they relate to such programs).

(7) Payment audits.

(A) Written notice for post-payment audits. Subject to subparagraph (C), if a medicare contractor decides to conduct a post-payment audit of a provider of services or supplier under this *title [42 USCS §§ 1395* et seq.], the contractor shall provide the provider of services or supplier with written notice (which may be in electronic form) of the intent to conduct such an audit.

(B) Explanation of findings for all audits. Subject to subparagraph (C), if a medicare contractor audits a provider of services or supplier under this *title [42 USCS §§ 1395* et seq.], the contractor shall--

(i) give the provider of services or supplier a full review and explanation of the findings of the audit in a manner that is understandable to the provider of services or supplier and permits the development of an appropriate corrective action plan;

(ii) inform the provider of services or supplier of the appeal rights under this *title [42 USCS §§ 1395* et seq.] as well as consent settlement options (which are at the discretion of the Secretary);

(iii) give the provider of services or supplier an opportunity to provide additional information to the contractor; and

(iv) take into account information provided, on a timely basis, by the provider of services or supplier under clause (iii).

(C) Exception. Subparagraphs (A) and (B) shall not apply if the provision of notice or findings would compromise pending law enforcement activities, whether civil or criminal, or reveal findings of law enforcement-related audits.

(8) Standard methodology for probe sampling. The Secretary shall establish a standard methodology for medicare contractors to use in selecting a sample of claims for review in the case of an abnormal billing pattern.

(g) Medicare-Medicaid Data Match Program.

(1) Expansion of program.

(A) In general. The Secretary shall enter into contracts with eligible entities for the purpose of ensuring that, beginning with 2006, the Medicare-Medicaid Data Match Program (commonly referred to as the "Medi-Medi Program") is conducted with respect to the program established under this *title [42 USCS §§ 1395* et seq.] and State Medicaid programs under title XIX [*42 USCS §§ 1396* et seq.] for the purpose of--

(i) identifying program vulnerabilities in the program established under this *title [42 USCS §§ 1395* et seq.] and the Medicaid program established under title XIX [*42 USCS §§ 1396* et seq.] through the use of computer algorithms to look for payment anomalies (including billing or billing patterns identified with respect to service, time, or patient that appear to be suspect or otherwise implausible);

(ii) working with States, the Attorney General, and the Inspector General of the Department of Health and Human Services to coordinate appropriate actions to protect the Federal and State share of expenditures under the Medicaid program under title XIX [*42 USCS §§ 1396* et seq.], as well as the program established under this *title [42 USCS §§ 1395* et seq.]; and

(iii) increasing the effectiveness and efficiency of both such programs through cost avoidance, savings, and recoupments of fraudulent, wasteful, or abusive expenditures.

(B) Reporting requirements. The Secretary shall make available in a timely manner any data and statistical information collected by the Medi-Medi Program to the Attorney General, the Director of the Federal Bureau of Investigation, the Inspector General of the Department of Health and Human Services, and the States (including a Medicaid fraud and abuse control unit described in section 1903(q) [*42 USCS § 1396b(q)*]). Such information shall be disseminated no less frequently than quarterly.

(2) Limited waiver authority. The Secretary shall waive only such requirements of this section and of titles XI and XIX [*42 USCS §§ 1301* et seq. and *§§ 1396* et seq.] as are necessary to carry out paragraph (1).

(h) Use of recovery audit contractors.

(1) In general. Under the Program, the Secretary shall enter into contracts with recovery audit contractors in accordance with this subsection for the purpose of identifying underpayments and overpayments and recouping overpayments under this *title [42 USCS §§ 1395* et seq.] with respect to all services for which payment is made under part A or B [*42 USCS §§ 1395c* et seq. or *1395j* et seq.]. Under the contracts--

(A) payment shall be made to such a contractor only from amounts recovered;

(B) from such amounts recovered, payment--

(i) shall be made on a contingent basis for collecting overpayments; and

(ii) may be made in such amounts as the Secretary may specify for identifying underpayments; and

(C) the Secretary shall retain a portion of the amounts recovered which shall be available to the program management account of the Centers for Medicare & Medicaid Services for purposes of activities conducted under the recovery audit program under this subsection.

(2) Disposition of remaining recoveries. The amounts recovered under such contracts that are not paid to the contractor under paragraph (1) or retained by the Secretary under paragraph (1)(C) shall be applied to reduce expenditures under parts A and B [*42 USCS §§ 1395c* et seq. and *1395j* et seq.].

(3) Nationwide coverage. The Secretary shall enter into contracts under paragraph (1) in a manner so as to provide for activities in all States under such a contract by not later than January 1, 2010.

(4) Audit and recovery periods. Each such contract shall provide that audit and recovery activities may be conducted during a fiscal year with respect to payments made under part A or B [*42 USCS §§ 1395c* et seq. or *1395j* et seq.]--

(A) during such fiscal year; and

(B) retrospectively (for a period of not more than 4 fiscal years prior to such fiscal year).

(5) Waiver. The Secretary shall waive such provisions of this title as may be necessary to provide for payment of recovery audit contractors under this subsection in accordance with paragraph (1).

(6) Qualifications of contractors.

(A) In general. The Secretary may not enter into a contract under paragraph (1) with a recovery audit contractor unless the contractor has staff that has the appropriate clinical knowledge of, and experience with, the payment rules and regulations under this *title [42 USCS §§ 1395* et seq.] or the contractor has, or will contract with, another entity that has such knowledgeable and experienced staff.

(B) Ineligibility of certain contractors. The Secretary may not enter into a contract under paragraph (1) with a recovery audit contractor to the extent the contractor is a fiscal intermediary under section 1816 [*42 USCS § 1395h*], a carrier under section 1842 [*42 USCS § 1395u*], or a medicare administrative contractor under section 1874A [*42 USCS § 1395kk-1*].

(C) Preference for entities with demonstrated proficiency. In awarding contracts to recovery audit contractors under paragraph (1), the Secretary shall give preference to those risk entities that the Secretary determines have demonstrated more than 3 years direct management experience and a proficiency for cost control or recovery audits with private insurers, health care providers, health plans, under the Medicaid program under title XIX [*42 USCS §§ 1396* et seq.], or under this *title [42 USCS §§ 1395* et seq.].

(7) Construction relating to conduct of investigation of fraud. A recovery of an overpayment to a individual or entity by a recovery audit contractor under this subsection shall not be construed to prohibit the Secretary or the Attorney General from investigating and prosecuting, if appropriate, allegations of fraud or abuse arising from such overpayment.

(8) Annual report. The Secretary shall annually submit to Congress a report on the use of recovery audit contractors under this subsection. Each such report shall include information on the performance of such contractors in identifying underpayments and overpayments and recouping overpayments, including an evaluation of the comparative performance of such contractors and savings to the program under this *title [42 USCS §§ 1395* et seq.].

HISTORY:

(July 1, 1944, ch 373, Title XVIII, Part E[D][C], § 1893, as added Aug. 21, 1996, P.L. 104-191, Title II, Subtitle A, § 202(a), 110 Stat. 1996; Aug. 5, 1997, P.L. 105-33, Title IV, Subtitle A, Ch 1, Subch A, § 4001, 111 Stat. 275; Dec. 8, 2003, P.L. 108-173, Title I, § 101(a)(1), Title VII, Subtitle D, § 736(c)(7), Title IX, Subtitle D, § 935(a), 117 Stat. 2071, 2356, 2407; Feb. 8, 2006, P.L. 109-171, Title VI, Subtitle A, Ch. 3, § 6034(d)(1), 120 Stat. 77; Dec. 20, 2006, P.L. 109-432, Div B, Title III, § 302(a), 120 Stat. 2991.)

§ 1395eee. Payments to, and coverage of benefits under, programs of all-inclusive care for the elderly (PACE)

(a) Receipt of benefits through enrollment in PACE program; definitions for PACE program related terms.

(1) Benefits through enrollment in a PACE program. In accordance with this section, in the case of an individual who is entitled to benefits under part A or enrolled under part B and who is a PACE program eligible individual (as defined in paragraph (5)) with respect to a PACE program offered by a PACE provider under a PACE program agreement--

(A) the individual may enroll in the program under this section; and

(B) so long as the individual is so enrolled and in accordance with regulations--

(i) the individual shall receive benefits under this *title [42 USCS §§ 1395* et seq.] solely through such program; and

(ii) the PACE provider is entitled to payment under and in accordance with this section and such agreement for provision of such benefits.

(2) PACE program defined. For purposes of this section, the term "PACE program" means a program of all-inclusive care for the elderly that meets the following requirements:

(A) Operation. The entity operating the program is a PACE provider (as defined in paragraph (3)).

(B) Comprehensive benefits. The program provides comprehensive health care services to PACE program eligible individuals in accordance with the PACE program agreement and regulations under this section.

(C) Transition. In the case of an individual who is enrolled under the program under this section and whose enrollment ceases for any reason (including that the individual no longer qualifies as a PACE program eligible individual, the termination of a PACE program agreement, or otherwise), the program provides assistance to the individual in obtaining necessary transitional care through appropriate referrals and making the individual's medical records available to new providers.

(3) PACE provider defined.

(A) In general. For purposes of this section, the term "PACE provider" means an entity that--

(i) subject to subparagraph (B), is (or is a distinct part of) a public entity or a private, nonprofit entity organized for charitable purposes under *section 501(c)(3) of the Internal Revenue Code of 1986* [*26 USCS § 501(c)(3)*]; and

(ii) has entered into a PACE program agreement with respect to its operation of a PACE program.

(B) Treatment of private, for-profit providers. Clause (i) of subparagraph (A) shall not apply--

(i) to entities subject to a demonstration project waiver under subsection (h); and

(ii) after the date the report under section 4804(b) of the Balanced Budget Act of 1997 [note to this section] is submitted, unless the Secretary determines that any of the findings described in subparagraph (A), (B), (C), or (D) of paragraph (2) of such section are true.

(4) PACE program agreement defined. For purposes of this section, the term "PACE program agreement" means, with respect to a PACE provider, an agreement, consistent with this section, section 1934 [*42 USCS § 1396u-4*] (if applicable), and regulations promulgated to carry out such sections, between the PACE provider and the Secretary, or an agreement between the PACE provider and a State administering agency for the operation of a PACE program by the provider under such sections.

(5) PACE program eligible individual defined. For purposes of this section, the term "PACE program eligible individual" means, with respect to a PACE program, an individual who--

(A) is 55 years of age or older;

(B) subject to subsection (c)(4), is determined under subsection (c) to require the level of care required under the State medicaid plan for coverage of nursing facility services;

(C) resides in the service area of the PACE program; and

(D) meets such other eligibility conditions as may be imposed under the PACE program agreement for the program under subsection (e)(2)(A)(ii).

(6) PACE protocol. For purposes of this section, the term "PACE protocol" means the Protocol for the Program of All-inclusive Care for the Elderly (PACE), as published by On Lok, Inc., as of April 14, 1995, or any successor protocol that may be agreed upon between the Secretary and On Lok, Inc.

(7) PACE demonstration waiver program defined. For purposes of this section, the term "PACE demonstration waiver program" means a demonstration program under either of the following sections (as in effect before the date of their repeal):

(A) Section 603(c) of the Social Security Amendments of 1983 (Public Law 98-21)) [unclassified], as extended by section 9220 of the Consolidated Omnibus Budget Reconciliation Act of 1985 (Public Law 99-272).

(B) Section 9412(b) of the Omnibus Budget Reconciliation Act of 1986 (Public Law 99-509) [unclassified].

(8) State administering agency defined. For purposes of this section, the term "State administering agency" means, with respect to the operation of a PACE program in a State, the agency of that State (which may be the single agency responsible for administration of the State plan under title XIX [*42 USCS §§ 1396* et seq.] in the State) responsible for administering PACE program agreements under this section and section 1934 [*42 USCS § 1396u-4*] in the State.

(9) Trial period defined.

(A) In general. For purposes of this section, the term "trial period" means, with respect to a PACE program operated by a PACE provider under a PACE program agreement, the first 3 contract years under such agreement with respect to such program.

(B) Treatment of entities previously operating PACE demonstration waiver programs. Each contract year (including a year occurring before the effective date of this section) during which an entity has operated a PACE demonstration waiver program shall be counted under subparagraph (A) as a contract year during which the entity operated a PACE program as a PACE provider under a PACE program agreement.

(10) Regulations. For purposes of this section, the term "regulations" refers to interim final or final regulations promulgated under subsection (f) to carry out this section and section 1934 [*42 USCS § 1396u-4*].

(b) Scope of benefits; beneficiary safeguards.

(1) In general. Under a PACE program agreement, a PACE provider shall--

(A) provide to PACE program eligible individuals enrolled with the provider, regardless of source of payment and directly or under contracts with other entities, at a minimum--

(i) all items and services covered under this *title [42 USCS §§ 1395* et seq.] (for individuals enrolled under this section) and all items and services covered under title XIX [*42 USCS §§ 1396* et seq.], but without any limitation or condition as to amount, duration, or scope and without application of deductibles, copayments, coinsurance, or other cost-sharing that would otherwise apply under this title or such title, respectively; and

(ii) all additional items and services specified in regulations, based upon those required under the PACE protocol;

(B) provide such enrollees access to necessary covered items and services 24 hours per day, every day of the year;

(C) provide services to such enrollees through a comprehensive, multidisciplinary health and social services delivery system which integrates acute and long-term care services pursuant to regulations; and

(D) specify the covered items and services that will not be provided directly by the entity, and to arrange for delivery of those items and services through contracts meeting the requirements of regulations.

(2) Quality assurance; patient safeguards. The PACE program agreement shall require the PACE provider to have in effect at a minimum--

(A) a written plan of quality assurance and improvement, and procedures implementing such plan, in accordance with regulations; and

(B) written safeguards of the rights of enrolled participants (including a patient bill of rights and procedures for grievances and appeals) in accordance with regulations and with other requirements of this *title [42 USCS §§ 1395* et seq.] and Federal and State law that are designed for the protection of patients.

(3) Treatment of medicare services furnished by noncontract physicians and other entities.

(A) Application of medicare advantage requirement with respect to medicare services furnished by noncontract physicians and other entities. Section 1852(k)(1) [*42 USCS § 1395w-22(k)(1)*] (relating to limitations on balance billing against MA organizations for noncontract physicians and other entities with respect to services covered under this *title [42 USCS §§ 1395* et seq.]) shall apply to PACE providers, PACE program eligible individuals enrolled with such PACE providers, and physicians and other entities that do not have a contract or other agreement establishing payment amounts for services furnished to such an individual in the same manner as such section applies to MA organizations, individuals enrolled with such organizations, and physicians and other entities referred to in such section.

(B) Reference to related provision for noncontract providers of services. For the provision relating to limitations on balance billing against PACE providers for services covered under this *title [42 USCS §§ 1395* et seq.] furnished by noncontract providers of services, see section 1866(a)(1)(O) [*42 USCS § 1395cc(a)(1)(O)*].

(4) Reference to related provision for services covered under title XIX but not under this title. For provisions relating to limitations on payments to providers participating under the State plan under title XIX [*42 USCS §§ 1396* et seq.] that do not have a contract or other agreement with a PACE provider establishing payment amounts for services covered under such plan (but not under this *title [42 USCS §§ 1395* et seq.]) when such services are furnished to enrollees of that PACE provider, see section 1902(a)(66) [*42 USCS § 1396a(a)(66)*].

(c) Eligibility determinations.

(1) In general. The determination of whether an individual is a PACE program eligible individual--

(A) shall be made under and in accordance with the PACE program agreement; and

(B) who is entitled to medical assistance under title XIX [*42 USCS §§ 1396* et seq.], shall be made (or who is not so entitled, may be made) by the State administering agency.

(2) Condition. An individual is not a PACE program eligible individual (with respect to payment under this section) unless the individual's health status has been determined by the Secretary or the State administering agency, in accordance with regulations, to be comparable to the health status of individuals who have participated in the PACE demonstration waiver programs. Such determination shall be based upon information on health status and related indicators (such as medical diagnoses and measures of activities of daily living, instrumental activities of daily living, and cognitive impairment) that are part of a uniform minimum data set collected by PACE providers on potential PACE program eligible individuals.

(3) Annual eligibility recertifications.

(A) In general. Subject to subparagraph (B), the determination described in subsection (a)(5)(B) for an individual shall be reevaluated at least annually.

(B) Exception. The requirement of annual reevaluation under subparagraph (A) may be waived during a period in accordance with regulations in those cases where the State administering agency determines that there is no reasonable expectation of improvement or significant change in an individual's condition during the period because of the severity of chronic condition, or degree of impairment of functional capacity of the individual involved.

(4) Continuation of eligibility. An individual who is a PACE program eligible individual may be deemed to continue to be such an individual notwithstanding a determination that the individual no longer meets the requirement of subsection (a)(5)(B) if, in accordance with regulations, in the absence of continued coverage under a PACE program the individual reasonably would be expected to meet such requirement within the succeeding 6-month period.

(5) Enrollment; disenrollment.

(A) Voluntary disenrollment at any time. The enrollment and disenrollment of PACE program eligible individuals in a PACE program shall be pursuant to regulations and the PACE program agreement and shall permit enrollees to voluntarily disenroll without cause at any time.

(B) Limitations on disenrollment.

(i) In general. Regulations promulgated by the Secretary under this section and section 1934 [*42 USCS § 1396u-4*], and the PACE program agreement, shall provide that the PACE program may not disenroll a PACE program eligible individual except--

(I) for nonpayment of premiums (if applicable) on a timely basis; or

(II) for engaging in disruptive or threatening behavior, as defined in such regulations (developed in close consultation with State administering agencies).

(ii) No disenrollment for noncompliant behavior. Except as allowed under regulations promulgated to carry out clause (i)(II), a PACE program may not disenroll a PACE program eligible individual on the ground that the individual has engaged in noncompliant behavior if such behavior is related to a mental or physical condition of the individual. For purposes of the preceding sentence, the term "noncompliant behavior" includes repeated noncompliance with medical advice and repeated failure to appear for appointments.

(iii) Timely review of proposed nonvoluntary disenrollment. A proposed disenrollment, other than a voluntary disenrollment, shall be subject to timely review and final determination by the Secretary or by the State administering agency (as applicable), prior to the proposed disenrollment becoming effective.

(d) Payments to PACE providers on a capitated basis.

(1) In general. In the case of a PACE provider with a PACE program agreement under this section, except as provided in this subsection or by regulations, the Secretary shall make prospective monthly payments of a capitation amount for each PACE program eligible individual enrolled under the agreement under this section in the same manner and from the same sources as payments are made to a Medicare + Choice organization under section 1853 [*42 USCS § 1395w-23*] (or, for periods beginning before January 1, 1999, to an eligible organization under a risk-sharing contract under section 1876 [*42 USCS § 1395mm*]). Such payments shall be subject to adjustment in the manner described in section 1853(a)(2) or section 1876(a)(1)(E) [*42 USCS § 1395w-23(a)(2)* or *1395mm(a)(1)(E)*], as the case may be.

(2) Capitation amount. The capitation amount to be applied under this subsection for a provider for a contract year shall be an amount specified in the PACE program agreement for the year. Such amount shall be based upon payment rates established for purposes of payment under section 1853 *[42 USCS § 1396w-23]* (or, for periods before January 1, 1999, for purposes of risk-sharing contracts under section 1876 [*42 USCS § 1395mm*]) and shall be adjusted to take into account the comparative frailty of PACE enrollees and such other factors as the Secretary determines to be appropriate. Such amount under such an agreement shall be computed in a manner so that the total payment level for all PACE program eligible individuals enrolled under a program is less than the projected payment under this *title [42 USCS §§ 1395* et seq.] for a comparable population not enrolled under a PACE program.

(3) Capitation rates determined without regard to the phase-out of the indirect costs of medical education from the annual Medicare Advantage capitation rate. Capitation amounts under this subsection shall be determined without regard to the application of section 1853(k)(4) [*42 USCS § 1395w-23(k)(4)*].

(e) PACE program agreement.

(1) Requirement.

(A) In general. The Secretary, in close cooperation with the State administering agency, shall establish procedures for entering into, extending, and terminating PACE program agreements for the operation of PACE programs by entities that meet the requirements for a PACE provider under this section, section 1934 [*42 USCS § 1396u-4*], and regulations.

(B) Numerical limitation.

(i) In general. The Secretary shall not permit the number of PACE providers with which agreements are in effect under this section or under section 9412(b) of the Omnibus Budget Reconciliation Act of 1986 [unclassified] to exceed--

(I) 40 as of the date of the enactment of this section [enacted Aug. 5, 1997]; or

(II) as of each succeeding anniversary of such date, the numerical limitation under this subparagraph for the preceding year plus 20.

Subclause (II) shall apply without regard to the actual number of agreements in effect as of a previous anniversary date.

(ii) Treatment of certain private, for-profit providers. The numerical limitation in clause (i) shall not apply to a PACE provider that--

(I) is operating under a demonstration project waiver under subsection (h); or

(II) was operating under such a waiver and subsequently qualifies for PACE provider status pursuant to subsection (a)(3)(B)(ii).

(2) Service area and eligibility.

(A) In general. A PACE program agreement for a PACE program--

(i) shall designate the service area of the program;

(ii) may provide additional requirements for individuals to qualify as PACE program eligible individuals with respect to the program;

(iii) shall be effective for a contract year, but may be extended for additional contract years in the absence of a notice by a party to terminate and is subject to termination by the Secretary and the State administering agency at any time for cause (as provided under the agreement);

(iv) shall require a PACE provider to meet all applicable State and local laws and requirements; and

(v) shall contain such additional terms and conditions as the parties may agree to, so long as such terms and conditions are consistent with this section and regulations.

(B) Service area overlap. In designating a service area under a PACE program agreement under subparagraph (A)(i), the Secretary (in consultation with the State administering agency) may exclude from designation an area that is already covered under another PACE program agreement, in order to avoid unnecessary duplication of services and avoid impairing the financial and service viability of an existing program.

(3) Data collection; development of outcome measures.

(A) Data collection.

(i) In general. Under a PACE program agreement, the PACE provider shall--

(I) collect data;

(II) maintain, and afford the Secretary and the State administering agency access to, the records relating to the program, including pertinent financial, medical, and personnel records; and

(III) make available to the Secretary and the State administering agency reports that the Secretary finds (in consultation with State administering agencies) necessary to monitor the operation, cost, and effectiveness of the PACE program under this section and section 1934 [*42 USCS § 1396u-4*].

(ii) Requirements during trial period. During the first 3 years of operation of a PACE program (either under this section or under a PACE demonstration waiver program), the PACE provider shall provide such additional data as the Secretary specifies in regulations in order to perform the oversight required under paragraph (4)(A).

(B) Development of outcome measures. Under a PACE program agreement, the PACE provider, the Secretary, and the State administering agency shall jointly cooperate in the development and implementation of health status and quality of life outcome measures with respect to PACE program eligible individuals.

(4) Oversight.

(A) Annual, close oversight during trial period. During the trial period (as defined in subsection (a)(9)) with respect to a PACE program operated by a PACE provider, the Secretary (in cooperation with the State administering agency) shall conduct a comprehensive annual review of the operation of the PACE program by the provider in order to assure compliance with the requirements of this section and regulations. Such a review shall include--

(i) an on-site visit to the program site;

(ii) comprehensive assessment of a provider's fiscal soundness;

(iii) comprehensive assessment of the provider's capacity to provide all PACE services to all enrolled participants;

(iv) detailed analysis of the entity's substantial compliance with all significant requirements of this section and regulations; and

(v) any other elements the Secretary or State administering agency considers necessary or appropriate.

(B) Continuing oversight. After the trial period, the Secretary (in cooperation with the State administering agency) shall continue to conduct such review of the operation of PACE providers and PACE programs as may be appropriate, taking into account the performance level of a provider and compliance of a provider with all significant requirements of this section and regulations.

(C) Disclosure. The results of reviews under this paragraph shall be reported promptly to the PACE provider, along with any recommendations for changes to the provider's program, and shall be made available to the public upon request.

(5) Termination of PACE provider agreements.

(A) In general. Under regulations--

(i) the Secretary or a State administering agency may terminate a PACE program agreement for cause; and

(ii) a PACE provider may terminate an agreement after appropriate notice to the Secretary, the State agency, and enrollees.

(B) Causes for termination. In accordance with regulations establishing procedures for termination of PACE program agreements, the Secretary or a State administering agency may terminate a PACE program agreement with a PACE provider for, among other reasons, the fact that--

(i) the Secretary or State administering agency determines that--

(I) there are significant deficiencies in the quality of care provided to enrolled participants; or

(II) the provider has failed to comply substantially with conditions for a program or provider under this section or section 1934 [*42 USCS § 1396u-4*]; and

(ii) the entity has failed to develop and successfully initiate, within 30 days of the date of the receipt of written notice of such a determination, a plan to correct the deficiencies, or has failed to continue implementation of such a plan.

(C) Termination and transition procedures. An entity whose PACE provider agreement is terminated under this paragraph shall implement the transition procedures required under subsection (a)(2)(C).

(6) Secretary's oversight; enforcement authority.

(A) In general. Under regulations, if the Secretary determines (after consultation with the State administering agency) that a PACE provider is failing substantially to comply with the requirements of this section and regulations, the Secretary (and the State administering agency) may take any or all of the following actions:

(i) Condition the continuation of the PACE program agreement upon timely execution of a corrective action plan.

(ii) Withhold some or all further payments under the PACE program agreement under this section or section 1934 [*42 USCS § 1396u-4*] with respect to PACE program services furnished by such provider until the deficiencies have been corrected.

(iii) Terminate such agreement.

(B) Application of intermediate sanctions. Under regulations, the Secretary may provide for the application against a PACE provider of remedies described in section 1857(g)(2) [*42 USCS § 1395w-27(g)(2)*] (or, for periods before January 1, 1999, section 1876(i)(6)(B) [*42 USCS § 1395mm(i)(6)(B)*]) or 1903(m)(5)(B) [*42 USCS § 1396b(m)(5)(B)*] in the case of violations by the provider of the type described in section 1857(g)(1) [*42 USCS § 1395w-27(g)(1)*] (or section 1876(i)(6)(A) [*42 USCS § 1395mm(i)(6)(A)*] for such periods) or 1903(m)(5)(A) [*42 USCS § 1396b(m)(5)(A)*], respectively (in relation to agreements, enrollees, and requirements under this section or section 1934 [*42 USCS § 1396u-4*], respectively).

(7) Procedures for termination or imposition of sanctions. Under regulations, the provisions of section 1857(h) [*42 USCS § 1395w-27(h)*] (or for periods before January 1, 1999, section 1876(i)(9) [*42 USCS § 1395mm(i)(9)*]) shall apply to termination and sanctions respecting a PACE program agreement and PACE provider under this subsection in the same manner as they apply to a termination and sanctions with respect to a contract and a Medicare + Choice organization under part C [*42 USCS §§ 1395w-21* et seq.] (or for such periods an eligible organization under section 1876 [*42 USCS § 1395mm*]).

(8) Timely consideration of applications for PACE program provider status. In considering an application for PACE provider program status, the application shall be deemed approved unless the Secretary, within 90 days after the date of the submission of the application to the Secretary, either denies such request in writing or informs the applicant in writing with respect to any additional information that is needed in order to make a final determination with respect to the application. After the date the Secretary receives such additional information, the application shall be deemed approved unless the Secretary, within 90 days of such date, denies such request.

(f) Regulations.

(1) In general. The Secretary shall issue interim final or final regulations to carry out this section and section 1934 [*42 USCS § 1396u-4*].

(2) Use of PACE protocol.

(A) In general. In issuing such regulations, the Secretary shall, to the extent consistent with the provisions of this section, incorporate the requirements applied to PACE demonstration waiver programs under the PACE protocol.

(B) Flexibility. In order to provide for reasonable flexibility in adapting the PACE service delivery model to the needs of particular organizations (such as those in rural areas or those that may determine it appropriate to use nonstaff physicians according to State licensing law requirements) under this section and section 1934 [*42 USCS § 1396u-4*], the Secretary (in close consultation with State administering agencies) may modify or waive provisions of the PACE protocol so long as any such modification or waiver is not inconsistent with and would not impair the essential elements, objectives, and requirements of this section, but may not modify or waive any of the following provisions:

(i) The focus on frail elderly qualifying individuals who require the level of care provided in a nursing facility.

(ii) The delivery of comprehensive, integrated acute and long-term care services.

(iii) The interdisciplinary team approach to care management and service delivery.

(iv) Capitated, integrated financing that allows the provider to pool payments received from public and private programs and individuals.

(v) The assumption by the provider of full financial risk.

(C) Continuation of modifications or waivers of operational requirements under demonstration status. If a PACE program operating under demonstration authority has contractual or other operating arrangements which are not otherwise recognized in regulation and which were in effect on July 1, 2000, the Secretary (in close consultation with, and with the concurrence of, the State administering agency) shall permit any such program to continue such arrangements so long as such arrangements are found by the Secretary and the State to be reasonably consistent with the objectives of the PACE program.

(3) Application of certain additional beneficiary and program protections.

(A) In general. In issuing such regulations and subject to subparagraph (B), the Secretary may apply with respect to PACE programs, providers, and agreements such requirements of part C [*42 USCS §§ 1395w-21* et seq.] (or, for periods before January 1, 1999, section 1876 [*42 USCS § 1395mm*]) and sections 1903(m) and 1932 [*42 USCS §§ 1396b(m),*

1396u-2] relating to protection of beneficiaries and program integrity as would apply to Medicare + Choice organizations under part C [*42 USCS §§ 1395w-21* et seq.] (or for such periods eligible organizations under risk-sharing contracts under section 1876 [*42 USCS § 1395mm*]) and to medicaid managed care organizations under prepaid capitation agreements under section 1903(m) [*42 USCS §§ 1396b(m)*].

(B) Considerations. In issuing such regulations, the Secretary shall--

(i) take into account the differences between populations served and benefits provided under this section and under part C [*42 USCS §§ 1395w-21* et seq.] (or, for periods before January 1, 1999, section 1876 [*42 USCS § 1395mm*]) and section 1903(m) [*42 USCS §§ 1396b(m)*];

(ii) not include any requirement that conflicts with carrying out PACE programs under this section; and

(iii) not include any requirement restricting the proportion of enrollees who are eligible for benefits under this title or title XIX [*42 USCS §§ 1395* et seq. or *1396* et seq.].

(4) Construction. Nothing in this subsection shall be construed as preventing the Secretary from including in regulations provisions to ensure the health and safety of individuals enrolled in a PACE program under this section that are in addition to those otherwise provided under paragraphs (2) and (3).

(g) Waivers of requirements. With respect to carrying out a PACE program under this section, the following requirements of this *title [42 USCS §§ 1395* et seq.] (and regulations relating to such requirements) are waived and shall not apply:

(1) Section 1812 [*42 USCS § 1395d*], insofar as it limits coverage of institutional services.

(2) Sections 1813, 1814, 1833, and 1886 [*42 USCS §§ 1395e, 1395f, 1395l, 1395ww*], insofar as such sections relate to rules for payment for benefits.

(3) Sections 1814(a)(2)(B), 1814(a)(2)(C), and 1835(a)(2)(A) [*42 USCS §§ 1395f(a)(2)(B)*, (C), 1395n(a)(2)(A)], insofar as they limit coverage of extended care services or home health services.

(4) Section 1861(i) [*42 USCS § 1395x(i)*], insofar as it imposes a 3-day prior hospitalization requirement for coverage of extended care services.

(5) Paragraphs (1) and (9) of section 1862(a) [*42 USCS § 1395y(a)*], insofar as they may prevent payment for PACE program services to individuals enrolled under PACE programs.

(h) Demonstration project for for-profit entities.

(1) In general. In order to demonstrate the operation of a PACE program by a private, for-profit entity, the Secretary (in close consultation with State administering agencies) shall grant waivers from the requirement under subsection (a)(3) that a PACE provider may not be a for-profit, private entity.

(2) Similar terms and conditions.

(A) In general. Except as provided under subparagraph (B), and paragraph (1), the terms and conditions for operation of a PACE program by a provider under this subsection shall be the same as those for PACE providers that are nonprofit, private organizations.

(B) Numerical limitation. The number of programs for which waivers are granted under this subsection shall not exceed 10. Programs with waivers granted under this subsection shall not be counted against the numerical limitation specified in subsection (e)(1)(B).

(i) Miscellaneous provisions. Nothing in this section or section 1934 [*42 USCS § 1396u-4*] shall be construed as preventing a PACE provider from entering into contracts with other governmental or nongovernmental payers for the care of PACE program eligible individuals who are not eligible for benefits under part A [*42 USCS §§ 1395c* et seq.], or enrolled under part B [*42 USCS §§ 1395j* et seq.], or eligible for medical assistance under title XIX [*42 USCS §§ 1396* et seq.].

HISTORY:

(Aug. 14, 1935, Ch 531, Title XVIII, Part E[D], § 1894, as added Aug. 5, 1997, P.L. 105-33, Title IV, Subtitle I, § 4801, 111 Stat. 528; Dec. 21, 2000, P.L. 106-554, § 1(a)(6), 114 Stat. 2763; Dec. 8, 2003, P.L. 108-173, Title I, § 101(a)(1), Title II, Subtitle D, § 236(a)(2), 117 Stat. 2071, 2210; July 15, 2008, P.L. 110-275, Title I, Subtitle D, § 161(c), 122 Stat. 2569.)

§ 1395fff. Prospective payment for home health services

(a) In general. Notwithstanding section 1861(v) [*42 USCS § 1395x(v)*], the Secretary shall provide, for portions of cost reporting periods occurring on or after October 1, 2000, for payments for home health services in accordance with a prospective payment system established by the Secretary under this section.

(b) System of prospective payment for home health services.

(1) In general. The Secretary shall establish under this subsection a prospective payment system for payment for all costs of home health services. Under the system under this subsection all services covered and paid on a reasonable cost basis under the medicare home health benefit as of the date of the enactment of this section [enacted Aug. 5, 1997], including medical supplies, shall be paid for on the basis of a prospective payment amount determined under this subsection and applicable to the services involved. In implementing the system, the Secretary may provide for a transition (of not longer than 4 years) during which a portion of such payment is based on agency-specific costs, but only if such transition does not result in aggregate payments under this *title [42 USCS §§ 1395* et seq.] that exceed the aggregate payments that would be made if such a transition did not occur.

(2) Unit of payment. In defining a prospective payment amount under the system under this subsection, the Secretary shall consider an appropriate unit of service and the number, type, and duration of visits provided within that unit, potential changes in the mix of services provided within that unit and their cost, and a general system design that provides for continued access to quality services.

(3) Payment basis.

(A) Initial basis.

(i) In general. Under such system the Secretary shall provide for computation of a standard prospective payment amount (or amounts) as follows:

(I) Such amount (or amounts) shall initially be based on the most current audited cost report data available to the Secretary and shall be computed in a manner so that the total amounts payable under the system for the 12-month period beginning on the date the Secretary implements the system shall be equal to the total amount that would have been made if the system had not been in effect and if section 1861(v)(1)(L)(ix) [*42 USCS § 1395x(v)(1)(L)(ix)*] had not been enacted.

(II) For the 12-month period beginning after the period described in subclause (I), such amount (or amounts) shall be equal to the amount (or amounts) determined under subclause (I), updated under subparagraph (B).

(III) For periods beginning after the period described in subclause (II), such amount (or amounts) shall be equal to the amount (or amounts) that would have been determined under subclause (I) that would have been made for fiscal year 2001 if the system had not been in effect and if section 1861(v)(1)(L)(ix) [*42 USCS § 1395x(v)(1)(L)(ix)*] had not been enacted but if the reduction in limits described in clause (ii) had been in effect, updated under subparagraph (B).

Each such amount shall be standardized in a manner that eliminates the effect of variations in relative case mix and area wage adjustments among different home health agencies in a budget neutral manner consistent with the case mix and wage level adjustments provided under paragraph (4)(A). Under the system, the Secretary may recognize regional differences or differences based upon whether or not the services or agency are in an urbanized area.

(ii) Reduction. The reduction described in this clause is a reduction by 15 percent in the cost limits and per beneficiary limits described in section 1861(v)(1)(L) [*42 USCS § 1395x(v)(1)(L)*], as those limits are in effect on September 30, 2000.

(B) Annual update.

(i) In general. The standard prospective payment amount (or amounts) shall be adjusted for fiscal year 2002 and for fiscal year 2003 and for each subsequent year (beginning with 2004) in a prospective manner specified by the Secretary by the home health applicable increase percentage (as defined in clause (ii)) applicable to the fiscal year or year involved.

(ii) Home health applicable increase percentage. For purposes of this subparagraph, the term "home health applicable increase percentage" means, with respect to--

(I) each of fiscal years 2002 and 2003, the home health market basket percentage increase (as defined in clause (iii)) minus 1.1 percentage points;

(II) for the last calendar quarter of 2003 and the first calendar quarter of 2004, the home health market basket percentage increase;

(III) the last 3 calendar quarters of 2004, and all of 2005 the home health market basket percentage increase minus 0.8 percentage points;

(IV) 2006, 0 percent; and

(V) any subsequent year, subject to clause (v), the home health market basket percentage increase.

(iii) Home health market basket percentage increase. For purposes of this subsection, the term "home health market basket percentage increase" means, with respect to a fiscal year or year, a percentage (estimated by the Secretary before the beginning of the fiscal year or year) determined and applied with respect to the mix of goods and services included in home health services in the same manner as the market basket percentage increase under section 1886(b)(3)(B)(iii) [*42 USCS § 1395ww(b)(3)(iii)*] is determined and applied to the mix of goods and services comprising inpatient hospital services for the fiscal year or year.

(iv) Adjustment for case mix changes. Insofar as the Secretary determines that the adjustments under paragraph (4)(A)(i) for a previous fiscal year or year (or estimates that such adjustments for a future fiscal year or year) did (or are likely to) result in a change in aggregate payments under this subsection during the fiscal year or year that are a result of changes in the coding or classification of different units of services that do not reflect real changes in case mix, the Secretary may adjust the standard prospective payment amount (or amounts) under paragraph (3) for subsequent fiscal years or years so as to eliminate the effect of such coding or classification changes.

(v) Adjustment if quality data not submitted.

(I) Adjustment. For purposes of clause (ii)(V), for 2007 and each subsequent year, in the case of a home health agency that does not submit data to the Secretary in accordance with subclause (II) with respect to such a year, the home health market basket percentage increase applicable under such clause for such year shall be reduced by 2 percentage points. Such reduction shall apply only with respect to the year involved, and the Secretary shall not take into account such reduction in computing the prospective payment amount under this section for a subsequent year, and the Medicare Payment Advisory Commission shall carry out the requirements under section 5201(d) of the Deficit Reduction Act of 2005 [unclassified].

(II) Submission of quality data. For 2007 and each subsequent year, each home health agency shall submit to the Secretary such data that the Secretary determines are appropriate for the measurement of health care quality. Such data shall be submitted in a form and manner, and at a time, specified by the Secretary for purposes of this clause.

(III) Public availability of data submitted. The Secretary shall establish procedures for making data submitted under subclause (II) available to the public. Such procedures shall ensure that a home health agency has the opportunity to review the data that is to be made public with respect to the agency prior to such data being made public.

(C) Adjustment for outliers. The Secretary shall reduce the standard prospective payment amount (or amounts) under this paragraph applicable to home health services furnished during a period by such proportion as will result in an aggregate reduction in payments for the period equal to the aggregate increase in payments resulting from the application of paragraph (5) (relating to outliers).

(4) Payment computation.

(A) In general. The payment amount for a unit of home health services shall be the applicable standard prospective payment amount adjusted as follows:

(i) Case mix adjustment. The amount shall be adjusted by an appropriate case mix adjustment factor (established under subparagraph (B)).

(ii) Area wage adjustment. The portion of such amount that the Secretary estimates to be attributable to wages and wage-related costs shall be adjusted for geographic differences in such costs by an area wage adjustment factor (established under subparagraph (C)) for the area in which the services are furnished or such other area as the Secretary may specify.

(B) Establishment of case mix adjustment factors. The Secretary shall establish appropriate case mix adjustment factors for home health services in a manner that explains a significant amount of the variation in cost among different units of services.

(C) Establishment of area wage adjustment factors. The Secretary shall establish area wage adjustment factors that reflect the relative level of wages and wage-related costs applicable to the furnishing of home health services in a geographic area compared to the national average applicable level. Such factors may be the factors used by the Secretary for purposes of section 1886(d)(3)(E) [*42 USCS § 1395ww(d)(3)(E)*].

(5) Outliers. The Secretary may provide for an addition or adjustment to the payment amount otherwise made in the case of outliers because of unusual variations in the type or amount of medically necessary care. The total amount of the additional payments or payment adjustments made under this paragraph with respect to a fiscal year or year may not exceed 5 percent of the total payments projected or estimated to be made based on the prospective payment system under this subsection in that year.

(6) Proration of prospective payment amounts. If a beneficiary elects to transfer to, or receive services from, another home health agency within the period covered by the prospective payment amount, the payment shall be prorated between the home health agencies involved.

(c) Requirements for payment information. With respect to home health services furnished on or after October 1, 1998, no claim for such a service may be paid under this *title [42 USCS §§ 1395* et seq.] unless--

(1) the claim has the unique identifier (provided under section 1842(r) [*42 USCS § 1395u(r)*]) for the physician who prescribed the services or made the certification described in section 1814(a)(2) or 1835(a)(2)(A) [*42 USCS § 1395f(a)(2)* or *1395n(a)(2)*]; and

(2) in the case of a service visit described in paragraph (1), (2), (3), or (4) of section 1861(m) [*42 USCS § 1395x(m)*], the claim contains a code (or codes) specified by the Secretary that identifies the length of time of the service visit, as measured in 15 minute increments.

(d) Limitation on review. There shall be no administrative or judicial review under section 1869, 1878 [*42 USCS § 1395ff, 1395oo*], or otherwise of--

(1) the establishment of a transition period under subsection (b)(1);

(2) the definition and application of payment units under subsection (b)(2);

(3) the computation of initial standard prospective payment amounts under subsection (b)(3)(A) (including the reduction described in clause (ii) of such subsection);

(4) the establishment of the adjustment for outliers under subsection (b)(3)(C);

(5) the establishment of case mix and area wage adjustments under subsection (b)(4); and

(6) the establishment of any adjustments for outliers under subsection (b)(5).

(e) Construction related to home health services.

(1) Telecommunications. Nothing in this section shall be construed as preventing a home health agency furnishing a home health unit of service for which payment is made under the prospective payment system established by this section for such units of service from furnishing services via a telecommunication system if such services--

(A) do not substitute for in-person home health services ordered as part of a plan of care certified by a physician pursuant to section 1814(a)(2)(C) or 1835(a)(2)(A) [*42 USCS § 1395f(a)(2)(C)* or *1395n(a)(2)(A)*]; and

(B) are not considered a home health visit for purposes of eligibility or payment under this *title [42 USCS §§ 1395* et seq.].

(2) Physician certification. Nothing in this section shall be construed as waiving the requirement for a physician certification under section 1814(a)(2)(C) or 1835(a)(2)(A) of such Act (*42 U.S.C. 1395f(a)(2)(C), 1395n(a)(2)(A)*) for the payment for home health services, whether or not furnished via a telecommunications system.

HISTORY:

(Aug. 14, 1935, ch 531, Title XVIII, Part E[D], § 1895, as added Aug. 5, 1997, P.L. 105-33, Title IV, Subtitle G, Ch 1, Subch A, § 4603(a), 111 Stat. 467; Oct. 21, 1998, P.L. 105-277, Div J, Title V, Subtitle A, § 5101(c)(1), (d)(2), 112 Stat. 2681-914; Nov. 29, 1999, P.L. 106-113, Div B, § 1000(a)(6), 113 Stat. 1536; Dec. 21, 2000, P.L. 106-554, § 1(a)(6), 114 Stat. 2763; Dec. 8, 2003, P.L. 108-173, Title I, § 101(a)(1), Title VII, Subtitle A, § 701, 117 Stat. 2071, 2334; Feb. 8, 2006, P.L. 109-171, Title V, Subtitle C, § 5201(a), (c), 120 Stat. 46.)

§ 1395ggg. Medicare subvention demonstration project for military retirees [Caution: See prospective amendment note below.]

(a) Definitions. In this section:

(1) Administering Secretaries. The term "administering Secretaries" means the Secretary and the Secretary of Defense acting jointly.

(2) Demonstration project; project. The terms "demonstration project" and "project" mean the demonstration project carried out under this section.

(3) Designated provider. The term "designated provider" has the meaning given that term in section 721(5) of the National Defense Authorization Act For Fiscal Year 1997 (Public Law 104-201; 110 Stat. 2593; *10 U.S.C. 1073* note).

(4) Medicare-eligible military retiree or dependent. The term "medicare-eligible military retiree or dependent" means an individual described in section 1074(b) or 1076(b) of title 10, United States Code, who--

(A) is eligible for health benefits under section 1086 of such title by reason of subsection (c)(1) of such section;

(B)

(i) is entitled to benefits under part A of this *title [42 USCS §§ 1395c* et seq.]; and

(ii) if the individual was entitled to such benefits before July 1, 1997, received health care items or services from a health care facility of the uniformed services before that date, but after becoming entitled to benefits under part A of this *title [42 USCS §§ 1395c* et seq.];

(C) is enrolled for benefits under part B of this *title [42 USCS §§ 1395j* et seq.]; and

(D) has attained age 65.

(5) Medicare health care services. The term "medicare health care services" means items or services covered under part A or B of this *title [42 USCS §§ 1395c* et seq. or *1395j* et seq.].

(6) Military treatment facility. The term "military treatment facility" means a facility referred to in *section 1074(a) of title 10, United States Code.*

(7) TRICARE. The term "TRICARE" has the same meaning as the term "TRICARE program" under section 711 of the National Defense Authorization Act for Fiscal Year 1996 (*10 U.S.C. 1073* note).

(8) Trust funds. The term "trust funds" means the Federal Hospital Insurance Trust Fund established in section 1817 [*42 USCS § 1395i*] and the Federal Supplementary Medical Insurance Trust Fund established in section 1841 [*42 USCS § 1395t*].

(b) Demonstration project.

(1) In general.

(A) Establishment. The administering Secretaries are authorized to establish a demonstration project (under an agreement entered into by the administering Secretaries) under which the Secretary shall reimburse the Secretary of Defense, from the trust funds, for medicare health care services furnished to certain medicare-eligible military retirees or dependents in a military treatment facility or by a designated provider.

(B) Agreement. The agreement entered into under subparagraph (A) shall include at a minimum--

(i) a description of the benefits to be provided to the participants of the demonstration project established under this section;

(ii) a description of the eligibility rules for participation in the demonstration project, including any cost sharing requirements;

(iii) a description of how the demonstration project will satisfy the requirements under this *title [42 USCS §§ 1395* et seq.];

(iv) a description of the sites selected under paragraph (2);

(v) a description of how reimbursement requirements under subsection (i) and maintenance of effort requirements under subsection (j) will be implemented in the demonstration project;

(vi) a statement that the Secretary shall have access to all data of the Department of Defense that the Secretary determines is necessary to conduct independent estimates and audits of the maintenance of effort requirement, the annual reconciliation, and related matters required under the demonstration project;

(vii) a description of any requirement that the Secretary waives pursuant to subsection (d); and

(viii) a certification, provided after review by the administering Secretaries, that any entity that is receiving payments by reason of the demonstration project has sufficient--

(I) resources and expertise to provide, consistent with payments under subsection (i), the full range of benefits required to be provided to beneficiaries under the project; and

(II) information and billing systems in place to ensure the accurate and timely submission of claims for benefits and to ensure that providers of services, physicians, and other health care professionals are reimbursed by the entity in a timely and accurate manner.

(2) Number of sites. The project established under this section shall be conducted in no more than 6 sites, designated jointly by the administering Secretaries after review of all TRICARE regions.

(3) Restriction. No new military treatment facilities will be built or expanded with funds from the demonstration project.

(4) Duration. The administering Secretaries shall conduct the demonstration project during the 4-year period beginning on January 1, 1998, except that the administering Secretaries may negotiate and (subject to section 712(f) of the Floyd D. Spence National Defense Authorization Act for Fiscal Year 2001 [note to this section]) enter into a new or revised agreement under paragraph (1)(A) to continue the project after the end of such period. If the project is so continued, the administering Secretaries may terminate the agreement under which the program operates after providing notice to Congress in accordance with subsection (k)(2)(B)(v).

(5) Report. At least 60 days prior to the commencement of the demonstration project, the administering Secretaries shall submit a copy of the agreement entered into under paragraph (1) to the committees of jurisdiction under this *title [42 USCS §§ 1395* et seq.].

(c) Crediting of payments. A payment received by the Secretary of Defense under the demonstration project shall be credited to the applicable Department of Defense medical appropriation (and within that appropriation). Any such payment received during a fiscal year for services provided during a prior fiscal year may be obligated by the Secretary of Defense during the fiscal year during which the payment is received.

(d) Waiver of certain medicare requirements.

(1) Authority.

(A) In general. Except as provided under subparagraph (B), the demonstration project shall meet all requirements of Medicare + Choice plans under part C of this *title [42 USCS §§ 1395w-21* et seq.] and regulations pertaining thereto, and other requirements for receiving medicare payments, except that the prohibition of payments to Federal providers of services under sections 1814(c) and 1835(d) [*42 USCS §§ 1395f(c)* and *1395n(d)*], and paragraphs (2) and (3) of section 1862(a) [*42 USCS § 1395y(a)(2)* and (3)] shall not apply.

(B) Waiver. Except as provided in paragraph (2), the Secretary is authorized to waive any requirement described under subparagraph (A), or approve equivalent or alternative ways of meeting such a requirement, but only if such waiver or approval--

(i) reflects the unique status of the Department of Defense as an agency of the Federal Government; and

(ii) is necessary to carry out the demonstration project.

(2) Beneficiary protections and other matters. The demonstration project shall comply with the requirements of part C of this *title [42 USCS §§ 1395w-21* et seq.] that relate to beneficiary protections and other matters, including such requirements relating to the following areas:

(A) Enrollment and disenrollment.

(B) Nondiscrimination.

(C) Information provided to beneficiaries.

(D) Cost-sharing limitations.

(E) Appeal and grievance procedures.

(F) Provider participation.

(G) Access to services.

(H) Quality assurance and external review.

(I) Advance directives.

(J) Other areas of beneficiary protections that the Secretary determines are applicable to such project.

(e) Inspector General. Nothing in the agreement entered into under subsection (b) shall limit the Inspector General of the Department of Health and Human Services from investigating any matters regarding the expenditure of funds under this *title [42 USCS §§ 1395* et seq.] for the demonstration project, including compliance with the provisions of this *title [42 USCS §§ 1395* et seq.] and all other relevant laws.

(f) Voluntary participation. Participation of medicare-eligible military retirees or dependents in the demonstration project shall be voluntary.

(g) TRICARE health care plans.

(1) Modification of TRICARE contracts. In carrying out the demonstration project, the Secretary of Defense is authorized to amend existing TRICARE contracts (including contracts with designated providers) in order to provide the medicare health care services to the medicare-eligible military retirees and dependents enrolled in the demonstration project consistent with part C of this *title [42 USCS §§ 1395w-21* et seq.].

(2) Health care benefits. The administering Secretaries shall prescribe the minimum health care benefits to be provided under such a plan to medicare-eligible military retirees or dependents enrolled in the plan. Those benefits shall include at least all medicare health care services covered under this *title [42 USCS §§ 1395* et seq.].

(h) Additional plans. Notwithstanding any provisions of title 10, United States Code, the administering Secretaries may agree to include in the demonstration project any of the Medicare + Choice plans described in section 1851(a)(2)(A) [*42 USCS § 1395w-21(a)(2)(A)*], and such agreement may include an agreement between the Secretary of Defense and the Medicare + Choice organization offering such plan to provide medicare health care services to medicare-eligible military retirees or dependents and for such Secretary to receive payments from such organization for the provision of such services.

(i) Payments based on regular medicare payment rates.

(1) In general. Subject to the succeeding provisions of this subsection, the Secretary shall reimburse the Secretary of Defense for services provided under the demonstration project at a rate equal to 95 percent of the amount paid to a Medicare + Choice organization under part C of this *title [42 USCS §§ 1395w-21* et seq.] with respect to such an enrollee. In cases in which a payment amount may not otherwise be readily computed, the Secretary shall establish rules for computing equivalent or comparable payment amounts.

(2) Exclusion of certain amounts. In computing the amount of payment under paragraph (1), the following shall be excluded:

(A) Special payments. Any amount attributable to an adjustment under subparagraphs (B) and (F) of section 1886(d)(5) [*42 USCS § 1395ww(d)(5)(B)* and (F)] and subsection (h) of such section.

(B) Percentage of capital payments. An amount determined by the administering Secretaries for amounts attributable to payments for capital-related costs under subsection (g) of such section.

(3) Periodic payments from medicare trust funds. Payments under this subsection shall be made--

(A) on a periodic basis consistent with the periodicity of payments under this *title [42 USCS §§ 1395* et seq.]; and

(B) in appropriate part, as determined by the Secretary, from the trust funds.

(4) Cap on amount. The aggregate amount to be reimbursed under this subsection pursuant to the agreement entered into between the administering Secretaries under subsection (b) shall not exceed a total of--

(A) $ 50,000,000 for calendar year 1998;

(B) $ 60,000,000 for calendar year 1999;

(C) $ 65,000,000 for calendar year 2000; and

(D) $ 70,000,000 for calendar year 2001.

(j) Maintenance of effort.

(1) Monitoring effect of demonstration program on costs to medicare program.

(A) In general. The administering Secretaries, in consultation with the Comptroller General, shall closely monitor the expenditures made under the medicare program for medicare-eligible military retirees or dependents during the period of the demonstration project compared to the expenditures that would have been made for such medicare-eligible military retirees or dependents during that period if the demonstration project had not been conducted. The agreement entered into by the administering Secretaries under subsection (b) shall require any participating military treatment facility to maintain the level of effort for space available care to medicare-eligible military retirees or dependents.

(B) Annual report by the Comptroller General. Not later than December 31 of each year during which the demonstration project is conducted, the Comptroller General shall submit to the administering Secretaries and the appropriate committees of Congress a report on the extent, if any, to which the costs of the Secretary under the medicare program under this *title [42 USCS §§ 1395* et seq.] increased during the preceding fiscal year as a result of the demonstration project.

(2) Required response in case of increase in costs.

(A) In general. If the administering Secretaries find, based on paragraph (1), that the expenditures under the medicare program under this *title [42 USCS §§ 1395* et seq.] increased (or are expected to increase) during a fiscal year because of the demonstration project, the administering Secretaries shall take such steps as may be needed--

(i) to recoup for the medicare program the amount of such increase in expenditures; and

(ii) to prevent any such increase in the future.

(B) Steps. Such steps--

(i) under subparagraph (A)(i) shall include payment of the amount of such increased expenditures by the Secretary of Defense from the current medical care appropriation of the Department of Defense to the trust funds; and

(ii) under subparagraph (A)(ii) shall include suspending or terminating the demonstration project (in whole or in part) or lowering the amount of payment under subsection (i)(1).

(k) Evaluation and reports.

(1) Independent evaluation. The Comptroller General of the United States shall conduct an evaluation of the demonstration project, and shall submit annual reports on the demonstration project to the administering Secretaries and to the committees of jurisdiction in the Congress. The first report shall be submitted not later than 12 months after the date on which the demonstration project begins operation, and the final report not later than 3 1/2 years after that date. The evaluation and reports shall include an assessment, based on the agreement entered into under subsection (b), of the following:

(A) Any savings or costs to the medicare program under this *title [42 USCS §§ 1395* et seq.] resulting from the demonstration project.

(B) The cost to the Department of Defense of providing care to medicare-eligible military retirees and dependents under the demonstration project.

(C) A description of the effects of the demonstration project on military treatment facility readiness and training and the probable effects of the project on overall Department of Defense medical readiness and training.

(D) Any impact of the demonstration project on access to care for active duty military personnel and their dependents.

(E) An analysis of how the demonstration project affects the overall accessibility of the uniformed services treatment system and the amount of space available for point-of-service care, and a description of the unintended effects (if any) upon the normal treatment priority system.

(F) Compliance by the Department of Defense with the requirements under this *title [42 USCS §§ 1395* et seq.].

(G) The number of medicare-eligible military retirees and dependents opting to participate in the demonstration project instead of receiving health benefits through another health insurance plan (including benefits under this *title [42 USCS §§ 1395* et seq.]).

(H) A list of the health insurance plans and programs that were the primary payers for medicare-eligible military retirees and dependents during the year prior to their participation in the demonstration project and the distribution of their previous enrollment in such plans and programs.

(I) Any impact of the demonstration project on private health care providers and beneficiaries under this *title [42 USCS §§ 1395* et seq.] that are not enrolled in the demonstration project.

(J) An assessment of the access to care and quality of care for medicare-eligible military retirees and dependents under the demonstration project.

(K) An analysis of whether, and in what manner, easier access to the uniformed services treatment system affects the number of medicare-eligible military retirees and dependents receiving medicare health care services.

(L) Any impact of the demonstration project on the access to care for medicare-eligible military retirees and dependents who did not enroll in the demonstration project and for other individuals entitled to benefits under this *title [42 USCS §§ 1395* et seq.].

(M) A description of the difficulties (if any) experienced by the Department of Defense in managing the demonstration project and TRICARE contracts.

(N) Any additional elements specified in the agreement entered into under subsection (b).

(O) Any additional elements that the Comptroller General of the United States determines is appropriate to assess regarding the demonstration project.

(2) [Repealed]

HISTORY:

(Aug. 14, 1935, ch 531, Title XVIII, Part E[D], § 1896, as added Aug. 5, 1997, P.L. 105-33, Title IV, Subtitle A, Ch 2, Subch C, § 4015(a), 111 Stat. 337; Oct. 30, 2000, P.L. 106-398, § 1, 114 Stat. 1654; Dec. 2, 2002, P.L. 107-314, Div A, Title VII, Subtitle B, § 713, 116 Stat. 2589; Dec. 8, 2003, P.L. 108-173, Title I, § 101(a)(1), Title VII, Subtitle D, § 736(c)(8), 117 Stat. 2071, 2356.)

§ 1395hhh. Health care infrastructure improvement program

(a) Establishment. The Secretary shall establish a loan program that provides loans to qualifying hospitals for payment of the capital costs of projects described in subsection (d).

(b) Application. No loan may be provided under this section to a qualifying hospital except pursuant to an application that is submitted and approved in a time, manner, and form specified by the Secretary. A loan under this section shall be on such terms and conditions and meet such requirements as the Secretary determines appropriate.

(c) Selection criteria.

(1) In general. The Secretary shall establish criteria for selecting among qualifying hospitals that apply for a loan under this section. Such criteria shall consider the extent to which the project for which loan is sought is nationally or regionally significant, in terms of expanding or improving the health care infrastructure of the United States or the region or in terms of the medical benefit that the project will have.

(2) Qualifying hospital defined. For purposes of this section, the term "qualifying hospital" means a hospital or an entity described in paragraph (3) that--

(A) is engaged in research in the causes, prevention, and treatment of cancer; and

(B) is designated as a cancer center for the National Cancer Institute or is designated by the State legislature as the official cancer institute of the State and such designation by the State legislature occurred prior to December 8, 2003.

(3) Entity described. An entity described in this paragraph is an entity that--

(A) is described in *section 501(c)(3) of the Internal Revenue Code of 1986* [*26 USCS § 501(c)(3)*] and exempt from tax under section 501(a) of such Code [*26 USCS § 501(a)*];

(B) has at least 1 existing memorandum of understanding or affiliation agreement with a hospital located in the State in which the entity is located; and

(C) retains clinical outpatient treatment for cancer on site as well as lab research and education and outreach for cancer in the same facility.

(d) Projects. A project described in this subsection is a project of a qualifying hospital that is designed to improve the health care infrastructure of the hospital, including construction, renovation, or other capital improvements.

(e) State and local permits. The provision of a loan under this section with respect to a project shall not--

(1) relieve any recipient of the loan of any obligation to obtain any required State or local permit or approval with respect to the project;

(2) limit the right of any unit of State or local government to approve or regulate any rate of return on private equity invested in the project; or

(3) otherwise supersede any State or local law (including any regulation) applicable to the construction or operation of the project.

(f) Forgiveness of indebtedness. The Secretary may forgive a loan provided to a qualifying hospital under this section under terms and conditions that are analogous to the loan forgiveness provision for student loans under part D of title IV of the Higher Education Act of 1965 (*20 U.S.C. 1087a* et seq.), except that the Secretary shall condition such forgiveness on the establishment by the hospital of--

(A) an outreach program for cancer prevention, early diagnosis, and treatment that provides services to a substantial majority of the residents of a State or region, including residents of rural areas;

(B) an outreach program for cancer prevention, early diagnosis, and treatment that provides services to multiple Indian tribes; and

(C) (i) unique research resources (such as population databases); or

(ii) an affiliation with an entity that has unique research resources.

(g) Funding.

(1) In general. There are appropriated, out of amounts in the Treasury not otherwise appropriated, to carry out this section, $ 200,000,000, to remain available during the period beginning on July 1, 2004, and ending on September 30, 2008.

(2) Administrative costs. From funds made available under paragraph (1), the Secretary may use, for the administration of this section, not more than $ 2,000,000 for each of fiscal years 2004 through 2008.

(3) Availability. Amounts appropriated under this section shall be available for obligation on July 1, 2004.

(h) Report to Congress. Not later than 4 years after the date of the enactment of this section [enacted Dec. 8, 2003], the Secretary shall submit to Congress a report on the projects for which loans are provided under this section and a recommendation as to whether the Congress should authorize the Secretary to continue loans under this section beyond fiscal year 2008.

(i) Limitation on review. There shall be no administrative or judicial review of any determination made by the Secretary under this section.

HISTORY:

(Aug. 14, 1935, ch 531, Title XVIII, Subtitle E, § 1897, as added Dec. 8, 2003, P.L. 108-173, Title X, Subtitle B, § 1016, 117 Stat. 2447; May 11, 2005, P.L. 109-13, Div A, Title VI, § 6045(a), (b), 119 Stat. 294.)

§ 1395iii. Medicare Improvement Fund

(a) Establishment. The Secretary shall establish under this *title [42 USCS §§ 1395* et seq.] a Medicare Improvement Fund (in this section referred to as the "Fund") which shall be available to the Secretary to make improvements under the original fee-for-service program under parts A and B [*42 USCS §§ 1395c* et seq. and *1395j* et seq.] for individuals entitled to, or enrolled for, benefits under part A [*42 USCS §§ 1395c* et seq.] or enrolled under part B [*42 USCS §§ 1395j* et seq.].

(b) Funding.

(1) In general. There shall be available to the Fund, for expenditures from the Fund for services furnished during fiscal year 2014, $ 2,290,000,000 and, in addition for services furnished during fiscal years 2014 through 2017, $ 19,900,000,000.

(2) Payment from trust funds. The amount specified under paragraph (1) shall be available to the Fund, as expenditures are made from the Fund, from the Federal Hospital Insurance Trust Fund and the Federal Supplementary Medical Insurance Trust Fund in such proportion as the Secretary determines appropriate.

(3) Funding limitation. Amounts in the Fund shall be available in advance of appropriations but only if the total amount obligated from the Fund does not exceed the amount available to the Fund under paragraph (1). The Secretary may obligate funds from the Fund only if the Secretary determines (and the Chief Actuary of the Centers for Medicare

& Medicaid Services and the appropriate budget officer certify) that there are available in the Fund sufficient amounts to cover all such obligations incurred consistent with the previous sentence.

HISTORY:

(Aug. 14, 1935, ch 531, Title XVIII, Subtitle E, § 1898, as added June 30, 2008, P.L. 110-252, Title VII, § 7002(a), 122 Stat. 2394; July 15, 2008, P.L. 110-275, Title I, Subtitle F, § 188(a)(2)(B), 122 Stat. 2589; Oct. 8, 2008, P.L. 110-379, § 6, 122 Stat. 4079.)