WEST VIRGINIA
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ADMINISTRATIVE LAW DIVISION

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OFFICE OF WEST VIRGINIA SECRETARY OF STATE

Form #2

NOTICE OF A COMMENT PERIOD ON A PROPOSED RULE

AGENCY: Division of Health Department of Health and Human Resources TITLE NUMBER: 64

RULE TYPE: Legislative ; CITE AUTHORITY WV Code § 27-5-9(g)

AMENDMENT TO AN EXISTING RULE: YES ____ NO X

IF YES, SERIES NUMBER OF RULE BEING AMENDED: _____

TITLE OF RULE BEING AMENDED: _____

IF NO, SERIES NUMBER OF RULE BEING PROPOSED: 74

TITLE OF RULE BEING PROPOSED: Behavioral Health Consumer Rights

IN LIEU OF A PUBLIC HEARING, A COMMENT PERIOD HAS BEEN ESTABLISHED DURING WHICH ANY INTERESTED PERSON MAY SEND COMMENTS CONCERNING THESE PROPOSED RULES. THIS COMMENT PERIOD WILL END ON July 31 1998 AT 4:30 p.m. . ONLY WRITTEN COMMENTS WILL BE ACCEPTED AND ARE TO BE MAILED TO THE FOLLOWING ADDRESS.

Regulatory Development

Department of Health & Human Resources

Capitol Complex - Building 3, Room 265

Charleston, WV 25305

ATTN: Marsha Dadisman, Acting Director

THE ISSUES TO BE HEARD SHALL BE LIMITED TO THIS PROPOSED RULE.

Joan E. Ohl

Joan E. Ohl, Secretary

$6.20 w/out attachment
$17.40 w/attachment

BRIEF SUMMARY OF THE RULE

This proposed rule defines the rights of individuals served in community-based behavioral health facilities. It provides for procedures for informing consumers of their rights and outlines grievance procedures when an individual believes his or her rights have been violated.

Statement of Circumstances Which Require the Proposed Rule

This proposed Rule was developed in response to a Request for Resolution discussed and agreed to by the parties to the consent decree resulting from the case of E.H. v. Matin, 168 W.Va. 248, 284 S.E.2d 232 (1981). This proposed Rule builds on a similar rights rule for persons who are committed or admitted to State-operated psychiatric hospitals or residential treatment centers for substance abuse.

The rule was developed by a task group composed of providers, family members, consumers, and Department personnel, which was formed by the Behavioral Health Work Group chaired by the Commissioner of the Bureau for Behavioral Health and Health Facilities. The task group obtained and reviewed the highest standards for rights of persons with mental illness, mental retardation, or addiction and prepared this proposed rule based on those standards.

FISCAL NOTE FOR PROPOSED RULE

Rule Title: Behavioral Health Consumer Rights

Type of Rule: X **Legislative** __ **Interpretive** __ **Procedural**

Agency: Division of Health
Department of Health and Human Resources

Address: Building 3, Capitol Complex
Charleston, WV 25305

1. Effect of the Proposed Rule	ANNUAL		FISCAL YEAR		
	Increase	Decrease	Current	Next	Thereafter
Estimated Total Cost	$	$	$	$ 0	$ 0
Personal Services					
Current Expense					
Repairs and Alterations					
Equipment					
Other					
Revenue					

2. Explanation of above estimates

It is not anticipated this rule will add any additional costs to the Department. Monitoring for protection of rights and investigation of complaints and grievances is already included in the Department's budget.

3. Objectives of this rule:

This rule establishes rights for persons served by community-based behavioral health programs.

4. Explanation of Overall Economic Impact of Proposed Rule.

A. Economic Impact on State Government.

This rule will have no economic impact on state government.

B. Economic Impact on Political Subdivisions; Specific Industries; Specific Groups of Citizens.

This rule may require the expansion of grievance procedures by providers of community-based behavioral health providers. Economic impact should be minimal.

C. Economic Impact on Citizens/Public at Large.

This rule will have no economic impact on citizens or public at large.

Date:

Signature of Agency Head or Authorized Representative

Joan E. Ohl, Secretary
Department of Health and Human Resources

QUESTIONNAIRE

(Please include a copy of this form with each filing of your rule: Notice of Public Hearing or Comment Period, Proposed Rule, and if needed, Emergency and Modified Rule.)

DATE: June 29, 1998

TO: LEGISLATIVE RULE-MAKING REVIEW COMMITTEE

FROM: (Agency name, Address & Phone No.) Department of Health and Human Resources

State Capitol Complex, Building 3, Room 265, Charleston, WV 25305

Telephone: (304) 558-3223

LEGISLATIVE RULE TITLE: Behavioral Health Consumer Rights, 64 CSR 74

1. Authorizing statute(s) citation: WV Code Section 27-5-9(g)

2. a. Date filed in State Register with Notice of Hearing or Public Comment Period:

June 29, 1998

b. What other notice, including advertising, did you give of the hearing?

Ted J. Johnson, Director of the Division of Mental Health and Community Rehabilitation in the Office of Behavioral Health Services, will report the proposed rule to all licensed providers, hospitals with psychiatric inpatient programs, the Office of Health Facilities Certification and Licensure, provider representative organizations, consumer representative organizations, anf family member representatives.

c. Date of Public Hearing(s) or Public Comment Period ended:

July 30, 1998

d. Attach list of persons who appeared at hearing, comments received, amendments, reasons for amendments.

Attached N/A No comments received N/A

e. Date you filed in State Register the agency approved proposed Legislative Rule following public hearing (be exact):

N/A

f. Name, title, address and phone/fax/e-mail numbers of agency person(s) to receive all written correspondence regarding this rule (please type):

Marsha Dadisman, Acting Director

Regulatory Development/Department of Health and Human Resources

Room 265, Capitol Complex

Charleston, West Virginia 25305

(304) 558-3223 FAX: (304) 558-1130 MDadisman@WVDHHR.ORG

g. IF DIFFERENT FROM ITEM 'f', please give Name, title, address and phone number(s) of agency person(s) who wrote and/or has responsibility for the contents of this rule (please type):

Ted J. Johnson, Director

Division of Mental Health and Community Rehabilitation Services

Department of Health and Human Resources

1900 Kanawha Blvd. East Building 6, Room B -717

Charleston, West Virginia 25305 (304) 558-0627

3. If the statute under which you promulgated the submitted rules requires certain findings and determinations to be made as a condition precedent to their promulgation:

a. Give the date upon which you filed in the State Register a notice of the time and place a hearing for the taking of evidence and a general description of the issues to be decided.

N/A

b. Date of hearing or comment period:

N/A

c. On what date did you file in the State Register the findings and determinations required together with the reasons therefore?

N/A

d. Attach findings and determinations and reasons:

Attached N/A

TITLE 64

WEST VIRGINIA LEGISLATIVE RULE
DIVISION OF HEALTH
DEPARTMENT OF HEALTH AND HUMAN RESOURCES

SERIES 74

BEHAVIORAL HEALTH CONSUMER RIGHTS

1998

TITLE 64
WEST VIRGINIA LEGISLATIVE RULE
DIVISION OF HEALTH
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BEHAVIORAL HEALTH CONSUMER RIGHTS

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TITLE 64
WEST VIRGINIA LEGISLATIVE RULES
DIVISION OF HEALTH
DEPARTMENT OF HEALTH AND HUMAN RESOURCES
SERIES 74
BEHAVIORAL HEALTH CONSUMER RIGHTS

§ 64-74-1. General.

1.1. Scope. -- This legislative rule establishes the rights of consumers of State-licensed behavioral health services.

1.2. Authority. -- WV Code § 27-5-9(g).

1.3. Filing Date. --

1.4. Effective Date. --

1.5. Construction. -- This rule shall be liberally construed to effectuate the rehabilitative goals of Chapter 27 of the West Virginia Code, consistent with the protection of consumer rights and dignity.

1.6. Applicability - This rule applies to behavioral health services licensed by the division of health, department of health and human resources.

§ 64-74-2. Definitions.

2.1. Administrator. -- The chief executive officer of a behavioral health service.

2.2. Advance Directive. -- Any directive written and signed by a consumer, describing preferences in health care, behavioral health care, or the conduct of business.

2.3. Aggrieved. -- An individual or family who believes rights accorded by this rule have been violated by a service or employee of the service.

2.4. Behavioral Health. -- Mental health, developmental disabilities, or substance abuse.

2.5. Behavioral Health Service. -- Any inpatient, residential or outpatient service for the care and treatment of persons with mental illness, developmental disability or addiction which is licensed by the department of health and human resources.

2.6. Chemical Restraint. -- The use of drugs or medication as a behavior control mechanism to substitute for seclusion or mechanical restraint.

2.7. Consumer. -- Any individual receiving treatment or services in or from a behavioral health service licensed by the department of health and human resources.

2.8. Clinical Director or Chief Medical Officer. -- The person who has the responsibility for decisions involving clinical and medical treatment of consumers in a behavioral health service.

2.9. Designated Grievance Representative. -- An individual employed by the service who has been appointed by the administrator of the service to assist any consumer wishing to file a grievance.

2.10. Individualized Program Plan (IPP). -- A master plan which is a written, individualized plan specifically tailored to individual needs, including a complete, thorough review of the consumer's needs, strengths, weaknesses, response to initial interventions and prognosis for resolution of acute symptoms, and other components as indicated in this rule.

2.11. Legal Representative.

2.11.a. A conservator, temporary conservator or limited conservator appointed pursuant to the West Virginia Guardianship and Conservatorship Act, WV Code, § 44-1-1-et seq., within the limits set by the order;

2.11.b. A guardian, temporary guardian or limited guardian appointed pursuant to the West Virginia Guardianship and Conservatorship Act, WV Code, § 44-1-1-et seq., within the limits set by the order;

2.11.c. An individual appointed as committee or guardian prior to June 9, 1994, within the limits set by the appointing order and WV Code 44A-1-2(d);

2.11.d. A person having a medical power of attorney pursuant to the West Virginia Medical Power of Attorney Act, WV Code §16-30A-1 et seq., within the limits set by the law and the appointment;

2.11.e. A representative payee under the U.S. Social Security Act, Title 42 US Code § 301 et seq., within the limits of the payee's legal authority;

2.11.f. A surrogate decision-maker appointed pursuant to the West Virginia Health Care Surrogate Act, WV Code §16-30B-1 et seq., or the West Virginia Do Not Resuscitate Act, §16-30C-1 et seq., within the limits set by the appointment;

2.11.g. An individual having a durable power of attorney pursuant to WV Code § 39-4-1, or a power of attorney under common law, within the limits of the appointment; or

2.11.h. An individual lawfully appointed in a similar or like relationship of responsibility for a consumer under the laws of this State, or another State or legal jurisdiction, within the limits of the applicable statute and appointing authority;

2.11.i. If a legal representative has been appointed for or designated by any consumer as having the authority to exercise on behalf of the consumer one or more of the consumer's rights under this rule, the service shall permit the individual's legal representative to act on behalf of the individual and to exercise the authority to the extent granted to the legal representative in the order

or other document naming the legal representative or pursuant to the statute authorizing the legal representative and to the extent that the legal representative's acts are not hostile or adverse to the best interests of the consumer. This provision does not relieve the service of the responsibility of informing the individual consumer as required by this rule, to the extent that the individual is capable of understanding the matter, nor does it in any way deprive the consumer of his or her legal rights granted under this rule or state or federal law or rules and regulations. If the consumer has a legal representative, the name, address and telephone number of the legal representative shall be recorded in the consumer's financial and clinical records, as applicable, along with the nature and scope of the authority granted to the legal representative by order, appointment or law. The service shall also maintain a copy of the document documenting or designating the legal representative. The service administrator and staff should note that the various types of legal representatives do not necessarily have the lawful authority to act on behalf of the resident in all matters which may require action by a legal representative. For example, a conservator may have responsibility for financial affairs, but not personal affairs, such as medical care.

2.12. Mechanical Restraints. -- Handcuffs, straight-jackets or "sleeves", or other restraining devices or variations of these devices which are designed and applied for the purpose of preventing an individual from engaging in assaultive or self-abusive behavior.

2.13. Mediation. -- Private, informal dispute resolution process in which a neutral third person, the mediator, helps disputing parties to reach an agreement.

2.14. Neglect. -- A negligent act or omission by an individual responsible for providing services in a behavioral health service rendering care or treatment which caused or may have caused injury or death to an individual or which placed an individual at risk of injury or death, and includes an act or omission such as the failure to establish or carry out an appropriate individual program plan or treatment plan for an individual, the failure to provide adequate nutrition, clothing, or health care to an individual, or the failure to provide a safe environment for an individual, including failure to maintain adequate numbers of appropriately trained staff.

2.15. Physical Abuse. -- Any act or failure to act by an employee of a behavioral health service which was performed, or which was failed to be performed, knowlingly, recklessly, or intentionally, and which caused, or may have caused, injury or death to an individual, and includes such acts as

2.15.a. The rape or sexual assault of an individual;

2.15.b. The striking of an individual;

2.15.c. The use of excessive force when placing an individual in bodily restraints; and

2.15.d. The use of bodily or chemical restraints on an individual which is not in compliance with federal and State laws and regulations.

2.16. Seclusion. -- The placement of any consumer alone in a room or enclosed space with closed doors which the consumer cannot open from inside.

2.17. Secretary. -- The secretary of the West Virginia department of health and human resources

or his or her designee.

2.18. Service. -- A behavioral health service.

2.19. Sexual Harassment. -- Physical advances or nonverbal conduct that is sexual in nature and is either: (1) unwelcome, offensive, or creates a hostile environment, when the staff member is aware or has been informed that his or her conduct falls into one of these categories; or (2) is sufficiently severe or intense to be abusive to a reasonable person in the particular context.

2.20. Verbal Abuse. -- The use of language, tone or inflection of voice that would likely be construed by an impartial observer as a threat to or, harassment, derogation or humiliation of a consumer. Verbal abuse includes, but is not limited to: the use of a threatening or abusive tone or manner in speaking to a consumer; the use of derogatory, vulgar, profane, abusive or threatening language; verbal threats; teasing, pestering, deriding, harassing, mimicking or humiliating a consumer; derogatory remarks about the consumer, his or her family or associates; or sexual innuendo, sexually provocative language or verbal suggestion.

§ 64-74-3. Adoption of Other Standards.

In addition to the standards set forth in this rule, the relevant portions of Conditions of Participation for Hospitals 42 C.F.R. Part 482 (Oct. 1, 1997), Subparts A through E (Sep. 1, 1994), and Conditions of Participation for Intermediate Care Facilities for the Mentally Retarded, 42 C.F.R. Part 483, Subpart I (Oct. 1, 1997), pertaining to certification for participation in Medicare and Medicaid (Feb. 2, 1989); the Licensing Requirements for Group Residential Facilities for Children, issued under the provisions of §74 of the Code of West Virginia (June 1, 1992); the standards set forth in the 1995 Comprehensive Accreditation Manual for Hospitals of the Joint Commission on the Accreditation of Health Care Organizations, pages 63-83; and the standards set forth in the 1993 edition of Outcome Based Performance Measures of the Accreditation Council on Services for People with Disabilities, pages 1-11 and 133-137, are hereby adopted by reference: Provided, That to the extent there is a conflict between the federal regulations or the accreditation standards and the standards specified in this rule, the more stringent standard applies, except that, if there is a conflict between a standard set forth in this rule and a federal standard required for purposes of certification for participation in Medicare or Medicaid, the relevant federal standard prevails.

§ 64-74-4. Consumers' Rights Generally.

4.1. Persons with behavioral health problems are more likely to have their human and civil rights denied because of their condition. Consequently, special attention and effort are required to assure that these human and civil rights are exercised and protected in all behavioral health services.

4.2. No Discrimination. All behavioral health services licensed by the department of health and human resources shall make available all offered services to persons in need without discrimination because of race, creed, color, gender, age, national origin, marital status, sexual preference, physical or mental disability, or duration of residence. Crisis services, if offered, cannot be denied on the basis of inability to pay.

4.3. Civil Rights of Consumers. Every consumer served by any behavioral health service

licensed by the department shall be permitted to exercise all of his or her civil rights, including but not limited to: civil service status and appointment; the right to register and vote at elections; the right to acquire and dispose of property; the right to execute instruments or rights relating to the granting, forfeiture or denial of a license, permit, privilege or benefit pursuant to any law; the right to enter into contractual relationships, to marry or to obtain a divorce; or the right to hold a professional, occupational or vehicle operator's licenses, unless he or she has had a legal representative appointed and the court has made a specific finding that the consumer is incompetent to exercise the specific right or category of rights.

4.4. Responsibility of Administrator. It is the responsibility of the service's administrator to assure that each consumer is informed of his or her rights and to make all necessary arrangements to allow the consumer to exercise his or her rights.

4.5. Consumers' Rights in a Group Setting Generally. Consumers shall be housed with other consumers of similar age and need, unless specific reasons such as the need to protect a consumer with a low level of adaptive skills and ability for self defense are noted in the treatment plan.

4.6. Right to Least Restrictive Residential Setting. The consumer has the right to access to treatment in the least restrictive setting. The goal of treatment for a consumer shall be to address needs so as to permit the consumer to be in the least restrictive setting.

4.7. Right of Privacy. A consumer has a right to privacy and the right to move about freely unless his or her safety or the safety of others is threatened.

4.8. No Deprivation of Rights As Punishment. No consumer can be deprived of a right provided by law or regulation as punishment. No consumer may be deprived of a right for clinical reasons except for an incident related to the exercise of that right and then only for so long as is necessary to permit correction of the situation or behavior.

4.9. Every consumer, upon his or her admission to a behavioral health service, and at any later time upon request, shall be given a summary of the rights afforded by this rule. A copy of this rule shall be available upon request.

4.10. The service shall establish simple and understandable rules for consumers and staff of the service which set the limits of behavior required of a group and individual consumers within the group.

§ 64-74-5. Advance Directives.

5.1. A consumer may enter a behavioral health service with an advance directive or may write and sign an advance directive during the time he or she is receiving service from the behavioral health service. Advance directives may address preferences in health care, behavioral health care, or conduct of business. Advance directives may be withdrawn verbally or in writing by the consumer at any time. The existence of an advance directive does not indicate a lack of competency or other inability to care for oneself.

5.2. The behavioral health service shall ascertain if a consumer has a written advance directive

at admission into the behavioral health service. If there is a written advance directive, it shall be copied into the consumer's record at the behavioral health service, with the consumer's permission. All members of the team shall be informed of the advance directive. The consumer should be informed of his or her rights concerning advance directives including:

5.2.a. All advance directives concerning preferences in health care shall be honored until withdrawn verbally or in writing;

5.2.b. All advance directives concerning preferences in the conduct of business shall be honored until withdrawn verbally or in writing; and

5.2.c. Advance directives concerning preferences in behavioral health services shall be honored to the extent resources are available, until withdrawn verbally or in writing, unless honoring the advance directive would cause serious harm to the consumer, endanger the consumer's life, or be dangerous to others. The behavioral health service shall consider initiating commitment proceedings whenever it is believed following an advance behavioral health service directive would pose a danger to the consumer or others.

5.3. If a consumer does not have an advance directive at the time of admission, the behavioral health service shall provide information and education concerning advance directives. The information shall cover advance directives for health care, behavioral health services, and conduct of business. Information presented shall be easily understood and shall be presented verbally and in writing.

5.3.a. Consumers may not be coerced into writing or signing an advance directive, nor shall the provision of service be conditioned on the existence of an advance directive.

§ 64-74-6. Consumers' Right to Treatment.

6.1. General. All consumers of behavioral health services have a right to treatment in the least restrictive setting, which may include care and treatment including habilitation, rehabilitation, medical care, education and training, when available and appropriate, and to behavioral health and support services suited to their individual needs. Treatment shall be provided humanely in an environment that affords civil, legal and regulatory rights, and provides freedom from verbal or physical abuse or neglect.

6.2. Trained and Competent Personnel. Every consumer of a behavioral health service has a right to treatment by trained and competent personnel in numbers sufficient to administer adequate treatment and individualized treatment plans.

6.3. Appropriate Treatment Based on Examination and Diagnosis. Every consumer of a behavioral health service has a right to treatment based on diagnosis and assessment of needs by a staff member operating within the scope of his or her professional license.

6.4. Program Plan. Every consumer of a behavioral health service has a right to a program or treatment plan. The plan shall identify immediate needs and interventions, determine data or assessment needs, and establish responsibility for implementing the plan. The plan shall be updated

on a regular basis, as the consumer's needs change. The consumer has the right to participate in the development of the program or treatment plan and any revisions.

6.5. Minimum Requirements of the Individualized Program Plan (IPP). Every consumer's program plan shall at a minimum:

6.5.a. Be based on a comprehensive assessment of the consumer's presenting problems, physical health, mental health, emotional status, behavioral status, and environmental status and needs;

6.5.b. Contain written, functional objectives, methods for achieving them, expected achievement dates, and anticipated or desired outcomes;

6.5.c. Describe treatment, services, activities, therapies, and programs to be accessed and provided;

6.5.d. Identify who is responsible for implementing the specific treatment services, activities, therapies, and programs;

6.5.e. Indicate the frequency and duration of treatment, services, activities, therapies and programs;

6.5.f. Delineate the specific criteria, including outcomes, to be met for termination of treatment or programming;

6.5.g. Document the extent of consumer and family participation in planning; and

6.5.h. Document by name and role all participants in developing the plan.

6.6. Evidence of Treatment. Evidence that recognized procedures applicable to meeting behavioral health needs have been administered to the consumer in accordance with his or her treatment plan, including but not limited to individual psychotherapy, group therapy, family therapy, physical therapy, appropriate physical fitness routines, chemotherapy, planned occupational therapy, and recreational therapy shall be documented in the consumer's record by the appropriate member of the interdisciplinary team.

6.7. Accepted Service Standards. Every consumer using a behavioral health service is entitled to care and treatment in accordance with accepted behavioral health and medical practice standards. If any of the rights set forth in this rule related to treatment are not afforded to the consumer, then the reasons for the restriction of the specific right shall be specified in the consumer's treatment plan in the consumer's clinical record.

§ 64-74-7. Informed Consent.

7.1. Treatment cannot be given without written consent unless committed pursuant to WV Code §§ 27-5-3, 27-5-4, 27-6A-2(b) or 27-6A-3 without his or her written consent. If no informed consent is documented in the chart, the physician or person prescribing treatment shall provide information

on his/her right to refuse treatment before treatment is begun.

7.2. Informed Consent. Consent is not valid unless it is informed consent. To assure informed consent, an appropriate behavioral health professional shall explain and discuss the following with each consumer:

7.2.a. The nature of the consumer's condition;

7.2.b. The reasons for taking any proposed medication, including the likelihood of the consumer's condition improving or not improving without the proposed medication;

7.2.c. That consent, once given, may be withdrawn at any time by stating the intention to any member of the treating staff;

7.2.d. The reasonable alternative treatments available, if any;

7.2.e. The type, range of frequency and amount, including the use of PRN (as needed) orders, the method (oral or injection) of administration, and the duration of taking the proposed medication;

7.2.f. The probable side effects to the proposed medication known to occur commonly, and any particular side effects likely to occur with the particular consumer;

7.2.g. Possible additional side effects of the proposed medications which may occur to consumers taking the medication beyond three (3) months; and

7.2.h. His or her rights under this rule.

7.2.i. This explanation and discussion shall be documented and signed by an appropriate behavioral health professional and consumer.

7.3. Requirement for Consent. Antipsychotic medication may be administered to an adult consumer only after the consumer has given informed, voluntary consent in writing, except as provided in the procedures set forth in this subsection.

7.3.a. Consent shall be considered to be informed only after the consumer has been provided with the information specified in subsection 7.2 of this rule by the physician prescribing the medication.

7.3.b. The consumer shall be asked to sign the consent form utilized in obtaining informed consent from voluntary consumers, and this signed consent form shall be included in his or her chart. In the event that the consumer has been shown the form and communicates consent but does not wish to sign the written consent form, it is sufficient for an appropriate behavioral health professional to place the unsigned form in the consumer's record together with the notation that while the consumer understands the nature and effect of antipsychotic medication and consents to the administration of the medication, the consumer does not want to sign a written consent form.

7.3.c. Consent is effective for ninety (90) days or until the consumer consents to a new/revised treatment plan, unless it is revoked by the consumer, whichever comes first.

7.4. Revocation of Consent. A consumer who has consented to treatment may refuse a specific treatment at any time, by stating or writing that he or she does not wish to continue that treatment. That treatment may not then be provided to the consumer, except as authorized in a psychiatric emergency. A revocation of consent shall be documented on the consent form and renders the previously given consent void.

7.5. Consent to Treatment. Except with respect to psychiatric emergencies, an individual has a right to refuse treatment. In some cases conditions exist which, if not treated, reasonably can be expected to cause permanent damage or severe pain. When considering whether to proceed with treatment in these instances, a decision shall be made in accordance with clear and objective criteria.

7.5.a. There is no statutory authority to provide treatment prior to actual commitment in the absence of informed consent. The procedures outlined in this rule are provide for use only when: (1) treatment is not refused; (2) no informed consent is forthcoming; (3) the risk of harm from failure to treat is demonstrably greater than the risks from treatment; and (4) the individual is unable to make any judgement to consent or refuse treatment.

7.5.b. When an individual is admitted to a behavioral health service, he or she shall be evaluated. The staff performing the evaluation shall employ the following procedures:

7.5.b.1. Determine whether the individual is clinically competent to understand the nature and purpose of the proposed treatment, as well as its prospective benefits and possible side effects. The examining physician and other behavioral health service staff shall utilize, and document the utilization of, accepted professional procedures for determining competency to understand the proposed treatment.

7.5.b.2. If the individual is determined to be able to make an informed decision relative to treatment, the proposed treatment shall be explained in detail and written consent to treatment shall be requested. No individual shall be asked to sign consent to treatment until the individual's competence to give consent has been determined. Treatment may be initiated if the individual gives consent, but a refusal to consent shall be honored and no treatment shall thereafter be forced upon the individual prior to receiving a written commitment order from the circuit court pursuant to a commitment hearing.

7.5.b.3. If it is determined that the individual is not capable of giving informed consent to treatment, and there is no legal representative or other advance directive to provide the consent, the examining physician shall determine whether there is a significant likelihood that the symptoms for which the treatment is proposed are likely to become either more severe or long-lasting or both if treatment is withheld, and whether the proposed treatment is likely to produce side effects which may be harmful to the individual. Proposed treatments shall be those which are commonly accepted and recognized as appropriate for the condition being treated. In every instance, the more conservative of the available treatment options shall be chosen.

7.5.b.4. If the examining physician determines that there is little risk of serious

deterioration in the absence of treatment and that the proposed treatment carries relatively little risk to the consumer, the physician shall present to another physician the facts upon which these conclusions were based.

7.5.b.5. If the other physician agrees with the recommendations, treatment may commence without consent for treatment.

7.5.b.6. All steps in this procedure, as well as all of the facts on which treatment decisions are based, shall be carefully documented in the medical record and signed by the attending physician.

7.5.c. The procedures outlined in this section are not intended to apply to those individuals who are in need of life-saving medication for chronic medical conditions such as diabetes or heart disease, who have been taking medications prior to admission and who are not actively refusing to continue the medication, notwithstanding that they may not currently be able to give consent.

§ 64-74-8. Right to Refuse Treatment.

8.1. General. As a participant in the program planning process, the consumer has the right to exercise a voice in his or her program plan and to object to or refuse aspects of the plan.

8.2. Use of Internal Discussion, Negotiation and Grievance Procedure. The consumer's right to object to or refuse treatment is recognized as legitimate, and shall be responded to in accordance with the provisions of the consumer grievance procedure if informal discussion and negotiation do not resolve differences.

8.3. Alternatives Offered and Provided. The treatment team for any consumer who has refused psychotropic medications or other recommended therapy shall meet and work toward an agreed-upon effective alternative treatment which is offered and provided if the consumer consents.

8.4. Oral Refusal Overrides Prior Written Consent. An individual consumer's oral refusal to accept medication or other treatment always overrides prior written consent except in emergency situations as defined in this rule.

§ 64-74-9. Research and Experimental Treatment. The federal regulations Protection of Human Subjects, 45 C.F.R. Part 46 (Oct. 1, 1997), are hereby adopted by reference, and all research, studies, or investigations conducted in behavioral health services shall comply with this rule.

§ 64-74-10. Seclusion and Restraints.

10.1. General. Consumers have the right to freedom from seclusion or mechanical or chemical restraints. Seclusion and restraint shall be used only where there is imminent danger that the consumer will injure himself or herself or others and only when all other less restrictive measures have been exhausted.

10.2. Seclusion Prohibited for People with Developmental Disabilities. Seclusion for developmentally disabled consumers is strictly prohibited. Only the "time-out" procedure developed

specifically for each consumer in his or her program plan in accordance with standards of the Accreditation Council on Services for People with Disabilities may be used for the developmentally disabled consumer.

10.3. Emergency Measure Only. Seclusion is an emergency control measure only and may be used only as a last resort to control imminent destructive behavior that is a threat to the consumer or others. It may be used only when the consumer has not responded to less restrictive measures and only as long as is necessary for the consumer to regain self-control. Under no circumstances may it be used as a preventive measure or for punishment.

10.4. Seclusion is a severely restrictive form of intervention. Each behavioral health service shall provide to appropriate staff annual training in commonly accepted and recognized procedures to be used as an alternative to seclusion. Training in these procedures shall be documented in personnel records. Whenever seclusion is ordered or provided, all steps taken prior to seclusion shall be documented, with reference to procedures used, which are relevant to training provided. The steps and procedures outlined below shall be followed prior to its use.

10.4.a. Examination by Physician. No consumer may be placed in seclusion until he or she is examined by the attending physician, and a discussion is held with available team members. In the event an attending physician is not immediately available, the person in charge shall discuss the situation with the team members and obtain a telephone order from the physician if the physician concurs that seclusion is required.

10.4.b. Telephone Orders. A telephone order for seclusion is valid for a maximum of eight (8) hours, notwithstanding time limitations noted below (e.g., section 10.7). Regardless of the length of seclusion and whether or not the consumer is still in seclusion, the attending physician shall examine a consumer within eight (8) hours of a telephone order for seclusion. The attending physician shall determine and document the appropriateness of seclusion, whether staff have complied with this rule regarding seclusion, and whether staff have followed and utilized training in alternative measures prior to requesting and/or instituting seclusion.

10.5. Time. The time spent in seclusion shall be the shortest time required for the consumer to regain his or her self-control.

10.6. Seclusion Inappropriate for Suicidal Consumers. Seclusion shall not be used for a consumer who is actively suicidal or for a consumer for whom constant observation has been ordered. If the physician determines that seclusion is necessary, special documentation and one-on-one observation are required.

10.7. Seclusion Orders Valid Only for Three (3) Hours. No seclusion order is valid for more than three (3) hours. Any consumer requiring seclusion beyond three (3) hours shall have his or her status reviewed by his or her treatment team and a written plan developed for responding to the consumer's crisis. Continued seclusion requires an examination and written order by a physician after every three (3) hour period. In the event an attending physician is not immediately available, the person in charge shall discuss the situation with the team members and obtain a telephone order from the physician if the physician concurs that seclusion is required. If a telephone order is obtained pursuant to Section 10.4.b above, a person may be placed in seclusion for up to three (3)

hours. If the treatment team believes the seclusion should be continued beyond the three (3) hour period, another telephone order is required if a physician is not immediately available. Within eight (8) hours of each of the two (or more) telephone orders (each lasting three hours), a physician shall document the appropriateness of the seclusion as required by Section 10.4.b above.

10.8. PRN (as needed) orders for seclusion are not permissible.

10.9. Items Entitled During Seclusion. A consumer who is placed in seclusion is entitled to clothing, a bed, a mattress, and bedding.

10.10. Supervision of Individuals in Seclusion. Any room used for seclusion shall permit constant supervision of the consumer by staff.

10.11. Seclusion Room Supervision. The person in charge of care or of the area containing the seclusion room is responsible for assuring that the following seclusion room checks and procedures are carried out:

10.11.a. Each consumer in seclusion shall be checked no less frequently than every five (5) minutes, and the seclusion room "check sheet" shall be updated and initialed to assure the presence and safety of the consumer in the seclusion room;

10.11.b. The consumer shall have access to fluids and to the toilet hourly, or more frequently if needed. Meals shall be delivered at regular meal times. Compliance with these requirements shall be documented on the check sheet; and

10.11.c. A member of the team or the person in charge of the area containing the seclusion room shall talk directly with the consumer and assess the need for continued seclusion at least every fifteen (15) minutes. The attending physician shall review and approve the documentation of assessments within eight (8) hours.

10.12. Mechanical Restraints As Emergency Measure. The use of mechanical restraints is an emergency control measure only, and may be used only as a last resort to control imminent destructive behavior that is a threat to the consumer or others and that has not responded to medications or other less restrictive measures.

10.12.a. All forms of physical restraint require constant monitoring and consideration of a consumer's physical needs and status.

10.12.b. Adequate numbers of staff are essential both for consumer monitoring and for safe placement of consumers in restraints.

10.13. Restraint Procedures for Consumers with Developmental Disabilities. Only procedures developed in accordance with standards of the Accreditation Council on Services for People with Disabilities may be used for consumers with developmental disabilities.

10.14. Examination by Physician. No consumer may be placed in mechanical restraints until he or she is examined by the attending physician and a discussion with available treatment team

members is held. Mechanical restraints may be initiated only on written order of a physician.

10.15. Mechanical Restraint Order Valid Only for Three (3) Hours. No mechanical restraint order is valid for more than three (3) hours. Any consumer requiring restraint beyond three (3) hours shall have his or her status reviewed by his or her treatment team, and the treatment team shall confer and develop a written plan which responds to the consumer's crisis. Continued use of mechanical restraints requires an examination and written order by the attending physician after every three (3) hour period in addition to the treatment team conference and plan.

10.16. PRN (as needed) orders for mechanical restraint are not permissible.

10.17. Supervision of Mechanical Restraints. If the physician determines that mechanical restraints are necessary, special documentation and one-on-one observation are necessary. The procedure for the application of mechanical restraints shall be followed to assure that no restraint is applied in a manner as to produce physical pain or damage to the consumer. Opportunity for motion and exercise shall be provided for a period of not less than ten (10) minutes during each two (2) hours in which restraint is employed.

10.18. Metal Handcuffs Unacceptable. Metal handcuffs are not considered an acceptable form of restraint for consumers and shall not be used for that purpose.

10.19. Continued Assessment. A team member or person in charge of the unit or shift shall talk directly with the consumer and assess the need for continued restraint at least once every fifteen (15) minutes.

10.20. Punishment or Convenience. Mechanical Restraints shall not be used as punishment or for the convenience of staff.

10.21. Limitation on Use of Chemical Restraint. Drugs or medications shall not be used as punishment, for the convenience of staff, as a substitute for adequate staffing, or as a substitute for a treatment plan. Drugs and medication may only be administered pursuant to informed consent.

10.22. Documentation. In every instance in which emergency control measures are used for any length of time and each time the consumer is reexamined and a new order written (every three (3) hours), a full report shall be made by the attending physician, describing in detail the rationale for the decision of the treatment team and the failure of less restrictive measures to resolve the crisis.

10.23. Copies. Copies of the attending physician's report shall be sent to the clinical director and shall be attached to the consumer's medical record.

10.24. Minimum Required Documentation. The following minimum required documentation is necessary for seclusion or restraint:

10.24.a. The attending physician's written order for seclusion or restraint shall be placed on the doctor's order sheet in the consumer's record. Staff securing a verbal order for seclusion shall document the date and time the attending physician was called and the reason for the order;

10.24.b. Documentation stating the time that the consumer was placed in seclusion or restraint, the time the physician examined the consumer, and the time the consumer was released;

10.24.c. A full report by the staff using emergency control measures of each and every incident in which the emergency control measures are used, describing the situation, other measures taken, the failure of less restrictive measures and the rationale for seclusion. The staff person responsible for the unit or shift shall see that this report is completed and sent to appropriate parties, including the clinical director, and attached to the consumer's medical record;

10.24.d. A reflection of the decision of the treatment team for handling the crisis in the consumer's program plan;

10.24.e. A note on the twenty-four (24) hour report;

10.24.f. The five (5) minute check sheet for use of seclusion;

10.24.g. Progress notes from other disciplines if applicable; and

10.24.h. Hourly assessment of the continued need for seclusion or restraints by a team member or supervisor of the unit or shift.

10.25. Trial Release Procedure for Seclusion and Restraint. Seclusion and restraint are intended to provide external controls for the protection of the consumer or to prevent the consumer from injuring others. Continued use of the controls beyond the time when they are needed is inappropriate, regardless of the maximum period of three (3) hours allowed. It is the responsibility of the staff person in charge to assure that the seclusion or restraint measures are stopped when the behavior of the consumer makes their continued use unnecessary.

10.25.a. When it is clear that the consumer has regained self-control, the person in charge of the area in which restraints have been applied shall authorize, in writing, release for a trial period prior to the expiration of the three (3) hour period allowed. Under these circumstances, staff should continue close observation of the consumer. Restraints shall be removed in a graduated, stepwise manner, negotiated with the consumer as part of an ongoing assessment of the consumer's clinical state. An inconsistent, impulsive, non-graduated, or non-negotiated "on-again, off-again" approach shall be avoided.

§ 64-74-11. Confidentiality.

11.1. Confidential Information

11.1.a. Communications and information obtained in the course of treatment or evaluation of any consumer is considered to be confidential information, including: the fact that a person is or has been a consumer; information transmitted by a consumer or his or her family for purposes relating to diagnosis or treatment; information transmitted by persons participating in the accomplishment of the objectives of diagnosis or treatment; all diagnoses or opinions formed regarding a consumer's physical, mental or emotional condition; any advice, instructions or prescriptions issued in the course of diagnosis or treatment; and any record or characterization of

these matters. Confidential information does not include information which does not identify a consumer, information from which a person acquainted with a consumer would not recognize the consumer, and encoded information from which there is no possible means to identify a consumer.

11.1.b. In order to protect the consumer from demeaning remarks about his or her condition, medical and behavioral health care professionals, staff and other employees shall not discuss a consumer's assessment, diagnosis, treatment, or any other aspects of his or her condition among themselves unless this discussion directly relates to the consumer's treatment.

11.2. Disclosure of Confidential Information.

11.2.a. Confidential information may be disclosed:

11.2.a.1. In a proceeding under WV Code § 27-5-4 to disclose the results of an involuntary examination made pursuant to WV Code §§ 27-5-2 or 27-5-3;

11.2.a.2. In a proceeding under WV Code § 27-6A-1 et seq. to disclose the results of an involuntary examination made pursuant thereto;

11.2.a.3. Pursuant to an order of any court based upon a finding that the information is sufficiently relevant to a proceeding before the court to outweigh the importance of maintaining the confidentiality established by this section. Once a subpoena is received it is the duty of the custodian of the records to request a determination from the court having jurisdiction to make this finding before the records are provided;

11.2.a.4. To protect against a clear and substantial danger of imminent injury by a consumer to himself or herself or to another; and

11.2.a.5. For treatment or internal review purposes, to staff of the behavioral health service where the consumer is being cared for or to other health professionals involved in treatment of the consumer.

11.2.b. Consumers shall be informed upon the commencement of any contact with medical or behavioral health professional that their rights to confidentiality are limited in the ways set forth in this rule.

11.3. Authorization for Disclosure.

11.3.a. All consents for the transmission or disclosure of confidential information, regardless of the mode of transmission, shall be in writing and signed by the consumer or by his or her legal representative. Every person signing an authorization shall be given a copy.

11.3.b. Every person requesting an authorization shall inform the consumer or authorized representative that refusal to give an authorization will in no way jeopardize his or her right to obtain present or future treatment except where and to the extent disclosure is necessary for treatment of the consumer or for the substantiation of a claim for payment from a person other than the consumer.

§ 64-74-12. Right to Unrestricted Communication.

12.1. Generally. Every consumer has the right to unimpeded and private communication with whomever the consumer chooses by mail, telephone, visits, or otherwise, except as specified in this rule.

12.2. Restrictions. Any deviation from the rights afforded by subsection 12.1 of this rule can only be authorized by the interdisciplinary team or the attending physician for a time specified by the team. A complete report relative to the restriction of telephone or mail rights and the reasons therefore shall be made a part of the consumer's medical record, signed and dated by the consumer's attending physician, and reflected in the consumer's treatment plan. Restrictions of mail and telephone rights shall expire in thirty (30) days.

§ 64-74-13. Consumers' Labor, Earnings and Funds.

13.1. Consumer Labor Generally.

13.1.a. No consumer may be required to perform uncompensated labor which involves the operation and maintenance of the behavioral health service. Privileges or discharge from the service shall not be conditional upon the performance of labor.

13.1.b. Consumers may be voluntarily employed in labor which involves the operation and maintenance of the behavioral health service, if the labor is compensated in accordance with the requirements of relevant State and federal law and regulations.

13.1.b.1. Consumers who are employed to perform work of economic benefit to the service shall be paid wages which are commensurate with those paid other workers for essentially the same type, quality and quantity of work.

13.2. Vocational Training/Employment. Consumers may perform vocational training tasks which do not involve the operation and maintenance of the service, so long as an assignment:

13.2.a. Is an integrated part of the consumer's interdisciplinary program plan;

13.2.b. Has been approved as a program activity by the professional responsible for the vocational training program; and

13.2.c. Is supervised by a staff member.

13.3. Sheltered Workshops. Approval for a sheltered workshop may be obtained for a specific workshop program. Sheltered workshops operated by a service are required to be in compliance with applicable State and federal laws, rules and regulations.

13.4. Training and Evaluation Program. A certificate can be obtained for programs which provide competent instruction and supervision and are designed to determine a working consumer's potential and to teach adjustment to a work environment or the skills related to one (1) or more types of work. The duration of the evaluation and training shall depend upon the total facts of the

situation, but in no case shall exceed twelve (12) months. Time spent in an employment relationship in the service, prior to the effective date of participation in the training program, shall be counted in determining the duration of the work evaluation and training. It is not permissible to place a consumer who has been involved in any work situation within the service for more than twelve (12) months in a work and training evaluation program without pay.

13.5. Personal Housekeeping. Consumers may be required to perform personal housekeeping tasks, such as making their bed, tidying their room, doing their laundry, etc.

13.6. Access to Personal Funds. Consumers shall have unlimited access to their funds except as provided by this rule or by West Virginia law.

13.6.a. Any service which establishes a system to be payee for consumers' Supplemental Security Income (SSI) or consumers' Disability Insurance (SSDI), or both, shall have written policies and procedures to ensure reasonable personal access to funds. The policies and procedures shall comply, at a minimum, with requirements imposed by federal rules promulgated by the Social Security Administration.

13.6.b. If a service is a payee for SSI or SSDI, there shall be information in the treatment record describing reasons for the service serving as a payee. The record shall indicate why the consumer needs a payee and why no other source was available or was chosen to be the payee. The necessity of a payee shall be documented quarterly. If there is no justification for a payee, the service shall assist the consumer in applying to be his or her own payee.

13.6.c. If a service is a payee, the service shall maintain records of income and expenses. Each consumer for whom the service is a payee shall receive a statement of income and expenses monthly.

13.6.d. Consumers who have been adjudicated incompetent and have had a conservator or other individual with financial authority appointed shall have the same access to their funds as set forth in subdivision 13.4 of this rule, subject to reasonable limitations by his or her conservator.

13.6.e. The treatment record of a consumer who has an appointed conservator or other individual with financial authority shall document this appointment and the reasons for the appointment. The need for a conservator shall be evaluated quarterly. If the service believes the consumer no longer requires an appointed conservator or other financial authority, the service shall assist the consumer in applying for release.

13.6.f. If a consumer who has an appointed conservator or other individual with financial authority believes he or she does not have sufficient access to his or her funds, the service shall evaluate the grievance and assist the consumer in filing to seek redress.

13.6.g. A consumer, conservator, or other court appointed financial authority may be required to pay for care and treatment provided by a service.

13.6.h. Any consumer who has a payee for SSI or SSDI, or has a court appointed conservator or other financial authority shall receive training in money management, unless the

treatment record indicates the consumer has refused such the training or will not benefit from such the training.

13.6.i. The service shall cease to be payee for SSI or SSDI and shall assist the consumer in applying for release from having a payee, conservator, or other court appointed financial authority, if the consumer demonstrates ability at money management.

13.7. Notification. All consumers assigned to a work situation shall be informed of the rights provided by this rule. The information shall be provided as follows:

13.7.a. The consumer workers and their responsible relative or legal representative may be notified in writing of these rights; and

13.7.b. Written notification of rights under this rule shall be posted in every licensed living unit.

§ 64-74-14. Legal Representative.

14.1. Generally. On admission to a behavioral health service, it shall be determined if the consumer has a legal representative. If the consumer has a legal representative, identifying information shall be entered in the consumer's record. The responsibilities and limitations of the legal representative shall be listed.

14.2. Protection of Rights. The behavioral health service shall not honor requests or demands of a consumer's legal representative which are in excess of the detailed responsibilities and limitations of the legal representative.

14.3. Reporting Violations. The behavioral health service shall, with written permission of the consumer, report any violations of the legal representative's responsibilities and limitations. Reports shall be provided to the consumer's choice of advocate, attorney, or both.

§ 64-74-15. Employee Responsibilities.

15.1. Duty of All Employees. Every employee has the responsibility to assure that all rights afforded to consumers by applicable State and federal laws, rules and regulations, including this rule, are protected and afforded to consumers.

15.2. Abuse and Neglect. No employee shall verbally or physically abuse, or neglect any consumer.

15.3. Sexual Harassment. Employees shall not engage in sexual harassment of consumers.

15.4. Mandatory reporting. Every employee has a duty to report any incident of actual or suspected abuse or neglect to the administrator and to adult protective services workers or child protective service workers.

15.5. Training of Employees. The administrator has the duty to train and educate all new

employees and all current employees on a periodic and consistent basis on the content of this rule so that all employees are thoroughly familiar with it.

§ 64-74-16. Juveniles' Additional Rights.

16.1. Separation. No consumer under eighteen (18) years of age shall be housed in any area licensed or operated by a behavioral health service and also occupied by any consumer over eighteen (18) years of age. Except that, individuals above the age of eighteen (18) who have not yet been emancipated can room with persons under the age of eighteen (18).

16.2. Education. Any behavioral health service serving consumers under twenty-one (21) years of age shall advocate for education for the consumers in conformity with applicable portions of relevant State or federal law.

16.3. Family Contact. The behavioral health service shall make every effort to assure appropriate family contact and communication between consumers under the age of eighteen (18) and their family members. These efforts, and the results of the efforts, shall be documented.

16.4. Inclusion. All rights under this rule apply equally to consumers under the age of eighteen (18).

16.5. The service shall establish simple and understandable rules which set the limits of behavior required for the protection of a group and individual consumers within the group. The rules shall be written for consumers under the age of eighteen (18) and staff serving these consumers.

16.5.a. No consumer under the age of eighteen (18) shall be withdrawn from any therapy program as a disciplinary measure.

§ 64-74-17. Consumer Advocacy and Grievance Procedure.

17.1. Each service shall offer clear and timely review of any alleged violation or infringement of the rights afforded by this rule.

17.2. During the admission process, consumers and their families shall be advised of their right to initiate a grievance concerning the quality of care or violation of their rights during time they receive service.

17.2.a. Consumers already being provided service shall be advised of the grievance policy and procedure at their next treatment planning meeting.

17.2.b. Each service affected by this rule shall conduct regular inservice training sessions for staff covering the grievance procedure.

17.2.c. Consumers shall be advised that if they believe their rights are being violated, they should talk to an advocate such as their doctor, social worker, therapist, nurse, other external advocate, or individual with whom they feel comfortable. Staff of any service affected by this rule shall assist a consumer in the initiation of the grievance process.

17.2.d. Each consumer shall be provided a brief, easily understood, statement of consumer rights, the service's grievance policy, and the name and telephone number of an external advocate.

17.2.e. Failure of a consumer to file a grievance shall not prevent pursuit of other relief.

17.3. Any complaint which does not contain allegations of abuse or neglect should be resolved through an attempt at informal problem resolution, including mediation.

17.4. Initiating the Grievance Process. The grievance may be initiated verbally or in writing. Grievance forms shall be made available to a consumer on request, by any person employed by the service.

17.4.a. Individuals with a grievance shall not be prevented from using the grievance procedure.

17.4.b. Individuals always have the right to withdraw grievance at any step in the process.

17.4.c. The designated grievance representative employed by the service shall offer assistance to any consumer unable to write the complaint and shall assure that the grievance report is fair and accurately represents the individual's concern.

17.4.d. Once finalized, the grievance shall be delivered by the designated grievance representative employed by the service to the appropriate designated internal committee.

17.5. Allegations of Abuse, Neglect, or other Serious Breach of Consumer Rights. The designated grievance representative employed by the service shall interview the grievant upon receipt of a grievance. A report of all violations or suspected violations of a consumer's rights accorded by this rule shall be made within twenty-four (24) hours to the appropriate designated internal committee of the service and the administrator of the service. In the event of abuse or neglect or suspicion of abuse or gross neglect, the appropriate designated committee and administrator shall be immediately notified following the interview.

17.5.a. Any reasonable suspicion of abuse or neglect shall be reported to civil and criminal authorities in accordance with the applicable West Virginia Adult Protective Services Act or West Virginia Child Protective Services Act, in addition to reporting to the appropriate designated internal committee and the administrator.

17.5.b. Reporting incidents of abuse or neglect in accordance with the Adult Protective Services Act or the Child Protective Services Act does not relieve the service of the obligation to respond to the grievance filed, monitor staff, and to enforce this rule. The duty of the service to conduct an investigation under this rule is independent of any investigation conducted under those Acts or by law enforcement officers or the prosecuting attorney.

17.6. Complaints of violations of rights, once filed, require a written administrative response. The service may delay or defer its investigation until law enforcement authorities have completed their investigation only if the administrator of the service concludes that a delay will not adversely

affect the health and safety of the grievant or other consumers.

17.7. Formal Complaints and Resolution. The appropriate designated committee of the service shall convene within five (5) working days of receiving a report of a grievance, to investigate the allegations contained in the written grievance.

17.7.a. The appropriate designated committee shall ascertain the facts by communicating with all parties involved in the complaint. The aggrieved, with his or her representatives shall have the opportunity to appear in person before the committee.

17.7.b. The appropriate designated committee shall render a decision on the grievance and report to the administrator of the service within ten (10) working days following the initial meeting convened for the purpose of hearing the grievance.

17.8. The governing board of the service, or the board member or members who have been appointed by the board as consumer grievance hearing officer or officers to render a decision on behalf of the board, shall convene within ten (10) working days after receipt by the administrator of the recommendation and report of the appropriate designated committee, review all evidence gathered, request any additional information, and to render a decision concerning the grievance. The aggrieved individual, with his or her representatives, shall have the opportunity to appear before the governing board or consumer grievance hearing officer or officers, as applicable, if he or she so chooses.

17.8.a. If the governing board or consumer grievance hearing officer or officers find evidence to substantiate the grievance, the board or a consumer grievance hearing officer shall notify all interested parties, and the governing body shall take appropriate action.

17.8.b. If the grievance is disapproved by the governing board, or consumer grievance hearing officer or officers, the board or a consumer grievance hearing officer shall:

17.8.b.1. Notify all interested parties of the grievant's right to request a hearing by the Secretary or to bring action in circuit court against the service;

17.8.b.2. Provide information on the process for requesting a hearing by the secretary; and

17.8.b.3. Provide the reason that no substantiation of the grievance was made.

17.9. A grievant may, after receipt of the decision on his or her grievance, request a hearing by the Secretary or bring action in circuit court against the service.

17.9.a. A hearing held by the Secretary shall be held in accordance with West Virginia Code Chapter 29A. Articles 4 and 5, and the Rules for Procedure for Contested Case Hearings and Declaratory Rulings, 64 CSR 1, except that: the "Director" defined in such rules shall be the Secretary; and the Secretary may at his or her discretion deny a hearing request, in which case the grievant may bring an action in circuit court against the service.

17.9.b. The governing body of the behavioral health service shall be a party to a hearing by the secretary.

17.9.c. The final order entered by the Secretary after a hearing shall be binding upon the parties unless appealed in accordance with West Virginia Code Chapter 29A, Articles 5 and 6.

§ 64-74-18. Severability. The provisions of this rule are severable. If any portion of this rule is held invalid, the remaining provisions remain in effect.

The Joint Commission on Accreditation of Healthcare Organizations

1995

Comprehensive Accreditation Manual for Hospitals

- Standards
- Scoring Guidelines
- Aggregation Rules
- Decision Rules

Contents

Standards

Foreword

Substance, form, clarity. These critical ingredients of expression underpin the ability of any communicator to influence the thinking, behavior, and actual performance of others. In this special new *Comprehensive Accreditation Manual for Hospitals* (*CAMH*), the Joint Commission is the communicator, and we have worked hard to provide the substance, form, and clarity necessary to help hospitals meet their new public accountabilities.

The substance of this *Manual* is the inspiration and final output of the Joint Commission's Agenda for Change. No longer a simple Agenda, the panoply of planned changes to transform the accreditation process has happened. The performance-based standards, scoring guidelines, aggregation rules, and decision rules that are woven together in this text bring together the overarching concepts that have guided the Joint Commission's vision for the future.

Much of that vision is admittedly simplistic, but what it acknowledges is that we in health care are only now beginning to embrace self-evaluation as a major opportunity for continuous improvement.

The principles embodied in this *Manual* are straightforward:

- Standards should emphasize actual performance, not simply the capacity to perform.
- Standards should address what counts: the care provided to the patient and the management of the organization. These are what make a difference in quality for the patient.
- In these broad areas of patient care and management, standards should focus on important activities, or functions, that significantly influence, directly or indirectly, eventual patient outcomes. Simply stated, hospitals should be doing the right things and doing them well.
- The performance expectations reflected in the standards should be set forth in a quality improvement context. The objective is not to punish competent practitioners and staff, but rather to improve the internal systems and work environment that help them and their organization realize their primary goal. That goal is excellent care that continues to improve over time.

The new standards framework, of which this *Manual* represents the culmination, is also a pragmatic framework. The organization functions that are addressed are common to *virtually* all types of health care organizations. As such, the functions and related standards simply reflect what the public expects hospitals and others to do and do well.

The standards themselves are framed primarily as performance objectives—performance objectives which, although always subject to refinement, are unlikely to change substantively over time. What will change and expand is the richness and diversity of ways through which hospitals achieve the intents of individual standards. The examples expressed in this *Manual's* scoring guidelines represent a further expansion of the creative approaches being used to meet performance objectives.

Since 1992, the *Accreditation Manual for Hospitals* has been a work in progress. We have now concluded the principal transition from a manual that articulated requirements for structures and processes as ends in themselves, to one that relates performance of essential processes to patient outcomes. That transition has permitted us to reduce the number of standards in the *Manual* by more than two-thirds over the four-year period.

Patient Rights and Organizational Ethics

Preamble

The goal of the function is to recognize and respect each patient in the provision of care in accord with fundamental human, civil, constitutional, and statutory rights to improve patient outcomes.

The organization respects the rights of patients, recognizes that each patient is an individual with unique health care needs, and, because of the importance of respecting each patient's personal dignity, provides considerate, respectful care focused on the patient's individual needs.

The organization affirms the patient's right to make decisions regarding his or her care, including the decision to discontinue treatment, to the extent permitted by law.

The organization assists the patient in the exercise of rights and informs the patient of any responsibilities* incumbent on him or her in the exercise of those rights.

The performance-improvement framework in the "Improving Organizational Performance" chapter of this *Manual* (page 219) is used to design, measure, assess, and improve the organization's performance of the patient rights and organizational ethics function.

The terms used in this chapter are defined as they are used in the context of the patient-focused function and may not reflect common dictionary usage.

* See the "Education" chapter of this *Manual* (page 189) for standards relating to educating the patient about his or her rights and responsibilities.

For example, there are hospital procedures for notifying the child's primary care physician if her parents are members of a health maintenance organization. As the child approaches discharge, she may require a service (for example, a prosthetic device fabrication) that is not available in the hospital but is available in a wholly-owned subsidiary of the hospital. If so, the parents will be informed of that relationship while the referral is being planned just to ensure they have no other prosthetic group practice they wish to use or that is required by their health maintenance organization.

The child's stay in the hospital from admission to emergency service to discharge from the pediatric unit is evaluated as part of the hospital's utilization management program, and her length of stay in the various component units is compared with data available from an external utilization management service. If the child had died, her parents would have been consulted about their wishes regarding organ or tissue donation.

If the child's condition had not responded to the medication regimen prescribed and the physician staff believed she could be helped by one of the hospital's medication clinical trials, hospital procedures would have been implemented requiring the full knowledge and consent of the parents relative to placing the child in the trial.

Staff rights issues are illustrated on the flowchart, and the requirements to consider such issues are addressed in the standards and scoring guidelines for HR.5 through HR.5.1.2 in the "Management of Human Resources" chapter of this *Manual* (page 372). See also flowcharts for "Assessment of Patients" (page 86), "Care of Patients" (pages 126 and 127), "Education" (page 190), "Continuum of Care" (page 208), and the chapters in Section 2 of this *Manual*.

- As appropriate, patients and their families are informed how to gain access to the ethics committee and ethical issue resolution process.
- The corporate entity of a multihospital system establishes policies that explain the framework bioethics mechanism required for each subentity based on the patient populations served. Each subentity establishes specific policies and procedures and reports activity, as required, to the corporate entity.
- An organization serving the Native American population has policies and procedures in place to address situations in which ethical care issues arise. The policies and procedures are based on tribal law and customs that reflect the specific needs of this population.

2. In an organization providing biopsychosocial care and treatment services, the statement of patient rights promotes their provision in a way that respects and fosters the patient's sense of dignity, autonomy, positive self-regard, and civil rights, and involvement in his or her own care. The individual's involvement includes perceptions of his or her strengths, weaknesses, and resources; relevant demands of his or her environments; and the requirements and expectations for participation by service providers and the individual.

This includes educating the patient regarding his or her psychiatric, physical, and functional diagnoses and prognoses. The communication of information regarding assessment and treatment options is done in a manner that facilitates comprehension and understanding and that elicits the individual's active participation in forming the rehabilitation plan.

Examples of Evidence of Performance — RI.1

- Document review of policies and procedures or other mechanisms for addressing ethical issues
- Interviews with organization leaders
- Interviews with clinical staff
- Meeting minutes of ethics committee
- Medical record documentation of resolution of actual ethical issues

Scoring for RI.1

Score 1 Evidence indicates that the organization has a functioning mechanism(s) in place that addresses the issues listed in the intent.

AND

A representative staff sample was able to explain implementation 91% to 100% of the time.

Score 3 Evidence indicates that the organization has a functioning mechanism(s) in place; however, one of the issues listed in the intent is not addressed.

OR

A representative staff sample was able to explain implementation only 51% to 75% of the time.

Score 5 Evidence indicates that the organization has a functioning mechanism(s) in place; however, more than one of the issues listed in the intent is not addressed.

OR

A representative staff sample was able to explain implementation less than 51% of the time.

OR

The organization does not have a functioning mechanism in place.

Standard

RI.1.1 Mechanisms to respect the patient's rights to treatment or service subject to the hospital's capability, mission, and applicable law and regulation.

A 1 2 3 4 5 NA

To ensure respectful, responsive care for the end-of-life patient, staff members foster the patient's comfort and dignity; as desired by the patient or designated representative, provide appropriate treatment for primary and secondary symptoms; effectively manage pain; and respond to the psychosocial, spiritual, and cultural-value concerns of the patient and, when appropriate, the patient's family.

To ensure compatibility with the organization's mission and resources, to gain diverse input, and to guarantee cross-organizational communication, the mechanisms are developed, approved, and maintained in a collaborative manner by the organization's leaders and others.

Examples of Evidence of Performance — RI.1.2

- Document review of policies and procedures or other mechanisms concerning
  - patient rights and responsibilities;
  - informed consent;
  - advanced directives;
  - research, investigation, and/or clinical trials;
  - resolution of conflict in care or treatment decisions;
  - withholding resuscitation, and forgoing or withdrawing life-sustaining treatment; and
  - pain management
- Interviews with organization leaders
- Interviews with clinical staff
- Interviews with patients and families
- Review of patient medical records

Scoring for RI.1.2

Score 1 Evidence indicates that 100% of medical records reviewed and 100% of interviews conducted with patients and families show that a functioning mechanism(s) exists to encourage and promote the patient's and, when appropriate, the family's involvement in care.

AND

Evidence also indicates that the supporting mechanism(s) has been developed, approved, and is maintained in a collaborative manner by the organization's leaders and others.

Score 2 Evidence indicates in only 95% to 99% of medical records reviewed and in only 95% to 99% of interviews with patients and families that a functioning mechanism(s) exists to encourage and promote the patient's and, when appropriate, the family's involvement in care.

OR

Evidence indicates that the mechanism(s) is not developed, approved, and maintained in a collaborative manner.

Score 3 Evidence indicates in only 90% to 94% of medical records reviewed and in only 90% to 94% of interviews with patients and families that a functioning mechanism(s) exists to encourage and promote the patient's and, when appropriate, the family's involvement in care.

Score 4 Evidence indicates in only 80% to 89% of medical records reviewed and in only 80% to 89% of interviews with patients and families that a functioning mechanism(s) exists to encourage and promote the patient's and, when appropriate, the family's involvement in care.

Score 5 Evidence indicates in less than 80% of medical records reviewed and in less than 80% of interviews with patients and families that a functioning mechanism(s) exists to encourage and promote the patient's and, when appropriate, the family's involvement in care.

Standard

RI.1.2.1 obtaining informed consent;

A 12345 NA

Intent of RI.1.2.1

The patient, and when appropriate the family, is given a clear, concise explanation of the patient's condition and any proposed treatment(s) or procedure(s), the potential benefit(s) and drawback(s) of the

Examples of Evidence of Performance — RI.1.2.2

- Document review of policies and procedures or other mechanisms concerning
  - patient rights and responsibilities;
  - informed consent;
  - advanced directives;
  - research, investigation, and/or clinical trials;
  - resolution of conflict in care or treatment decisions;
  - withholding resuscitation, and forgoing or withdrawing life-sustaining treatment; and
  - pain management
- Interviews with organization leaders
- Interviews with clinical staff
- Interviews with patients and families
- Review of patient medical records

Scoring for RI.1.2.2

Score 1 The organization has a functioning mechanism in place to actively involve the family and/or surrogate decision maker(s) in facilitating care when appropriate.

Score 5 The organization does not have a functioning mechanism in place to actively involve the family and/or surrogate decision maker(s) in facilitating care when appropriate.

Standard

RI.1.2.3 decisions to participate in investigational studies and/or clinical trials;

A 1 2 3 4 5 NA

Intent of RI.1.2.3

The patient has the right to be informed of any investigational, research, or educational activities related to his or her care. The patient also has the right to refuse to participate in any such activity and to review that decision periodically.

Example of Implementation — RI.1.2.3

An Institutional Review Board (IRB) reviews the organization's conduct of investigational studies, research, and clinical trials.

When a patient has been selected for participation in an investigational study, research project, or clinical trial, the patient is informed of the focus of the activity as it relates to his or her care. Directed by an informed consent process developed by the IRB, the patient is allowed to refuse participation and assured that the decision will in no way affect quality of care. (See also RI.3.)

Examples of Evidence of Performance — RI.1.2.3

- Document review of policies and procedures or other mechanisms concerning
  - patient rights and responsibilities;
  - informed consent;
  - advanced directives;
  - research, investigation, and/or clinical trials;
  - resolution of conflict in care or treatment decisions;
  - withholding resuscitation, and forgoing or withdrawing life-sustaining treatment; and
  - pain management
- Interviews with organization leaders
- Interviews with clinical staff
- Interviews with patients and families
- Review of patient medical records

Scoring for RI.1.2.3

Score 1 The organization has a functioning mechanism in place to address the patient's choice to participate or refuse to participate in investigational, research, or educational activity related to his or her care.

training in this area or by the attending physician. The course of discussion, including any educational materials used, and its outcome documented in the medical record. At anytime throughout the episode of care, the patient and/or surrogate decision maker (if appropriate) may review and modify the advance directives.

Examples of Evidence of Performance — RI.1.2.5

- Policies and procedures
- Decision algorithms (if they exit)
- Document review of policies and procedures or other mechanisms concerning
  - patient rights and responsibilities;
  - informed consent;
  - advanced directives;
  - research, investigation, and/or clinical trials;
  - resolution of conflict in care or treatment decisions;
  - withholding resuscitation, and forgoing or withdrawing life-sustaining treatment; and
  - pain management
- Interviews with organization leaders
- Interviews with clinical staff
- Interviews with patients and families
- Review of patient medical records

Scoring for RI.1.2.5

Score 1 Evidence indicates that the organization has a functioning mechanism(s) in place to address the patient's right to formulate advance directives.

Score 5 Evidence indicates that the organization does not have a functioning mechanism(s) in place to address the patient's right to formulate advance directives.

Standards

RI.1.2.6 decisions to withhold resuscitative services; A 1 2 3 4 5 NA

RI.1.2.7 decisions to forgo and/or withdraw life-sustaining treatment; and A 1 2 3 4 5 NA

Intent of RI.1.2.6 and RI.1.2.7

No single mechanism can anticipate the various situations in which difficult decisions will need to be made about withholding resuscitative services or forgoing or withdrawing life-sustaining treatment. However, organizations can develop the framework for a decision-making mechanism. Such a framework includes activities designed to assist the organization in identifying its position on initiating resuscitative services and using and removing life-sustaining treatment. These mechanisms will need to conform to the legal requirements of the organization's jurisdiction. Additionally, the mechanisms address situations in which such decisions are modified as the patient progresses through the episode of care.

Organizational activities that provide a framework for the decision-making mechanisms for withholding resuscitative services or forgoing or withdrawing life-sustaining treatment offer guidance to health professionals on the ethical and legal issues involved in such decisions. These activities also decrease the uncertainty about the practices permitted by the organization. It is vital that the mechanisms guiding such decisions be formally adopted by the organization's medical staff and approved by the governing body to ensure the mechanisms' consistency and accountability for the decisions made.

Example of Implementation — RI.1.2.6 and RI.1.2.7

When a decision must be made to withdraw life-sustaining treatment or withhold resuscitative services, the clinician is able to refer to policies and procedures, developed by the medical staff (and others in collaboration) and approved by the governing body, to provide direction.

- Interviews with organization leaders
- Interviews with clinical staff
- Interviews with patients and families
- Review of patient medical records

Scoring for RI.1.2.8

Score 1 The organization has functioning mechanisms in place to address the involvement of patients and, when appropriate, family members and/or surrogate decision makers in every aspect of care during the end of life and to support specific care issues including pain management.

Score 5 The organization does not have functioning mechanisms in place to address the involvement of patients and, when appropriate, family members and/or surrogate decision makers in every aspect of care during the end of life and to support specific care issues including pain management.

Standards

RI.1.3 *Mechanisms that provide for consideration of the patient's other needs, including*

RI.1.3.1 *confidentiality of information;*

A 1 2 3 4 5 NA

RI.1.3.2 privacy and security;

A 1 2 3 4 5 NA

RI.1.3.3 communication needs; and

A 1 2 3 4 5 NA

RI.1.3.4 resolution of complaints.

Intent of RI.1.3 Through RI.1.3.4

In addition to the impact of cultural, psychosocial, and spiritual beliefs on the course of the patient's treatment, other issues of respect come into play:

- Privacy and security;
- The patient's right to voice complaints regarding the care received and to have those complaints reviewed and, when possible, resolved;
- The availability of mechanisms to ensure effective communication* for each patient served;
- Mechanisms to ensure that the needs of the hearing and speech impaired are addressed; and
- The right to confidentiality of information.

*** effective communication** Any form of communication (for example, writing or speech) that leads to demonstrable understanding.

Example of Implementation — RI.1.3.1

Policies and procedures, based on applicable law and regulation, address confidentiality of patient information. The patient is informed of the organization's policy on confidentiality at the time of admission.

Example of Implementation — RI.1.3.2

Partitioning in patient rooms affords privacy and respect without visual obstruction to the nursing staff.

In the emergency department, cubicle curtains assure visual privacy, while the spacing of stretchers and examination areas affords auditory privacy.

At outpatient sites, patients are interviewed out of the hearing range of patients in the waiting room.

Procedures for bathing, positioning, and the use of bed pan and bedside commodes are developed to assure patient privacy and comfort in all situations.

Locked storage areas are available for the securing of some personal items; however, patients are encouraged upon admission not to store valuables on hospital premises.

Score 5 The organization does not have a functioning mechanism in place addressing the resolution of complaints from the patient and family.

Standard

RI.2 The organization, with the collaborative participation of the medical staff, has established and implemented a policy and mechanism(s) for the procurement and donation of organs and other tissues.

A 12345 NA

Intent of RI.2

The mechanism addressing procurement and donation of organs and other tissues includes at least the following:

- Criteria for identifying potential organ and tissue donors.
- A mechanism for notifying the family of each potential organ or tissue donor of the option to donate or to decline to donate any organs or tissues as well as a mechanism for recording the decision.
- The use of discretion and sensitivity, as appropriate, to the circumstances, beliefs, and desires of the families of potential donors.
- Procedures for directly notifying organ procurement organizations of the potential availability of a human heart, kidney, liver, lung, or pancreas and, as applicable, for directly notifying tissue banks of the potential availability of other organs and tissues. In Department of Defense hospitals, Veterans Affairs Medical Centers, or other federally administered health care agencies, such notification procedures are carried out in accordance with procedures approved by the respective agency.
- If a human heart, kidney, liver, lung, pancreas, or other tissue is procured within a nonfederal organ or tissue procurement organization, the organization is a member of the Organ Procurement and Transplantation Network established under section 372 of the Public Health Service Act and abides by its rules and regulations. If such organs or other tissues are procured in Department of Defense hospitals, Veterans Affairs medical centers, or other federally administered healthcare agencies, such organizations are appropriately designated for this activity by the respective agency.
- The organization identifies the organ or tissue procurement agency with which it is affiliated.
- The organization can provide forms that have been completed by patients and/or their families that indicate that they accept the patients' becoming potential organ or tissue donors. There is also evidence that the families have declined patients' becoming potential organ or tissue donors (for example, staff members document this decision in the patients' medical records).
- The organization can provide lists of potential organ donors that have been sent to organ or tissue procurement organizations.

Example of Implementation — RI.2

Specially trained members of the organization's bioethics staff act as counselors for the families of potential donors and interface with the appropriate agencies.

Examples of Evidence of Performance — RI.2

- Document review of policies and procedures or other mechanisms concerning procurement and donation of organs and other tissues
- Contract or affiliation agreement with organ or tissue procurement agency
- Lists of potential organ donors
- Interviews with clinical staff
- Review of patient medical records
- Interviews with patients and families

Aggregation Summary

Enter A score here

A **Enter the worst score of all the A's left of or under the solid bar. Do not use the scores right of the bar.**

Enter grid element score

The A score is the score for the Patient Rights grid element.

Patient Rights and Organizational Ethics	
Patient Rights	
Organizational Ethics	

Scoring for RI.4

Score 1 The organization has established and implemented a code of ethical behavior.

Score 5 The organization has not established and implemented a code of ethical behavior.

Scoring for RI.4.1

Score 1 The code of ethical behavior addresses ethical billing practices; resolution of conflicts associated with patient billing; ethical marketing practices; and ethical admission practices.

Score 5 The code of ethical behavior does not address ethical billing practices; resolution of conflicts associated with patient billing; ethical marketing practices; and ethical admission practices.

Scoring for RI.4.2

Score 1 The code of ethical behavior addresses potential conflicts of interest in contractual relationships between the organization being surveyed (including the governing body members and other leadership) and other organizations.

Score 5 The code of ethical behavior does not address potential conflicts of interest in contractual relationships between the organization being surveyed (including the governing body members and other leadership) and other organizations.

Aggregation Summary

Enter A score here

A Enter the worst score of all the A 's left of or under the solid bar. Do not use the scores right of the bar.

Enter grid element score

The A score is the score for the Organizational Ethics grid element.

Patient Rights and Organizational Ethics	
Patient Rights	
Organizational Ethics	

Paridy N: Complying with the patient self-determination act: legal, ethical, and practical challenges for hospitals. *Hospital and Health Services Administration* 38: 287–296, Summer 1993.

Discusses PSDA history, why it came into being, its provisions, how to comply with it, and what can happen if a health care provider fails to comply.

Q&A: Hospitals and Advance Directives. American Hospital Association, 1993.

Designed to answer questions that may arise as hospitals develop or revise their advanced directives policies or procedures. Developed by the AHA Technical Panel on Biomedical Ethics to assist hospitals in addressing issues of PSDA implementation.

Shields JM, Johnson A: Collision between law and ethics: consent for treatment with adolescents. *Bull Am Acad Psychiatry Law* 20 (3): 309–23, 1992.

Uses case examples to address some of the legal, ethical, and treatment issues of adolescent treatment when parental consent is problematic. Outlines the components of informed consent, and discusses the issue of the competence of minors to provide informed consent.

Solomon MZ, et al: Decisions near the end of life: Professional views on life-sustaining treatments. *Am J Public Health* 83: 14–23, Jan 1993.

Presents the results of a five-hospital survey designed to determine whether or not clinicians agree with national recommendations regarding the care of patients near the end of life, and how they themselves view the issues. Reveals a gap between the views of the practicing clinicians and the prevailing guidelines. Analyzes these differences and suggests strategies for bridging the gap and improving the care of patients near the end of life.

Weber LJ: The business of ethics: Hospitals need to focus on managerial ethics as much as clinical ethics. *Health Prog* 71: 87–88, 102, Jan–Feb 1990.

Presents four key values in business decisions and practices. Examines the two main approaches in contemporary business ethics and discusses the attention to conflict of interest.

OUTCOME BASED PERFORMANCE MEASURES

THE ACCREDITATION COUNCIL
ON SERVICES FOR PEOPLE WITH DISABILITIES

THE ACCREDITATION COUNCIL
on Services for People with Disabilities

The Accreditation Council on Services for People with Disabilities is a national quality enhancement organization representing national consumer and professional organizations and service providers dedicated to providing leadership and improving the quality of services for people with disabilities through the establishment of standards; provision of education, consultation, and training; dissemination of publications, accreditation of organizations and the recognition of excellence.

Sponsoring Organizations

American Association on Mental Retardation
American Occupational Therapy Association
American Psychological Association
The Arc
Association for Behavior Analysis
Autism Society of America
Epilepsy Foundation of America
National Association of Private Residential Resources
United Cerebral Palsy Associations

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James F. Gardner, Ph.D.
Chief Executive Officer

Foreword

With the publication of the *Outcome Based Performance Measures*, The Accreditation Council signals a new focus and offers a new challenge to the traditional assessment of quality in human services. The *Outcome Based Performance Measures* describe the outcomes that people with disabilities want from their support or service programs. These outcomes are the core of a new system for quality improvement and measurement that emphasizes responsiveness to individual needs rather than traditional compliance with established standards.

These new measures are:

- **Outcome Based**--They focus on outcomes for people, rather than the organizational processes that contribute to the outcomes.
- **Concise**--They consist of those priority outcomes that people with disabilities indicate are most important to them.
- **Applicable to all Supports and Services**--They can be used with all services and programs--residential, vocational, social or educational--and for people with different disabilities.

Two significant trends in the field of disability have supported this fundamental change. The first concerns the question of "*What do we measure?*" Traditional approaches to quality--which emphasize compliance with standards and regulations--addressed variables such as environmental and living conditions, habilitation process, developmental gain, or behavior. As the themes of civil rights, empowerment, and self direction found expression in the Americans with Disabilities Act, the answer to "*What do we measure?*" became clear--**the only relevant measure is what people with disabilities say is important**. With the *Outcome Based Performance Measures* and the review methodology designed by The Accreditation Council, people with disabilities are brought into the quality improvement process.

The second significant change is that we now recognize *how to measure* outcomes. Earlier measurements of quality focused on the organizational activities, resources and services that were provided. However, measurements of planning, assessments, placements, or training address quality in terms of what the service or organization has achieved, not the person. With the *Outcome Based Performance Measures* and the review methodology designed by The Accreditation Council, quality is defined by the outcome of the service, rather than delivery of the service.

Building on a twenty-five year foundation of developing and measuring standards that emphasize values-based services and supports, individualized planning, and person-centered outcomes, The Accreditation Council is proud to introduce the *Outcome Based Performance Measures*. We welcome the opportunity to join with people with disabilities, their families and friends, providers, professionals and others to further define and enhance this new vision of quality.

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Section I
Introduction

Outcome Based Performance Measures

INTRODUCTION

Purpose

These *Outcome Based Performance Measures* are designed to examine the outcomes on the lives of people with disabilities that result from the provision of supports and services.

The Accreditation Council has shifted attention from assuring compliance with hundreds of organizational processes to emphasizing a limited number of the most important outcomes for people. These *Outcomes* were identified by people with disabilities through individual and focus group interviews.

The *Outcome Based Performance Measures* apply across service and support programs and to people with different disabilities. Because the outcomes are generic, and because The Accreditation Council has designed a valid and reliable measurement process, they can support quality enhancement programs for organizations providing services and supports to people.

This edition of the *Outcome Based Performance Measures* serves three purposes. First, the *Outcome Based Performance Measures* refocus the organization's attention on outcomes for people. From an educational perspective, the *Outcomes* emphasize that policy, procedure, and organizational process are a framework for providing services. The *Outcomes* assist employees, volunteers, and friends to design expectations around people rather than programs, structure, and process.

The *Outcome Based Performance Measures* also enable the organization to conduct its own self assessment. This manual provides the instructions, content, and decision criteria that enable small groups to determine the extent to which organizations are assisting people to achieve outcomes in their lives.

Finally, this edition of the *Outcome Based Performance Measures* serves as the basis for an independent quality review. The discussion of the content of the *Outcomes*, the identification of individualized organizational processes that contribute to outcomes, and the presentation of the decision criteria regarding outcomes indicate the methodology of the independent review process. Accreditation with the *Outcome Based Performance Measures* indicates a high degree of responsiveness to needs, expectations and outcomes for people.

Development

These measures were developed after initial input from people with disabilities participating in the Community Integrated Living Arrangements (CILA) program in the State of Illinois. Successive drafts of the measures were circulated to people with disabilities, providers, representatives of state and federal agencies, families and professionals.

The *Outcome Based Performance Measures* were field tested at ten sites in the United States and Canada. The field test sites provided a wide variety of services and supports to people with a wide range of disability. The Accreditation Council collected and disseminated information and data from the field tests and will continue to collect and analyze information concerning inter-rater reliability, content validity, and construct validity of the *Outcome Based Performance Measures*.

APPLICATION OF THE OUTCOME BASED PERFORMANCE MEASURES

On-Site Presence

The *Outcome Based Performance Measures* are designed to determine the presence of outcomes for people. As such, the on-site visit will require that review teams visit, interview, and observe each person for whom the measures will be applied. Review teams will also interview staff, other persons receiving supports and services, and, when appropriate, family members. These directed interviews and observations will enable review teams to gather information to determine whether the outcomes identified in the measures are present.

The *Outcome Measures* and the questions that follow them are designed to obtain information from the person and from those who know the person best. If a person has difficulty communicating his or her preferences, activities and satisfaction to the interviewer, the questions would be asked of those who know the person best and who are sensitive to, and aware of, how the person expresses likes and dislikes, choices, preferences, and desires. Those people (family members, guardians, those who provide personal support) would contribute their knowledge of the person for assessment and planning purposes and would respond on his or her behalf about experiences with regard to the *Outcome Measures*.

Visits and Interviews

Self assessment and independent quality reviews are grounded in visits and interviews with people receiving services and supports. The organization conducting the self assessment or participating in an independent quality review should identify a group of people who are representative of the people receiving supports and services.

The organization should explain the purpose of the visits and interviews and obtain the person's informed consent to participate in the self assessment or independent quality review process. Prior to the visits and interviews, the organization should identify the person's preferred communication mode, preferences for location of the interview, and whether or not they wish other persons to participate in the interview. Interviews with the individuals are followed by interviews with other people, staff, and friends, observations, and, when necessary, record reviews to verify information.

In some instances, interviews with people will not yield sufficient information to make decisions about outcomes. In such cases, interviews are conducted with persons who know the individual the best, such as family, staff, or friends.

Information Collection and Decision Making

Each of the thirty *Outcome Based Performance Measures* will be applied for a representative sampling of people receiving supports and services from the organization. All of the Outcome Questions will be asked of each person in the sample.

These *Outcome Measures* have been designed to determine whether outcomes are present for people with disabilities. The first step in the decision process is to record information gathered in response to the questions on the Outcome Information Gathering page in the manual. The second step is to answer the questions found on the Outcome Decision Making page to determine whether the outcome is present.

The OUTCOME measurement question asks:

Is the outcome present?

An organization process question then asks about the individualized supports and services the organization has provided to enable the person to reach the outcome.

The ORGANIZATIONAL PROCESS question is:

Has the organization designed and initiated a process that enables (or will enable) the person to overcome barriers and achieve the outcome?

If the answer is yes, what is the organizational process?

For each of the thirty *Outcome Measures* there is both an outcome question and an individualized organizational process question.

The application of the *Outcome Based Performance Measures* focuses first on outcomes. After the outcome question is answered, the inquiry shifts to the individualized organizational process that contributed to the outcome. The individualized organizational process is not a policy, procedure, or program. In contrast, the individualized organizational process is the specific application of the policy, procedure, or program to enable a person to achieve his or her outcomes.

The optimal response is the presence of both an outcome and an individualized organizational process. Outcomes are present and the organization has tailored its services and supports to assist the person to achieve the outcome.

In some instances, the outcome will not be present and there will be no indication that the organization has initiated an individualized process to assist the individual to achieve the outcome. In general, this response indicates that the organization does not value the outcome for the person.

In other instances, the outcome will not be present, but an identifiable organizational process is assisting the person to achieve the outcome. The Accreditation Council recognizes that achieving outcomes for people may be more difficult than complying with processes. For this reason, the review process is designed to allow The Accreditation Council to acknowledge effort on the part of organizations to achieve outcomes, even when they are not yet totally successful.

Finally, there will be some instances where individuals achieve outcomes even when there are no individualized organizational processes designed to assist the person to achieve an outcome. This can signal that a person no longer needs significant supports or services. In contrast, the achievement of outcomes without organizational support may indicate particularly strong individual efforts and/or the presence of an informal support network.

Feedback Through the Outcome Based Performance Measures

Self assessment or independent quality reviews will provide timely and relevant information to an organization. The feedback will indicate the extent to which outcomes are present, on average, in people's lives. The organization can compare its averages with those of other organizations.

In addition, the feedback will identify those people who are achieving relatively few outcomes or for whom there are fewer organizational processes in place. Because the feedback focuses on individuals, organizations demonstrate a sense of urgency as they begin to solve problems and remove barriers to outcomes for people. The focus on outcomes for people rather than organizational process and policy adds energy and resolve to the follow-up process.

Finally, the information can be formatted by outcome. This information identifies the outcomes that are most often and least often achieved by persons receiving services and supports. The organization can then identify the individualized organizational processes that contribute most frequently to the achieved outcomes. Those successful individualized organizational processes can then, perhaps, be adapted to other outcomes and individuals.

PRINCIPLES OF THE OUTCOME BASED PERFORMANCE MEASURES

The *Outcome Based Performance Measures* begin with the identification of goals, preferences, experiences, and range of choices (People choose personal goals) and conclude with questions concerning satisfaction with services and supports and general state-of-life satisfaction (People are satisfied with services and People are satisfied with their personal life situations). This sequence does not reflect a hierarchy of the measures.

Because the individual outcomes assume a different level of importance for each individual, they cannot be ranked or weighted. All of the *Outcome Measures* have the same weight, although some people may attach special importance to particular outcomes at particular times in their lives.

The Role of Choice and Decision Making

The *Outcome Based Performance Measures for People* are applied to each person. The performance measures do not, however, prescribe a specific outcome for any person. All thirty performance measures consider individual choice and decision making as key variables. For example, a performance measure may indicate that *people participate in the life of the community*. However, in instances where a person *chooses* not to participate in the life of the community, the measure would be considered to be present.

There are three dimensions of choice and decision making that must be present in order for individuals to make meaningful choices and decisions.

Experiential context for choice--In order to make meaningful choices, people need concrete life experiences related to possible choices. The provider organization has a responsibility to provide the person with training, counseling, and opportunities to experience and try the options involved in making choices. In some cases, people with more significant disabilities may require additional supports, experiences and options from which to choose, in order to make outcomes possible and relevant.

Social context for choice--Social support networks assist people in making choices. Most people seek advice from family, friends, and peers when faced with significant or difficult choices. No one wants to make hard choices by him or herself. People need access to groups of trusted peers, friends and families on a regular basis to share feelings and information and to seek support and counsel.

Creative context for choice--Choices and decisions seldom consist of an "either-or" situation. Instead, most people attempt to find the creative alternative to either Choice A or Choice B. This search for creative compromises between apparent "givens" contributes to personal esteem and satisfaction. The provider of supports and services has a responsibility to assist people in identifying creative alternatives that meet their individual needs and expectations, yet stay within the boundaries of Choice A and Choice B.

The Role of Rights and Responsibilities

These Performance Measures for People stress both the rights and responsibilities that apply to all citizens. All people are protected by basic constitutional rights, federal and state statute, and court decisions. These legal rights are particularly important to people with disabilities.

Rights are balanced by responsibilities. People cannot always exercise rights when the results would burden others. The importance of rights does not diminish people's responsibilities for their own lives. The provider organization has a responsibility to

assist people to both exercise their own rights and be responsible for the outcome of their actions on others. Rights confer an obligation to act in a responsible manner.

The Role of Comprehensive Planning for People

During the past four decades, organizations have gained knowledge and expertise in the design of systems for service and support. A general consensus and tradition has emerged in the literature about program planning and treatment services. These new *Outcome Based Performance Measures* build upon that tradition. The Accreditation Council believes that a well designed and well managed service process will lead to outcomes for people.

Each organization defines its own unique role in supporting people to achieve their outcomes. Each organization will have some role in supporting a person to achieve all outcomes. The scope of responsibility will be defined by the organization's mission and purview. This role may involve direct action through supports or services, or the organization may address outcomes through referral, advocacy, or consultation.

There is a shift in the way organization responsibility is defined that accompanies the shift from "process" to "outcome." In the program paradigm of quality, service activities and professional practice defined the expectations for agency responsibility. With a focus on individual outcomes, the organization must define its own unique role in relation to supporting people to achieve their outcomes.

However, unlike current practice where responsibility is defined by "program" focus, an organization cannot choose to ignore an outcome area for an individual because it is not directly related to the program's mission or emphasis. In those instances where outcome areas are beyond an organization's mission or purpose, the responsibility for attention to outcomes remains, but the organizational role and response may be more restricted. Rather than take direct action through supports or services, organizations may address outcomes through referral, advocacy or consultation.

This approach is more holistic in nature. It acknowledges that daily events are interconnected and that seemingly random and unconnected events merge when they impact a single person. A commitment to holistic patterns of support and service is demonstrated either through direct service provision or through service coordination involving support and service staff, providers and public agencies.

Individualization

The Accreditation Council's traditional emphasis on the individual is increased in these *Outcome Based Performance Measures*. These measures ask whether the outcome is present for each person. In addition, the outcomes are non-prescriptive. They will vary from individual to individual. As a result, the outcome measures can only be applied after meeting the person, inquiring about his or her goals and desires for the future, and asking about choices he or she has made in the past and may wish to make in the future.

This focus on outcomes for the person challenges organizations to individualize service and support. The outcomes on each of the thirty measures will vary from person to person. One person may have a very high need for privacy; another person may place a primary emphasis on friendships. One person's choice of a work setting might not satisfy another person. Choice from a variety of options ensures individualization.

In addition, the question of what organizational processes contributed to an outcome are answered for each specific individual. General organizational processes such as policy and procedure must then be explained in terms of the person. The process question asks *"How was the policy and procedure applied to an individual?"*

Organizational Process and Personal Outcomes

The increased importance of outcomes does not diminish the contribution that organizational process can make to the achievement of outcomes. The *Outcome Based Performance Measures* identify the specific organizational processes that enable people to realize outcomes. The use of *Outcome Measures* directs policy and procedure to be individualized and implemented for each person. Program planning, interdisciplinary process, the monitoring of supports and services are valued and important when they contribute to outcomes for people.

Quality by Design

Quality must be built into services and supports when they are designed. Services and supports must be designed around the individual from the beginning. Quality cannot be achieved through compliance inspection. Designing services and supports to achieve outcomes for people, rather than conforming to a predetermined program architecture, is the key to continuous quality improvement.

Section II
Outcome Measures for People

OUTCOME MEASURES FOR PEOPLE

PERSONAL GOALS	1.	People choose personal goals.
	2.	People realize personal goals.
CHOICE	3.	People choose where and with whom they live.
	4.	People choose where they work.
	5.	People decide how to use their free time.
	6.	People choose services.
	7.	People choose their daily routine.
SOCIAL INCLUSION	8.	People participate in the life of the community.
	9.	People interact with other members of the community.
	10.	People perform different social roles.
RELATIONSHIPS	11.	People have friends.
	12.	People remain connected to natural support networks.
	13.	People have intimate relationships.
RIGHTS	14.	People exercise rights.
	15.	People are afforded due process if rights are limited.
	16.	People are free from abuse and neglect.
DIGNITY AND RESPECT	17.	People are respected.
	18.	People have time, space and opportunity for privacy.
	19.	People have and keep personal possessions.
	20.	People decide when to share personal information.
HEALTH	21.	People have health care services.
	22.	People have the best possible health.
ENVIRONMENT	23.	People are safe.
	24.	People use their environments.
	25.	People live in integrated environments.
SECURITY	26.	People have economic resources.
	27.	People have insurance to protect their resources.
	28.	People experience continuity and security.
SATISFACTION	29.	People are satisfied with services.
	30.	People are satisfied with their personal life situations.

Section III
Performance Measures for Organizations

Performance Measures for Organizations

INTRODUCTION

The Performance Measures for Organizations represent key factors that influence the organization's capacity to assist people to achieve outcomes. They reflect the incorporation and use of fundamental management practices in the organization and operation of services and supports. Like the Outcome Measures for People, these measures are not prescriptive. The principles contained in the measures can be addressed in a variety of ways. Each organization is responsible for identifying and implementing methods to accomplish the intent of each measure as it applies to the organization.

The Performance Measures for Organizations are applicable to all organizations. The information following each of the measures for organizations provides guidelines for understanding and implementing the measures. Many of these issues will be discussed during the review of individual outcomes for people. Additional information about these measures is gathered through discussions with supervisory and management staff.

The presence or absence of the Performance Measures for Organizations will not be routinely factored into the making of accreditation decisions. Information about the measures will be gathered through discussions and interviews with people during the review unless significant and severe shortcomings in organizational performance are found to be impacting the lives of people served. In these situations, an additional, more in-depth review of organizational practices will occur. Findings about organizational practice will be noted and included in the accreditation review summary. Organizational performance that negatively impacts many people will be reviewed by the accreditation committee and may influence the final accreditation decision.

The inclusion of these Performance Measures indicates The Council's commitment to the ongoing improvement of organizational capability to respond to individual needs and desired outcomes. The measures provide a framework for consistency in organizational practice while providing flexibility for differences in organizational needs and structure. We believe that these measures reflect essential performance areas for organizations committed to supporting outcomes for people served.

PERFORMANCE MEASURES FOR ORGANIZATIONS

PERSONAL HEALTH, SAFETY, WELFARE	31. The organization protects the rights of people.
	32. The organization demonstrates a commitment to using positive approaches in all service and support activities.
	33. The organization's service practices and staff demonstrate sensitivity and concern for personal dignity and respect.
	34. The organization implements procedures for investigation and intervention in all instances of alleged abuse and neglect.
	35. The organization owns, operates or leases buildings that comply with all applicable fire and sanitation codes.
	36. The organization implements procedures for meeting all emergencies, such as fire, severe weather, and health.
	37. The organization implements employment screening procedures that minimize unnecessary or unreasonable risk.
FISCAL MANAGEMENT	38. The organization has a budgeting and accounting system.
	39. The organization has an independent audit of its fiscal activities annually.
	40. The organization has separate accounting for funds managed for people.
HUMAN RESOURCE MANAGEMENT	41. The organization's personnel practices meet all state and federal Fair Labor regulations.
	42. The organization provides opportunities for staff training and personal development.
	43. The organization regularly evaluates and provides feedback to its staff on their performance.
PLANNING AND EVALUATION	44. The organization has a clear statement of its mission and purpose.
	45. The organization conducts an ongoing evaluation of success in achieving desired outcomes.
	46. The organization includes input and involvement from people served and others in its evaluation and planning activities.
	47. The organization implements a program for ongoing quality improvement.

[Code of Federal Regulations]
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[Revised as of October 1, 1997]
From the U.S. Government Printing Office via GPO Access
[CITE: 42CFR482]

TITLE 42--PUBLIC HEALTH

CHAPTER IV--HEALTH CARE FINANCING ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES--(Continued)

PART 482--CONDITIONS OF PARTICIPATION FOR HOSPITALS--Table of Contents

(a) Statutory basis. (1) Section 1861(e) of the Act provides that--
(i) Hospitals participating in Medicare must meet certain specified requirements; and
(ii) The Secretary may impose additional requirements if they are found necessary in the interest of the health and safety of the individuals who are furnished services in hospitals.
(2) Section 1861(f) of the Act provides that an institution participating in Medicare as a psychiatric hospital must meet certain specified requirements imposed on hospitals under section 1861(e), must be primarily engaged in providing, by or under the supervision of a physician, psychiatric services for the diagnosis and treatment of mentally ill persons, must maintain clinical records and other records that the Secretary finds necessary, and must meet staffing requirements that the Secretary finds necessary to carry out an active program of treatment for individuals who are furnished services in the hospital. A distinct part of an institution can participate as a psychiatric hospital if the institution meets the specified 1861(e) requirements and is primarily engaged in providing psychiatric services, and if the distinct part meets the records and staffing requirements that the Secretary finds necessary.

(3) Sections 1861(k) and 1902(a)(30) of the Act provide that hospitals participating in Medicare and Medicaid must have a utilization review plan that meets specified requirements.
(4) Section 1883 of the Act sets forth the requirements for hospitals that provide long term care under an agreement with the Secretary.
(5) Section 1905(a) of the Act provides that ``medical assistance'' (Medicaid) payments may be applied to various hospital services. Regulations interpreting those provisions specify that hospitals receiving payment under Medicaid must meet the requirements for participation in Medicare (except in the case of medical supervision of nurse-midwife services. See Secs. 440.10 and 440.165 of this chapter.).
(b) Scope. Except as provided in subpart A of part 488 of this chapter, the provisions of this part serve as the basis of survey activities for the purpose of determining whether a hospital qualifies for a provider agreement under Medicare and Medicaid.

[51 FR 22042, June 17, 1986, as amended at 60 FR 50442, Sept. 29, 1995]

Sec. 482.2 Provision of emergency services by nonparticipating hospitals.

(a) The services of an institution that does not have an agreement to participate in the Medicare program may, nevertheless, be reimbursed under the program if--
(1) The services are emergency services; and
(2) The institution meets the requirements of section 1861(e) (1) through (5) and (7) of the Act. Rules applicable to emergency services furnished by nonparticipating hospitals are set forth in subpart G of part 424 of this chapter.
(b) Secton 440.170(e) of this chapter defines emergency hospital services for purposes of Medicaid reimbursement.

[51 FR 22042, June 17, 1986, as amended at 53 FR 6648, Mar. 2, 1988]

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[Revised as of October 1, 1997]
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[CITE: 42CFR482]

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Subpart B--Administration

(a) The hospital must be in compliance with applicable Federal laws related to the health and safety of patients.

(b) The hospital must be--

(1) Licensed; or

(2) Approved as meeting standards for licensing established by the agency of the State or locality responsible for licensing hospitals.

(c) The hospital must assure that personnel are licensed or meet other applicable standards that are required by State or local laws.

Sec. 482.12 Condition of participation: Governing body.

The hospital must have an effective governing body legally responsible for the conduct of the hospital as an institution. If a hospital does not have an organized governing body, the persons legally responsible for the conduct of the hospital must carry out the functions specified in this part that pertain to the governing body.

(a) Standard: Medical staff. The governing body must:

(1) Determine, in accordance with State law, which categories of practitioners are eligible candidates for appointment to the medical staff;

(2) Appoint members of the medical staff after considering the recommendations of the existing members of the medical staff;

(3) Assure that the medical staff has bylaws;

(4) Approve medical staff bylaws and other medical staff rules and regulations;

(5) Ensure that the medical staff is accountable to the governing body for the quality of care provided to patients;

(6) Ensure the criteria for selection are individual character, competence, training, experience, and judgment; and

(7) Ensure that under no circumstances is the accordance of staff membership or professional privileges in the hospital dependent solely upon certification, fellowship, or membership in a specialty body or society.

(b) Standard: Chief executive officer. The governing body must appoint a chief executive officer who is responsible for managing the hospital.

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(c) Standard: Care of patients. In accordance with hospital policy, the governing body must ensure that the following requirements are met:

(1) Every Medicare patient is under the care of:

(i) A doctor of medicine or osteopathy (This provision is not to be construed to limit the authority of a doctor of medicine or osteopathy to delegate tasks to other qualified health care personnel to the extent recognized under State law or a State's regulatory mechanism.);

(ii) A doctor of dental surgery or dental medicine who is legally authorized to practice dentistry by the State and who is acting within the scope of his or her license;

(iii) A doctor of podiatric medicine, but only with respect to functions which he or she is legally authorized by the State to perform;

(iv) A doctor of optometry who is legally authorized to practice optometry by the State in which he or she practices;

(v) A chiropractor who is licensed by the State or legally authorized to perform the services of a chiropractor, but only with respect to treatment by means of manual manipulation of the spine to correct a subluxation demonstrated by x-ray to exist.

(2) Patients are admitted to the hospital only on the recommendation of a licensed practitioner permitted by the State to admit patients to a hospital. If a Medicare patient is admitted by a practitioner not specified in paragraph (c)(1) of this section, that patient is under the care of a doctor of medicine or osteopathy.

(3) A doctor of medicine or osteopathy is on duty or on call at all times.

(4) A doctor of medicine or osteopathy is responsible for the care of each Medicare patient with respect to any medical or psychiatric problem that--

(i) is present on admission or develops during hospitalization; and

(ii) Is not specifically within the scope of practice of a doctor of dental surgery, dental medicine, podiatric medicine or optometry, or a chiropractor, as that scope is--

(A) Defined by the medical staff;

(B) Permitted by State law; and

(C) Limited, under paragraph (c)(1)(v) of this section, with respect to chiropractors.

(5)(i) To identify potential organ donors as defined in Sec. 485.302 of this chapter, the hospital has written protocols that--

(A) Assure that the family of each potential organ donor knows of its option either to donate organs or tissues or to decline to donate;

(B) Encourage discretion and sensitivity with respect to the circumstances, views and beliefs of the families of potential donors; and

(C) Require that an organ procurement organization designated by the Secretary under Sec. 485.308 of this chapter be notified of potential organ donors.

(ii) In the case of a hospital in which organ transplants are performed, the hospital must be a member of the Organ Procurement and Transplantation Network (OPTN) established and operated in accordance with section 372 of the Public Health Service 'PHS) Act (42 U.S.C. 274) and abide by its rules. The term ``rules of the OPTN'' means those rules provided for in regulations issued by the Secretary in accordance with section 372 of the PHS Act. No hospital is considered to be out of compliance with section 1138(a)(1)(B) of the Act or with the requirements in this paragraph, unless the Secretary has given the OPTN formal notice that he or she approves the decision to exclude the hospital from the OPTN and has notified the hospital in writing.

(iii) For purposes of this subparagraph, the term ``organ'' means a human kidney, liver, heart, lung, or pancreas.

(d) Standard: Institutional plan and budget. The institution must have an overall institutional plan that meets the following conditions:

(1) The plan must include an annual operating budget that is prepared according to generally accepted accounting principles.

(2) The budget must include all anticipated income and expenses. This provision does not require that the budget identify item by item the components of each anticipated income or expense.

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(3) The plan must provide for capital expenditures for at least a 3-year period, including the year in which the operating budget specified in paragraph (d)(2) of this section is applicable.

(4) The plan must include and identify in detail the objective of, and the anticipated sources of financing for, each anticipated capital expenditure in excess of $600,000 (or a lesser amount that is established, in accordance with section 1122(g)(1) of the Act, by the State in which the hospital is located) that relates to any of the following:

(i) Acquisition of land;

(ii) Improvement of land, buildings, and equipment; or

(iii) The replacement, modernization, and expansion of buildings and equipment.

(5) The plan must be submitted for review to the planning agency designated in accordance with section 1122(b) of the Act, or if an agency is not designated, to the appropriate health planning agency in the State. (See part 100 of this title.) A capital expenditure is not subject to section 1122 review if 75 percent of the health care facility's patients who are expected to use the service for which the capital expenditure is made are individuals enrolled in a health maintenance organization (HMO) or competitive medical plan (CMP) that meets the requirements of section 1876(b) of the Act, and if the Department determines that the capital expenditure is for services and facilities that are needed by the HMO or CMP in order to operate efficiently and economically and that are not otherwise readily accessible to the HMO or CMP because--

(i) The facilities do not provide common services at the same site;

(ii) The facilities are not available under a contract of reasonable duration;

(iii) Full and equal medical staff privileges in the facilities are not available;

(iv) Arrangements with these facilities are not administratively feasible; or

(v) The purchase of these services is more costly than if the HMO or CMP provided the services directly.

(6) The plan must be reviewed and updated annually.

(7) The plan must be prepared--

(i) Under the direction of the governing body; and

(ii) By a committee consisting of representatives of the governing body, the administrative staff, and the medical staff of the institution.

(e) Standard: Contracted services. The governing body must be

responsible for services furnished in the hospital whether or not they are furnished under contracts. The governing body must ensure that a contractor of services (including one for shared services and joint ventures) furnishes services that permit the hospital to comply with all applicable conditions of participation and standards for the contracted services.

(1) The governing body must ensure that the services performed under a contract are provided in a safe and effective manner.

(2) The hospital must maintain a list of all contracted services, including the scope and nature of the services provided.

(f) Standard: Emergency services. (1) If emergency services are provided at the hospital, the hospital must comply with the requirements of Sec. 482.55.

(2) If emergency services are not provided at the hospital, the governing body must assure that the medical staff has written policies and procedures for appraisal of emergencies, initial treatment, and referral when appropriate.

[51 FR 22042, June 17, 1986; 51 FR 27847, Aug. 4, 1986, as amended at 53 FR 6549, Mar. 1, 1988; 53 FR 18987, May 26, 1988; 56 FR 8852, Mar. 1, 1991; 56 FR 23022, May 20, 1991; 59 FR 46514, Sept. 8, 1994]

[Code of Federal Regulations]
[Title 42, Volume 3, Parts 430 to end]
[Revised as of October 1, 1997]
From the U.S. Government Printing Office via GPO Access
[CITE: 42CFR482]

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Subpart C--Basic Hospital Functions

Sec. 482.21 Condition of participation: Quality assurance.

The governing body must ensure that there is an effective, hospital-wide quality assurance program to evaluate the provision of patient care.

(a) Standard: Clinical plan. The organized, hospital-wide quality assurance program must be ongoing and have a written plan of implementation.

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(1) All organized services related to patient care, including services furnished by a contractor, must be evaluated.

(2) Nosocomial infections and medication therapy must be evaluated.

(3) All medical and surgical services performed in the hospital must be evaluated as they relate to appropriateness of diagnosis and treatment.

(b) Standard: Medically-related patient care services. The hospital must have an ongoing plan, consistent with available community and hospital resources, to provide or make available social work, psychological, and educational services to meet the medically-related needs of its patients.

(c) Standard: Implementation. The hospital must take and document appropriate remedial action to address deficiencies found through the quality assurance program. The hospital must document the outcome of the remedial action.

[51 FR 22042, June 17, 1986, as amended at 59 FR 64152, Dec. 13, 1994]

Sec. 482.22 Condition of participation: Medical staff.

The hospital must have an organized medical staff that operates under bylaws approved by the governing body and is responsible for the quality of medical care provided to patients by the hospital.

(a) Standard: Composition of the medical staff. The medical staff must be composed of doctors of medicine or osteopathy and, in accordance with State law, may also be composed of other practitioners appointed by the governing body.

(1) The medical staff must periodically conduct appraisals of its members.

(2) The medical staff must examine credentials of candidates for medical staff membership and make recommendations to the governing body on the appointment of the candidates.

(b) Standard: Medical staff organization and accountability. The medical staff must be well organized and accountable to the governing body for the quality of the medical care provided to patients.

(1) The medical staff must be organized in a manner approved by the governing body.

(2) If the medical staff has an executive committee, a majority of the members of the committee must be doctors of medicine or osteopathy.

(3) The responsibility for organization and conduct of the medical staff must be assigned only to an individual doctor of medicine or osteopathy or, when permitted by State law of the State in which the hospital is located, a doctor of dental surgery or dental medicine.

(c) Standard: Medical staff bylaws. The medical staff must adopt and enforce bylaws to carry out its responsibilities. The bylaws must:

(1) Be approved by the governing body.

(2) Include a statement of the duties and privileges of each category of medical staff (e.g., active, courtesy, etc.)

(3) Describe the organization of the medical staff.

(4) Describe the qualifications to be met by a candidate in order for the medical staff to recommend that the candidate be appointed by the governing body.

(5) Include a requirement that a physical examination and medical history be done no more than 7 days before or 48 hours after an admission for each patient by a doctor of medicine or osteopathy, or, for patients admitted only for oromaxillofacial surgery, by an

oromaxillofacial surgeon who has been granted such privileges by the medical staff in accordance with State law.

(6) Include criteria for determining the privileges to be granted to individual practitioners and a procedure for applying the criteria to individuals requesting privileges.

(d) Standard: Autopsies. The medical staff should attempt to secure autopsies in all cases of unusual deaths and of medical-legal and educational interest. The mechanism for documenting permission to perform an autopsy must be defined. There must be a system for notifying the medical staff, and specifically the attending practitioner, when an autopsy is being performed.

[51 FR 22042, June 17, 1986, as amended at 59 FR 64152, Dec. 13, 1994]

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Sec. 482.23 Condition of participation: Nursing services.

The hospital must have an organized nursing service that provides 24-hour nursing services. The nursing services must be furnished or supervised by a registered nurse.

(a) Standard: Organization. The hospital must have a well-organized service with a plan of administrative authority and delineation of responsibilities for patient care. The director of the nursing service must be a licensed registered nurse. He or she is responsible for the operation of the service, including determining the types and numbers of nursing personnel and staff necessary to provide nursing care for all areas of the hospital.

(b) Standard: Staffing and delivery of care. The nursing service must have adequate numbers of licensed registered nurses, licensed practical (vocational) nurses, and other personnel to provide nursing care to all patients as needed. There must be supervisory and staff personnel for each department or nursing unit to ensure, when needed, the immediate availability of a registered nurse for bedside care of any patient.

(1) The hospital must provide 24-hour nursing services furnished or supervised by a registered nurse, and have a licensed practical nurse or registered nurse on duty at all times, except for rural hospitals that have in effect a 24-hour nursing waiver granted under Sec. 405.1910(c) of this chapter.

(2) The nursing service must have a procedure to ensure that hospital nursing personnel for whom licensure is required have valid and current licensure.

(3) A registered nurse must supervise and evaluate the nursing care for each patient.

(4) The hospital must ensure that the nursing staff develops, and keeps current, a nursing care plan for each patient.

(5) A registered nurse must assign the nursing care of each patient to other nursing personnel in accordance with the patient's needs and the specialized qualifications and competence of the nursing staff available.

(6) Non-employee licensed nurses who are working in the hospital must adhere to the policies and procedures of the hospital. The director of nursing service must provide for the adequate supervision and evaluation of the clinical activities of non-employee nursing personnel which occur within the responsibility of the nursing service.

(c) Standard: Preparation and administration of drugs. Drugs and biologicals must be prepared and administered in accordance with Federal and State laws, the orders of the practitioner or practitioners responsible for the patient's care as specified under Sec. 482.12(c), and accepted standards of practice.

(1) All drugs and biologicals must be administered by, or under supervision of, nursing or other personnel in accordance with Federal and State laws and regulations, including applicable licensing requirements, and in accordance with the approved medical staff policies and procedures.

(2) All orders for drugs and biologicals must be in writing and signed by the practitioner or practitioners responsible for the care of the patient as specified under Sec. 482.12(c). When telephone or oral orders must be used, they must be--

(i) Accepted only by personnel that are authorized to do so by the medical staff policies and procedures, consistent with Federal and State law;

(ii) Signed or initialed by the prescribing practitioner as soon as possible; and

(iii) Used infrequently.

(3) Blood transfusions and intravenous medications must be administered in accordance with State law and approved medical staff policies and procedures. If blood transfusions and intravenous medications are administered by personnel other than doctors of medicine or osteopathy, the personnel must have special training for this duty.

(4) There must be a hospital procedure for reporting transfusion reactions, adverse drug reactions, and errors in administration of drugs.

Sec. 482.24 Condition of participation: Medical record services.

The hospital must have a medical record service that has administrative responsibility for medical records. A

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medical record must be maintained for every individual evaluated or treated in the hospital.

(a) Standard: Organization and staffing. The organization of the medical record service must be appropriate to the scope and complexity of the services performed. The hospital must employ adequate personnel to ensure prompt completion, filing, and retrieval of records.

(b) Standard: Form and retention of record. The hospital must maintain a medical record for each inpatient and outpatient. Medical records must be accurately written, promptly completed, properly filed and retained, and accessible. The hospital must use a system of author identification and record maintenance that ensures the integrity of the authentification and protects the security of all record entries.

(1) Medical records must be retained in their original or legally reproduced form for a period of at least 5 years.

(2) The hospital must have a system of coding and indexing medical records. The system must allow for timely retrieval by diagnosis and procedure, in order to support medical care evaluation studies.

(3) The hospital must have a procedure for ensuring the confidentiality of patient records. In-formation from or copies of records may be released only to authorized individuals, and the hospital must ensure that unauthorized individuals cannot gain access to or alter patient records. Original medical records must be released by the hospital only in accordance with Federal or State laws, court orders, or subpoenas.

(c) Standard: Content of record. The medical record must contain information to justify admission and continued hospitalization, support the diagnosis, and describe the patient's progress and response to medications and services.

(1) All entries must be legible and complete, and must be authenticated and dated promptly by the person (identified by name and discipline) who is responsible for ordering, providing, or evaluating the service furnished.

(i) The author of each entry must be identifed and must authenticate his or her entry.

(ii) Authentication may include signatures, written initials or computer entry.

(2) All records must document the following, as appropriate:

(i) Evidence of a physical examination, including a health history, performed no more than 7 days prior to admission or within 48 hours after admission.

(ii) Admitting diagnosis.

(iii) Results of all consultative evaluations of the patient and appropriate findings by clinical and other staff involved in the care of the patient.

(iv) Documentation of complications, hospital acquired infections, and unfavorable reactions to drugs and anesthesia.

(v) Properly executed informed consent forms for procedures and treatments specified by the medical staff, or by Federal or State law if applicable, to require written patient consent.

(vi) All practitioners' orders, nursing notes, reports of treatment, medication records, radiology, and laboratory reports, and vital signs and other information necessary to monitor the patient's condition.

(vii) Discharge summary with outcome of hospitalization, disposition of case, and provisions for follow-up care.

(viii) Final diagnosis with completion of medical records within 30 days following discharge.

Sec. 482.25 Condition of participation: Pharmaceutical services.

The hospital must have pharmaceutical services that meet the needs of the patients. The institution must have a pharmacy directed by a registered pharmacist or a drug storage area under competent supervision. The medical staff is responsible for developing policies and procedures that minimize drug errors. This function may be delegated to the hospital's organized pharmaceutical service.

(a) Standard: Pharmacy management and administration. The pharmacy or drug storage area must be administered in accordance with accepted professional principles.

(1) A full-time, part-time, or consulting pharmacist must be responsible for

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developing, supervising, and coordinating all the activities of the pharmacy services.

(2) The pharmaceutical service must have an adequate number of personnel to ensure quality pharmaceutical services, including emergency services.

(3) Current and accurate records must be kept of the receipt and disposition of all scheduled drugs.

(b) Standard: Delivery of services. In order to provide patient safety, drugs and biologicals must be controlled and distributed in accordance with applicable standards of practice, consistent with Federal and State law.

(1) All compounding, packaging, and dispensing of drugs and biologicals must be under the supervision of a pharmacist and performed consistent with State and Federal laws.

(2) Drugs and biologicals must be kept in a locked storage area.

(3) Outdated, mislabeled, or otherwise unusable drugs and biologicals must not be available for patient use.

(4) When a pharmacist is not available, drugs and biologicals must be removed from the pharmacy or storage area only by personnel designated in the policies of the medical staff and pharmaceutical service, in accordance with Federal and State law.

(5) Drugs and biologicals not specifically prescribed as to time or number of doses must automatically be stopped after a reasonable time that is predetermined by the medical staff.

(6) Drug administration errors, adverse drug reactions, and incompatibilities must be immediately reported to the attending physician and, if appropriate, to the hospital-wide quality assurance program.

(7) Abuses and losses of controlled substances must be reported, in accordance with applicable Federal and State laws, to the individual responsible for the pharmaceutical service, and to the chief executive officer, as appropriate.

(8) Information relating to drug interactions and information of drug therapy, side effects, toxicology, dosage, indications for use, and routes of administration must be available to the professional staff.

(9) A formulary system must be established by the medical staff to assure quality pharmaceuticals at reasonable costs.

[51 FR 22042, June 17, 1986; 51 FR 27848, Aug. 4, 1986]

Sec. 482.26 Condition of participation: Radiologic services.

The hospital must maintain, or have available, diagnostic radiologic services. If therapeutic services are also provided, they, as well as the diagnostic services, must meet professionally approved standards for safety and personnel qualifications.

(a) Standard: Radiologic services. The hospital must maintain, or have available, radiologic services according to needs of the patients.

(b) Standard: Safety for patients and personnel. The radiologic services, particularly ionizing radiology procedures, must be free from hazards for patients and personnel.

(1) Proper safety precutions must be maintained against radiation hazards. This includes adequate shielding for patients, personnel, and facilities, as well as appropriate storage, use, and disposal of radioactive materials.

(2) Periodic inspection of equipment must be made and hazards identified must be promptly corrected.

(3) Radiation workers must be checked periodically, by the use of exposure meters or badge tests, for amount of radiation exposure.

(4) Radiologic services must be provided only on the order of practitioners with clinical privileges or, consistent with State law, of other practitioners authorized by the medical staff and the governing body to order the services.

(c) Standard: Personnel. (1) A qualified full-time, part-time, or consulting radiologist must supervise the ionizing radiology services and must interpret only those radiologic tests that are determined by the medical staff to require a radiologist's specialized knowledge. For purposes of this section, a radiologist is a doctor of medicine or osteopathy who is qualified by education and experience in radiology.

(2) Only personnel designated as qualified by the medical staff may use the radiologic equipment and administer procedures.

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(d) Standard: Records. Records of radiologic services must be maintained.

(1) The radiologist or other practitioner who performs radiology services must sign reports of his or her interpretations.

(2) The hospital must maintain the following for at least 5 years:

(i) Copies of reports and printouts.

(ii) Films, scans, and other image records, as appropriate.

[51 FR 22042, June 17, 1986; 51 FR 27848, Aug. 4, 1986]

Sec. 482.27 Condition of participation: Laboratory services.

(a) The hospital must maintain, or have available, adequate laboratory services to meet the needs of its patients. The hospital must ensure that all laboratory services provided to its patients are performed in a facility certified in accordance with part 493 of this

chapter.

(b) Standard: Adequacy of laboratory services. The hospital must have laboratory services available, either directly or through a contractual agreement with a certified laboratory that meets requirements of part 493 of this chapter.

(1) Emergency laboratory services must be available 24 hours a day.

(2) A written description of services provided must be available to the medical staff.

(3) The laboratory must make provision for proper receipt and reporting of tissue specimens.

(4) The medical staff and a pathologist must determine which tissue specimens require a macroscopic (gross) examination and which require both macroscopic and microscopic examinations.

(c) Standard: Potentially infectious blood and blood products--(1) Potentially HIV infectious blood and blood products are prior collections from a donor who tested negative at the time of donation but tests repeatedly reactive for the antibody to the human immunodeficiency virus (HIV) on a later donation, and the FDA-licensed, more specific test or other followup testing recommended or required by FDA is positive and the timing of seroconversion cannot be precisely estimated.

(2) Services furnished by an outside blood bank. If a hospital regularly uses the services of an outside blood bank, it must have an agreement with the blood bank that governs the procurement, transfer, and availability of blood and blood products. The agreement must require that the blood bank promptly notify the hospital of the following:

(i) If it supplied blood and blood products collected from a donor who tested negative at the time of donation but tests repeatedly reactive for the antibody to HIV on a later donation; and

(ii) The results of the FDA-licensed, more specific test or other followup testing recommended or required by FDA completed within 30 calendar days after the donor's repeatedly reactive screening test. (FDA regulations concerning HIV testing and lookback procedures are set forth at 21 CFR 610.45-et seq.)

(3) Quarantine of blood and blood products pending completion of testing. If the blood bank notifies the hospital of the repeatedly reactive HIV screening test results as required by paragraph (c)(2)(i) of this section, the hospital must determine the disposition of the blood or blood product and quarantine all blood and blood products from previous donations in inventory.

(i) If the blood bank notifies the hospital that the result of the FDA-licensed, more specific test or other followup testing recommended or required by FDA is negative, absent other informative test results, the hospital may release the blood and blood products from quarantine.

(ii) If the blood bank notifies the hospital that the result of the FDA-licensed, more specific test or other followup testing recommended or required by FDA is positive, the hospital must dispose of the blood and blood products in accordance with 21 CFR 606.40 and notify patients in accordance with paragraph (c)(4) of this section.

(4) Patient notification. If the hospital has administered potentially HIV infectious blood or blood products (either directly through its own blood bank or under an agreement described in paragraph (c)(2) of this section) or released

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such blood or blood products to another entity or appropriate individual, the hospital must take the following actions:

(i) Promptly make at least three attempts to notify the patient's attending physician (that is, the physician of record) or the physician who ordered the blood or blood product that potentially HIV infectious blood or blood products were transfused to the patient.

(ii) Ask the physician to immediately notify the patient, or other individual as permitted under paragraph (c)(8) of this section, of the need for HIV testing and counseling.

(iii) If the physician is unavailable, declines to make the notification, or later informs the hospital that he or she was unable to notify the patient, promptly make at least three attempts to notify the patient, or other individual as permitted under paragraph (c)(8) of this section, of the need for HIV testing and counseling.

(iv) Document in the patient's medical record the notification or attempts to give the required notification.

(5) Timeframe for notification. The notification effort begins when the blood bank notifies the hospital that it received potentially HIV infectious blood and blood products and continues for 8 weeks unless--

(i) The patient is located and notified; or

(ii) The hospital is unable to locate the patient and documents in the patient's medical record the extenuating circumstances beyond the hospital's control that caused the notification timeframe to exceed 8 weeks.

(6) Content of notification. The notification given under paragraphs (c)(4) (ii) and (iii) of this section must include the following information:

(i) A basic explanation of the need for HIV testing and counseling.

(ii) Enough oral or written information so that the transfused patient can make an informed decision about whether to obtain HIV testing and counseling.

(iii) A list of programs or places where the patient can obtain HIV testing and counseling, including any requirements or restrictions the program may impose.

(7) Policies and procedures. The hospital must establish policies and procedures for notification and documentation that conform to Federal, State, and local laws, including requirements for confidentiality and medical records.

(8) Notification to legal representative or relative. If the patient has been adjudged incompetent by a State court, the physician or hospital must notify a legal representative designated in accordance with State law. If the patient is competent, but State law permits a legal representative or relative to receive the information on the patient's behalf, the physician or hospital must notify the patient or his or her legal representative or relative. If the patient is deceased, the physician or hospital must continue the notification process and inform the deceased patient's legal representative or relative.

[57 FR 7136, Feb. 28, 1992, as amended at 61 FR 47433, Sept. 9, 1996]

Sec. 482.28 Condition of participation: Food and dietetic services.

The hospital must have organized dietary services that are directed and staffed by adequate qualified personnel. However, a hospital that has a contract with an outside food management company may be found to meet this Condition of participation if the company has a dietitian who serves the hospital on a full-time, part-time, or consultant basis, and if the company maintains at least the minimum standards specified in this section and provides for constant liaison with the hospital medical staff for recommendations on dietetic policies affecting patient treatment.

(a) Standard: Organization. (1) The hospital must have a full-time employee who--

(i) Serves as director of the food and dietetic service;

(ii) Is responsible for the daily management of the dietary services; and

(iii) Is qualified by experience or training.

(2) There must be a qualified dietitian, full-time, part-time, or on a consultant basis.

(3) There must be administrative and technical personnel competent in their respective duties.

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(b) Standard: Diets. Menus must meet the needs of the patients.

(1) Therapeutic diets must be prescribed by the practitioner or practitioners responsible for the care of the patients.

(2) Nutritional needs must be met in accordance with recognized dietary practices and in accordance with orders of the practitioner or practitioners responsible for the care of the patients.

(3) A current therapeutic diet manual approved by the dietitian and medical staff must be readily available to all medical, nursing, and food service personnel.

Sec. 482.30 Condition of participation: Utilization review.

The hospital must have in effect a utilization review (UR) plan that provides for review of services furnished by the institution and by members of the medical staff to patients entitled to benefits under the Medicare and Medicaid programs.

(a) Applicability. The provisions of this section apply except in either of the following circumstances:

(1) A Utilization and Quality Control Peer Review Organization (PRO) has assumed binding review for the hospital.

(2) HCFA has determined that the UR procedures established by the State under title XIX of the Act are superior to the procedures required in this section, and has required hospitals in that State to meet the UR plan requirements under Secs. 456.50 through 456.245 of this chapter.

(b) Standard: Composition of utilization review committee. A UR committee consisting of two or more practitioners must carry out the UR function. At least two of the members of the committee must be doctors of medicine or osteopathy. The other members may be any of the other types of practitioners specified in Sec. 482.12(c)(1).

(1) Except as specified in paragraphs (b) (2) and (3) of this section, the UR committee must be one of the following:

(i) A staff committee of the institution;

(ii) A group outside the institution--

(A) Established by the local medical society and some or all of the hospitals in the locality; or

(B) Established in a manner approved by HCFA.

(2) If, because of the small size of the institution, it is impracticable to have a properly functioning staff committee, the UR committee must be established as specified in paragraph (b)(1)(ii) of this section.

(3) The committee's or group's reviews may not be conducted by any individual who--

(i) Has a direct financial interest (for example, an ownership interest) in that hospital; or

(ii) Was professionally involved in the care of the patient whose case is being reviewed.

(c) Standard: Scope and frequency of review. (1) The UR plan must provide for review for Medicare and Medicaid patients with respect to the medical necessity of--

(i) Admissions to the institution;

(ii) The duration of stays; and

(iii) Professional services furnished, including drugs and biologicals.

(2) Review of admissions may be performed before, at, or after hospital admission.

(3) Except as specified in paragraph (e) of this section, reviews may be conducted on a sample basis.

(4) Hospitals that are paid for inpatient hospital services under the prospective payment system set forth in Part 412 of this chapter must conduct review of duration of stays and review of professional services as follows:

(i) For duration of stays, these hospitals need review only cases that they reasonably assume to be outlier cases based on extended length of stay, as described in Sec. 412.80(a)(1)(i) of this chapter; and

(ii) For professional services, these hospitals need review only cases that they reasonably assume to be outlier cases based on extraordinarily high costs, as described in Sec. 412.80(a)(1)(ii) of this chapter.

(d) Standard: Determination regarding admissions or continued stays. (1) The determination that an admission or continued stay is not medically necessary--

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(i) May be made by one member of the UR committee if the practitioner or practitioners responsible for the care of the patient, as specified of Sec. 482.12(c), concur with the determination or fail to present their views when afforded the opportunity; and

(ii) Must be made by at least two members of the UR committee in all other cases.

(2) Before making a determination that an admission or continued stay is not medically necessary, the UR committee must consult the practitioner or practitioners responsible for the care of the patient, as specified in Sec. 482.12(c), and afford the practitioner or practitioners the opportunity to present their views.

(3) If the committee decides that admission to or continued stay in the hospital is not medically necessary, written notification must be given, no later than 2 days after the determination, to the hospital, the patient, and the practitioner or practitioners responsible for the care of the patient, as specified in Sec. 482.12(c);

(e) Standard: Extended stay review. (1) In hospitals that are not paid under the prospective payment system, the UR committee must make a periodic review, as specified in the UR plan, of each current inpatient receiving hospital services during a continuous period of extended duration. The scheduling of the periodic reviews may--

(i) Be the same for all cases; or

(ii) Differ for different classes of cases.

(2) In hospitals paid under the prospective payment system, the UR committee must review all cases reasonably assumed by the hospital to be outlier cases because the extended length of stay exceeds the threshold criteria for the diagnosis, as described in Sec. 412.80(a)(1)(i). The hospital is not required to review an extended stay that does not exceed the outlier threshold for the diagnosis.

(3) The UR committee must make the periodic review no later than 7 days after the day required in the UR plan.

(f) Standard: Review of professional services. The committee must review professional services provided, to determine medical necessity and to promote the most efficient use of available health facilities and services.

Sec. 482.41 Condition of participation: Physical environment.

The hospital must be constructed, arranged, and maintained to ensure the safety of the patient, and to provide facilities for diagnosis and treatment and for special hospital services appropriate to the needs of the community.

(a) Standard: Buildings. The condition of the physical plant and the overall hospital environment must be developed and maintained in such a manner that the safety and well-being of patients are assured.

(1) There must be emergency power and lighting in at least the operating, recovery, intensive care, and emergency rooms, and stairwells. In all other areas not serviced by the emergency supply source, battery lamps and flashlights must be available.

(2) There must be facilities for emergency gas and water supply.

(b) Standard: Life safety from fire. (1) Except as provided in paragraphs (b)(1)(i) through (b)(1)(iii) of this section, the hospital must meet the applicable provisions of the 1985 edition of the Life Safety Code of the National Fire Protection Association (which is

incorporated by reference).\1\

\1\ See footnote to Sec. 405.1134(a) of this chapter.

(i) Any hospital that on November 26, 1982, complied, with or without waivers, with the requirements of the 1967 edition of the Life Safety Code, or on May 9, 1988, complied with the 1981 edition of the Life Safety Code, is considered to be in compliance with this standard as long as the facility continues to remain in compliance with that edition of the Code.

(ii) After consideration of State survey agency findings, HCFA may waive specific provisions of the Life Safety Code which, if rigidly applied, would result in unreasonable hardship upon the facility, but only if the waiver does not adversely affect the health and safety of patients.

(iii) The provisions of the Life Safety Code do not apply in a State where HCFA finds that a fire and safety code

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imposed by State law adequately protects patients in hospitals.

(2) The hospital must have procedures for the proper routine storage and prompt disposal of trash.

(3) The hospital must have written fire control plans that contain provisions for prompt reporting of fires; extinguishing fires; protection of patients, personnel and guests; evacuation; and cooperation with fire fighting authorities.

(4) The hospital must maintain written evidence of regular inspection and approval by State or local fire control agencies.

(c) Standard: Facilities. The hospital must maintain adequate facilities for its services.

(1) Diagnostic and therapeutic facilities must be located for the safety of patients.

(2) Facilities, supplies, and equipment must be maintained to ensure an acceptable level of safety and quality.

(3) The extent and complexity of facilities must be determined by the services offered.

(4) There must be proper ventilation, light, and temperature controls in pharmaceutical, food preparation, and other appropriate areas.

[51 FR 22042, June 17, 1986, as amended at 53 FR 11509, Apr. 7, 1988]

Sec. 482.42 Condition of participation: Infection control.

The hospital must provide a sanitary environment to avoid sources and transmission of infections and communicable diseases. There must be an active program for the prevention, control, and investigation of infections and communicable diseases.

(a) Standard: Organization and policies. A person or persons must be designated as infection control officer or officers to develop and implement policies governing control of infections and communicable diseases.

(1) The infection control officer or officers must develop a system for identifying, reporting, investigating, and controlling infections and communicable diseases of patients and personnel.

(2) The infection control officer or officers must maintain a log of incidents related to infections and communicable diseases.

(b) Standard: Responsibilities of chief executive officer, medical staff, and director of nursing services. The chief executive officer, the medical staff, and the director of nursing services must--

(1) Ensure that the hospital-wide quality assurance program and training programs address problems identified by the infection control officer or officers; and

(2) Be responsible for the implementation of successful corrective action plans in affected problem areas.

Sec. 482.43 Condition of participation: Discharge planning.

The hospital must have in effect a discharge planning process that applies to all patients. The hospital's policies and procedures must be specified in writing.

(a) Standard: Identification of patients in need of discharge planning. The hospital must identify at an early stage of hospitalization all patients who are likely to suffer adverse health consequences upon discharge if there is no adequate discharge planning.

(b) Standard: Discharge planning evaluation. (1) The hospital must provide a discharge planning evaluation to the patients identified in paragraph (a) of this section, and to other patients upon the patient's request, the request of a person acting on the patient's behalf, or the request of the physician.

(2) A registered nurse, social worker, or other appropriately qualified personnel must develop, or supervise the development of, the

evaluation.

(3) The discharge planning evaluation must include an evaluation of the likelihood of a patient needing post- hospital services and of the availability of the services.

(4) The discharge planning evaluation must include an evaluation of the likelihood of a patient's capacity for self-care or of the possibility of the patient being cared for in the environment from which he or she entered the hospital.

(5) The hospital personnel must complete the evaluation on a timely basis so that appropriate arrangements for

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post-hospital care are made before discharge, and to avoid unnecessary delays in discharge.

(6) The hospital must include the discharge planning evaluation in the patient's medical record for use in establishing an appropriate discharge plan and must discuss the results of the evaluation with the patient or individual acting on his or her behalf.

(c) Standard: Discharge plan. (1) A registered nurse, social worker, or other appropriately qualified personnel must develop, or supervise the development of, a discharge plan if the discharge planning evaluation indicates a need for a discharge plan.

(2) In the absence of a finding by the hospital that a patient needs a discharge plan, the patient's physician may request a discharge plan. In such a case, the hospital must develop a discharge plan for the patient.

(3) The hospital must arrange for the initial implementation of the patient's discharge plan.

(4) The hospital must reassess the patient's discharge plan if there are factors that may affect continuing care needs or the appropriateness of the discharge plan.

(5) As needed, the patient and family members or interested persons must be counseled to prepare them for post-hospital care.

(d) Standard: Transfer or referral. The hospital must transfer or refer patients, along with necessary medical information, to appropriate facilities, agencies, or outpatient services, as needed, for followup or ancillary care.

(e) Standard: Reassessment. The hospital must reassess its discharge planning process on an on-going basis. The reassessment must include a review of discharge plans to ensure that they are responsive to discharge needs.

[59 FR 64152, Dec. 13, 1994]

[Code of Federal Regulations]
[Title 42, Volume 3, Parts 430 to end]
[Revised as of October 1, 1997]
From the U.S. Government Printing Office via GPO Access
[CITE: 42CFR482]

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TITLE 42--PUBLIC HEALTH

CHAPTER IV--HEALTH CARE FINANCING ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES--(Continued)

PART 482--CONDITIONS OF PARTICIPATION FOR HOSPITALS--Table of Contents

Subpart D--Optional Hospital Services

Sec. 482.51 Condition of participation: Surgical services.

If the hospital provides surgical services, the services must be well organized and provided in accordance with acceptable standards of practice. If outpatient surgical services are offered the services must be consistent in quality with inpatient care in accordance with the complexity of services offered.

(a) Standard: Organization and staffing. The organization of the surgical services must be appropriate to the scope of the services offered.

(1) The operating rooms must be supervised by an experienced registered nurse or a doctor of medicine or osteopathy.

(2) Licensed practical nurses (LPNs) and surgical technologists (operating room technicians) may serve as ``scrub nurses'' under the supervision of a registered nurse.

(3) Qualified registered nurses may perform circulating duties in the operating room. In accordance with applicable State laws and approved medical staff policies and procedures, LPNs and surgical technologists may assist in circulatory duties under the surpervision of a qualified registered nurse who is immediately available to respond to emergencies.

(4) Surgical privileges must be delineated for all practitioners performing surgery in accordance with the competencies of each practitioner. The surgical service must maintain a roster of practitioners specifying the surgical privileges of each practitioner.

(b) Standard: Delivery of service. Surgical services must be consistent with needs and resources. Policies governing surgical care must be designed to assure the achievement and maintenance of high standards of medical practice and patient care.

(1) There must be a complete history and physical work-up in the chart of every patient prior to surgery, except in emergencies. If this has been dictated, but not yet recorded in the patient's chart, there must be a statement to that effect and an admission note in the chart by the practitioner who admitted the patient.

(2) A properly executed informed consent form for the operation must be in the patient's chart before surgery, except in emergencies.

(3) The following equipment must be available to the operating room suites: call-in-system, cardiac monitor, resuscitator, defibrillator, aspirator, and tracheotomy set.

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(4) There must be adequate provisions for immediate post-operative care.

(5) The operating room register must be complete and up-to-date.

(6) An operative report describing techniques, findings, and tissues removed or altered must be written or dictated immediately following surgery and signed by the surgeon.

Sec. 482.52 Condition of participation; Anesthesia services.

If the hospital furnishes anesthesia services, they must be provided in a well-organized manner under the direction of a qualified doctor of medicine or osteopathy. The service is responsible for all anesthesia administered in the hospital.

(a) Standard: Organization and staffing. The organization of anesthesia services must be appropriate to the scope of the services offered. Anesthesia must be administered by only--

(1) A qualified anesthesiologist:

(2) A doctor of medicine or osteopathy (other than an anesthesiologist);

(3) A dentist, oral surgeon, or podiatrist who is qualified to administer anesthesia under State law;

(4) A certified registered nurse anesthetist (CRNA), as defined in Sec. 410.69(b) of this chapter, who is under the supervision of the operating practitioner or of an anesthesiologist who is immediately available if needed; or

(5) An anesthesiologist's assistant, as defined in Sec. 410.69(b) of this chapter, who is under the supervision of an anesthesiologist who is immediately available if needed.

(b) Standard: Delivery of services. Anesthesia services must be consistent with needs and resources. Policies on anesthesia procedures must include the delineation of preanesthesia and post anesthesia responsibilities. The policies must ensure that the following are provided for each patient:

(1) A preanesthesia evaluation by an individual qualified to administer anesthesia under paragraph (a) of this section performed within 48 hours prior to surgery.

(2) An intraoperative anesthesia record.

(3) With respect to inpatients, a postanesthesia followup report by the individual who administers the anesthesia that is written within 48 hours after surgery.

(4) With respect to outpatients, a postanesthesia evaluation for proper anesthesia recovery performed in accordance with policies and procedures approved by the medical staff.

[51 FR 22042, June 17, 1986 as amended at 57 FR 33900, July 31, 1992]

Sec. 482.53 Condition of participation: Nuclear medicine services.

If the hospital provides nuclear medicine services, those services must meet the needs of the patients in accordance with acceptable standards of practice.

(a) Standard: Organization and staffing. The organization of the nuclear medicine service must be appropriate to the scope and complexity of the services offered.

(1) There must be a director who is a doctor of medicine or osteopathy qualified in nuclear medicine.

(2) The qualifications, training, functions, and responsibilities of nuclear medicine personnel must be specified by the service director and approved by the medical staff.

(b) Standard: Delivery of service. Radioactive materials must be prepared, labeled, used, transported, stored, and disposed of in accordance with acceptable standards of practice.

(1) In-house preparation of radiopharmaceuticals is by, or under, the direct supervision of an appropriately trained registered pharmacist or a doctor of medicine or osteopathy.

(2) There is proper storage and disposal of radioactive material.

(3) If laboratory tests are performed in the nuclear medicine service, the service must meet the applicable requirement for laboratory services specified in Sec. 482.27.

(c) Standard: Facilities. Equipment and supplies must be appropriate for the types of nuclear medicine services offered and must be maintained for safe and efficient performance. The equipment must be--

(1) Maintained in safe operating condition; and

(2) Inspected, tested, and calibrated at least annually by qualified personnel.

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(d) Standard: Records. The hospital must maintain signed and dated reports of nuclear medicine interpretations, consultations, and procedures.

(1) The hospital must maintain copies of nuclear medicine reports for at least 5 years.

(2) The practitioner approved by the medical staff to interpret diagnostic procedures must sign and date the interpretation of these tests.

(3) The hospital must maintain records of the receipt and disposition of radiopharmaceuticals.

(4) Nuclear medicine services must be ordered only by practitioner whose scope of Federal or State licensure and whose defined staff privileges allow such referrals.

[51 FR 22042, June 17, 1986, as amended at 57 FR 7136, Feb. 28, 1992]

Sec. 482.54 Condition of participation: Outpatient services.

If the hospital provides outpatient services, the services must meet the needs of the patients in accordance with acceptable standards of practice.

(a) Standard: Organization. Outpatient services must be appropriately organized and integrated with inpatient services.

(b) Standard: Personnel. The hospitals must--

(1) Assign an individual to be responsible for outpatient services; and

(2) Have appropriate professional and nonprofessional personnel available.

Sec. 482.55 Condition of participation: Emergency services.

The hospital must meet the emergency needs of patients in accordance

with acceptable standards of practice.
(a) Standard: Organization and direction. If emergency services are provided at the hospital--
(1) The services must be organized under the direction of a qualified member of the medical staff;
(2) The services must be integrated with other departments of the hospital;
(3) The policies and procedures governing medical care provided in the emergency service or department are established by and are a continuing responsibility of the medical staff.
(b) Standard: Personnel. (1) The emergency services must be supervised by a qualified member of the medical staff.
(2) There must be adequate medical and nursing personnel qualified in emergency care to meet the written emergency procedures and needs anticipated by the facility.

Sec. 482.56 Condition of participation: Rehabilitation services.

If the hospital provides rehabilitation, physical therapy, occupational therapy, audiology, or speech pathology services, the services must be organized and staffed to ensure the health and safety of patients.
(a) Standard: Organization and staffing. The organization of the service must be appropriate to the scope of the services offered.
(1) The director of the services must have the necessary knowledge, experience, and capabilities to properly supervise and administer the services.
(2) Physical therapy, occupational therapy, or speech therapy, or audiology services, if provided, must be provided by staff who meet the qualifications specified by the medical staff, consistent with State law.
(b) Standard: Delivery of services. Services must be furnished in accordance with a written plan of treatment. Services must be given in accordance with orders of practitioners who are authorized by the medical staff to order the services, and the orders must be incorporated in the patient's record.

Sec. 482.57 Condition of participation: Respiratory care services.

The hospital must meet the needs of the patients in accordance with acceptable standards of practice. The following requirements apply if the hospital provides respiratory care service.
(a) Standard: Organization and Staffing. The organization of the respiratory care services must be appropriate to the scope and complexity of the services offered.
(1) There must be a director of respiratory care services who is a doctor of medicine or osteopathy with the knowledge experience, and capabilities to supervise and administer the service properly. The director may serve on either a full-time or part-time basis.

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(2) There must be adequate numbers of respiratory therapists, respiratory therapy technicians, and other personnel who meet the qualifications specified by the medical staff, consistent with State law.
(b) Standard: Delivery of Services. Services must be delivered in accordance with medical staff directives.
(1) Personnel qualified to perform specific procedures and the amount of supervision required for personnel to carry out specific procedures must be designated in writing.
(2) If blood gases or other laboratory tests are performed in the respiratory care unit, the unit must meet the applicable requirements for laboratory services specified in Sec. 482.27.
(3) Services must be provided only on, and in accordance with, the orders of a doctor of medicine or osteopathy.

[51 FR 22042, June 17, 1986; 51 FR 27848, Aug. 4, 1986, as amended at 57 FR 7136, Feb. 28, 1992]

[Code of Federal Regulations]
[Title 42, Volume 3, Parts 430 to end]
[Revised as of October 1, 1997]
From the U.S. Government Printing Office via GPO Access
[CITE: 42CFR482]

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TITLE 42--PUBLIC HEALTH

CHAPTER IV--HEALTH CARE FINANCING ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES--(Continued)

PART 482--CONDITIONS OF PARTICIPATION FOR HOSPITALS--Table of Contents

Subpart E--Requirements for Specialty Hospitals

Psychiatric hospital must--

(a) Be primarily engaged in providing, by or under the supervision of a doctor of medicine or osteopathy, psychiatric services for the diagnosis and treatment of mentally ill persons;

(b) Meet the conditions of participation specified in Secs. 482.1 through 482.23 and Secs. 482.25 through 482.57;

(c) Maintain clinical records on all patients, including records sufficient to permit HCFA to determine the degree and intensity of treatment furnished to Medicare beneficiaries, as specified in Sec. 482.61; and

(d) Meet the staffing requirements specified in Sec. 482.62.

[51 FR 22042, June 17, 1986; 51 FR 27848, Aug. 4, 1986]

Sec. 482.61 Condition of participation: Special medical record requirements for psychiatric hospitals.

The medical records maintained by a psychiatric hospital must permit determination of the degree and intensity of the treatment provided to individuals who are furnished services in the institution.

(a) Standard: Development of assessment/diagnostic data. Medical records must stress the psychiatric components of the record, including history of findings and treatment provided for the psychiatric condition for which the patient is hospitalized.

(1) The identification data must include the patient's legal status.

(2) A provisional or admitting diagnosis must be made on every patient at the time of admission, and must include the diagnoses of intercurrent diseases as well as the psychiatric diagnoses.

(3) The reasons for admission must be clearly documented as stated by the patient and/or others significantly involved.

(4) The social service records, including reports of interviews with patients, family members, and others, must provide an assessment of home plans and family attitudes, and community resource contacts as well as a social history.

(5) When indicated, a complete neurological examination must be recorded at the time of the admission physical examination.

(b) Standard: Psychiatric evaluation. Each patient must receive a psychiatric evaluation that must--

(1) Be completed within 60 hours of admission;

(2) Include a medical history;

(3) Contain a record of mental status;

(4) Note the onset of illness and the circumstances leading to admission;

(5) Describe attitudes and behavior;

(6) Estimate intellectual functioning, memory functioning, and orientation; and

(7) Include an inventory of the patient's assets in descriptive, not interpretative, fashion.

(c) Standard: Treatment plan. (1) Each patient must have an individual comprehensive treatment plan that must be based on an inventory of the patient's strengths and disabilities. The written plan must include--

(i) A substantiated diagnosis;

(ii) Short-term and long-range goals;

(iii) The specific treatment modalities utilized;

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(iv) The responsibilities of each member of the treatment team; and

(v) Adequate documentation to justify the diagnosis and the treatment and rehabilitation activities carried out.

(2) The treatment received by the patient must be documented in such a way to assure that all active therapeutic efforts are included.

(d) Standard: Recording progress. Progress notes must be recorded by the doctor of medicine or osteopathy responsible for the care of the

patient as specified in Sec. 482.12(c), nurse, social worker and, when appropriate, others significantly involved in active treatment modalities. The frequency of progress notes is determined by the condition of the patient but must be recorded at least weekly for the first 2 months and at least once a month thereafter and must contain recommendations for revisions in the treatment plan as indicated as well as precise assessment of the patient's progress in accordance with the original or revised treatment plan.

(e) Standard: Discharge planning and discharge summary. The record of each patient who has been discharged must have a discharge summary that includes a recapitulation of the patient's hospitalization and recommendations from appropriate services concerning follow-up or aftercare as well as a brief summary of the patient's condition on discharge.

[51 FR 22042, June 17, 1986; 51 FR 27848, Aug. 4, 1986]

Sec. 482.62 Condition of participation: Special staff requirements for psychiatric hospitals.

The hospital must have adequate numbers of qualified professional and supportive staff to evaluate patients, formulate written, individualized comprehensive treatment plans, provide active treatment measures, and engage in discharge planning.

(a) Standard: Personnel. The hospital must employ or undertake to provide adequate numbers of qualified professional, technical, and consultative personnel to:

(1) Evaluate patients;

(2) Formulate written individualized, comprehensive treatment plans;

(3) Provide active treatment measures; and

(4) Engage in discharge planning.

(b) Standard: Director of inpatient psychiatric services; medical staff. Inpatient psychiatric services must be under the supervision of a clinical director, service chief, or equivalent who is qualified to provide the leadership required for an intensive treatment program. The number and qualifications of doctors of medicine and osteopathy must be adequate to provide essential psychiatric services.

(1) The clinical director, service chief, or equivalent must meet the training and experience requirements for examination by the American Board of Psychiatry and Neurology or the American Osteopathic Board of Neurology and Psychiatry.

(2) The director must monitor and evaluate the quality and appropriateness of services and treatment provided by the medical staff.

(c) Standard: Availability of medical personnel. Doctors of medicine or osteopathy and other appropriate professional personnel must be available to provide necessary medical and surgical diagnostic and treatment services. If medical and surgical diagnostic and treatment services are not available within the institution, the institution must have an agreement with an outside source of these services to ensure that they are immediately available or a satisfactory agreement must be established for transferring patients to a general hospital that participates in the Medicare program.

(d) Standard: Nursing services. The hospital must have a qualified director of psychiatric nursing services. In addition to the director of nursing, there must be adequate numbers of registered nurses, licensed practical nurses, and mental health workers to provide nursing care necessary under each patient's active treatment program and to maintain progress notes on each patient.

(1) The director of psychiatric nursing services must be a registered nurse who has a master's degree in psychiatric or mental health nursing, or its equivalent from a school of nursing accredited by the National League for Nursing, or be qualified by education

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and experience in the care of the mentally ill. The director must demonstrate competence to participate in interdisciplinary formulation of individual treatment plans; to give skilled nursing care and therapy; and to direct, monitor, and evaluate the nursing care furnished.

(2) The staffing pattern must insure the availability of a registered professional nurse 24 hours each day. There must be adequate numbers of registered nurses, licensed practical nurses, and mental health workers to provide the nursing care necessary under each patient's active treatment program.

(e) Standard: Psychological services. The hospital must provide or have available psychological services to meet the needs of the patients.

(f) Standard: Social services. There must be a director of social services who monitors and evaluates the quality and appropriateness of social services furnished. The services must be furnished in accordance with accepted standards of practice and established policies and procedures.

(1) The director of the social work department or service must have a master's degree from an accredited school of social work or must be qualified by education and experience in the social services needs of the mentally ill. If the director does not hold a masters degree in social work, at least one staff member must have this qualification.

(2) Social service staff responsibilities must include, but are not limited to, participating in discharge planning, arranging for follow-up care, and developing mechanisms for exchange of appropriate, information with sources outside the hospital.

(g) Standard: Therapeutic activities. The hospital must provide a therapeutic activities program.

(1) The program must be appropriate to the needs and interests of patients and be directed toward restoring and maintaining optimal levels of physical and psychosocial functioning.

(2) The number of qualified therapists, support personnel, and consultants must be adequate to provide comprehensive therapeutic activities consistent with each patient's active treatment program.

[51 FR 22042, June 17, 1986; 51 FR 27848, Aug. 4, 1986]

Sec. 482.66 Special requirements for hospital providers of long-term care services (``swing-beds'').

A hospital that has a Medicare provider agreement must meet the following requirements in order to be granted an approval from HCFA to provide post-hospital extended care services, as specified in Sec. 409.30 of this chapter, and be reimbursed as a swing-bed hospital, as specified in Sec. 413.114 of this chapter:

(a) Eligibility. A hospital must meet the following eligibility requirements:

(1) The facility has fewer than 100 hospital beds, excluding beds for newborns and beds in intensive care type inpatient units (for eligibility of hospitals with distinct parts electing the optional reimbursement method, see Sec. 413.24(d)(5) of this chapter).

(2) The hospital is located in a rural area. This includes all areas not delineated as ``urbanized'' areas by the Census Bureau, based on the most recent census.

(3) When required by State in which it is located, the hospital has been granted a certificate of need for the provision of long-term care services from the State health planning and development agency (designated under section 1521 of the Public Health Service Act).

(4) The hospital does not have in effect a 24-hour nursing waiver granted under Sec. 488.54(c) of this chapter.

(5) The hospital has not had a swing-bed approval terminated within the two years previous to application.

(6) A hospital with more than 49 beds (but fewer than 100) approved under this section after March 31, 1988, must--

(i) Unless a Medicare-participating SNF is not available or the SNFs are not willing to enter into an agreement when one is offered, have an availability agreement with each SNF in its geographic region that requires the SNF to notify the hospital of the availability of posthospital SNF care beds and the dates when those beds will be available; and

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(ii) Transfer the extended care patient within 5 days (excluding weekends and holidays) after learning that a SNF bed is available or in the case of prospective notification by the SNF, within 5 days of the date the bed becomes available, unless the patient's physician certifies, as required under Sec. 424.20, that the transfer is not medically appropriate.

(7) The hospital must provide written assurance to HCFA that the hospital will not operate over 49 or over 99 beds except in connection with a catastrophic event. The hospital bed count is determined as follows:

(i) A hospital bed count is calculated by excluding from the count, beds that because of their special nature, such as newborn and intensive care beds, would not be available for swing-bed use. Also excluded from the bed count are beds in separately certified ``distinct part'' SNFs and NFs and beds in a psychiatric or rehabilitation unit that is excluded from the prospective payment system.

(ii) A hospital licensed for more than 49 or 99 beds, is considered to have the number of beds that it consistently utilizes and staffs. Hospitals, at a minimum, document their count by staffing schedules and census information for the previous 12 months before application to be a swing-bed hospital.

(b) Skilled nursing facility services. The facility is substantially in compliance with the following skilled nursing facility requirements contained in **subpart** B of part 483 of this chapter.

(1) Resident rights (Sec. 483.10 (b)(3), (b)(4), (b)(5), (b)(6), (d), (e), (h), (i), (j)(1)(vii), (j)(1)(viii), (l), and (m)).

(2) Admission, transfer, and discharge rights (Sec. 483.12 (a)(1), (a)(2), (a)(3), (a)(4), (a)(5), (a)(6), and (a)(7)).

(3) Resident behavior and facility practices (Sec. 483.13).

(4) Patient activities (Sec. 483.15(f)).

(5) Social services (Sec. 483.15(g)).

(6) Discharge planning (Sec. 483.20(e)).

(7) Specialized rehabilitative services (Sec. 483.45).

(8) Dental services (Sec. 483.55).

[51 FR 22042, June 17, 1986; 51 FR 27848, Aug. 4, 1986, as amended at 51 FR 34833, Sept. 30, 1986; 54 FR 37275, Sept. 7, 1989; 56 FR 54546, Oct. 22, 1991; 59 FR 45403, Sept. 1, 1994]

[Code of Federal Regulations]
[Title 42, Volume 3, Parts 430 to end]
[Revised as of October 1, 1997]
From the U.S. Government Printing Office via GPO Access
[CITE: 42CFR483]

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TITLE 42--PUBLIC HEALTH

CHAPTER IV--HEALTH CARE FINANCING ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES--(Continued)

PART 483--REQUIREMENTS FOR STATES AND LONG TERM CARE FACILITIES--Table of Contents

Subpart I--Conditions of Participation for Intermediate Care Facilities for the Mentally Retarded

Source: 53 FR 20496, June 3, 1988. Redesignated at 56 FR 48918, Sept. 26, 1991.

Sec. 483.400 Basis and purpose.

This **subpart** implements section 1905 (c) and (d) of the Act which gives the Secretary authority to prescribe regulations for intermediate care facility services in facilities for the mentally retarded or persons with related conditions.

Sec. 483.405 Relationship to other HHS regulations.

In addition to compliance with the regulations set forth in this **subpart**, facilities are obliged to meet the applicable provisions of other HHS regulations, including but not limited to those pertaining to nondiscrimination on the basis of race, color, or national origin (45 CFR Part 80), nondiscrimination on the basis of handicap (45 CFR Part 84), nondiscrimination on the basis of age (45 CFR Part 91), protection of human subjects of research (45 CFR Part 46), and fraud and abuse (42 CFR Part 455). Although those regulations are not in themselves considered conditions of participation under this Part, their violation may result in the termination or suspension of, or the refusal to grant or continue, Federal financial assistance.

Sec. 483.410 Condition of participation: Governing body and management.

(a) Standard: Governing body. The facility must identify an individual or individuals to constitute the governing body of the facility. The governing body must--

(1) Exercise general policy, budget, and operating direction over the facility;

(2) Set the qualifications (in addition to those already set by State law, if any) for the administrator of the facility; and

(3) Appoint the administrator of the facility.

(b) Standard: Compliance with Federal, State, and local laws. The facility must be in compliance with all applicable provisions of Federal, State and local laws, regulations and codes pertaining to health, safety, and sanitation.

(c) Standard: Client records. (1) The facility must develop and maintain a recordkeeping system that includes a separate record for each client and that documents the client's health care, active treatment, social information, and protection of the client's rights.

(2) The facility must keep confidential all information contained in the clients' records, regardless of the form or storage method of the records.

(3) The facility must develop and implement policies and procedures governing the release of any client information, including consents necessary from the client, or parents (if the client is a minor) or legal guardian.

(4) Any individual who makes an entry in a client's record must make it legibly, date it, and sign it.

(5) The facility must provide a legend to explain any symbol or abbreviation used in a client's record.

(6) The facility must provide each identified residential living unit with appropriate aspects of each client's record.

(d) Standard: Services provided under agreements with outside sources. (1) If a service required under this **subpart** is not provided directly, the facility must

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have a written agreement with an outside program, resource, or service to furnish the necessary service, including emergency and other health care.

(2) The agreement must--

(i) Contain the responsibilities, functions, objectives, and other terms agreed to by both parties; and

(ii) Provide that the facility is responsible for assuring that the outside services meet the standards for quality of services contained in this subpart.

(3) The facility must assure that outside services meet the needs of each client.

(4) If living quarters are not provided in a facility owned by the ICF/MR, the ICF/MR remains directly responsible for the standards relating to physical environment that are specified in Sec. 483.470 (a) through (g), (j) and (k).

(e) Standard: Licensure. The facility must be licensed under applicable State and local law.

[53 FR 20496, June 3, 1988. Redesignated at 56 FR 48918, Sept. 26, 1991, and amended at 57 FR 43925, Sept. 23, 1992]

Sec. 483.420 Condition of participation: Client protections.

(a) Standard: Protection of clients' rights. The facility must ensure the rights of all clients. Therefore, the facility must--

(1) Inform each client, parent (if the client is a minor), or legal guardian, of the client's rights and the rules of the facility;

(2) Inform each client, parent (if the client is a minor), or legal guardian, of the client's medical condition, developmental and behavioral status, attendant risks of treatment, and of the right to refuse treatment;

(3) Allow and encourage individual clients to exercise their rights as clients of the facility, and as citizens of the United States, including the right to file complaints, and the right to due process;

(4) Allow individual clients to manage their financial affairs and teach them to do so to the extent of their capabilities;

(5) Ensure that clients are not subjected to physical, verbal, sexual or psychological abuse or punishment;

(6) Ensure that clients are free from unnecessary drugs and physical restraints and are provided active treatment to reduce dependency on drugs and physical restraints;

(7) Provide each client with the opportunity for personal privacy and ensure privacy during treatment and care of personal needs;

(8) Ensure that clients are not compelled to perform services for the facility and ensure that clients who do work for the facility are compensated for their efforts at prevailing wages and commensurate with their abilities;

(9) Ensure clients the opportunity to communicate, associate and meet privately with individuals of their choice, and to send and receive unopened mail;

(10) Ensure that clients have access to telephones with privacy for incoming and outgoing local and long distance calls except as contraindicated by factors identified within their individual program plans;

(11) Ensure clients the opportunity to participate in social, religious, and community group activities;

(12) Ensure that clients have the right to retain and use appropriate personal possessions and clothing, and ensure that each client is dressed in his or her own clothing each day; and

(13) Permit a husband and wife who both reside in the facility to share a room.

(b) Standard: Client finances. (1) The facility must establish and maintain a system that--

(i) Assures a full and complete accounting of clients' personal funds entrusted to the facility on behalf of clients; and

(ii) Precludes any commingling of client funds with facility funds or with the funds of any person other than another client.

(2) The client's financial record must be available on request to the client, parents (if the client is a minor) or legal guardian.

(c) Standard: Communication with clients, parents, and guardians. The facility must--

(1) Promote participation of parents (if the client is a minor) and legal guardians in the process of providing active treatment to a client unless their participation is unobtainable or inappropriate;

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(2) Answer communications from clients' families and friends promptly and appropriately;

(3) Promote visits by individuals with a relationship to the client (such as family, close friends, legal guardians and advocates) at any reasonable hour, without prior notice, consistent with the right of that client's and other clients' privacy, unless the interdisciplinary team determines that the visit would not be appropriate;

(4) Promote visits by parents or guardians to any area of the facility that provides direct client care services to the client, consistent with the right of that client's and other clients' privacy;

(5) Promote frequent and informal leaves from the facility for visits, trips, or vacations; and

(6) Notify promptly the client's parents or guardian of any significant incidents, or changes in the client's condition including, but not limited to, serious illness, accident, death, abuse, or

unauthorized absence.
(d) Standard: Staff treatment of clients. (1) The facility must develop and implement written policies and procedures that prohibit mistreatment, neglect or abuse of the client.
(i) Staff of the facility must not use physical, verbal, sexual or psychological abuse or punishment.
(ii) Staff must not punish a client by withholding food or hydration that contributes to a nutritionally adequate diet.
(iii) The facility must prohibit the employment of individuals with a conviction or prior employment history of child or client abuse, neglect or mistreatment.
(2) The facility must ensure that all allegations of mistreatment, neglect or abuse, as well as injuries of unknown source, are reported immediately to the administrator or to other officials in accordance with State law through established procedures.
(3) The facility must have evidence that all alleged violations are thoroughly investigated and must prevent further potential abuse while the investigation is in progress.
(4) The results of all investigations must be reported to the administrator or designated representative or to other officials in accordance with State law within five working days of the incident and, if the alleged violation is verified, appropriate corrective action must be taken.

Sec. 483.430 Condition of participation: Facility staffing.

(a) Standard: Qualified mental retardation professional. Each client's active treatment program must be integrated, coordinated and monitored by a qualified mental retardation professional who--
(1) Has at least one year of experience working directly with persons with mental retardation or other developmental disabilities; and
(2) Is one of the following:
(i) A doctor of medicine or osteopathy.
(ii) A registered nurse.
(iii) An individual who holds at least a bachelor's degree in a professional category specified in paragraph (b)(5) of this section.
(b) Standard: Professional program services. (1) Each client must receive the professional program services needed to implement the active treatment program defined by each client's individual program plan. Professional program staff must work directly with clients and with paraprofessional, nonprofessional and other professional program staff who work with clients.
(2) The facility must have available enough qualified professional staff to carry out and monitor the various professional interventions in accordance with the stated goals and objectives of every individual program plan.
(3) Professional program staff must participate as members of the interdisciplinary team in relevant aspects of the active treatment process.
(4) Professional program staff must participate in on-going staff development and training in both formal and informal settings with other professional, paraprofessional, and nonprofessional staff members.
(5) Professional program staff must be licensed, certified, or registered, as applicable, to provide professional services by the State in which he or

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she practices. Those professional program staff who do not fall under the jurisdiction of State licensure, certification, or registration requirements, specified in Sec. 483.410(b), must meet the following qualifications:
(i) To be designated as an occupational therapist, an individual must be eligible for certification as an occupational therapist by the American Occupational Therapy Association or another comparable body.
(ii) To be designated as an occupational therapy assistant, an individual must be eligible for certification as a certified occupational therapy assistant by the American Occupational Therapy Association or another comparable body.
(iii) To be designated as a physical therapist, an individual must be eligible for certification as a physical therapist by the American Physical Therapy Association or another comparable body.
(iv) To be designated as a physical therapy assistant, an individual must be eligible for registration by the American Physical Therapy Association or be a graduate of a two year college-level program approved by the American Physical Therapy Association or another comparable body.
(v) To be designated as a psychologist, an individual must have at least a master's degree in psychology from an accredited school.
(vi) To be designated as a social worker, an individual must--
(A) Hold a graduate degree from a school of social work accredited or approved by the Council on Social Work Education or another comparable body; or
(B) Hold a Bachelor of Social Work degree from a college or university accredited or approved by the Council on Social Work Education or another comparable body.

(vii) To be designated as a speech-language pathologist or audiologist, an individual must--

(A) Be eligible for a Certificate of Clinical Competence in Speech-Language Pathology or Audiology granted by the American Speech-Language-Hearing Association or another comparable body; or

(B) Meet the educational requirements for certification and be in the process of accumulating the supervised experience required for certification.

(viii) To be designated as a professional recreation staff member, an individual must have a bachelor's degree in recreation or in a specialty area such as art, dance, music or physical education.

(ix) To be designated as a professional dietitian, an individual must be eligible for registration by the American Dietetics Association.

(x) To be designated as a human services professional an individual must have at least a bachelor's degree in a human services field (including, but not limited to: sociology, special education, rehabilitation counseling, and psychology).

(xi) If the client's individual program plan is being successfully implemented by facility staff, professional program staff meeting the qualifications of paragraph (b)(5) (i) through (x) of this section are not required--

(A) Except for qualified mental retardation professionals;

(B) Except for the requirements of paragraph (b)(2) of this section concerning the facility's provision of enough qualified professional program staff; and

(C) Unless otherwise specified by State licensure and certification requirements.

(c) Standard: Facility staffing. (1) The facility must not depend upon clients or volunteers to perform direct care services for the facility.

(2) There must be responsible direct care staff on duty and awake on a 24-hour basis, when clients are present, to take prompt, appropriate action in case of injury, illness, fire or other emergency, in each defined residential living unit housing--

(i) Clients for whom a physician has ordered a medical care plan;

(ii) Clients who are aggressive, assaultive or security risks;

(iii) More than 16 clients; or

(iv) Fewer than 16 clients within a multi-unit building.

(3) There must be a responsible direct care staff person on duty on a 24 hour

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basis (when clients are present) to respond to injuries and symptoms of illness, and to handle emergencies, in each defined residential living unit housing--

(i) Clients for whom a physician has not ordered a medical care plan;

(ii) Clients who are not aggressive, assaultive or security risks; and

(iii) Sixteen or fewer clients,

(4) The facility must provide sufficient support staff so that direct care staff are not required to perform support services to the extent that these duties interfere with the exercise of their primary direct client care duties.

(d) Standard: Direct care (residential living unit) staff. (1) The facility must provide sufficient direct care staff to manage and supervise clients in accordance with their individual program plans.

(2) Direct care staff are defined as the present on-duty staff calculated over all shifts in a 24-hour period for each defined residential living unit.

(3) Direct care staff must be provided by the facility in the following minimum ratios of direct care staff to clients:

(i) For each defined residential living unit serving children under the age of 12, severely and profoundly retarded clients, clients with severe physical disabilities, or clients who are aggressive, assaultive, or security risks, or who manifest severely hyperactive or psychotic-like behavior, the staff to client ratio is 1 to 3.2.

(ii) For each defined residential living unit serving moderately retarded clients, the staff to client ratio is 1 to 4.

(iii) For each defined residential living unit serving clients who function within the range of mild retardation, the staff to client ratio is 1 to 6.4.

(4) When there are no clients present in the living unit, a responsible staff member must be available by telephone.

(e) Standard: Staff training program. (1) The facility must provide each employee with initial and continuing training that enables the employee to perform his or her duties effectively, efficiently, and competently.

(2) For employees who work with clients, training must focus on skills and competencies directed toward clients' developmental, behavioral, and health needs.

(3) Staff must be able to demonstrate the skills and techniques necessary to administer interventions to manage the inappropriate behavior of clients.

(4) Staff must be able to demonstrate the skills and techniques

necessary to implement the individual program plans for each client for whom they are responsible.

Sec. 483.440 Condition of participation: Active treatment services.

(a) Standard: Active treatment. (1) Each client must receive a continuous active treatment program, which includes aggressive, consistent implementation of a program of specialized and generic training, treatment, health services and related services described in this subpart, that is directed toward--

(i) The acquisition of the behaviors necessary for the client to function with as much self determination and independence as possible; and

(ii) The prevention or deceleration of regression or loss of current optimal functional status.

(2) Active treatment does not include services to maintain generally independent clients who are able to function with little supervision or in the absence of a continuous active treatment program.

(b) Standard: Admissions, transfers, and discharge. (1) Clients who are admitted by the facility must be in need of and receiving active treatment services.

(2) Admission decisions must be based on a preliminary evaluation of the client that is conducted or updated by the facility or by outside sources.

(3) A preliminary evaluation must contain background information as well as currently valid assessments of functional developmental, behavioral, social, health and nutritional status to determine if the facility can provide for the client's needs and if the client is likely to benefit from placement in the facility.

(4) If a client is to be either transferred or discharged, the facility must--

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(i) Have documentation in the client's record that the client was transferred or discharged for good cause; and

(ii) Provide a reasonable time to prepare the client and his or her parents or guardian for the transfer or discharge (except in emergencies).

(5) At the time of the discharge, the facility must--

(i) Develop a final summary of the client's developmental, behavioral, social, health and nutritional status and, with the consent of the client, parents (if the client is a minor) or legal guardian, provide a copy to authorized persons and agencies; and

(ii) Provide a post-discharge plan of care that will assist the client to adjust to the new living environment.

(c) Standard: Individual program plan. (1) Each client must have an individual program plan developed by an interdisciplinary team that represents the professions, disciplines or service areas that are relevant to--

(i) Identifying the client's needs, as described by the comprehensive functional assessments required in paragraph (c)(3) of this section; and

(ii) Designing programs that meet the client's needs.

(2) Appropriate facility staff must participate in interdisciplinary team meetings. Participation by other agencies serving the client is encouraged. Participation by the client, his or her parent (if the client is a minor), or the client's legal guardian is required unless that participation is unobtainable or inappropriate.

(3) Within 30 days after admission, the interdisciplinary team must perform accurate assessments or reassessments as needed to supplement the preliminary evaluation conducted prior to admission. The comprehensive functional assessment must take into consideration the client's age (for example, child, young adult, elderly person) and the implications for active treatment at each stage, as applicable, and must--

(i) Identify the presenting problems and disabilities and where possible, their causes;

(ii) Identify the client's specific developmental strengths;

(iii) Identify the client's specific developmental and behavioral management needs;

(iv) Identify the client's need for services without regard to the actual availability of the services needed; and

(v) Include physical development and health, nutritional status, sensorimotor development, affective development, speech and language development and auditory functioning, cognitive development, social development, adaptive behaviors or independent living skills necessary for the client to be able to function in the community, and as applicable, vocational skills.

(4) Within 30 days after admission, the interdisciplinary team must prepare for each client an individual program plan that states the specific objectives necessary to meet the client's needs, as identified by the comprehensive assessment required by paragraph (c)(3) of this section, and the planned sequence for dealing with those objectives. These objectives must--

(i) Be stated separately, in terms of a single behavioral outcome;
(ii) Be assigned projected completion dates;
(iii) Be expressed in behavioral terms that provide measurable indices of performance;
(iv) Be organized to reflect a developmental progression appropriate to the individual; and
(v) Be assigned priorities.
(5) Each written training program designed to implement the objectives in the individual program plan must specify:
(i) The methods to be used;
(ii) The schedule for use of the method;
(iii) The person responsible for the program;
(iv) The type of data and frequency of data collection necessary to be able to assess progress toward the desired objectives;
(v) The inappropriate client behavior(s), if applicable; and
(vi) Provision for the appropriate expression of behavior and the replacement of inappropriate behavior, if applicable, with behavior that is adaptive or appropriate.

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(6) The individual program plan must also:
(i) Describe relevant interventions to support the individual toward independence.
(ii) Identify the location where program strategy information (which must be accessible to any person responsible for implementation) can be found.
(iii) Include, for those clients who lack them, training in personal skills essential for privacy and independence (including, but not limited to, toilet training, personal hygiene, dental hygiene, self-feeding, bathing, dressing, grooming, and communication of basic needs), until it has been demonstrated that the client is developmentally incapable of acquiring them.
(iv) Identify mechanical supports, if needed, to achieve proper body position, balance, or alignment. The plan must specify the reason for each support, the situations in which each is to be applied, and a schedule for the use of each support.
(v) Provide that clients who have multiple disabling conditions spend a major portion of each waking day out of bed and outside the bedroom area, moving about by various methods and devices whenever possible.
(vi) Include opportunities for client choice and self-management.
(7) A copy of each client's individual program plan must be made available to all relevant staff, including staff of other agencies who work with the client, and to the client, parents (if the client is a minor) or legal guardian.
(d) Standard: Program implementation. (1) As soon as the interdisciplinary team has formulated a client's individual program plan, each client must receive a continuous active treatment program consisting of needed interventions and services in sufficient number and frequency to support the achievement of the objectives identified in the individual program plan.
(2) The facility must develop an active treatment schedule that outlines the current active treatment program and that is readily available for review by relevant staff.
(3) Except for those facets of the individual program plan that must be implemented only by licensed personnel, each client's individual program plan must be implemented by all staff who work with the client, including professional, paraprofessional and nonprofessional staff.
(e) Standard: Program documentation. (1) Data relative to accomplishment of the criteria specified in client individual program plan objectives must be documented in measureable terms.
(2) The facility must document significant events that are related to the client's individual program plan and assessments and that contribute to an overall understanding of the client's ongoing level and quality of functioning.
(f) Standard: Program monitoring and change. (1) The individual program plan must be reviewed at least by the qualified mental retardation professional and revised as necessary, including, but not limited to situations in which the client--
(i) Has successfully completed an objective or objectives identified in the individual program plan;
(ii) Is regressing or losing skills already gained;
(iii) Is failing to progress toward identified objectives after reasonable efforts have been made; or
(iv) Is being considered for training towards new objectives.
(2) At least annually, the comprehensive functional assessment of each client must be reviewed by the interdisciplinary team for relevancy and updated as needed, and the individual program plan must be revised, as appropriate, repeating the process set forth in paragraph (c) of this section.
(3) The facility must designate and use a specially constituted committee or committees consisting of members of facility staff, parents, legal guardians, clients (as appropriate), qualified persons who have either experience or training in contemporary practices to change inappropriate client behavior, and persons with no ownership or

controlling interest in the facility to--
(i) Review, approve, and monitor individual programs designed to manage inappropriate behavior and other programs that, in the opinion of the committee, involve risks to client protection and rights;

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(ii) Insure that these programs are conducted only with the written informed consent of the client, parent (if the client is a minor), or legal guardian; and
(iii) Review, monitor and make suggestions to the facility about its practices and programs as they relate to drug usage, physical restraints, time-out rooms, application of painful or noxious stimuli, control of inappropriate behavior, protection of client rights and funds, and any other area that the committee believes need to be addressed.
(4) The provisions of paragraph (f)(3) of this section may be modified only if, in the judgment of the State survey agency, Court decrees, State law or regulations provide for equivalent client protection and consultation.

Sec. 483.450 Condition of participation: Client behavior and facility practices.

(a) Standard: Facility practices--Conduct toward clients. (1) The facility must develop and implement written policies and procedures for the management of conduct between staff and clients. These policies and procedures must--
(i) Promote the growth, development and independence of the client;
(ii) Address the extent to which client choice will be accommodated in daily decision-making, emphasizing self-determination and self-management, to the extent possible;
(iii) Specify client conduct to be allowed or not allowed; and
(iv) Be available to all staff, clients, parents of minor children, and legal guardians.
(2) To the extent possible, clients must participate in the formulation of these policies and procedures.
(3) Clients must not discipline other clients, except as part of an organized system of self-government, as set forth in facility policy.
(b) Standard: Management of inappropriate client behavior. (1) The facility must develop and implement written policies and procedures that govern the management of inappropriate client behavior. These policies and procedures must be consistent with the provisions of paragraph (a) of this section. These procedures must--
(i) Specify all facility approved interventions to manage inappropriate client behavior;
(ii) Designate these interventions on a hierarchy to be implemented, ranging from most positive or least intrusive, to least positive or most intrusive;
(iii) Insure, prior to the use of more restrictive techniques, that the client's record documents that programs incorporating the use of less intrusive or more positive techniques have been tried systematically and demonstrated to be ineffective; and
(iv) Address the following:
(A) The use of time-out rooms.
(B) The use of physical restraints.
(C) The use of drugs to manage inappropriate behavior.
(D) The application of painful or noxious stimuli.
(E) The staff members who may authorize the use of specified interventions.
(F) A mechanism for monitoring and controlling the use of such interventions.
(2) Interventions to manage inappropriate client behavior must be employed with sufficient safeguards and supervision to ensure that the safety, welfare and civil and human rights of clients are adequately protected.
(3) Techniques to manage inappropriate client behavior must never be used for disciplinary purposes, for the convenience of staff or as a substitute for an active treatment program.
(4) The use of systematic interventions to manage inappropriate client behavior must be incorporated into the client's individual program plan, in accordance with Sec. 483.440(c) (4) and (5) of this subpart.
(5) Standing or as needed programs to control inappropriate behavior are not permitted.
(c) Standard: Time-out rooms. (1) A client may be placed in a room from which egress is prevented only if the following conditions are met:
(i) The placement is a part of an approved systematic time-out program as required by paragraph (b) of this section. (Thus, emergency placement of a client into a time-out room is not allowed.)

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(ii) The client is under the direct constant visual supervision of designated staff.

(iii) The door to the room is held shut by staff or by a mechanism requiring constant physical pressure from a staff member to keep the mechanism engaged.

(2) Placement of a client in a time-out room must not exceed one hour.

(3) Clients placed in time-out rooms must be protected from hazardous conditions including, but not limited to, presence of sharp corners and objects, uncovered light fixtures, unprotected electrical outlets.

(4) A record of time-out activities must be kept.

(d) Standard: Physical restraints. (1) The facility may employ physical restraint only--

(i) As an integral part of an individual program plan that is intended to lead to less restrictive means of managing and eliminating the behavior for which the restraint is applied;

(ii) As an emergency measure, but only if absolutely necessary to protect the client or others from injury; or

(iii) As a health-related protection prescribed by a physician, but only if absolutely necessary during the conduct of a specific medical or surgical procedure, or only if absolutely necessary for client protection during the time that a medical condition exists.

(2) Authorizations to use or extend restraints as an emergency must be:

(i) In effect no longer than 12 consecutive hours; and

(ii) Obtained as soon as the client is restrained or stable.

(3) The facility must not issue orders for restraint on a standing or as needed basis.

(4) A client placed in restraint must be checked at least every 30 minutes by staff trained in the use of restraints, released from the restraint as quickly as possible, and a record of these checks and usage must be kept.

(5) Restraints must be designed and used so as not to cause physical injury to the client and so as to cause the least possible discomfort.

(6) Opportunity for motion and exercise must be provided for a period of not less than 10 minutes during each two hour period in which restraint is employed, and a record of such activity must be kept.

(7) Barred enclosures must not be more than three feet in height and must not have tops.

(e) Standard: Drug usage. (1) The facility must not use drugs in doses that interfere with the individual client's daily living activities.

(2) Drugs used for control of inappropriate behavior must be approved by the interdisciplinary team and be used only as an integral part of the client's individual program plan that is directed specifically towards the reduction of and eventual elimination of the behaviors for which the drugs are employed.

(3) Drugs used for control of inappropriate behavior must not be used until it can be justified that the harmful effects of the behavior clearly outweigh the potentially harmful effects of the drugs.

(4) Drugs used for control of inappropriate behavior must be--

(i) Monitored closely, in conjunction with the physician and the drug regimen review requirement at Sec. 483.460(j), for desired responses and adverse consequences by facility staff; and

(ii) Gradually withdrawn at least annually in a carefully monitored program conducted in conjunction with the interdisciplinary team, unless clinical evidence justifies that this is contraindicated.

Sec. 483.460 Condition of participation: Health care services.

(a) Standard: Physician services.

(1) The facility must ensure the availability of physician services 24 hours a day.

(2) The physician must develop, in coordination with licensed nursing personnel, a medical care plan of treatment for a client if the physician determines that an individual client requires 24-hour licensed nursing care. This plan must be integrated in the individual program plan.

(3) The facility must provide or obtain preventive and general medical care as well as annual physical examinations of each client that at a minimum include the following:

(i) Evaluation of vision and hearing.

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(ii) Immunizations, using as a guide the recommendations of the Public Health Service Advisory Commitee on Immunization Practices or of the Committee on the Control of Infectious Diseases of the American Academy of Pediatrics.

(iii) Routine screening laboratory examinations as determined necessary by the physician, and special studies when needed.

(iv) Tuberculosis control, appropriate to the facility's population, and in accordance with the recommendations of the American College of Chest Physicians or the section of diseases of the chest of the American Academy of Pediatrics, or both.

(4) To the extent permitted by State law, the facility may utilize physician assistants and nurse practitioners to provide physician

services as described in this section.

(b) Standard: Physician participation in the individual program plan. A physician must participate in--

(1) The establishment of each newly admitted client's initial individual program plan as required by Sec. 456.380 of this chapter that specified plan of care requirements for ICFs; and

(2) If appropriate, physicians must participate in the review and update of an individual program plan as part of the interdisciplinary team process either in person or through written report to the interdisciplinary team.

(c) Standard: Nursing services. The facility must provide clients with nursing services in accordance with their needs. These services must include--

(1) Participation as appropriate in the development, review, and update of an individual program plan as part of the interdisciplinary team process;

(2) The development, with a physician, of a medical care plan of treatment for a client when the physician has determined that an individual client requires such a plan;

(3) For those clients certified as not needing a medical care plan, a review of their health status which must--

(i) Be by a direct physical examination;

(ii) Be by a licensed nurse;

(iii) Be on a quarterly or more frequent basis depending on client need;

(iv) Be recorded in the client's record; and

(v) Result in any necessary action (including referral to a physician to address client health problems).

(4) Other nursing care as prescribed by the physician or as identified by client needs; and

(5) Implementing, with other members of the interdisciplinary team, appropriate protective and preventive health measures that include, but are not limited to--

(i) Training clients and staff as needed in appropriate health and hygiene methods;

(ii) Control of communicable diseases and infections, including the instruction of other personnel in methods of infection control; and

(iii) Training direct care staff in detecting signs and symptoms of illness or dysfunction, first aid for accidents or illness, and basic skills required to meet the health needs of the clients.

(d) Standard: Nursing staff. (1) Nurses providing services in the facility must have a current license to practice in the State.

(2) The facility must employ or arrange for licensed nursing services sufficient to care for clients health needs including those clients with medical care plans.

(3) The facility must utilize registered nurses as appropriate and required by State law to perform the health services specified in this section.

(4) If the facility utilizes only licensed practical or vocational nurses to provide health services, it must have a formal arrangement with a registered nurse to be available for verbal or onsite consultation to the licensed practical or vocational nurse.

(5) Non-licensed nursing personnel who work with clients under a medical care plan must do so under the supervision of licensed persons.

(e) Standard: Dental services. (1) The facility must provide or make arrangements for comprehensive diagnostic and treatment services for each client from qualified personnel, including licensed dentists and dental hygienists either through organized dental services in-house or through arrangement.

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(2) If appropriate, dental professionals must participate, in the development, review and update of an individual program plan as part of the interdisciplinary process either in person or through written report to the interdisciplinary team.

(3) The facility must provide education and training in the maintenance of oral health.

(f) Standard: Comprehensive dental diagnostic services. Comprehensive dental diagnostic services include--

(1) A complete extraoral and intraoral examination, using all diagnostic aids necessary to properly evaluate the client's oral condition, not later than one month after admission to the facility (unless the examination was completed within twelve months before admission);

(2) Periodic examination and diagnosis performed at least annually, including radiographs when indicated and detection of manifestations of systemic disease; and

(3) A review of the results of examination and entry of the results in the client's dental record.

(g) Standard: Comprehensive dental treatment. The facility must ensure comprehensive dental treatment services that include--

(1) The availability for emergency dental treatment on a 24-hour-a-day basis by a licensed dentist; and

(2) Dental care needed for relief of pain and infections, restoration of teeth, and maintenance of dental health.

(h) Standard: Documentation of dental services. (1) If the facility maintains an in-house dental service, the facility must keep a permanent dental record for each client, with a dental summary maintained in the client's living unit.

(2) If the facility does not maintain an in-house dental service, the facility must obtain a dental summary of the results of dental visits and maintain the summary in the client's living unit.

(i) Standard: Pharmacy services. The facility must provide or make arrangements for the provision of routine and emergency drugs and biologicals to its clients. Drugs and biologicals may be obtained from community or contract pharmacists or the facility may maintain a licensed pharmacy.

(j) Standard: Drug regimen review. (1) A pharmacist with input from the interdisciplinary team must review the drug regimen of each client at least quarterly.

(2) The pharmacist must report any irregularities in clients' drug regimens to the prescribing physician and interdisciplinary team.

(3) The pharmacist must prepare a record of each client's drug regimen reviews and the facility must maintain that record.

(4) An individual medication administration record must be maintained for each client.

(5) As appropriate the pharmacist must participate in the development, implementation, and review of each client's individual program plan either in person or through written report to the interdisciplinary team.

(k) Standard: Drug administration. The facility must have an organized system for drug administration that identifies each drug up to the point of administration. The system must assure that--

(1) All drugs are administered in compliance with the physician's orders;

(2) All drugs, including those that are self-administered, are administered without error;

(3) Unlicensed personnel are allowed to administer drugs only if State law permits;

(4) Clients are taught how to administer their own medications if the interdisciplinary team determines that self administration of medications is an appropriate objective, and if the physician does not specify otherwise;

(5) The client's physician is informed of the interdisciplinary team's decision that self-administration of medications is an objective for the client;

(6) No client self-administers medications until he or she demonstrates the competency to do so;

(7) Drugs used by clients while not under the direct care of the facility are packaged and labeled in accordance with State law; and

(8) Drug administration errors and adverse drug reactions are recorded and reported immediately to a physician.

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(l) Standard: Drug storage and recordkeeping. (1) The facility must store drugs under proper conditions of sanitation, temperature, light, humidity, and security.

(2) The facility must keep all drugs and biologicals locked except when being prepared for administration. Only authorized persons may have access to the keys to the drug storage area. Clients who have been trained to self administer drugs in accordance with Sec. 483.460(k)(4) may have access to keys to their individual drug supply.

(3) The facility must maintain records of the receipt and disposition of all controlled drugs.

(4) The facility must, on a sample basis, periodically reconcile the receipt and disposition of all controlled drugs in schedules II through IV (drugs subject to the Comprehensive Drug Abuse Prevention and Control Act of 1970, 21 U.S.C. 801 et seq., as implemented by 21 CFR part 308).

(5) If the facility maintains a licensed pharmacy, the facility must comply with the regulations for controlled drugs.

(m) Standard: Drug labeling. (1) Labeling of drugs and biologicals must--

(i) Be based on currently accepted professional principles and practices; and

(ii) Include the appropriate accessory and cautionary instructions, as well as the expiration date, if applicable.

(2) The facility must remove from use--

(i) Outdated drugs; and

(ii) Drug containers with worn, illegible, or missing labels.

(3) Drugs and biologicals packaged in containers designated for a particular client must be immediately removed from the client's current medication supply if discontinued by the physician.

(n) Standard: Laboratory services. (1) If a facility chooses to provide laboratory services, the laboratory must meet the requirements specified in part 493 of this chapter.

(2) If the laboratory chooses to refer specimens for testing to another laboratory, the referral laboratory must be certified in the appropriate specialties and subspecialities of service in accordance with the requirements of part 493 of this chapter.

[53 FR 20496, June 3, 1988, as amended at 57 FR 7136, Feb. 28, 1992]

Sec. 483.470 Condition of participation: Physical environment.

(a) Standard: Client living environment. (1) The facility must not house clients of grossly different ages, developmental levels, and social needs in close physical or social proximity unless the housing is planned to promote the growth and development of all those housed together.

(2) The facility must not segregate clients solely on the basis of their physical disabilities. It must integrate clients who have ambulation deficits or who are deaf, blind, or have seizure disorders, etc., with others of comparable social and intellectual development.

(b) Standard: Client bedrooms. (1) Bedrooms must--

(i) Be rooms that have at least one outside wall;

(ii) Be equipped with or located near toilet and bathing facilities;

(iii) Accommodate no more than four clients unless granted a variance under paragraph (b)(3) of this section;

(iv) Measure at least 60 square feet per client in multiple client bedrooms and at least 80 square feet in single client bedrooms; and

(v) In all facilities initially certified, or in buildings constructed or with major renovations or conversions on or after October 3, 1988, have walls that extend from floor to ceiling.

(2) If a bedroom is below grade level, it must have a window that--

(i) Is usable as a second means of escape by the client(s) occupying the room; and

(ii) Is no more than 44 inches (measured to the window sill) above the floor unless the facility is surveyed under the Health Care Occupancy Chapter of the Life Safety Code, in which case the window must be no more than 36 inches (measured to the window sill) above the floor.

(3) The survey agency may grant a variance from the limit of four clients per room only if a physician who is a member of the interdisciplinary team and who is a qualified mental retardation professional--

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(i) Certifies that each client to be placed in a bedroom housing more than four persons is so severely medically impaired as to require direct and continuous monitoring during sleeping hours; and

(ii) Documents the reasons why housing in a room of only four or fewer persons would not be medically feasible.

(4) The facility must provide each client with--

(i) A separate bed of proper size and height for the convenience of the client;

(ii) A clean, comfortable, mattress;

(iii) Bedding appropriate to the weather and climate; and

(iv) Functional furniture appropriate to the client's needs, and individual closet space in the client's bedroom with clothes racks and shelves accessible to the client.

(c) Standard: Storage space in bedroom. The facility must provide--

(1) Space and equipment for daily out-of-bed activity for all clients who are not yet mobile, except those who have a short-term illness or those few clients for whom out-of-bed activity is a threat to health and safety; and

(2) Suitable storage space, accessible to clients, for personal possessions, such as TVs, radios, prosthetic equipment and clothing.

(d) Standard: Client bathrooms. The facility must--

(1) Provide toilet and bathing facilities appropriate in number, size, and design to meet the needs of the clients;

(2) Provide for individual privacy in toilets, bathtubs, and showers; and

(3) In areas of the facility where clients who have not been trained to regulate water temperature are exposed to hot water, ensure that the temperature of the water does not exceed 110 deg. Fahrenheit.

(e) Standard: Heating and ventilation. (1) Each client bedroom in the facility must have--

(i) At least one window to the outside; and

(ii) Direct outside ventilation by means of windows, air conditioning, or mechanical ventilation.

(2) The facility must--

(i) Maintain the temperature and humidity within a normal comfort range by heating, air conditioning or other means; and

(ii) Ensure that the heating apparatus does not constitute a burn or smoke hazard to clients.

(f) Standard: Floors. The facility must have--

(1) Floors that have a resilient, nonabrasive, and slip-resistant surface;

(2) Nonabrasive carpeting, if the area used by clients is carpeted and serves clients who lie on the floor or ambulate with parts of their bodies, other than feet, touching the floor; and

(3) Exposed floor surfaces and floor coverings that promote mobility in areas used by clients, and promote maintenance of sanitary conditions.

(g) Standard: Space and equipment. The facility must--

(1) Provide sufficient space and equipment in dining, living, health services, recreation, and program areas (including adequately equipped and sound treated areas for hearing and other evaluations if they are conducted in the facility) to enable staff to provide clients with needed services as required by this **subpart** and as identified in each client's individual program plan.

(2) Furnish, maintain in good repair, and teach clients to use and to make informed choices about the use of dentures, eyeglasses, hearing and other communications aids, braces, and other devices identified by the interdisciplinary team as needed by the client.

(3) Provide adequate clean linen and dirty linen storage areas.

(h) Standard: Emergency plan and procedures. (1) The facility must develop and implement detailed written plans and procedures to meet all potential emergencies and disasters such as fire, severe weather, and missing clients.

(2) The facility must communicate, periodically review, make the plan available, and provide training to the staff.

(i) Standard: Evacuation drills. (1) The facility must hold evacuation drills at least quarterly for each shift of personnel and under varied conditions to--

(i) Ensure that all personnel on all shifts are trained to perform assigned tasks;

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(ii) Ensure that all personnel on all shifts are familiar with the use of the facility's fire protection features; and

(iii) Evaluate the effectiveness of emergency and disaster plans and procedures.

(2) The facility must--

(i) Actually evacuate clients during at least one drill each year on each shift;

(ii) Make special provisions for the evacuation of clients with physical disabilities;

(iii) File a report and evaluation on each evacuation drill;

(iv) Investigate all problems with evacuation drills, including accidents, and take corrective action; and

(v) During fire drills, clients may be evacuated to a safe area in facilities certified under the Health Care Occupancies Chapter of the Life Safety Code.

(3) Facilities must meet the requirements of paragraphs (i)(1) and (2) of this section for any live-in and relief staff they utilize.

(j) Standard: Fire protection--(1) General. (i) Except as specified in paragraph (j)(2) of this section, the facility must meet the applicable provisions of either the Health Care Occupancies Chapters or the Residential Board and Care Occupancies Chapter of the Life Safety Code (LSC) of the National Fire Protection Association, 1985 edition, which is incorporated by reference.\2\

\2\ Incorporation of the 1985 edition of the National Fire Protection Association's Life Safety Code (published February 7, 1985; ANSI/NFPA 101) was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51 that govern the use of incorporations by reference. The Code is available for inspection at the Office of the Federal Register Information Center, 800 North Capitol Street, NW., suite 700, Washington, DC. Copies may be obtained from the National Fire Protection Association, Batterymarch Park, Quincy, Mass. 02269.

If any changes in this Code are also to be incorporated by reference, a notice to that effect will be published in the Federal Register.

(ii) The State survey agency may apply a single chapter of the LSC to the entire facility or may apply different chapters to different buildings or parts of buildings as permitted by the LSC.

(iii) A facility that meets the LSC definition of a residential board and care occupancy and that has 16 or fewer beds, must have its evacuation capability evaluated in accordance with the Evacuation Difficulty Index of the LSC (appendix F).

(2) Exceptions. (i) For facilities that meet the LSC definition of a health care occupancy:

(A) The State survey agency may waive, for a period it considers appropriate, specific provisions of the LSC if--

(1) The waiver would not adversely affect the health and safety of the clients; and

(2) Rigid application of specific provisions would result in an unreasonable hardship for the facility.

(B) The State survey agency may apply the State's fire and safety code instead of the LSC if the Secretary finds that the State has a code imposed by State law that adequately protects a facility's clients.

(C) Compliance on November 26, 1982 with the 1967 edition of the LSC or compliance on April 18, 1986 with the 1981 edition of the LSC, with or without waivers, is considered to be compliance with this standard as

[Code of Federal Regulations]
[Title 45, Volume 1, Parts 1 to 199]
[Revised as of October 1, 1997]
From the U.S. Government Printing Office via GPO Access
[CITE: 45CFR46]

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TITLE 45--PUBLIC WELFARE

SUBTITLE A--DEPARTMENT OF HEALTH AND HUMAN SERVICES

PART 46--PROTECTION OF HUMAN SUBJECTS--Table of Contents

Subpart A--Basic HHS Policy for Protection of Human Research Subjects

Authority: 5 U.S.C. 301; 42 U.S.C. 289, 42 U.S.C. 300v-1(b).

Source: 56 FR 28012, 28022, June 18, 1991, unless otherwise noted.

Sec. 46.101 To what does this policy apply?

(a) Except as provided in paragraph (b) of this section, this policy applies to all research involving human subjects conducted, supported or otherwise subject to regulation by any federal department or agency which takes appropriate administrative action to make the policy applicable to such research. This includes research conducted by federal civilian employees or military personnel, except that each department or agency head may adopt such procedural modifications as may be appropriate from an administrative standpoint. It also includes research conducted, supported, or otherwise subject to regulation by the federal government outside the United States.

(1) Research that is conducted or supported by a federal department or agency, whether or not it is regulated as defined in Sec. 46.102(e), must comply with all sections of this policy.

(2) Research that is neither conducted nor supported by a federal department or agency but is subject to regulation as defined in Sec. 46.102(e) must be reviewed and approved, in compliance with Sec. 46.101, Sec. 46.102, and Sec. 46.107 through Sec. 46.117 of this policy, by an institutional review board (IRB) that operates in accordance with the pertinent requirements of this policy.

(b) Unless otherwise required by department or agency heads, research activities in which the only involvement of human subjects will be in one or more of the following categories are exempt from this policy:

(1) Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

(2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:

(i) Information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

(3) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (b)(2) of this section, if:

(i) The human subjects are elected or appointed public officials or candidates for public office; or (ii) federal statute(s) require(s) without exception that the confidentiality of the personally

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identifiable information will be maintained throughout the research and thereafter.

(4) Research, involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

(5) Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine:

(i) Public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or

services under those programs.

(6) Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

(c) Department or agency heads retain final judgment as to whether a particular activity is covered by this policy.

(d) Department or agency heads may require that specific research activities or classes of research activities conducted, supported, or otherwise subject to regulation by the department or agency but not otherwise covered by this policy, comply with some or all of the requirements of this policy.

(e) Compliance with this policy requires compliance with pertinent federal laws or regulations which provide additional protections for human subjects.

(f) This policy does not affect any state or local laws or regulations which may otherwise be applicable and which provide additional protections for human subjects.

(g) This policy does not affect any foreign laws or regulations which may otherwise be applicable and which provide additional protections to human subjects of research.

(h) When research covered by this policy takes place in foreign countries, procedures normally followed in the foreign countries to protect human subjects may differ from those set forth in this policy. [An example is a foreign institution which complies with guidelines consistent with the World Medical Assembly Declaration (Declaration of Helsinki amended 1989) issued either by sovereign states or by an organization whose function for the protection of human research subjects is internationally recognized.] In these circumstances, if a department or agency head determines that the procedures prescribed by the institution afford protections that are at least equivalent to those provided in this policy, the department or agency head may approve the substitution of the foreign procedures in lieu of the procedural requirements provided in this policy. Except when otherwise required by statute, Executive Order, or the department or agency head, notices of these actions as they occur will be published in the Federal Register or will be otherwise published as provided in department or agency procedures.

(i) Unless otherwise required by law, department or agency heads may waive the applicability of some or all of the provisions of this policy to specific research activities or classes of research activities otherwise covered by this policy. Except when otherwise required by statute or Executive Order, the department or agency head shall forward advance notices of these actions to the Office for Protection from Research Risks, Department of Health and Human Services (HHS), and shall also publish them in the Federal Register or in such other manner as provided in department or agency procedures.\1\

\1\ Institutions with HHS-approved assurances on file will abide by provisions of title 45 CFR part 46 subparts A-D. Some of the other Departments and Agencies have incorporated all provisions of title 45 CFR part 46 into their policies and procedures as well. However, the exemptions at 45 CFR 46.101(b) do not apply to research involving prisoners, fetuses, pregnant women, or human in vitro fertilization, subparts B and C. The exemption at 45 CFR 46.101(b)(2), for research involving survey or interview procedures or observation of public behavior, does not apply to research with children, **subpart** D, except for research involving observations of public behavior when the investigator(s) do not participate in the activities being observed.

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[56 FR 28012, 28022, June 18, 1991; 56 FR 29756, June 28, 1991]

Sec. 46.102 Definitions.

(a) Department or agency head means the head of any federal department or agency and any other officer or employee of any department or agency to whom authority has been delegated.

(b) Institution means any public or private entity or agency (including federal, state, and other agencies).

(c) Legally authorized representative means an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research.

(d) Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute

to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities.

(e) Research subject to regulation, and similar terms are intended to encompass those research activities for which a federal department or agency has specific responsibility for regulating as a research activity, (for example, Investigational New Drug requirements administered by the Food and Drug Administration). It does not include research activities which are incidentally regulated by a federal department or agency solely as part of the department's or agency's broader responsibility to regulate certain types of activities whether research or non-research in nature (for example, Wage and Hour requirements administered by the Department of Labor).

(f) Human subject means a living individual about whom an investigator (whether professional or student) conducting research obtains

(1) Data through intervention or interaction with the individual, or

(2) Identifiable private information.

Intervention includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes. Interaction includes communication or interpersonal contact between investigator and subject. Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.

(g) IRB means an institutional review board established in accord with and for the purposes expressed in this policy.

(h) IRB approval means the determination of the IRB that the research has been reviewed and may be conducted at an institution within the constraints set forth by the IRB and by other institutional and federal requirements.

(i) Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

(j) Certification means the official notification by the institution to the supporting department or agency, in accordance with the requirements of this

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policy, that a research project or activity involving human subjects has been reviewed and approved by an IRB in accordance with an approved assurance.

Sec. 46.103 Assuring compliance with this policy--research conducted or supported by any Federal Department or Agency.

(a) Each institution engaged in research which is covered by this policy and which is conducted or supported by a federal department or agency shall provide written assurance satisfactory to the department or agency head that it will comply with the requirements set forth in this policy. In lieu of requiring submission of an assurance, individual department or agency heads shall accept the existence of a current assurance, appropriate for the research in question, on file with the Office for Protection from Research Risks, HHS, and approved for federalwide use by that office. When the existence of an HHS-approved assurance is accepted in lieu of requiring submission of an assurance, reports (except certification) required by this policy to be made to department and agency heads shall also be made to the Office for Protection from Research Risks, HHS.

(b) Departments and agencies will conduct or support research covered by this policy only if the institution has an assurance approved as provided in this section, and only if the institution has certified to the department or agency head that the research has been reviewed and approved by an IRB provided for in the assurance, and will be subject to continuing review by the IRB. Assurances applicable to federally supported or conducted research shall at a minimum include:

(1) A statement of principles governing the institution in the discharge of its responsibilities for protecting the rights and welfare of human subjects of research conducted at or sponsored by the institution, regardless of whether the research is subject to federal regulation. This may include an appropriate existing code, declaration, or statement of ethical principles, or a statement formulated by the institution itself. This requirement does not preempt provisions of this policy applicable to department- or agency-supported or regulated

research and need not be applicable to any research exempted or waived under Sec. 46.101 (b) or (i).

(2) Designation of one or more IRBs established in accordance with the requirements of this policy, and for which provisions are made for meeting space and sufficient staff to support the IRB's review and recordkeeping duties.

(3) A list of IRB members identified by name; earned degrees; representative capacity; indications of experience such as board certifications, licenses, etc., sufficient to describe each member's chief anticipated contributions to IRB deliberations; and any employment or other relationship between each member and the institution; for example: full-time employee, part-time employee, member of governing panel or board, stockholder, paid or unpaid consultant. Changes in IRB membership shall be reported to the department or agency head, unless in accord with Sec. 46.103(a) of this policy, the existence of an HHS-approved assurance is accepted. In this case, change in IRB membership shall be reported to the Office for Protection from Research Risks, HHS.

(4) Written procedures which the IRB will follow (i) for conducting its initial and continuing review of research and for reporting its findings and actions to the investigator and the institution; (ii) for determining which projects require review more often than annually and which projects need verification from sources other than the investigators that no material changes have occurred since previous IRB review; and (iii) for ensuring prompt reporting to the IRB of proposed changes in a research act vity, and for ensuring that such changes in approved research, during the period for which IRB approval has already been given, may not be initiated without IRB review and approval except when necessary to eliminate apparent immediate hazards to the subject.

(5) Written procedures for ensuring prompt reporting to the IRB, appropriate institutional officials, and the department or agency head of (i) any unanticipated problems involving risks to subjects or others or any serious or

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continuing noncompliance with this policy or the requirements or determinations of the IRB and (ii) any suspension or termination of IRB approval.

(c) The assurance shall be executed by an individual authorized to act for the institution and to assume on behalf of the institution the obligations imposed by this policy and shall be filed in such form and manner as the department or agency head prescribes.

(d) The department or agency head will evaluate all assurances submitted in accordance with this policy through such officers and employees of the department or agency and such experts or consultants engaged for this purpose as the department or agency head determines to be appropriate. The department or agency head's evaluation will take into consideration the adequacy of the proposed IRB in light of the anticipated scope of the institution's research activities and the types of subject populations likely to be involved, the appropriateness of the proposed initial and continuing review procedures in light of the probable risks, and the size and complexity of the institution.

(e) On the basis of this evaluation, the department or agency head may approve or disapprove the assurance, or enter into negotiations to develop an approvable one. The department or agency head may limit the period during which any particular approved assurance or class of approved assurances shall remain effective or otherwise condition or restrict approval.

(f) Certification is required when the research is supported by a federal department or agency and not otherwise exempted or waived under Sec. 46.101 (b) or (i). An institution with an approved assurance shall certify that each application or proposal for research covered by the assurance and by Sec. 46.103 of this Policy has been reviewed and approved by the IRB. Such certification must be submitted with the application or proposal or by such later date as may be prescribed by the department or agency to which the application or proposal is submitted. Under no condition shall research covered by Sec. 46.103 of the Policy be supported prior to receipt of the certification that the research has been reviewed and approved by the IRB. Institutions without an approved assurance covering the research shall certify within 30 days after receipt of a request for such a certification from the department or agency, that the application or proposal has been approved by the IRB. If the certification is not submitted within these time limits, the application or proposal may be returned to the institution.

(Approved by the Office of Management and Budget under control number 9999-0020)

[56 FR 28012, 28022, June 18, 1991; 56 FR 29756, June 28, 1991]

Secs. 46.104--46.106 [Reserved]

Sec. 46.107 IRB membership.

(a) Each IRB shall have at least five members, with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution. The IRB shall be sufficiently qualified through the experience and expertise of its members, and the diversity of the members, including consideration of race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects. In addition to possessing the professional competence necessary to review specific research activities, the IRB shall be able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice. The IRB shall therefore include persons knowledgeable in these areas. If an IRB regularly reviews research that involves a vulnerable category of subjects, such as children, prisoners, pregnant women, or handicapped or mentally disabled persons, consideration shall be given to the inclusion of one or more individuals who are knowledgeable about and experienced in working with these subjects.

(b) Every nondiscriminatory effort will be made to ensure that no IRB consists entirely of men or entirely of women, including the institution's consideration of qualified persons of both sexes, so long as no selection is made to the IRB on the basis of gender. No

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IRB may consist entirely of members of one profession.

(c) Each IRB shall include at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas.

(d) Each IRB shall include at least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution.

(e) No IRB may have a member participate in the IRB's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB.

(f) An IRB may, in its discretion, invite individuals with competence in special areas to assist in the review of issues which require expertise beyond or in addition to that available on the IRB. These individuals may not vote with the IRB.

Sec. 46.108 IRB functions and operations.

In order to fulfill the requirements of this policy each IRB shall:

(a) Follow written procedures in the same detail as described in Sec. 46.103(b)(4) and, to the extent required by, Sec. 46.103(b)(5).

(b) Except when an expedited review procedure is used (see Sec. 46.110), review proposed research at convened meetings at which a majority of the members of the IRB are present, including at least one member whose primary concerns are in nonscientific areas. In order for the research to be approved, it shall receive the approval of a majority of those members present at the meeting.

Sec. 46.109 IRB review of research.

(a) An IRB shall review and have authority to approve, require modifications in (to secure approval), or disapprove all research activities covered by this policy.

(b) An IRB shall require that information given to subjects as part of informed consent is in accordance with Sec. 46.116. The IRB may require that information, in addition to that specifically mentioned in Sec. 46.116, be given to the subjects when in the IRB's judgment the information would meaningfully add to the protection of the rights and welfare of subjects.

(c) An IRB shall require documentation of informed consent or may waive documentation in accordance with Sec. 46.117.

(d) An IRB shall notify investigators and the institution in writing of its decision to approve or disapprove the proposed research activity, or of modifications required to secure IRB approval of the research activity. If the IRB decides to disapprove a research activity, it shall include in its written notification a statement of the reasons for its decision and give the investigator an opportunity to respond in person or in writing.

(e) An IRB shall conduct continuing review of research covered by this policy at intervals appropriate to the degree of risk, but not less than once per year, and shall have authority to observe or have a third party observe the consent process and the research.

(Approved by the Office of Management and Budget under control number 9999-0020)

Sec. 46.110 Expedited review procedures for certain kinds of research involving no more than minimal risk, and for minor changes in approved research.

(a) The Secretary, HHS, has established, and published as a Notice

in the Federal Register, a list of categories of research that may be reviewed by the IRB through an expedited review procedure. The list will be amended, as appropriate after consultation with other departments and agencies, through periodic republication by the Secretary, HHS, in the Federal Register. A copy of the list is available from the Office for Protection from Research Risks, National Institutes of Health, HHS, Bethesda, Maryland 20892.

(b) An IRB may use the expedited review procedure to review either or both of the following:

(1) Some or all of the research appearing on the list and found by the reviewer(s) to involve no more than minimal risk,

(2) Minor changes in previously approved research during the period (of

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one year or less) for which approval is authorized.

Under an expedited review procedure, the review may be carried out by the IRB chairperson or by one or more experienced reviewers designated by the chairperson from among members of the IRB. In reviewing the research, the reviewers may exercise all of the authorities of the IRB except that the reviewers may not disapprove the research. A research activity may be disapproved only after review in accordance with the non-expedited procedure set forth in Sec. 46.108(b).

(c) Each IRB which uses an expedited review procedure shall adopt a method for keeping all members advised of research proposals which have been approved under the procedure.

(d) The department or agency head may restrict, suspend, terminate, or choose not to authorize an institution's or IRB's use of the expedited review procedure.

Sec. 46.111 Criteria for IRB approval of research.

(a) In order to approve research covered by this policy the IRB shall determine that all of the following requirements are satisfied:

(1) Risks to subjects are minimized: (i) By using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and (ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.

(2) Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.

(3) Selection of subjects is equitable. In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.

(4) Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by Sec. 46.116.

(5) Informed consent will be appropriately documented, in accordance with, and to the extent required by Sec. 46.117.

(6) When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.

(7) When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

(b) When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.

Sec. 46.112 Review by institution.

Research covered by this policy that has been approved by an IRB may be subject to further appropriate review and approval or disapproval by officials of the institution. However, those officials may not approve the research if it has not been approved by an IRB.

Sec. 46.113 Suspension or termination of IRB approval of research.

An IRB shall have authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to

subjects. Any suspension or termination of approval shall include a statement of the reasons for the IRB's action and shall be

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reported promptly to the investigator, appropriate institutional officials, and the department or agency head.

(Approved by the Office of Management and Budget under control number 9999-0020)

Sec. 46.114 Cooperative research.

Cooperative research projects are those projects covered by this policy which involve more than one institution. In the conduct of cooperative research projects, each institution is responsible for safeguarding the rights and welfare of human subjects and for complying with this policy. With the approval of the department or agency head, an institution participating in a cooperative project may enter into a joint review arrangement, rely upon the review of another qualified IRB, or make similar arrangements for avoiding duplication of effort.

Sec. 46.115 IRB records.

(a) An institution, or when appropriate an IRB, shall prepare and maintain adequate documentation of IRB activities, including the following:

(1) Copies of all research proposals reviewed, scientific evaluations, if any, that accompany the proposals, approved sample consent documents, progress reports submitted by investigators, and reports of injuries to subjects.

(2) Minutes of IRB meetings which shall be in sufficient detail to show attendance at the meetings; actions taken by the IRB; the vote on these actions including the number of members voting for, against, and abstaining; the basis for requiring changes in or disapproving research; and a written summary of the discussion of controverted issues and their resolution.

(3) Records of continuing review activities.

(4) Copies of all correspondence between the IRB and the investigators.

(5) A list of IRB members in the same detail as described is Sec. 46.103(b)(3).

(6) Written procedures for the IRB in the same detail as described in Sec. 46.103(b)(4) and Sec. 46.103(b)(5).

(7) Statements of significant new findings provided to subjects, as required by Sec. 46.116(b)(5).

(b) The records required by this policy shall be retained for at least 3 years, and records relating to research which is conducted shall be retained for at least 3 years after completion of the research. All records shall be accessible for inspection and copying by authorized representatives of the department or agency at reasonable times and in a reasonable manner.

(Approved by the Office of Management and Budget under control number 9999-0020)

Sec. 46.116 General requirements for informed consent.

Except as provided elsewhere in this policy, no investigator may involve a human being as a subject in research covered by this policy unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative. An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. The information that is given to the subject or the representative shall be in language understandable to the subject or the representative. No informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence.

(a) Basic elements of informed consent. Except as provided in paragraph (c) or (d) of this section, in seeking informed consent the following information shall be provided to each subject:

(1) A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;

(2) A description of any reasonably foreseeable risks or discomforts to the subject;

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(3) A description of any benefits to the subject or to others which may reasonably be expected from the research;

(4) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;

(5) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;

(6) For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;

(7) An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject; and

(8) A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

(b) Additional elements of informed consent. When appropriate, one or more of the following elements of information shall also be provided to each subject:

(1) A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable;

(2) Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;

(3) Any additional costs to the subject that may result from participation in the research;

(4) The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;

(5) A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject; and

(6) The approximate number of subjects involved in the study.

(c) An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth above, or waive the requirement to obtain informed consent provided the IRB finds and documents that:

(1) The research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine: (i) Public benefit of service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs; and

(2) The research could not practicably be carried out without the waiver or alteration.

(d) An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth in this section, or waive the requirements to obtain informed consent provided the IRB finds and documents that:

(1) The research involves no more than minimal risk to the subjects;

(2) The waiver or alteration will not adversely affect the rights and welfare of the subjects;

(3) The research could not practicably be carried out without the waiver or alteration; and

(4) Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

(e) The informed consent requirements in this policy are not intended to preempt any applicable federal, state, or local laws which require additional information to be disclosed in order for informed consent to be legally effective.

(f) Nothing in this policy is intended to limit the authority of a physician to provide emergency medical care, to the extent the physician is permitted to do

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so under applicable federal, state, or local law.

(Approved by the Office of Management and Budget under control number 9999-0020)

Sec. 46.117 Documentation of informed consent.

(a) Except as provided in paragraph (c) of this section, informed consent shall be documented by the use of a written consent form approved by the IRB and signed by the subject or the subject's legally authorized representative. A copy shall be given to the person signing the form.

(b) Except as provided in paragraph (c) of this section, the consent form may be either of the following:

(1) A written consent document that embodies the elements of informed consent required by Sec. 46.116. This form may be read to the

subject or the subject's legally authorized representative, but in any event, the investigator shall give either the subject or the representative adequate opportunity to read it before it is signed; or

(2) A short form written consent document stating that the elements of informed consent required by Sec. 46.116 have been presented orally to the subject or the subject's legally authorized representative. When this method is used, there shall be a witness to the oral presentation. Also, the IRB shall approve a written summary of what is to be said to the subject or the representative. Only the short form itself is to be signed by the subject or the representative. However, the witness shall sign both the short form and a copy of the summary, and the person actually obtaining consent shall sign a copy of the summary. A copy of the summary shall be given to the subject or the representative, in addition to a copy of the short form.

(c) An IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds either:

(1) That the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; or

(2) That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

In cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research.

(Approved by the Office of Management and Budget under control number 9999-0020)

Sec. 46.118 Applications and proposals lacking definite plans for involvement of human subjects.

Certain types of applications for grants, cooperative agreements, or contracts are submitted to departments or agencies with the knowledge that subjects may be involved within the period of support, but definite plans would not normally be set forth in the application or proposal. These include activities such as institutional type grants when selection of specific projects is the institution's responsibility; research training grants in which the activities involving subjects remain to be selected; and projects in which human subjects' involvement will depend upon completion of instruments, prior animal studies, or purification of compounds. These applications need not be reviewed by an IRB before an award may be made. However, except for research exempted or waived under Sec. 46.101 (b) or (i), no human subjects may be involved in any project supported by these awards until the project has been reviewed and approved by the IRB, as provided in this policy, and certification submitted, by the institution, to the department or agency.

Sec. 46.119 Research undertaken without the intention of involving human subjects.

In the event research is undertaken without the intention of involving human subjects, but it is later proposed to involve human subjects in the research, the research shall first be reviewed and approved by an IRB, as provided in this policy, a certification submitted, by the institution, to the department or agency, and final approval

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given to the proposed change by the department or agency.

Sec. 46.120 Evaluation and disposition of applications and proposals for research to be conducted or supported by a Federal Department or Agency.

(a) The department or agency head will evaluate all applications and proposals involving human subjects submitted to the department or agency through such officers and employees of the department or agency and such experts and consultants as the department or agency head determines to be appropriate. This evaluation will take into consideration the risks to the subjects, the adequacy of protection against these risks, the potential benefits of the research to the subjects and others, and the importance of the knowledge gained or to be gained.

(b) On the basis of this evaluation, the department or agency head may approve or disapprove the application or proposal, or enter into negotiations to develop an approvable one.

Sec. 46.121 [Reserved]

Sec. 46.122 Use of Federal funds.

Federal funds administered by a department or agency may not be expended for research involving human subjects unless the requirements of this policy have been satisfied.

Sec. 46.123 Early termination of research support: Evaluation of applications and proposals.

(a) The department or agency head may require that department or agency support for any project be terminated or suspended in the manner prescribed in applicable program requirements, when the department or agency head finds an institution has materially failed to comply with the terms of this policy.

(b) In making decisions about supporting or approving applications or proposals covered by this policy the department or agency head may take into account, in addition to all other eligibility requirements and program criteria, factors such as whether the applicant has been subject to a termination or suspension under paragarph (a) of this section and whether the applicant or the person or persons who would direct or has have directed the scientific and technical aspects of an activity has have, in the judgment of the department or agency head, materially failed to discharge responsibility for the protection of the rights and welfare of human subjects (whether or not the research was subject to federal regulation).

Sec. 46.124 Conditions.

With respect to any research project or any class of research projects the department or agency head may impose additional conditions prior to or at the time of approval when in the judgment of the department or agency head additional conditions are necessary for the protection of human subjects.

[Code of Federal Regulations]
[Title 45, Volume 1, Parts 1 to 199]
[Revised as of October 1, 1997]
From the U.S. Government Printing Office via GPO Access
[CITE: 45CFR46]

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TITLE 45--PUBLIC WELFARE

SUBTITLE A--DEPARTMENT OF HEALTH AND HUMAN SERVICES

PART 46--PROTECTION OF HUMAN SUBJECTS--Table of Contents

Subpart B--Additional Protections Pertaining to Research, Development, and Related Activities Involving Fertilization

Source: 40 FR 33528, Aug. 8, 1975, unless otherwise noted.

Sec. 46.201 Applicability.

(a) The regulations in this **subpart** are applicable to all Department of Health and Human Services grants and contracts supporting research, development, and related activities involving: (1) The fetus, (2) pregnant women, and (3) human in vitro fertilization.

(b) Nothing in this **subpart** shall be construed as indicating that compliance with the procedures set forth herein will in any way render inapplicable pertinent State or local laws bearing upon activities covered by this **subpart**.

(c) The requirements of this **subpart** are in addition to those imposed under the other subparts of this part.

Sec. 46.202 Purpose.

It is the purpose of this **subpart** to provide additional safeguards in reviewing activities to which this **subpart** is applicable to assure that they conform to appropriate ethical standards and relate to important societal needs.

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Sec. 46.203 Definitions.

As used in this **subpart**:

(a) Secretary means the Secretary of Health and Human Services and any other officer or employee of the Department of Health and Human Services to whom authority has been delegated.

(b) Pregnancy encompasses the period of time from confirmation of implantation (through any of the presumptive signs of pregnancy, such as missed menses, or by a medically acceptable pregnancy test), until expulsion or extraction of the fetus.

(c) Fetus means the product of conception from the time of implantation (as evidenced by any of the presumptive signs of pregnancy, such as missed menses, or a medically acceptable pregnancy test), until a determination is made, following expulsion or extraction of the fetus, that it is viable.

(d) Viable as it pertains to the fetus means being able, after either spontaneous or induced delivery, to survive (given the benefit of available medical therapy) to the point of independently maintaining heart beat and respiration. The Secretary may from time to time, taking into account medical advances, publish in the Federal Register guidelines to assist in determining whether a fetus is viable for purposes of this **subpart**. If a fetus is viable after delivery, it is a premature infant.

(e) Nonviable fetus means a fetus ex utero which, although living, is not viable.

(f) Dead fetus means a fetus ex utero which exhibits neither heartbeat, spontaneous respiratory activity, spontaneous movement of voluntary muscles, nor pulsation of the umbilical cord (if still attached).

(g) In vitro fertilization means any fertilization of human ova which occurs outside the body of a female, either through admixture of donor human sperm and ova or by any other means.

[40 FR 33528, Aug. 8, 1975, as amended at 43 FR 1759, Jan. 11, 1978]

Sec. 46.204 Ethical Advisory Boards.

(a) One or more Ethical Advisory Boards shall be established by the Secretary. Members of these board(s) shall be so selected that the

board(s) will be competent to deal with medical, legal, social, ethical, and related issues and may include, for example, research scientists, physicians, psychologists, sociologists, educators, lawyers, and ethicists, as well as representatives of the general public. No board member may be a regular, full-time employee of the Department of Health and Human Services.

(b) At the request of the Secretary, the Ethical Advisory Board shall render advice consistent with the policies and requirements of this part as to ethical issues, involving activities covered by this **subpart**, raised by individual applications or proposals. In addition, upon request by the Secretary, the Board shall render advice as to classes of applications or proposals and general policies, guidelines, and procedures.

(c) A Board may establish, with the approval of the Secretary, classes of applications or proposals which: (1) Must be submitted to the Board, or (2) need not be submitted to the Board. Where the Board so establishes a class of applications or proposals which must be submitted, no application or proposal within the class may be funded by the Department or any component thereof until the application or proposal has been reviewed by the Board and the Board has rendered advice as to its acceptability from an ethical standpoint.

[40 FR 33528, Aug. 8, 1975, as amended at 43 FR 1759, Jan. 11, 1978; 59 FR 28276, June 1, 1994]

Sec. 46.205 Additional duties of the Institutional Review Boards in connection with activities involving fetuses, pregnant women, or human in vitro fertilization.

(a) In addition to the responsibilities prescribed for Institutional Review Boards under **Subpart** A of this part, the applicant's or offeror's Board shall, with respect to activities covered by this **subpart**, carry out the following additional duties:

(1) Determine that all aspects of the activity meet the requirements of this **subpart**;

(2) Determine that adequate consideration has been given to the manner

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in which potential subjects will be selected, and adequate provision has been made by the applicant or offeror for monitoring the actual informed consent process (e.g., through such mechanisms, when appropriate, as participation by the Institutional Review Board or subject advocates in: (i) Overseeing the actual process by which individual consents required by this **subpart** are secured either by approving induction of each individual into the activity or verifying, perhaps through sampling, that approved procedures for induction of individuals into the activity are being followed, and (ii) monitoring the progress of the activity and intervening as necessary through such steps as visits to the activity site and continuing evaluation to determine if any unanticipated risks have arisen);

(3) Carry out such other responsibilities as may be assigned by the Secretary.

(b) No award may be issued until the applicant or offeror has certified to the Secretary that the Institutional Review Board has made the determinations required under paragraph (a) of this section and the Secretary has approved these determinations, as provided in Sec. 46.120 of **Subpart** A of this part.

(c) Applicants or offerors seeking support for activities covered by this **subpart** must provide for the designation of an Institutional Review Board, subject to approval by the Secretary, where no such Board has been established under **Subpart** A of this part.

[40 FR 33528, Aug. 8, 1975, as amended at 46 FR 8386, Jan. 26, 1981]

Sec. 46.206 General limitations.

(a) No activity to which this **subpart** is applicable may be undertaken unless:

(1) Appropriate studies on animals and nonpregnant individuals have been completed;

(2) Except where the purpose of the activity is to meet the health needs of the mother or the particular fetus, the risk to the fetus is minimal and, in all cases, is the least possible risk for achieving the objectives of the activity.

(3) Individuals engaged in the activity will have no part in: (i) Any decisions as to the timing, method, and procedures used to terminate the pregnancy, and (ii) determining the viability of the fetus at the termination of the pregnancy; and

(4) No procedural changes which may cause greater than minimal risk to the fetus or the pregnant woman will be introduced into the procedure for terminating the pregnancy solely in the interest of the activity.

(b) No inducements, monetary or otherwise, may be offered to terminate pregnancy for purposes of the activity.

[40 FR 33528, Aug. 8, 1975, as amended at 40 FR 51638, Nov. 6, 1975]

Sec. 46.207 Activities directed toward pregnant women as subjects.

(a) No pregnant woman may be involved as a subject in an activity covered by this **subpart** unless: (1) The purpose of the activity is to meet the health needs of the mother and the fetus will be placed at risk only to the minimum extent necessary to meet such needs, or (2) the risk to the fetus is minimal.

(b) An activity permitted under paragraph (a) of this section may be conducted only if the mother and father are legally competent and have given their informed consent after having been fully informed regarding possible impact on the fetus, except that the father's informed consent need not be secured if: (1) The purpose of the activity is to meet the health needs of the mother; (2) his identity or whereabouts cannot reasonably be ascertained; (3) he is not reasonably available; or (4) the pregnancy resulted from rape.

Sec. 46.208 Activities directed toward fetuses in utero as subjects.

(a) No fetus in utero may be involved as a subject in any activity covered by this **subpart** unless: (1) The purpose of the activity is to meet the health needs of the particular fetus and the fetus will be placed at risk only to the minimum extent necessary to meet such needs, or (2) the risk to the fetus imposed by the research is minimal and the purpose of the activity is the development of important biomedical knowledge which cannot be obtained by other means.

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(b) An activity permitted under paragraph (a) of this section may be conducted only if the mother and father are legally competent and have given their informed consent, except that the father's consent need not be secured if: (1) His identity or whereabouts cannot reasonably be ascertained, (2) he is not reasonably available, or (3) the pregnancy resulted from rape.

Sec. 46.209 Activities directed toward fetuses ex utero, including nonviable fetuses, as subjects.

(a) Until it has been ascertained whether or not a fetus ex utero is viable, a fetus ex utero may not be involved as a subject in an activity covered by this **subpart** unless:

(1) There will be no added risk to the fetus resulting from the activity, and the purpose of the activity is the development of important biomedical knowledge which cannot be obtained by other means, or

(2) The purpose of the activity is to enhance the possibility of survival of the particular fetus to the point of viability.

(b) No nonviable fetus may be involved as a subject in an activity covered by this **subpart** unless:

(1) Vital functions of the fetus will not be artificially maintained,

(2) Experimental activities which of themselves would terminate the heartbeat or respiration of the fetus will not be employed, and

(3) The purpose of the activity is the development of important biomedical knowledge which cannot be obtained by other means.

(c) In the event the fetus ex utero is found to be viable, it may be included as a subject in the activity only to the extent permitted by and in accordance with the requirements of other subparts of this part.

(d) An activity permitted under paragraph (a) or (b) of this section may be conducted only if the mother and father are legally competent and have given their informed consent, except that the father's informed consent need not be secured if: (1) His identity or whereabouts cannot reasonably be ascertained, (2) he is not reasonably available, or (3) the pregnancy resulted from rape.

[40 FR 33528, Aug. 8, 1975, as amended at 43 FR 1759, Jan. 11, 1978]

Sec. 46.210 Activities involving the dead fetus, fetal material, or the placenta.

Activities involving the dead fetus, mascerated fetal material, or cells, tissue, or organs excised from a dead fetus shall be conducted only in accordance with any applicable State or local laws regarding such activities.

Sec. 46.211 Modification or waiver of specific requirements.

Upon the request of an applicant or offeror (with the approval of its Institutional Review Board), the Secretary may modify or waive specific requirements of this **subpart**, with the approval of the Ethical Advisory Board after such opportunity for public comment as the Ethical Advisory Board considers appropriate in the particular instance. In

making such decisions, the Secretary will consider whether the risks to the subject are so outweighed by the sum of the benefit to the subject and the importance of the knowledge to be gained as to warrant such modification or waiver and that such benefits cannot be gained except through a modification or waiver. Any such modifications or waivers will be published as notices in the Federal Register.

[Code of Federal Regulations]
[Title 45, Volume 1, Parts 1 to 199]
[Revised as of October 1, 1997]
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[CITE: 45CFR46]

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TITLE 45--PUBLIC WELFARE

SUBTITLE A--DEPARTMENT OF HEALTH AND HUMAN SERVICES

PART 46--PROTECTION OF HUMAN SUBJECTS--Table of Contents

Subpart C--Additional Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners

Source: 43 FR 53655, Nov. 16, 1978, unless otherwise noted.

Sec. 46.301 Applicability.

(a) The regulations in this **subpart** are applicable to all biomedical and behavioral research conducted or supported by the Department of Health and Human Services involving prisoners as subjects.

(b) Nothing in this **subpart** shall be construed as indicating that compliance with the procedures set forth herein will authorize research involving prisoners as subjects, to the extent

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such research is limited or barred by applicable State or local law.

(c) The requirements of this **subpart** are in addition to those imposed under the other subparts of this part.

Sec. 46.302 Purpose.

Inasmuch as prisoners may be under constraints because of their incarceration which could affect their ability to make a truly voluntary and uncoerced decision whether or not to participate as subjects in research, it is the purpose of this **subpart** to provide additional safeguards for the protection of prisoners involved in activities to which this **subpart** is applicable.

Sec. 46.303 Definitions.

As used in this **subpart**:

(a) Secretary means the Secretary of Health and Human Services and any other officer or employee of the Department of Health and Human Services to whom authority has been delegated.

(b) DHHS means the Department of Health and Human Services.

(c) Prisoner means any individual involuntarily confined or detained in a penal institution. The term is intended to encompass individuals sentenced to such an institution under a criminal or civil statute, individuals detained in other facilities by virtue of statutes or commitment procedures which provide alternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial, or sentencing.

(d) Minimal **risk** is the probability and magnitude of physical or psychological harm that is normally encountered in the daily lives, or in the routine medical, dental, or psychological examination of healthy persons.

Sec. 46.304 Composition of Institutional Review Boards where prisoners are involved.

In addition to satisfying the requirements in Sec. 46.107 of this part, an Institutional Review Board, carrying out responsibilities under this part with respect to research covered by this **subpart**, shall also meet the following specific requirements:

(a) A majority of the Board (exclusive of prisoner members) shall have no association with the prison(s) involved, apart from their membership on the Board.

(b) At least one member of the Board shall be a prisoner, or a prisoner representative with appropriate background and experience to serve in that capacity, except that where a particular research project is reviewed by more than one Board only one Board need satisfy this requirement.

[43 FR 53655, Nov. 16, 1978, as amended at 46 FR 8386, Jan. 26, 1981]

Sec. 46.305 Additional duties of the Institutional Review Boards where prisoners are involved.

(a) In addition to all other responsibilities prescribed for Institutional Review Boards under this part, the Board shall review research covered by this **subpart** and approve such research only if it finds that:

(1) The research under review represents one of the categories of research permissible under Sec. 46.306(a)(2);

(2) Any possible advantages accruing to the prisoner through his or her participation in the research, when compared to the general living conditions, medical care, quality of food, amenities and opportunity for earnings in the prison, are not of such a magnitude that his or her ability to weigh the risks of the research against the value of such advantages in the limited choice environment of the prison is impaired;

(3) The risks involved in the research are commensurate with risks that would be accepted by nonprisoner volunteers;

(4) Procedures for the selection of subjects within the prison are fair to all prisoners and immune from arbitrary intervention by prison authorities or prisoners. Unless the principal investigator provides to the Board justification in writing for following some other procedures, control subjects must be selected randomly from the group of available prisoners who meet the characteristics needed for that particular research project;

(5) The information is presented in language which is understandable to the subject population;

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(6) Adequate assurance exists that parole boards will not take into account a prisoner's participation in the research in making decisions regarding parole, and each prisoner is clearly informed in advance that participation in the research will have no effect on his or her parole; and

(7) Where the Board finds there may be a need for follow-up examination or care of participants after the end of their participation, adequate provision has been made for such examination or care, taking into account the varying lengths of individual prisoners' sentences, and for informing participants of this fact.

(b) The Board shall carry out such other duties as may be assigned by the Secretary.

(c) The institution shall certify to the Secretary, in such form and manner as the Secretary may require, that the duties of the Board under this section have been fulfilled.

Sec. 46.306 Permitted research involving prisoners.

(a) Biomedical or behavioral research conducted or supported by DHHS may involve prisoners as subjects only if:

(1) The institution responsible for the conduct of the research has certified to the Secretary that the Institutional Review Board has approved the research under Sec. 46.305 of this **subpart**; and

(2) In the judgment of the Secretary the proposed research involves solely the following:

(i) Study of the possible causes, effects, and processes of incarceration, and of criminal behavior, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects;

(ii) Study of prisons as institutional structures or of prisoners as incarcerated persons, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects;

(iii) Research on conditions particularly affecting prisoners as a class (for example, vaccine trials and other research on hepatitis which is much more prevalent in prisons than elsewhere; and research on social and psychological problems such as alcoholism, drug addiction and sexual assaults) provided that the study may proceed only after the Secretary has consulted with appropriate experts including experts in penology medicine and ethics, and published notice, in the Federal Register, of his intent to approve such research; or

(iv) Research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the subject. In cases in which those studies require the assignment of prisoners in a manner consistent with protocols approved by the IRB to control groups which may not benefit from the research, the study may proceed only after the Secretary has consulted with appropriate experts, including experts in penology medicine and ethics, and published notice, in the Federal Register, of his intent to approve such research.

(b) Except as provided in paragraph (a) of this section, biomedical or behavioral research conducted or supported by DHHS shall not involve prisoners as subjects.

[Code of Federal Regulations]
[Title 45, Volume 1, Parts 1 to 199]
[Revised as of October 1, 1997]
From the U.S. Government Printing Office via GPO Access
[CITE: 45CFR46]

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TITLE 45--PUBLIC WELFARE

SUBTITLE A--DEPARTMENT OF HEALTH AND HUMAN SERVICES

PART 46--PROTECTION OF HUMAN SUBJECTS--Table of Contents

Subpart D--Additional Protections for Children Involved as Subjects in Research

Source: 48 FR 9818, Mar. 8, 1983, unless otherwise noted.

Sec. 46.401 To what do these regulations apply?

(a) This **subpart** applies to all research involving children as subjects, conducted or supported by the Department of Health and Human Services.

(1) This includes research conducted by Department employees, except that each head of an Operating Division of the Department may adopt such nonsubstantive, procedural modifications as may be appropriate from an administrative standpoint.

(2) It also includes research conducted or supported by the Department of Health and Human Services outside the United States, but in appropriate circumstances, the Secretary may, under paragraph (e) of Sec. 46.101 of **Subpart** A, waive the applicability of some or all of the requirements of these regulations for research of this type.

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(b) Exemptions at Sec. 46.101(b)(1) and (b)(3) through (b)(6) are applicable to this **subpart**. The exemption at Sec. 46.101(b)(2) regarding educational tests is also applicable to this **subpart**. However, the exemption at Sec. 46.101(b)(2) for research involving survey or interview procedures or observations of public behavior does not apply to research covered by this **subpart**, except for research involving observation of public behavior when the investigator(s) do not participate in the activities being observed.

(c) The exceptions, additions, and provisions for waiver as they appear in paragraphs (c) through (i) of Sec. 46.101 of **Subpart** A are applicable to this **subpart**.

[48 FR 9818, Mar. 8, 1983; 56 FR 28032, June 18, 1991; 56 FR 29757, June 28, 1991]

Sec. 46.402 Definitions.

The definitions in Sec. 46.102 of **Subpart** A shall be applicable to this **subpart** as well. In addition, as used in this **subpart**:

(a) Children are persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted.

(b) Assent means a child's affirmative agreement to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as assent.

(c) Permission means the agreement of parent(s) or guardian to the participation of their child or ward in research.

(d) Parent means a child's biological or adoptive parent.

(e) Guardian means an individual who is authorized under applicable State or local law to consent on behalf of a child to general medical care.

Sec. 46.403 IRB duties.

In addition to other responsibilities assigned to IRBs under this part, each IRB shall review research covered by this **subpart** and approve only research which satisfies the conditions of all applicable sections of this **subpart**.

Sec. 46.404 Research not involving greater than minimal risk.

HHS will conduct or fund research in which the IRB finds that no greater than minimal risk to children is presented, only if the IRB finds that adequate provisions are made for soliciting the assent of the children and the permission of their parents or guardians, as set forth in Sec. 46.408.

Sec. 46.405 Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual subjects.

HHS will conduct or fund research in which the IRB finds that more than minimal risk to children is presented by an intervention or procedure that holds out the prospect of direct benefit for the individual subject, or by a monitoring procedure that is likely to contribute to the subject's well-being, only if the IRB finds that:

(a) The risk is justified by the anticipated benefit to the subjects;

(b) The relation of the anticipated benefit to the risk is at least as favorable to the subjects as that presented by available alternative approaches; and

(c) Adequate provisions are made for soliciting the assent of the children and permission of their parents or guardians, as set forth in Sec. 46.408.

Sec. 46.406 Research involving greater than minimal risk and no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject's disorder or condition.

HHS will conduct or fund research in which the IRB finds that more than minimal risk to children is presented by an intervention or procedure that does not hold out the prospect of direct benefit for the individual subject, or by a monitoring procedure which is not likely to contribute to the well-being of the subject, only if the IRB finds that:

(a) The risk represents a minor increase over minimal risk;

(b) The intervention or procedure presents experiences to subjects that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social, or educational situations;

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(c) The intervention or procedure is likely to yield generalizable knowledge about the subjects' disorder or condition which is of vital importance for the understanding or amelioration of the subjects' disorder or condition; and

(d) Adequate provisions are made for soliciting assent of the children and permission of their parents or guardians, as set forth in Sec. 46.408.

Sec. 46.407 Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children.

HHS will conduct or fund research that the IRB does not believe meets the requirements of Sec. 46.404, Sec. 46.405, or Sec. 46.406 only if:

(a) The IRB finds that the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children; and

(b) The Secretary, after consultation with a panel of experts in pertinent disciplines (for example: science, medicine, education, ethics, law) and following opportunity for public review and comment, has determined either:

(1) That the research in fact satisfies the conditions of Sec. 46.404, Sec. 46.405, or Sec. 46.406, as applicable, or

(2) The following:

(i) The research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children;

(ii) The research will be conducted in accordance with sound ethical principles;

(iii) Adequate provisions are made for soliciting the assent of children and the permission of their parents or guardians, as set forth in Sec. 46.408.

Sec. 46.408 Requirements for permission by parents or guardians and for assent by children.

(a) In addition to the determinations required under other applicable sections of this subpart, the IRB shall determine that adequate provisions are made for soliciting the assent of the children, when in the judgment of the IRB the children are capable of providing assent. In determining whether children are capable of assenting, the IRB shall take into account the ages, maturity, and psychological state of the children involved. This judgment may be made for all children to be involved in research under a particular protocol, or for each child, as the IRB deems appropriate. If the IRB determines that the capability of some or all of the children is so limited that they cannot reasonably be consulted or that the intervention or procedure involved in the research holds out a prospect of direct benefit that is important to the health or well-being of the children and is available only in the

context of the research, the assent of the children is not a necessary condition for proceeding with the research. Even where the IRB determines that the subjects are capable of assenting, the IRB may still waive the assent requirement under circumstances in which consent may be waived in accord with Sec. 46.116 of Subpart A.

(b) In addition to the determinations required under other applicable sections of this subpart, the IRB shall determine, in accordance with and to the extent that consent is required by Sec. 46.116 of Subpart A, that adequate provisions are made for soliciting the permission of each child's parents or guardian. Where parental permission is to be obtained, the IRB may find that the permission of one parent is sufficient for research to be conducted under Sec. 46.404 or Sec. 46.405. Where research is covered by Secs. 46.406 and 46.407 and permission is to be obtained from parents, both parents must give their permission unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child.

(c) In addition to the provisions for waiver contained in Sec. 46.116 of Subpart A, if the IRB determines that a research protocol is designed for conditions or for a subject population for which parental or guardian permission is not a reasonable requirement to protect the subjects (for example, neglected or abused children), it may waive the consent requirements in Subpart A of this part and paragraph (b) of this section, provided an appropriate mechanism for protecting the children

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who will participate as subjects in the research is substituted, and provided further that the waiver is not inconsistent with Federal, state or local law. The choice of an appropriate mechanism would depend upon the nature and purpose of the activities described in the protocol, the risk and anticipated benefit to the research subjects, and their age, maturity, status, and condition.

(d) Permission by parents or guardians shall be documented in accordance with and to the extent required by Sec. 46.117 of Subpart A.

(e) When the IRB determines that assent is required, it shall also determine whether and how assent must be documented.

Sec. 46.409 Wards.

(a) Children who are wards of the state or any other agency, institution, or entity can be included in research approved under Sec. 46.406 or Sec. 46.407 only if such research is:

(1) Related to their status as wards; or

(2) Conducted in schools, camps, hospitals, institutions, or similar settings in which the majority of children involved as subjects are not wards.

(b) If the research is approved under paragraph (a) of this section, the IRB shall require appointment of an advocate for each child who is a ward, in addition to any other individual acting on behalf of the child as guardian or in loco parentis. One individual may serve as advocate for more than one child. The advocate shall be an individual who has the background and experience to act in, and agrees to act in, the best interests of the child for the duration of the child's participation in the research and who is not associated in any way (except in the role as advocate or member of the IRB) with the research, the investigator(s), or the guardian organization.