WEST VIRGINIA
SECRETARY OF STATE
KEN HECHLER
ADMINISTRATIVE LAW DIVISION

Do Not Mark In This Box
Filing Data

RECEIVED
1992 SEP 16 AM 9:01
OFFICE OF WEST VIRGINIA
SECRETARY OF STATE

Form #7

Effective Date

10/21/92 w/exception

NOTICE OF AN EMERGENCY RULE

AGENCY: State Board of Pharmacy TITLE NUMBER: 15

CITE AUTHORITY: W. Va. Code §30-5-19

EMERGENCY AMENDMENT TO AN EXISTING RULE: YES X NO _____

IF YES, SERIES NUMBER OF RULE BEING AMENDED: Series 1

TITLE OF RULE BEING AMENDED Rules of the West Virginia Board of Pharmacy

IF NO, SERIES NUMBER OF RULE BEING FILED AS AN EMERGENCY: _____

TITLE OF RULE BEING FILED AS AN EMERGENCY: _____

THE ABOVE RULE IS BEING FILED AS AN EMERGENCY RULE TO BECOME EFFECTIVE AFTER APPROVAL BY SECRETARY OF STATE OR 35TH DAY AFTER FILING, WHICHEVER OCCURS FIRST.

THE FACTS AND CIRCUMSTANCES CONSTITUTING THE EMERGENCY ARE AS FOLLOWS:

OBRA 90 is a Federal Law that will be implemented by the Health Care Financing Administration. The responsibility has been reserved to the State Board of Pharmacy. It must implement the OBRA 90 patient counseling requirements for medicaid patients by June 1, 1993. These regulations meet that requirement. Failure to implement these rules could cost the State Medicaid Program Federal Funds.

Use Additional Sheets If Necessary.

State of West Virginia
Board of Pharmacy

Phone (304) 348-0558
Fax (304) 348-0572

Office
238 Capitol Street
Charleston, West Virginia 25301

October 21, 1992

To: Renee Coe
Secretary of State

From: Betty Jo Payne

As of this date, approved by Board Member Lydia Main the date of June 1, 1993 is a typographical error and should read January 1, 1993 in the Emergency Rule submitted on OBRA 90.

DATE: September 16, 1992

RECEIVED
1992 SEP 16 AM 8:01
OFFICE OF WEST VIRGINIA
SECRETARY OF STATE

TO: LEGISLATIVE RULE-MAKING REVIEW COMMITTEE

FROM: STATE BOARD OF PHARMACY

EMERGENCY RULE TITLE: RULES OF THE WEST VIRGINIA BOARD OF PHARMACY

1. Date of filing: September 16, 1992

2. Statutory authority for promulgating the emergency rule:

W. Va. Code §30-5-19

3. Date of filing of proposed legislative rule: August 10, 1992

4. Does the emergency rule adopt new language or does it amend or repeal a current legislative rule?

Amends a current rule.

5. Has the same or similar emergency rule previously been filed and expired?

No

6. State, with particularity, those facts and circumstances which make the emergency rule necessary for the immediate preservation of public peace, health, safety or welfare.

N/A

7. If the emergency rule was promulgated in order to comply with a time limit established by the Code or federal statute or regulation, cite the Code provision, federal statute or regulation and time limit established therein.

Must comply with OBRA 90 and be established by January 1, 1993.

8. State, with particularity, those facts and circumstances which make the emergency rule necessary to prevent substantial harm to the public interest.

Could cost the West Virginia Medicaid Program Federal dollars.

Amendment to Legislative Rules Board of Pharmacy
Series 1
Rules and Regulations of the Board of Pharmacy

Amend Section 16.14 by deleting sub-section (f) language and adding new language as follows:

16.14 Duties.

It shall be the duty of a registered pharmacist in every pharmacy to perform the following duties:

(a) Accept all new prescriptions transmitted by oral communication.

(b) Affix typed prescription labels to prescription containers.

(c) To reconstitute, subtract from, or add to prescription medications.

(d) Record date and dispensing pharmacist's initials on original or refilled prescription.

(e) Deliver completed prescription to patient when instructions regarding its use are to be imparted to the patient.

~~(f)======Discuss with patient matters pertaining to the drug, its reasons for usage, contradictions or answer questions regarding the practitioner's intent.~~

(f) An offer to counsel shall be made by the pharmacist or the pharmacist's designee in a face-to-face communication with the patient or caregiver or agent who presents a new prescription, unless, in the professional judgment of the pharmacist it is deemed inappropriate or unnecessary. In such instances, it would be permissible for the offer to counsel to be made in a written communication, by telephone or in a manner determined by the pharmacist to be appropriate.

The above requirements shall constitute an acceptable offer to provide counseling to all parties including recipients of Medicaid and other third party programs or plans in the state.

(g) In those cases, when the offer to counsel, as described above, has been accepted, a pharmacist who provides prescription services to patients, shall discuss with the patient or caregiver or agent who presents a new prescription, any matter which in the exercise of the pharmacist's professional judgment the pharmacist deems significant, which may or may not include any of the following:

(1) The name and description of the medication;

(2) The route, dosage form, dosage route of administration, and duration of drug therapy;

(3) Special directions and precautions for preparation, administration, and use by patient;

(4) Common severe side or adverse effects or interactions and therapeutic contraindications that be encountered, including their avoidance and the action required if they occur;

(5) Techniques for self-monitoring drug therapy;

(6) Proper storage;

(7) Prescription refill information; and

(8) Action to be taken in the event of a missed dose.

(h) Nothing in this section shall be construed as requiring a pharmacist to provide consultation if the recipient or caregiver or agent does not accept the offer to counsel. Such refusal may be noted whether manually or electronically in the patient's profile.

(i) A pharmacist must make a reasonable effort to obtain, record, and maintain at least the following information at the individual pharmacy:

(1) Name, address, telephone number, date of birth or age, and gender.

(2) Individual history when significant, known allergies and drug reactions, and a comprehensive list of medications and relevant devices; and

(3) Pharmacist comments relevant to the individual's drug therapy.

~~(g)~~ (j) Perform any of the above functions except, nothing shall restrict registered interns from performing any and all of above functions under the supervision of a registered pharmacist.

~~(h)~~ (k) Perform any other functions of any nature or kind which requires the knowledge, ability or skill of a registered pharmacist.

(l) Patient counseling, as described herein, shall not be required for inpatients of a hospital or institution where other licensed health care practitioners are authorized to administer the drug(s).

Strike-through indicates language that would be stricken from

the present regulation, and underscoring indicates new language that would be added.

(7) The term "cosmetic," which shall be held to include "dentifrice" and "toilet article," means (a) articles intended to be rubbed, poured, sprinkled or sprayed on, introduced into, or otherwise applied to the human body, or any part thereof for cleansing, beautifying, promoting attractiveness or altering the appearance, and (b) articles intended for use as a component of any such articles, except that such term shall not include soap. (1951, c. 148; 1976, c. 102; 1984, c. 141.)

Editor's notes. — The Federal Food, Drug and Cosmetic Act is codified as 21 U.S.C. §§ 301-392.

Applied in Ye Olde Apothecary v. McClellan, 163 W. Va. 19, 253 S.E.2d 545 (1979).

§ 30-5-2. Board of pharmacy; appointment, qualifications and terms of members; powers and duties generally.

There shall be a state board of pharmacy, known as the "West Virginia board of pharmacy," which shall consist of five practicing pharmacists, who shall be appointed by the governor by and with the advice and consent of the senate. Each member of the board, at the time of his appointment, shall be a citizen and registered pharmacist of this state, and actively engaged in the practice of pharmacy.

The members of the board in office on the date this code takes effect [January 1, 1931] shall, unless sooner removed, continue to serve until their respective terms expire and until their successors have been appointed and have qualified. On or before the first day of July, one thousand nine hundred thirty-one, and on or before the first day of July of each year thereafter, the governor shall appoint one member to serve for a term of five years, commencing on said first day of July, and any member shall be eligible for reappointment.

The board, in addition to the authority, powers and duties granted to the board by this chapter and chapter sixteen [§ 16-1-1 et seq.] of the code, shall have the authority to: (a) Regulate the practice of the profession of pharmacy; (b) regulate the employment of apprentices and interns in pharmacy; (c) appoint, within the limit of appropriations, inspectors who shall be registered pharmacists, and investigators, both intended to act as agents of the board within the provisions of this chapter and chapter sixteen [§ 16-1-1 et seq.] of the code and such rules and regulations as the board shall promulgate; and (d) adopt rules of professional conduct appropriate to the establishment and maintenance of high standards of integrity and dignity in a profession. (1881, c. 2, § 3; 1882, c. 112, § 3; 1907, Ex. Sess., c. 12, § 3; 1915, c. 34, § 29b(3); Code 1923, c. 150, § 29b(3); 1951, c. 148; 1965, c. 119; 1983, c. 158.)

Cited in Ye Olde Apothecary v. McClellan, 163 W. Va. 19, 253 S.E.2d 545 (1979).

TITLE 15
LEGISLATIVE RULES
BOARD OF PHARMACY

SERIES I
RULES AND REGULATIONS OF THE BOARD OF PHARMACY

§15-1-1. General.

1.1. Scope. -- The West Virginia Code, section nineteen, article five, chapter thirty et. seq. mandates that the Board of Pharmacy shall make such Rules and Regulations, not inconsistent with law, as necessary, to carry out the purposes and enforce the provisions of this article.

1.2. Authority. -- W. Va. Code §30-5-19

1.3. Filing Date. -- April 9, 1990

1.4. Effective Date. -- April 10, 1990

1.5. Repeal of Former Rule. -- This repeals rules filed previously.

§15-1-2. Definitions.

The following words and phrases as used in these Rules and Regulations shall have the following meanings, unless the context otherwise requires:

2.1. The term "Drug" means (a) substances recognized as drugs in the official "United States Pharmacopoeia, Official Homeopathic Pharmacopoeia of the United States, or Official National Formulary," or any supplement to any of them; (b) substances intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or animals; (c) substances (other than food) intended to affect the structure or any function of the body of man or animals; and (d) substances intended for use as a component of any article specified in clauses (a), (b) or (c) of this subdivision. It does not include devices or their components, parts or accessories.

2.2. The term "Poisonous Drug" means any drug likely to be destructive to adult human life in quantities of five (5) grains or less.

2.3. The term "Deleterious Drug" means any drug likely to be destructive to adult human life in quantities of sixty (60) grains or less.

2.4. The term "Habit-Forming Drug" means any drug which has been or may be designated as habit-forming under the regulations promulgated in accordance with Section 502(d) of the Federal Food, Drug and Cosmetic Act of June 25, 1938, or any amendments, revisions, alterations, additions or modifications thereof.

2.5. "Patent or Proprietary Preparation" means a medicinal preparation which is intended for use in the cure, mitigation, treatment or prevention of disease in man or other animal pursuant to self-diagnosis; when the same is identified by and sold under a trademark, trade name or other trade symbol, privately owned or registered with the U.S. Patent Office; which preparation is sold in the original and unopened package of the manufacturer or primary distributor; which preparation in itself is not poisonous; which preparation is sold or offered for sale and is advertised for sale to the general public by the manufacturer or primary distributor; which preparation meets all of the requirements of the Federal Food, Drug and Cosmetic Act 1938 as amended and the laws of the State of West Virginia and regulations promulgated under either of these; and the labeling of which preparation does not contain the legend, "Caution: Federal Law Prohibits Dispensing Without Prescription" or any other legend or statement of like import.

Drugs and medicinal preparations considered not safe for self-medication under the

Food, Drug and Cosmetic Act 1938 as amended are defined as "Dangerous Drugs" and shall be used only under the supervision and on the prescription of a licensed medical practitioner.

2.6. "Controlled Substance" means a drug, substance or immediate precursor in Schedule I through V of article two, chapter sixty-a, of the West Virginia Code, (Uniform Controlled Substances Act).

2.7. The term "Prescription" shall be held to mean an order for drugs or medicines or combinations or mixtures thereof, written or signed by a duly licensed physician, an authorized Type A physician assistant at the direction of his or her supervising physician in accordance with the provisions of section sixteen, article three of this chapter, dentist, optometrist, as authorized by section two, article eight of this chapter, veterinarian or other medical practitioner licensed to write prescriptions intended for the treatment or prevention of disease of man or animals. Any prescription written or signed by an authorized Type A physician assistant shall be printed with the name of his or her supervising physician, the name of the physician assistant, and a list of drugs approved under the Type A physician assistant's job description, in accordance with the provision of section sixteen, article three of this chapter. The term "Prescription" shall also include orders for drugs or medicines or combinations or mixtures thereof transmitted to the pharmacist by word of mouth, telephone or other means of communication by a duly licensed physician, an authorized Type A physician assistant, dentist, optometrist, veterinarian or other medical practitioner licensed to write prescriptions intended for treatment or prevention of disease of man or animals and such prescriptions received by word of mouth, telephone or other means of communication shall be recorded in writing by the pharmacist and the record so made by the pharmacist shall constitute the original prescription to be filed by the pharmacist. A pharmacist receiving a prescription by word of mouth, telephone or other means of communication from an authorized Type A physician assistant shall require a copy of the list of drugs approved under the job description of such Type A physician assistant prior to accepting such orders. All such descriptions shall be preserved on file for a period of five (5) years, subject to inspection by the proper officer of the law. The above shall apply except for narcotic prescriptions, when all narcotic laws and regulations must be complied with.

2.8. The term "Cosmetic" which shall be held to include "Dentrifice" and "Toilet Articles", means; (a) articles intended to be rubbed, poured, sprinkled or sprayed on, introduced into, or otherwise applied to the human body, or any part thereof for cleansing, beautifying, promoting attractiveness or altering the appearance; and (b) articles intended for use as a component of any such articles, except that such term shall not include soap.

2.9. The term "Pharmacy" or "Drug Store" or "Apothecary" shall be held to mean any place where the practice of pharmacy is conducted and shall include every store or shop or other place (including, but not limited to, rest homes, nursing homes, hospitals, orphanages, clinics, homes for the aged and governmental agencies or institutions; (a) where drugs are administered, dispensed or compounded by or pursuant to the orders of a duly licensed medical practitioner in the course of professional practice, or where drugs are sold at retail or displayed for sale at retail; or (b) where appropriate licensed practitioners' prescriptions are compounded; or (c) which has upon it or displayed within it, or affixed to or used in connection with it, a sign bearing the word or words "Pharmacy", "Pharmacist", "Apothecary", "Drug Store", "Drugs", "Druggist", "Medicine", "Medicine Store", "Drug Sundries", "Remedies" or any word or words of similar or like import; or (d) any store or shop or other place, with respect to which any of the above words are used in any advertisement.

2.10. The "Practice of Pharmacy" is the practice concerned with the preparing, compounding and dispensing of drugs, medicines and medical supplies used in the

diagnosis, treatment or prevention of disease, whether compounded or dispensed on the prescription of a medical practitioner, or otherwise legally dispensed or sold and shall include the proper and safe storage, the maintenance of proper records and the dissemination of information concerning the therapeutic values and uses of such drugs and medicines.

2.11. "Dispensing" is that aspect of the practice of pharmacy which is concerned with the processing and handling of prescription orders of a licensed medical practitioner, including the delivery of the prescribed medication to the patient with consultation.

"Pharmaceutical Dispensing" shall not be construed to include the prescribing and administering of controlled substances as is included under the general definition of "Dispensing" controlled substances found in article two, chapter sixty-a of the Uniform Controlled Substances Act.

2.12. "Pharmacist" or "Druggist" means any person registered and/or licensed by the West Virginia Board of Pharmacy to practice the profession of Pharmacy in the State of West Virginia and whose license is in good standing.

2.13. "Assistant Pharmacist" means any person licensed by the West Virginia Board of Pharmacy to practice the profession of pharmacy as an assistant pharmacist, whose license was issued prior to the first day of January, one thousand nine hundred thirty-nine, and which is in good standing.

2.14. "Medical Practitioner" means an individual physician, dentist, veterinarian, podiatrist, osteopath or other practitioner duly licensed to practice in this State by the appropriate professional licensing board and to prescribe drugs necessary in the course of professional practice intended for the treatment of prevention of disease of man or animals.

The term "Practitioner" as pertains to persons and places handling controlled substances and as defined under article two, chapter sixty-a of the Uniform Controlled Substances Act shall not be construed to have the same meaning as the definitions for medical practitioners under chapter thirty of the West Virginia Code.

2.15. The term "Board" means the West Virginia Board of Pharmacy.

2.16. The term "President" means the President of the West Virginia Board of Pharmacy.

2.17. The term "Vice-President" means the Vice-President of the West Virginia Board of Pharmacy.

2.18. The term "Secretary" means the Secretary of the West Virginia Board of Pharmacy.

2.19. "Original Drug Store Permit" means a permit issued for a pharmacy, drug store or apothecary under the following conditions:

(a) A new business;

(b) Transfer of an established business to a successor;

(c) Transfer of fifty percent (50%) or more of the ownership (as evidenced by interest listed on renewal application for previous years) of an established business to a successor;

(d) Transfer of ownership which results in controlling interest being acquired by one (1) or more persons; and

(e) A pharmacy or drug store is moved to a new location.

Only pharmacy or drug store permits issued under section four, article eleven, chapter thirty of the West Virginia Code shall be considered a renewal.

2.20. The term "Person" means individual corporation, government or governmental subdivision or agency, business trust, estate,

trust, partnership, association or any other legal entity.

2.21. "Recognized School of Pharmacy" means a school of pharmacy whose physical equipment, course of instruction and teaching personnel conforms to the standards and specifications or the equivalent thereof required by the American Council on Pharmaceutical Education for Accreditation.

2.22. "Intern" means an individual working in a pharmacy or drug store under the instruction and supervision of a registered pharmacist preceptor who has been duly registered and certified by the Board. The term "intern" through common usage in the profession has become the usual term referring to apprentices, externs or interns who are gaining their practical experience during or after their formal college education. Hereinafter the Board will use "intern" to refer to individuals registered with the Board to obtain the practical experience requirement.

2.23. The term "Internship" shall be used to describe the practical experience requirement, and "Nine (9) months practical experience" shall mean an average work week of not less than forty (40) hours for a period of one (1) calendar year, except as herein provided for concurrent training programs.

2.24. "Gross Immorality" means conduct, acts and practices which are inconsistent with decency, good order and propriety of professional or personal conduct and/or which are hostile to the welfare of the general public. The word "gross" means willful and flagrant, rather than great or excessive.

2.25. "Person Addicted" means one who has acquired the habit of using spirituous liquors or narcotic or hypnotic drugs or other agents to such an extent as to deprive him of reasonable self-control.

2.26. "Act" or "Uniform Controlled Substances Act" when used in these regulations shall mean and refer to chapter sixty-a of the West Virginia Code as enacted by the West Virginia Legislature in 1971.

§15-1-3. General Provisions.

3.1. Board in general. -- The state Board of Pharmacy, known as the "West Virginia Board of Pharmacy" shall consist of five (5) practicing pharmacists who shall be appointed by the governor, by and with the advice and consent of the Senate. Each member of the Board, at the time of his appointment, shall be a citizen and a registered pharmacist of the State of West Virginia and actively engaged in the practice of pharmacy.

3.2. Officers of the Board. -- The members of the board shall annually elect as officers of said Board one (1) member to serve for a period of one (1) year as President of the said Board; one (1) member to serve for a period on one (1) year as vice president of said Board; and, one (1) member to serve for a period of one (1) year as Secretary of said Board, all of whom shall hold their offices for one (1) year and until their successors are elected. Said election to be held in the month of June each year.

The Secretary shall execute a surety bond conditioned as required by law, which bond shall be approved by the attorney general as to form, and by the auditor as to sufficiency, and when so approved, shall be filed and recorded in the office of the Secretary of State. The premium on said bond shall be regarded as a proper and necessary expense of the Board.

3.3. Official seal. -- The Board hereby reaffirms and readopts, as the official seal of the Board the following: The outer circle of the seal has inscribed therein "West Virginia Board of Pharmacy"; and the inner circle of the seal consists of a base upon which rests a graduate entwined about which there is an Aesculapius serpent and holding in balance a set of scales, an impression of which is affixed hereto.

3.4. Meeting of the Board. -- The Board shall hold at least two (2) meetings each year for the purpose of examining applicants for license to practice pharmacy in West Virginia and for

the transaction of such other business as may legally come before it and it may hold such other examination meetings as it might deem appropriate. In addition thereto, it may hold such additional meetings as may be necessary which shall be called by the Secretary at the direction of the President or upon the written request of any three (3) members.

3.5. Quorums. -- Before any action can be taken, on any matter properly in the consideration of the board, at least four (4) members must be in attendance at the place and time set for the meeting of the Board. A majority vote of the members in attendance is required before any motion is passed.

3.6. Location of office. -- The office of the Board is, unless otherwise designated by the Board, located at the office of the Secretary.

3.7. Disposition of moneys; report to auditor. -- The Secretary of the Board shall receive and account for, all moneys derived by virtue of the provisions of article one and five, chapter thirty of the West Virginia Code and shall pay such moneys into the State Treasury monthly on or before the tenth day of the month in which such moneys are received. He shall also, on the first day of January and first day of July of each year or within five (5) days thereafter, certify to the State Auditor, a detailed statement of all such moneys received by him during the preceding six (6) months.

3.8. Compensation of members; expenses. -- Every member of the Board shall receive thirty-five dollars ($35.00) for each day actually spent in attending the sessions of the Board or of its committees and the necessary travel, and shall be reimbursed for all actual and necessary expenses incurred in carrying out the provisions of chapter thirty of the West Virginia Code applicable to the Board.

The Secretary shall receive such salary as may be prescribed by the Board but in proceedings relative to the fixing of his salary, the Secretary shall have no vote.

All authorized compensation and all expenses certified by the Board as properly and necessarily incurred in the discharge of its duties, shall be paid out of the State Treasury from funds appropriated for that purpose on warrants of the State Auditor issued on the requisition signed by the President and Secretary of the Board.

3.9. Record of proceedings; registration of applicant; certified copies of records prima facie evidence; report to governor. -- The Secretary of the Board shall keep a record of its precedings and a register of all applicants for license or registration, showing for each, the date of his application, his name, age, educational and other qualifications, place of residence, whether an examination was required, whether the applicant was rejected or certificate of license or certificate of registration granted, the date of such action, the license or registration number, if required, and any suspension or revocation thereof. The books and register of the Board shall be open to public inspection at all reasonable times, and such books and register, or a copy of any part thereof, certified by the Secretary and attested by the seal of the Board, shall be prima facie evidence of all matters recorded therein.

On or before the first day of January of each year in which the Legislature meets in regular session, the Board shall submit to the Governor a report of its transactions for the preceding one year, together with an itemized statement of its receipts and disbursements, and a full list of the names of all persons licensed or registered by it during such period, certified by the President and the Secretary. A copy of the report shall be filed with the Secretary of State.

3.10. Roster of licensed or registered practitioners. -- The Secretary of the Board shall also prepare and maintain a complete roster of the names and office addresses of all persons licensed or registered and practicing within or without this State, the profession or occupation arranged alphabetically by name and also by the counties in which their offices are situated. The Board may call for and require a

registration whenever it deems it necessary or expedient to secure an accurate roster.

§15-1-4. Internship; Requirements For Certificate.

4.1. The principal purpose of serving an internship is to acquire practical experience under the direct supervision and instruction of a registered pharmacist preceptor in the providing of pharmaceutical services including the compounding and dispensing of prescriptions.

The Board shall certify internship, except as herein provided, only for an individual:

(a) Who has made application to the Board for registration as an intern and who in turn has been issued an intern certificate, which expires after three (3) years from the date of issue by the Board. The intern certificate shall be displayed at the location of interning.

(b) Who notifies the Board at least ten (10) days prior to the commencement of interning of the name and location of his registered pharmacist preceptor.

(c) Who notifies the Board within ten (10) days subsequent to termination of any internship under a pharmacist preceptor.

(d) Whose internship is certified by the submission of "Certification by Pharmacist as to Internship" form executed by the pharmacist preceptor immediately after termination of the internship. (Forms are available from the Board of Pharmacy.)

4.2. No intern shall be certified by the Board unless the individual is enrolled in the last three (3) years of the pharmacy curriculum or is a graduate of a recognized school of pharmacy.

4.3. Credit shall be received for experience for any period of time that is concurrent with enrollment in a recognized school of pharmacy except that the Board may grant four (4) months experience time for students participating or enrolled in supervised concurrent internship or clinical pharmacy training programs concurrent with the last year of the professional pharmacy curriculum.

4.4. No internship will be certified in a pharmacy or drug store in which the volume of prescription dispensing is less than ten thousand (10,000) prescriptions per year, unless any particular or extenuating situation warrants deviating from this figure in the judgment and discretion of the Board as provided for in the West Virginia Code, sections two and three, article five, chapter thirty.

4.5. Any pharmacist preceptor supervising the practical internship training shall be a qualified preceptor and employ the training concepts outlined in a "Guide for Preceptors and Interns" available through the West Virginia Board of Pharmacy.

4.6. The Board may accept internship experience gained outside the State of West Virginia on a letter of credit or certification from the Board of Pharmacy of the state in which the applicant acquired internship experience.

§15-1-5. Licensure And Annual Renewal; Requirement For.

5.1. Application.

All applicants for examination shall apply therefore in writing to the Secretary of the Board at least fifteen (15) days before the date the examination is to be conducted and shall transmit with his application a fee of one hundred twenty-five dollars ($125) which sum the Board is authorized to charge for an examination or investigation into such applicant's qualification to practice. The application shall be made on a form provided by the Board.

5.2. Requirements for application.

(a) Age.

The applicant must be not less than eighteen (18) years of age, proof of which must

be shown by a birth certificate or other proof when a birth certificate is not available.

(b) Moral character.

Every application for registration as a pharmacist shall present to the Board satisfactory evidence that he is a person of good moral character and not addicted to drunkenness or the use of controlled substances and that he has not been convicted of violating the provisions of any law relating to the practice of pharmacy and that he has not been convicted of a crime involving moral turpitude: **Provided,** That an applicant, who has been arrested pursuant to section four hundred one, article four, chapter sixty-a of the West Virginia Code, and who has later been discharged pursuant to section four hundred seven of the same article, may, upon otherwise having satisfied the requirements of this section, be deemed to have fully satisfied its requirements.

(c) Education.

The applicant shall present to the board satisfactory evidence that he is a graduate of a recognized school of pharmacy as defined in article one of these rules and regulations.

(d) Internship.

The applicant shall have acquired at least nine (9) months of internship experience under the supervision of a registered pharmacist preceptor as defined in Sections 2.22 and 4 of these Rules and Regulations.

5.3. Examinations.

(a) Examinations shall be held at a time and place designated by the Board. At least thirty (30) days' notice shall be given by the Board prior to the holding of any examination. Notice of such examination shall be given by mail to all registered pharmacies or drug stores in the State of West Virginia as appearing on the roster kept by the Secretary of the Board as required under section thirteen, article one, chapter thirty of the West Virginia Code, and to such other persons and schools of pharmacy as the Board may from time to time designate.

(b) A maximum of three (3) days shall be allowed for the examinations, including written, oral and laboratory.

(c) An applicant must pass a written examination in subjects determined by the Board as being reasonable, in testing his technical knowledge; and an applicant must also pass a practical examination determined by the Board as being a reasonable test of the applicant's ability to translate his technical knowledge into terms of actual practice.

(d) For the purpose of grading or rating, answers to the questions shall be valued by marks or points based on their importance and as determined by the judgment of the examiner. A general average of seventy-five percent (75%) shall be necessary for an applicant to pass the examination.

An applicant failing to pass the practical examination satisfactorily to the Board shall at either the first or second succeeding examination conducted by the Board, be entitled to a reexamination without further cost but one such reexamination shall exhaust his privilege under his original application.

5.4. Certificate of registration.

An applicant who has successfully passed all the examinations of the Board will receive a letter signed by the Secretary of the Board granting him the right to practice pharmacy in the State of West Virginia until such time as the permanent certificate as a registered pharmacist may be prepared for him. The permanent certificate of registration shall bear a serial number, the full name of the applicant, the date of its issuance, the seal of the Board, shall be signed by at least three (3) members of the Board and attested by the President and Secretary. Unless otherwise provided, the Board shall charge a fee of five dollars ($5.00) for every duplicate thereof, which fee shall be paid before such certificate or duplicate is issued. No such certificate shall be assignable.

5.5. Annual renewal of registration.

(a) Annual renewal.

Every registered pharmacist, who desires to continue in the practice of his profession, shall on or before the first day of July annually apply to the State Board of Pharmacy for a renewal of his registration, and shall transmit with his application a thirty dollar ($30.00) fee. If the Board shall find that such applicant has been legally registered in this State, and is entitled to a renewal of the certificate it shall issue to him a renewal certificate attesting that fact.

(b) Notification.

Notification of the annual renewal shall be given by the Secretary of the Board at least thirty (30) days prior to said first day of July.

(c) Failure to renew.

If any pharmacist shall fail for a period of thirty (30) days after the first day of July to apply to the Board for a renewal of his registration, his name shall be erased from the register of registered pharmacists.

Such person, in order to again become registered, shall be required to appear personally before the Board to show cause for permitting the certificate to lapse. If such person submits to the Board satisfactory reasons for allowing the certificate to lapse, and satisfies the Board by oral, written or practical examination as to his qualifications to practice the profession, such person shall be reregistered and required to pay for renewal the same fee as in the case of examination. If necessary, the Board may charge an additional fee.

§15-1-6. Reciprocity; Registration Of Pharmacists From Other States.

6.1. Qualifications. -- The Board may register and admit to practice as pharmacists in this state without examination, such persons as have been legally registered or licensed as pharmacists in other states: **Provided,** That

(a) Applicants must be at least eighteen (18) years of age.

(b) The original state in which the applicant is registered must accord similar recognition to registered pharmacists of the State of West Virginia.

(c) Applicant must be in good standing in the state of original licensing; a "Reciprocal Registration" is not recognized for reciprocity purposes.

(d) The applicant is, in fact, competent and physically and mentally qualified to function as a pharmacist.

(e) The applicant is of good moral character and is not addicted to the use of alcohol or controlled substances.

(f) The applicant has not been convicted, fined or had his license suspended or revoked for violation of pharmacy, liquor, narcotic or food and drug laws.

(g) An applicant must have originally passed a written examination in subjects determined by the Board as being reasonable, in testing his technical knowledge and applicant must have also passed a practical examination determined by the Board as being a reasonable test of the applicant's ability to translate his technical knowledge into terms of actual practice and the applicant must have made a general average of not less than seventy-five percent (75%) in the practical examination.

(h) Applicants who have become registered since 1945 must have graduated from a recognized school of pharmacy and in addition thereto, must have had not less than nine (9) months of practical experience as an intern and/or a registered pharmacist. Applicants who were registered prior to 1945 must have had not less than two (2) years of practical experience requirements for registration as a pharmacist in West Virginia at the time of their registration as a pharmacist by examination.

(i) If an applicant has not been engaged as a practicing pharmacist as evidence by an employer's affidavit during the year immediately prior to application for reciprocity, the Board will determine competency to practice by a practical examination.

(j) Applicants must become familiar with the West Virginia Laws and Regulations governing the practice of pharmacy and the rules of professional conduct established by the Board.

(k) Applicants for reciprocity and others coming into West Virginia from other states are warned not to accept positions as pharmacists or attempt to work as pharmacists until such time as they received a certificate of registration from the State of West Virginia.

6.2. Application.

(a) A preliminary application form obtained from the Secretary of the National Association of Boards of Pharmacy shall be completed by the applicant informing him in which state or states the applicant has previously registered and in what state he wishes to register submitted with a required fee of one hundred twenty-five dollars ($125) to the Secretary of the National Association of Boards of Pharmacy, O'Hare Corporate Center, 1300 Higgins Road, Suite 103, Park Ridge, Illinois, 60068.

On receiving the application for licensing by reciprocity, the National Association of Boards of Pharmacy contacts authorities in states where the applicant may have been licensed to secure verification, and, in addition, runs a character check on all applicants. An applicant who possesses the necessary qualifications will be supplied with the application forms which must be completed and submitted with the required supporting documents to the Secretary of this Board with a fee of one hundred twenty-five dollars ($125) plus five dollars ($5.00).

(b) The application must include the following:

(1) A certified copy of proof of experience, or original preceptor's affidavit proving same, that were filed by applicant when he took the examination in the state from which he applies.

(2) A recent bust photograph with a statement thereon, signed by the applicant, affirming that it is a photograph of said applicant and has been made within the previous twelve (12) months.

6.3. Appearance before the Board.

Applicants for registration by reciprocity are required to appear before the Board at such time as directed, for checking of credentials, interview, and such questioning and investigation as may be necessary to determine the fitness of the applicant to practice in West Virginia. Misrepresentations shall serve to void any registration that may be granted.

§15-1-7. Proceedings For Suspension Or Revocation Of License Or Registration; Effective Suspension Or Revocation; Transcript; Report.

7.1. In all proceedings before the Board for the suspension or revocation of any license or registration, a statement of the charges against the holder thereof and a notice of the time and place of hearing shall be served upon such person as a notice is served under section one, article two, chapter fifty-six of the West Virginia Code at least thirty (30) days prior to the hearing and he may appear with witnesses and be heard in person, by counsel, or both.

7.2. The Board may take such oral or written proof for or against the party charged as it may deem advisable.

7.3. The Board shall have the power to compel the attendance of witnesses and to take testimony concerning any proof on matters within its jurisdiction and for such purposes, the President and Secretary of the Board shall have the power to administer oath.

7.4. If, upon such hearing, the Board finds that such charges are true, it may suspend, or revoke the certificate of registration and such suspension or revocation shall take from the person, all rights and privileges acquired thereby. A stenographic report of each proceeding to suspend or revoke such certificate of registration shall be made at the expense of the Board and a transcript thereof retained in its files. The Board shall make a written report of its findings which shall constitute part of the record and copies thereof shall be filed with the Secretary of State and with the appropriate office of a sister state and with the Secretary of the National Association of Boards of Pharmacy if a reciprocal license is involved.

7.5. The following rules of procedure shall control such hearing before the Board:

(a) Hearings for the revocation, cancellation or suspension of a license or a permit.

(1) Initiating proceedings before the Board, proceedings for revocation, cancellation or suspension of a license or permit before the Board shall be begun by filing charges with the Board in writing and under oath. Said charges may be made by any person or persons.

(2) Settings: The President of the Board shall set a time and a place for hearings on the revocation, cancellation or suspension of a license or a permit.

(3) Representation: At any hearing the respondent shall have the right to appear either personally or by counsel, or both, to produce witnesses or evidence in his behalf, to cross-examine witnesses and to have subpoenas issued by the Board.

(4) Recording of hearings: A record of proceedings at hearings may be made in shorthand or by mechanical or electronic recordings at the discretion of the President of the Board or other person presiding over the hearing.

(5) The Board may deputize an employee to conduct the questioning at any hearing. It shall be the duty of such appointee to require an orderly presentation in accordance with these rules.

(b) Order of presentation.

(1) When any licensee or permittee shall be served with charges previously filed before the Board as provided in these rules, he shall appear before the Board on the day at the time specified in the notice of hearing.

(2) The absence of a licensee will in no way affect the power of the Board to act, provided proper notice has been given.

(3) At any hearing based upon charges previously filed with the Board as provided in these rules, the President of said Board or the Board's appointee shall commence such hearing by causing said charges to be read, and thereafter receiving the answer of the respondent to such charges, if any. The answer may be given either guilty or not guilty.

(4) The Board shall then proceed to hear evidence, both written or oral, in support of the charges. Each witness appearing in support of the charges shall first give direct testimony and immediately thereafter be available for cross-examination by the respondent or his attorney. Such testimony shall be given under oath.

(5) After the presentation of evidence in support of the charges, the respondent or his attorney shall then proceed with the presentation of evidence in opposition to the charges. The evidence may be written or oral. Witnesses appearing in behalf of the respondent shall give direct testimony and immediately thereafter, be subject to cross-examination by the Board or its duly authorized appointee. All such testimony shall be given under oath.

(6) Any member of the Board may examine any witness or respondent during their

presentation of direct testimony or upon cross-examination.

(7) At the close of the presentation of evidence in support of the complaint and evidence in opposition of the complaint, respondent or his attorney may be permitted oral argument before the Board.

(8) Evidence: All oral testimony shall be given under the oath of the witness. Evidence, both oral and written, which has probative value shall be received by the Board. Such evidence may be received even though the evidence is not presented in a form which would make it admissible if offered in court of law. However, evidence which is irrelevant to the issue shall be excluded. The President of the Board or other persons presiding over the hearing shall rule on the admissibility of the evidence.

(9) Effective date of official acts or orders: All official acts or orders of the Board shall be evidenced by a written record, and the date of the order or act unless some other effective date is stated in the writing itself. An appeal from the action of the Board shall not operate as a stay of the Board's action unless specifically directed as such by the Board.

(c) Application for reissuance of license or registration.

Upon application, the Board may reissue a license or registration to a person whose license or registration has been canceled or revoked. Such application, the case of cancellation or revocation, shall not be made prior to one (1) year after the cancellation or revocation.

Upon application, the Board may reinstate a license which has been suspended. Such application for reinstatement of a license shall be in a manner and form that the Board may require.

(d) Appearances before the Board by invitation of the Board.

(1) Appearances by invitation: When any licensee, permittee or other person shall receive an invitation to appear before the Board, such invitation shall in no manner be considered a subpoena or a demand to appear, but shall only be considered a request, to be complied with at the discretion of the person so invited.

(2) Representation at such hearings: Such person so invited, should he so desire, may have legal counsel accompany him to said hearing before the Board.

(3) Appearances by invitation shall be informal: All hearings before the Board based upon invitation by the Board shall be informal. No record of such proceedings shall be made.

(e) Hearings by Board upon complaint.

(1) Any person aggrieved by the Rules and Regulations promulgated by the Board shall be entitled to have his complaint set down for hearing by said Board.

(2) Requests for such hearings must be filed with the Board in accordance with the following requirements:

A) Complaint, depositions, briefs and other papers of importance shall be printed or typewritten and only one side of the paper shall be used.

B) Requests for such hearings shall specify in detail the basis for complaint.

C) Complaint shall specify reasonable evidence that such rule or regulation is inconsistent with the law governing the practice of pharmacy in West Virginia.

(3) Hearings for such complaint shall be held in ten (10) days from the date of receipt of said request by the Board, unless postponed by mutual agreement.

§15-1-8. Review By Circuit Court And Supreme Court Of Board's Refusal To Issue

Suspension Or Revocation Of License Or Registration.

8.1. Any person who has been refused a license or registration for any cause other than failure to pass the examination given by the Board or whose certificate of registration has been suspended or revoked, may, within thirty (30) days after the decision of the Board, present his petition in writing to the Circuit Court of the county in which he resides or to the judge of such court in vacation, praying for the review and reversal of such decision.

8.2. Before presenting his petition to the court or judge, petitioner shall mail copies thereof to the President and Secretary, respectively, of the Board.

8.3. Upon receipt of such copy, the Secretary shall forthwith transmit to the clerk of such court, the record of the proceedings before the Board.

8.4. The court or judge shall affix a time for review of said proceedings at its earliest convenience.

8.5. Notice of the time and place, in writing, of such hearing shall be given by the clerk of the court, to the President and Secretary of the Board, at least ten (10) days before the date set therefore.

8.6. The court or judge may enter an order affirming, revising or reversing the decision of the Board if it appears that the decision was clearly wrong.

8.7. Prior to the entry of such order by the court or judge, no order shall be made or entered by the court or judge to stay or supersede said suspension, revocation or cancellation of any such certificate of registration.

8.8. The judgment of the Circuit Court or the judge thereof, may be reviewed upon appeal in the Supreme Court of Appeal.

§15-1-9. Refilling Prescriptions.

9.1. It shall be unlawful for a pharmacist to refill any prescription containing a drug wherein the label of the original container of such drug bears the statement, "Caution: Federal Law Prohibits Dispensing Without Prescription," unless the licensed practitioner has authorized such by written notation on the original prescription, or has authorized such by oral order which is reduced promptly to writing and filled by the pharmacist.

9.2. If a prescription is refillable, the date of such refill and the initials of the pharmacist refilling said prescription shall be recorded upon the original written prescription, or upon the oral prescription which has been reduced to writing and filed by the pharmacist.

9.3. The refilling of prescriptions shall be limited by the provisions of the Uniform Controlled Substances Act, section three hundred eight, article three, chapter sixty-a of the West Virginia Code applicable to prescriptions and any Rules and Regulations adopted pursuant thereto.

(a) No prescription for a Schedule II controlled substance may be refilled.

(b) The prescription for a Schedule III or IV controlled substance shall not be filled or refilled more than six (6) months after the date written or be refilled more than five (5) times unless renewed by the practitioner.

§15-1-10. Prohibitions On Resale.

10.1. No controlled substance, drug, chemical or medicine after leaving the pharmacy shall be accepted for return and placed in stock for reuse or resale.

§15-1-11. Drug Product Selection Regulations.

11.1. The Board of Pharmacy of the State of West Virginia adopts the Food and Drug Administration's approved Drug Products and Legal Requirements Publication, the 1989 Ninth Edition and its supplements, as published by the United States Pharmacopeia Drug Product, listed in the Publication as a

nonequivalent therapeutic, after providing an opportunity for public comment.

§15-1-12. Regulation Governing Pharmacy Permits.

12.1. Pharmacy permits and annual registration.

Pharmacies or drug stores opening for business must first secure a permit and be registered with the Board of Pharmacy before they may lawfully conduct a pharmacy or drug store. The annual registration for renewal of permits shall be effective on the first day of July of each year.

12.2. Applications for permits.

The Board of Pharmacy shall require and provide for the annual registration of every pharmacy or drug store, as defined, doing business in this State. Any person, firm, corporation or copartnership desiring to operate, maintain, open or establish a pharmacy or drug store, as defined, in this State, shall apply to the Board of Pharmacy for a permit to do so. Every such place of business so registered shall be under the direct charge of a registered pharmacist and operate in compliance with the general provisions governing the practice of pharmacy and the operation of a drug store and pharmacy.

(a) The application for such permit shall be made on a form prescribed and furnished by the Board of Pharmacy, which when properly executed, shall indicate the owner, manager, trustee, lessee, receiver, or other person or persons desiring such permit, as well as the location of such pharmacy or drug store, including street and number, the name and registration number of the pharmacist in charge, the names and registration numbers of all other pharmacists providing pharmaceutical services and the times when the pharmacy or drug store is open for service. Said applications should be delivered to the Secretary by the fifteenth day of June to allow matriculation.

(b) Separate applications shall be made and separate permits shall be issued for each pharmacy or drug store.

(c) Any pharmacy or drug store operating more than twelve (12) hours a day will be required to operate with not less than two (2) registered pharmacists.

(d) All pharmacies or drug stores, as defined, must have on file a recent edition of the United States Pharmacopoeia and the National Formulary, or other publications embodying these texts, and also shall have such equipment, as may be required to render such service as public needs may dictate, or the proper protection of the public health may indicate. The minimum Board requirements are found in Sections 13 and 14 of these regulations.

(e) Each initial application for a permit shall be accompanied by the required fee of one hundred fifty dollars ($150). The fee for renewal of such permit shall be seventy-five dollars ($75.00) annually.

(f) Parenteral / enteral compounding.

(1) A pharmacy engaged in the practice of parenteral / enteral compounding shall comply with the following regulations:

(a) A parenteral / enteral compounding pharmacy is a type of special pharmacy which is limited in scope of pharmacy practice to render parenteral / enteral compounding functions. This pharmacy practice facilitates the utilization of certain institutional therapeutic measures by patients in the home environment or by patients in an institutional environment where such pharmacy service is unavailable or by patients in a hospital. Pharmacy services and parenteral / enteral products provided by a parenteral / enteral compounding pharmacy pursuant to prescription as defined in West Virginia Code subsection (6), section one, article five, chapter thirty, shall be limited to the compounding and/or dispensing of:

All sterile preparations for parenteral therapy and parenteral nutrition, including but not limited to:

(a) Sterile preparations for jejunostomy feeding and sterile irrigation solutions; and/or

(b) Sterile preparations of parenteral cytotoxic, antineoplastic, anti-infective and analgesic agents.

Any pharmacy, prior to engaging in parenteral / enteral compounding, shall obtain a parenteral / enteral compounding permit as provided herein.

(2) Pharmacy environment.

(a) The compounding and dispensing of sterile parenteral / enteral prescription preparations shall be accomplished in a pharmacy environment subject to the pharmacy permit laws of this State and in accordance with those requirements for the safe handling of drugs. The environment for this practice shall be set apart, and equipped to facilitate controlled aseptic conditions. Aseptic techniques shall prevail in this practice to minimize the possibility of microbial contamination.

(3) General requirements.

(a) Parenteral / enteral compounding shall be under the control and supervision of a licensed pharmacist, who shall be designated pharmacist manager on the application for a parenteral / enteral compounding permit. The pharmacist manager or other licensed qualified pharmacist as provided herein shall be present on duty during all hours of product preparation. Changes in pharmacist manager shall be reported to the Board of Pharmacy office within ten (10) days by the permit holder and pharmacist manager of record. A pharmacist manager of parenteral / enteral compounding pharmacy shall not be designated pharmacist manager of record of more than one parenteral / enteral compounding pharmacy.

(b) A pharmacy engaged in parenteral / enteral compounding shall provide special handling and packaging of compounded parenteral and enteral preparations when delivering from the pharmacy to the patient or institution as required to maintain stability of the preparations. All such preparations shall include time and/or date of expiration on the label and control number subcompounds. A parenteral / enteral compounding pharmacy shall provide telephone accessibility to its pharmacist for its patients at all hours.

(c) A patient profile shall be maintained for each patient. Said profile must contain available medical information consistent with prevailing pharmacy standards.

(d) A Policy and Procedure Manual shall be prepared and maintained at each parenteral / enteral compounding pharmacy, and be available for inspection by authorized agents of the Board of Pharmacy and the department. The Policy and Procedure Manual shall set forth in detail the objectives and operational guidelines of the permittee. It shall include a Quality Assurance Program which monitors personnel qualifications, training and performance, equipment facilities and random product sampling consistent with recommended standards for compounding and dispensing intravenous admixtures and a comprehensive patient drug profile and other parenteral medication as set forth by the Joint Commission on Accreditation of Hospitals, the National Coordinating Committee and Large Volume Parenterals and as provided by the West Virginia Board of Pharmacy. The manual shall be maintained in current status. A copy of the Policy and Procedure Manual shall be provided to the Board of Pharmacy when applying for a permit.

(e) Additional requirements are necessary for the storage, compounding, dispensing and discarding of cytotoxic agents. The pharmacy shall provide protection for its personnel involved in the handling of cytotoxic agents by utilizing the proper equipment and having a separate Policy and Procedure Manual for said agents. The manual shall identify, but

not be limited to, the following special procedures:

(1) All compounding should be conducted within a certified vertical laminar air flow hood. Type A or B VLAP hood used should be dependent upon the volume of work anticipated.

(2) Protective garb (gloves, face and eye, and gowns) shall be provided and used.

(3) Proper aseptic procedures must be used at all times to prevent bacterial contamination of the product as well as chemical contamination of the operator.

(4) All unused drug and material used in the preparation of cytotoxic agents must be disposed of properly in accordance with accepted professional standards and applicable law.

(f) An applicant for a parenteral / enteral compounding pharmacy permit shall provide the Board of Pharmacy with the following:

(1) Completed Board of Pharmacy permit application form.

(2) Copy of Policy and Procedure Manual.

(3) Minimum requirements for space, equipment, supplies and publications.

(a) To ensure compliance with the general requirements as set forth, the following minimum requirements for space, equipment, supplies and publications shall be met by a pharmacy which operates under the special permit of a parenteral / enteral compounding pharmacy. These requirements are in addition to the minimum requirements for space and equipment required of other types of pharmacies when applicable. The minimum permit requirements are set forth as follows:

(b) Space:

(1) The area for preparing sterile prescriptions as provided for in this rule referred to as the sterile admixture room shall be set apart from general work and storage areas. The room shall be adequately air conditioned or under positive pressure.

(2) The sterile admixture room shall provide space for a minimum of one laminar flow hood. Additionally, the space shall be adequate size to accommodate other equipment as provided herein and sufficient space to allow pharmacists and other employees working therein to adequately, safely and accurately fulfill their duties related to prescriptions.

(3) Compounding and dispensing of cytotoxic agents should be performed in an area separate from the area used to prepare other sterile solutions. The use of a vertical laminar flow hood is required in the preparation of cytotoxic agents. A sink and running water shall be provided for in the sterile admixture space room.

(c) Equipment:

(1) Laminar air flow hood(s).

(a) Vertical.

(2) Refrigerator/freezer.

(3) Sink and wash area (as provided in (1)(c) above).

(4) Appropriate waste containers for:

A) Used needles and syringes.

B) All cytotoxic waste including disposal apparel used in the preparation act.

(d) Supplies:

(1) Gloves, masks and gowns.

(2) Disposable needles and syringes of various standard sizes.

(3) Disinfectant cleaning agents.

(4) Clean towels.

(5) Liquid handwashing materials with bactericidal properties.

(6) Vacuum containers and various transfer sets.

(7) "Spill Kits" for cytotoxic agent spills.

(e) Current references:

(1) United States Pharmacopia and National Formulary.

(2) Handbook of Injectable Drugs by American Society of Hospital Pharmacists.

(3) Procedures for handling cytotoxic drugs by American Society of Hospital Pharmacists, Inc.

12.3. Issuance of permit.

(a) If an applicant is found satisfactory, the Secretary of the Board of Pharmacy shall issue to the applicant a permit for each pharmacy or drug store for which application is made.

(b) The permit registers the pharmacy or drug store to which it is issued and is not transferable. It is issued on the application of the owner and the registered pharmacist in charge, on the sworn statement that it will be conducted in accordance with the provisions of the law.

(c) In the case where a pharmacy or drug store is owned by a person not himself a registered pharmacist, the permit will be issued jointly to the registered pharmacist in charge and to the person owning said pharmacy, as defined in the definitions under these regulations.

(d) Permits must be posted in a conspicuous place. This requirement is not met when a permit is locked in a safe, placed in a desk drawer, or otherwise concealed.

12.4. Renewal of permit.

The annual registration for renewal of permit takes place on the first day of July of each year. The fee for annual renewal shall be seventy-five dollars ($75.00). Permits issued under this section shall not be transferable and shall expire on the thirtieth day of June of each calendar year, and if application for renewal of permit is not made on or before the first day of August each year, the permit shall lapse and become null and void.

12.5. Surrender of permit.

(a) Where a registered pharmacist in whose name a permit has been issued leaves the employment of such pharmacy or drug store he will be held responsible for proper notification of such termination of his services, and also for the surrender of the permit in his name. Neglect on the part of the pharmacist to so notify the Board may prevent his securing a permit to take charge or operate another pharmacy or drug store at a subsequent date.

(b) Whenever a pharmacy or a drug store is to be moved to a new location or when a pharmacy or a drug store changes ownership, the original permit becomes void and must be surrendered to the Board and a new permit secured by the new owners.

(c) When the registered pharmacist in whose name a pharmacy permit has been issued for any reason ceases to be actually the registered pharmacist who has responsible supervision over said pharmacy or drug store, the permit becomes void, and must be surrendered to the Board. A duplicate permit may be issued by the Board for the same pharmacy under a new pharmacist in charge. A fee of five dollars ($5.00) is charged for issuing such permit.

(d) Pharmacists employed and in charge of pharmacies or drug stores, owned by persons not registered pharmacists, are required to notify the Board and surrender for cancellation the permit issued immediately upon the termination of such employment. It shall also be

the duty of the owner of such pharmacies or drug stores, who are not registered pharmacists, to immediately notify the Board upon the termination of employment of registered pharmacists and to cause the surrender of permit as indicated. The further operation of the pharmacy or drug store, in the absence of a replacement and the issuance of a new permit is forbidden by law and each day so operated will be considered a separate offense.

12.6. Violations.

(a) The violation of these regulations may be considered cause for suspension of permits or the refusal to grant new ones.

(b) All registered pharmacists must notify the Board immediately of any change in employment and change of address. Not to do so may be considered sufficient cause for suspension.

(c) It shall be the duty of any person who employs any registered pharmacist to immediately notify the Board of any discharge, termination or change of place of employment of said registered pharmacist. Failure to so notify the Board may be deemed sufficient cause for suspension of any permit or license held by such person.

12.7. Security.

In the event that a prescription department is to be operated for a period less than the regular business hours of the entire store, the following Rules and Regulations shall be observed:

(a) The prescription area shall be separated from other departments of the store by a floor to ceiling, permanent barrier or partition, with entry doors that can be securely locked. If the pharmacy area is continually attended by a pharmacist when other people are in the store, the pharmacy area need not be enclosed by the permanent barrier. The barrier shall be so designed that only a pharmacist with a key shall have access to the area where prescription drugs, dangerous drugs, controlled substances, and other drugs and devices restricted to sales by pharmacists are stored, compounded, and dispensed.

(b) Types of permanent barriers: The permanent barrier may be constructed of other than a solid material. If constructed of a solid barrier, the openings or interstices in the material shall not be large enough to permit removal of items in the pharmacy area, by any means. Any material used in the construction must be of sufficient strength and thickness that it cannot be readily or easily removed, penetrated or bent. The plans and specifications of the permanent barrier shall be submitted to the Board for approval showing that it affords adequate security. Plans shall be submitted prior to proceeding with any construction, which plan shall indicate the pharmacy area which shall be of adequate space. Before a pharmacy permit shall be issued, the plans submitted must meet the approval of the Board.

(c) Signs: In the absence of a pharmacist, a sign with a minimum of 4 inch letters shall be prominently displayed stating: "Pharmacy Closed, No Pharmacist On Duty."

(d) Telephone: Separate phone (listing) answered only in pharmacy area. No telephone extensions of this listing are permitted outside the pharmacy area.

(e) Receipt and delivery: Written prescription orders and refill requests can be delivered to a pharmacy at any time. But if no pharmacist is present when the prescription order(s) must be deposited, by the patient or his agent delivering the prescription order or refill request to the establishment, into a "Mail Slot" or "Drug Box" so that the prescription orders are stored in the pharmacy area. The times that the pharmacy is open for business must be displayed so that they are prominently visible to the person depositing the prescription order(s).

(f) Completed prescription orders shall be stored in the pharmacy and cannot be removed from the pharmacy unless the pharmacist is present and the removal is for the immediate delivery to patient, person picking up

the prescription for the patient, or person delivering the prescription to the patient at his residence or similar place.

(g) Adequate working space shall be allotted to the pharmacy area subject to the approval of the Board.

(h) Mobile pharmacy units are prohibited.

12.8. List of drugs and prices; posting required; penalties for failure to comply.

(a) The Board of Pharmacy shall annually in the month of August distribute to all pharmacies licensed by the Board such forms as adopted and the same shall be publicly displayed for the convenience of the public.

(b) The official forms will contain not less than one hundred (100) most commonly prescribed prescription drugs by brand name and approved generic equivalent name (established name). The Board of Pharmacy has deemed that an approved generic equivalent shall mean the established name of a prescription drug or drug product designated by an official compendium of the United States and recognized by this Board in the list of prescription drugs or drug products to be posted by price, strength, manufacturer and quantity in every licensed pharmacy.

(c) Such forms shall bear a title across the top portion reading, "Prescription Price List and Services." The pharmacist shall designate the prices, and such prices shall reflect all of the services and conveniences that are included. A pharmacy may change the current posted selling price at any time. No prices shall be erased or crossed out. Price overlay stickers shall be used to effect any price change. Where the established or generic name is so designated, the pharmacy shall also list the name of the manufacturer.

(d) The price as shown shall indicate the current selling price and which professional and convenience services are included.

(e) Each pharmacy shall place in a prominent location which can be seen by the public, a sign furnished by the Board to read: "This pharmacy has for your information a list of drugs so priced as required by the West Virginia Code, section twelve-a, article five, chapter thirty."

(f) The owner of the pharmacy, member of firm, or officer of corporation shall certify on the forms provided by the Board that a list of current prices and other information as required by the West Virginia Code, section twelve-a, article five, chapter thirty is available to the public as required by appropriate Rules and Regulations.

(g) Any pharmacy that does not comply with the West Virginia Code, section twelve or section twelve-a, article five, chapter thirty of the regulations of this Board is subject to the penalties as prescribed in the West Virginia Code, section nineteen, article five, chapter thirty, revocation of permits.

(h) The Rules and Regulations so adopted shall be distributed along with the required forms to each pharmacy registered with this Board.

§15-1-13. Professional And Technical Equipment.

13.1. No permit shall be issued to operate a pharmacy or drug store, unless the minimum professional and technical equipment requirements have been fulfilled.

13.2. Every pharmacy or drug store shall at all times possess the following minimum professional and technical equipment:

(a) The current editions of the United States Pharmacopoeia and the National Formulary, or the equivalent thereof in pharmaceutic and therapeutic reference books.

(b) Class "A" prescription balances and weights shall meet the minimum standards adopted by the National Bureau of Standards as outlined in Handbook 44.

(c) A set of graduates ranging from 5 ml. to 250 ml.

(d) Mortars and pestles, spatulas, ointment pads, funnels, stirring rods, etc., to meet the current needs for extemporaneous compounding.

(e) Pharmacies compounding opthalmic preparations, IV additives or other pharmaceuticals requiring more sophisticated techniques must have the proper equipment to prepare sterile products or to meet other requirements of good compounding practices.

(f) Adequate facilities for the proper storage of pharmaceuticals which require refrigeration or protection from heat, light, or high humidity.

(g) Facilities for the safe storage of "Controlled Substances."

(h) An acceptable system for keeping records of prescriptions dispensed as required by the Uniform Controlled Substances Act and any Rules and Regulations adopted pursuant thereto.

(i) A record book for the disposition of "Schedule V Controlled Substances."

(j) Current copies of laws, rules and regulations pertaining to the practice of pharmacy in West Virginia.

§15-1-14. Sanitary Regulation Of Pharmacies.

14.1. The pharmacist in charge of a pharmacy, drug store, or apothecary shop in which prescriptions are compounded shall maintain such place and the equipment therein in a clean and orderly condition.

14.2. All such places shall comply with the sanitation laws of this State pertaining to any business conducted within a licensed pharmacy or drug store.

14.3. The prescription counter upon which prescriptions are compounded shall be used for no other purpose than for the compounding of prescriptions.

14.4. Upon the completion of compounding a prescription the prescription counter shall be cleaned and the refuse or waste materials shall be placed in a closed receptacle, and all instruments used in the compounding of such prescriptions shall be thoroughly cleaned and placed in a clean cabinet or storage space.

14.5. The sink or wash basin in the prescription room shall be used for no other purpose than for the cleansing of instruments and articles in the preparation of prescriptions or the cleansing of the hands of those preparing and compounding prescriptions.

14.6. All pharmacists when compounding prescriptions or working in the prescription room shall wear clean linen, either apron or coat, and shall be required to keep themselves and their apparel in a clean and sanitary condition.

14.7. The prescription room shall be maintained in an orderly and clean condition. All instruments, articles, stock bottles, containers, shelving, cabinets and equipment shall be free from dust, insects, rodents or any other foreign material.

14.8. The prescription room shall be well ventilated, free from obnoxious odors and equipped with adequate lighting facilities.

§15-1-15. Sale Of Drugs By Mechanical Devices; Sharing Compensation.

15.1. Sale of drugs and medicines by mechanical devices or vending machines are prohibited. The use of any mechanical device or vending machine in connection with the sales or disposition of drugs and/or medicines is unlawful.

15.2. Sharing compensation. -- The independent judgment of a pharmacist is a public trust, and his first allegiance is to the patient whom he serves. No pharmacist shall, except with a person licensed to practice

pharmacy, or in the course of his employment with a duly licensed institution, clinic or foundation, directly or indirectly share compensation arising out of or incidental to his professional employment with, or accept professional employment from any person or persons who for compensation prescribe drugs used in the compounding or dispensing prescriptions.

As used in this rule, the words "Person or Persons" includes firms, associations, partnerships or corporations in which an individual who for compensation prescribes drugs used in the compounding or dispensing of prescriptions has a proprietary interest sufficient to permit him to exercise a substantial degree of supervision, direction or control over the pharmacist.

§15-1-16. Rules Of Professional Conduct.

The practice of pharmacy is a profession dedicated to the service of public health which requires knowledge, skill and integrity. The state law restricts the practice of pharmacy to persons who possess special training and qualifications and licenses to them privileges which are denied to others. The pharmacist recognizing his responsibility to the public in safeguarding the preparation, compounding and dispensing of drugs, the storage and handling of drugs and medical supplies and the dissemination of information on medicinal agents obligates himself to the highest standards of professional conduct.

In order that the citizens of West Virginia shall receive the best possible pharmaceutical services, and that the public health, welfare and safety be fully protected, the following rules of professional conduct have been adopted by the West Virginia Board of Pharmacy as authorized by section seven, article five, chapter thirty of the West Virginia Code, 1931, as amended.

16.1. Professional responsibilities.

No pharmacist shall engage in conduct, in the practice of pharmacy or the operation of a pharmacy which tends to reduce the public confidence in the ability and integrity of the profession of pharmacy, or endangers the public health, safety and welfare; nor shall he engage in pharmaceutical practice or offer pharmaceutical services under any terms or conditions which tend to interfere with or impair the free and complete exercise of professional judgment and skill of a pharmacist. He shall at all times practice his profession in conformity with federal and state laws and regulations and the regulations of the West Virginia State Board of Pharmacy.

16.2. Uncertain prescription orders.

No pharmacist shall compound or dispense any prescription which, in his professional opinion, contains any error, omission, irregularity or ambiguity, but upon the receipt of such prescription order he shall contact the prescriber and confer with him before dispensing the prescription order if he has any doubt existing in his mind that such prescription order is not legitimate.

16.3. Refusal of prescription.

It is the duty of a pharmacist to make his professional services available to the public. Every pharmacy offering pharmaceutical services to the general public shall provide complete pharmaceutical service, including the compounding or dispensing of all prescription orders which may be reasonably expected to be compounded or dispensed by pharmacists. No pharmacist shall refuse to accept and fill, or cause to be filled, for payment thereof any prescription order presented to him unless there is a valid reason for his inability to fill such prescription order.

16.4. Betrayal of confidence.

No pharmacist shall exhibit, discuss or reveal the contents of any prescription, the therapeutic effect thereof, or the nature, extent, or degree of illness suffered by a patient served by him with any person other than (1) another pharmacist when necessary for the proper fulfillment of duties devolving upon the pharmacist; (2) the patient or his authorized

representative; (3) the prescriber; or (4) any person authorized by law to receive such information. He shall not, however, discuss with patient or his authorized representative such matters that should be discussed with the prescriber only.

16.5. Diagnosis or treatment.

No pharmacist shall attempt to diagnose, treat or prescribe for any disease, illness or organic disorder. This prohibition shall not be construed so as to prevent any pharmacist from advising individuals on matters concerning simple ailments, first aid measures, sanitary measures or the merits and quality of preparations which may be distributed legally without a prescription order.

16.6. Coded prescription orders.

No pharmacist shall compound or dispense any prescription order which is coded. A "Coded" prescription order is one which bears letters, numbers, words or symbols, or any other device used in lieu of the name, quantity, strength and directions for its use, other than those normal letters, numbers, words or symbols recognized by the profession of pharmacy as a means for conveying information by prescription order.

16.7. False or misleading advertising.

No pharmacist or pharmacy shall make, permit to be made, conduct or otherwise participate in any false, misleading or fraudulent advertising.

16.8. Promotion of drugs.

No pharmacist or pharmacy shall promote to the public by any means a controlled substance or any other drug which may only be dispensed pursuant to a prescription order, which promotion tends to cause such drugs to be used in excess of the requirements established in a legitimate physician-patient relationship.

16.9. Unreliable drugs.

No pharmacist shall purchase, accept, compound or dispense any medicinal preparation, whether by prescription order or otherwise, which in his professional opinion is not therapeutically reliable. Drugs shall be obtained only in original containers and only from authentic sources. No pharmacist shall accept from a patron, except for the purpose of destruction, any part of any unused prescription.

16.10. Changes in prescription.

No pharmacist shall dispense medication or devices which differ in any manner from the medication or device which is prescribed unless prior approval has been obtained from the prescriber, except when professional judgment requires the use of pharmaceutical adjuncts which do not compromise the therapeutic properties but are necessary for proper compounding. Any approved change in the prescription order shall immediately be recorded upon it and it shall show the date, time and method of ascertaining such approval.

16.11. Prescription order forms.

No pharmacist shall solicit professional practice by means of providing physicians or other medical practitioners with prescription order forms imprinted with any reference to a pharmacy or pharmacist.

16.12. Place of practice.

No pharmacist shall maintain a place of practice or location from which to solicit, accept or dispense prescriptions other than a pharmacy for which a permit has been issued by the West Virginia Board of Pharmacy.

16.13. Physician agreements.

No pharmacist shall enter into or engage in any agreement or arrangement with any physician or other practitioner which may tend to exploit the sick or for the payment or acceptance of compensation in any form or type for the recommending of the professional services of either; nor shall he enter into an agreement of any kind whereby in any way a

patient's free choice of a pharmacist or pharmacy is or may be limited.

16.14 Duties.

It shall be the duty of a registered pharmacist in every pharmacy to perform the following duties:

(a) Accept all new prescriptions transmitted by oral communication.

(b) Affix typed prescription labels to prescription containers.

(c) To reconstitute, subtract from, or add to prescription medications.

(d) Record date and dispensing pharmacist's initials on original or refilled prescription.

(e) Deliver completed prescription to patient when instructions regarding its use are to be imparted to the patient.

~~(f) Discuss with patient matters pertaining to the drug, its reasons for usage, contradictions or answer questions regarding the practitioner's intent.~~

(f) An offer to counsel shall be made by the pharmacist or the pharmacist's designee in a face-to-face communication with the patient or caregiver or agent who presents a new prescription, unless, in the professional judgment of the pharmacist it is deemed inappropriate or unnecessary. In such instances, it would be permissible for the offer to counsel to be made in a written communication, by telephone or in a manner determined by the pharmacist to be appropriate.

The above requirements shall constitute an acceptable offer to provide counseling to all parties including recipients of Medicaid and other third party programs or plans in the state.

(g) In those cases, when the offer to counsel, as described above, has been accepted, a pharmacist who provides prescription services to patients, shall discuss with the patient or caregiver or agent who presents a new prescription, any matter which in the exercise of the pharmacist's professional judgment the pharmacist deems significant, which may or may not include any of the following:

(1) The name and description of the medication;

(2) The route, dosage form, dosage route of administration, and duration of drug therapy;

(3) Special directions and precautions for preparation, administration, and use by patient;

(4) Common severe side or adverse effects or interactions and therapeutic contraindications that be encountered, including their avoidance and the action required if they occur;

(5) Techniques for self-monitoring drug therapy;

(6) Proper storage;

(7) Prescription refill information; and

(8) Action to be taken in the event of a missed dose.

(h) Nothing in this section shall be construed as requiring a pharmacist to provide consultation if the recipient or caregiver or agent does not accept the offer to counsel. Such refusal may be noted whether manually or electronically in the patient's profile.

(i) A pharmacist must make a reasonable effort to obtain, record, and maintain at least the following information at the individual pharmacy:

(1) Name, address, telephone number, date of birth or age, and gender.

(2) Individual history when significant, known allergies and drug reactions, and a comprehensive list of medications and relevant devices; and

(3) Pharmacist comments relevant to the individual's drug therapy.

~~(g)~~ (j) Perform any of the above functions except, nothing shall restrict registered interns from performing any and all of above functions under the supervision of a registered pharmacist.

~~(h)~~ (k) Perform any other functions of any nature or kind which requires the knowledge, ability or skill of a registered pharmacist.

(l) Patient counseling, as described herein, shall not be required for inpatients of a hospital or institution where other licensed health care practitioners are authorized to administer the drug(s).

16.15 Evasion or violation of the rules of professional conduct.

These rules of professional conduct are intended to govern all pharmacist licensed to practice in West Virginia by the State Board of Pharmacy, their employees or agents, a violation of any provisions of these rules shall constitute unprofessional conduct.

Any pharmacist who knowingly accepts professional employment from any person, firm or corporation who violates or evades these rules or regulations shall be deemed guilty of violation of the rules the same as if he had personally engaged in such evasion or violation.

16.16 Publication and posting of rules.

The Secretary of the West Virginia Board of Pharmacy shall make a copy of these Rules of Professional Conduct available to every pharmacy and pharmacist licensed by the West Virginia Board of Pharmacy. A copy of said rules shall be posted in the prescription department of every such establishment where it can be seen by all persons entering said department.

§15-1-17. **Pharmacist Consultants And Coordinators Of Pharmaceutical Services.**

Where, increasing numbers of pharmacists are serving as pharmacy consultants to, or serving as coordinators of pharmaceutical services in hospitals, skilled nursing facilities and intermediate care facilities, nursing homes, clinics, rest homes, homes for the aged, governmental agencies and other places where a pharmacy permit is not held, and the Board of Pharmacy has the responsibility to maintain standards of professional conduct and to regulate professional practice, the Board of Pharmacy hereby promulgates the following Rules and Regulation:

17.1. Requirements.

(a) The Board of Pharmacy shall maintain a roster of all pharmacist consultants and coordinators of pharmaceutical services. All persons serving as consultants or coordinators shall be licensed and registered to practice pharmacy in West Virginia.

(b) Any pharmacist consultant to hospitals, skilled nursing facilities, intermediate care facilities, nursing homes, clinics, rest homes, homes for the aged, governmental agencies and any other pharmaceutical consultation practice, shall register initially and annually in each instance such practice and place with the West Virginia Board of Pharmacy on forms provided by the Board.

(c) Any pharmacist providing pharmaceutical consultation to, or coordinating pharmaceutical services in hospitals, skilled nursing facilities, intermediate care facilities, nursing homes, clinics, rest homes, homes for the aged, governmental agencies and any other place where a pharmacy permit is not held shall register initially and annually in each instance such practice and place with the West Virginia Board of Pharmacy on forms provided by the Board and signed by the consultant and the administrator of such facility.

(d) All applicants certified as consultant pharmacists shall meet such additional educational and experienced backgrounds as required by the Board and comply with the regulation as set forth by the Board.

(e) Consultants shall document by time and date his activities consistent with the level of institutional care requirements.

17.2. Responsibilities.

(a) The pharmacist consultant or coordinator shall be responsible to initiate and maintain in each instance appropriate records and procedures for the receipt, labeling, storage and disposition of all drugs, including investigational drugs, medication samples and emergency kits.

(b) The pharmacist consultant or coordinator shall cause to be developed, issued and implemented a "Policy and Procedures" manual for pharmaceutical services. This manual shall be open to inquire by all authorized governmental agencies including the Board of Pharmacy. This manual shall enumerate provisions for, but not limited to the following:

(1) Drug recall.

(2) Separate reconciliation for controlled substances.

(3) Automatic stop orders.

(4) Systematic review of drug orders.

(5) Formulary or minimum standards for drug quality.

(6) Assist in-service drug education.

(7) Outline the procedure which shall spell out how drug orders are to be taken from the patient's chart and transcribed to drug orders.

(c) The pharmacist consultant or coordinator shall be responsible for maintaining an adequate professional library of pharmaceutical references within the facility.

(d) The pharmacist consultant or coordinator shall insure compliance with rules of professional conduct as adopted by the Board of Pharmacy under West Virginia Code, section two, article five, chapter thirty.

(e) The pharmacist consultant or coordinator shall insure compliance with all federal, state and local laws concerning drugs and pharmaceutical services.

(f) Nothing under these regulations shall preclude a patient in a skilled nursing facility or intermediate care facility from free choice of pharmaceutical supplies and drugs.

LAW OFFICES
SPILMAN, THOMAS, BATTLE & KLOSTERMEYER

Suite F Grand Plaza
1100 9th Street
P.O. Box 5116
Vienna, West Virginia 26105
Telephone (304) 295-6400
Telecopier (304) 295-8526
☐ Reply to Above Address

Suite 1200 United Center
P. O. Box 273
Charleston, West Virginia 25321-0273
Telephone (304) 340-3800
Telecopier (304) 340-3801
Writer's Direct Dial No. 340-3829
☑ Reply to Above Address

Suite 205 CB&T Executive Plaza
990 Elmer Prince Dr.
Morgantown, West Virginia 26505
Telephone (304) 599-8175
Telecopier (304) 599-8229
☐ Reply to Above Address

October 15, 1992

VIA HAND-DELIVERY

Office of the Secretary of State
Administrative Law Division
State Capitol
Charleston, WV 25305

FILED
Oct 16 2 53 PM '92
OFFICE OF SECRETARY OF WEST VIRGINIA STATE

RE: Emergency Rule
State Board of Pharmacy
Title No. 15

Dear Sir or Madam:

The purpose of this letter is to offer the Health Insurance Association of America's ("HIAA") comments concerning the request by the State Board of Pharmacy for the Secretary of State to approve as an emergency rule, the Board of Pharmacy's amendment to Title No. 15, Series 1, Regulations. The Health Insurance Association of America is a national trade association of approximately 300 health insurers representing the health insurance industry, with its principal place of business at 1025 Connecticut Avenue, N.W., Washington D.C. 20036-3998. Spilman, Thomas, Battle & Klostermeyer represents HIAA in West Virginia as its West Virginia counsel and is filing these comments on its behalf. HIAA's comments are as follows:

HIAA does not take a position one way or the other with respect to the Board of Pharmacy's contention that an emergency rule is necessary. In particular, the Board of Pharmacy states in response to question 7 posed by the Secretary of State's office that:

> "Must comply with OBRA 90 and be established by January 1, 1993."

Accordingly, the Board of Pharmacy concludes that it must implement the OBRA 90 patient counseling requirements for Medicaid patients by January 1, 1993.

Nevertheless, assuming an emergency exists, HIAA believes that the proposed amendment offered by the Board of Pharmacy is over inclusive in that it applies to more areas than are necessary to meet the OBRA 90 mandate. In particular, Section 15-1-16.14(f) provides in pertinent part:

> The above requirement shall constitute an acceptable offer to provide counseling to all parties including recipients of Medicaid and other third-party programs or plans in this state. (Emphasis added).

HIAA's objections go to the inclusion of "and other third-party programs or plans in this state." While this additional language may have merit, it is not necessary to satisfy the emergency imposed by OBRA 90. HIAA would suggest that this additional language be deleted and only be considered for inclusion after being subject to the regular rulemaking process.

Thank you for the opportunity to comment on these regulations.

Very truly yours,

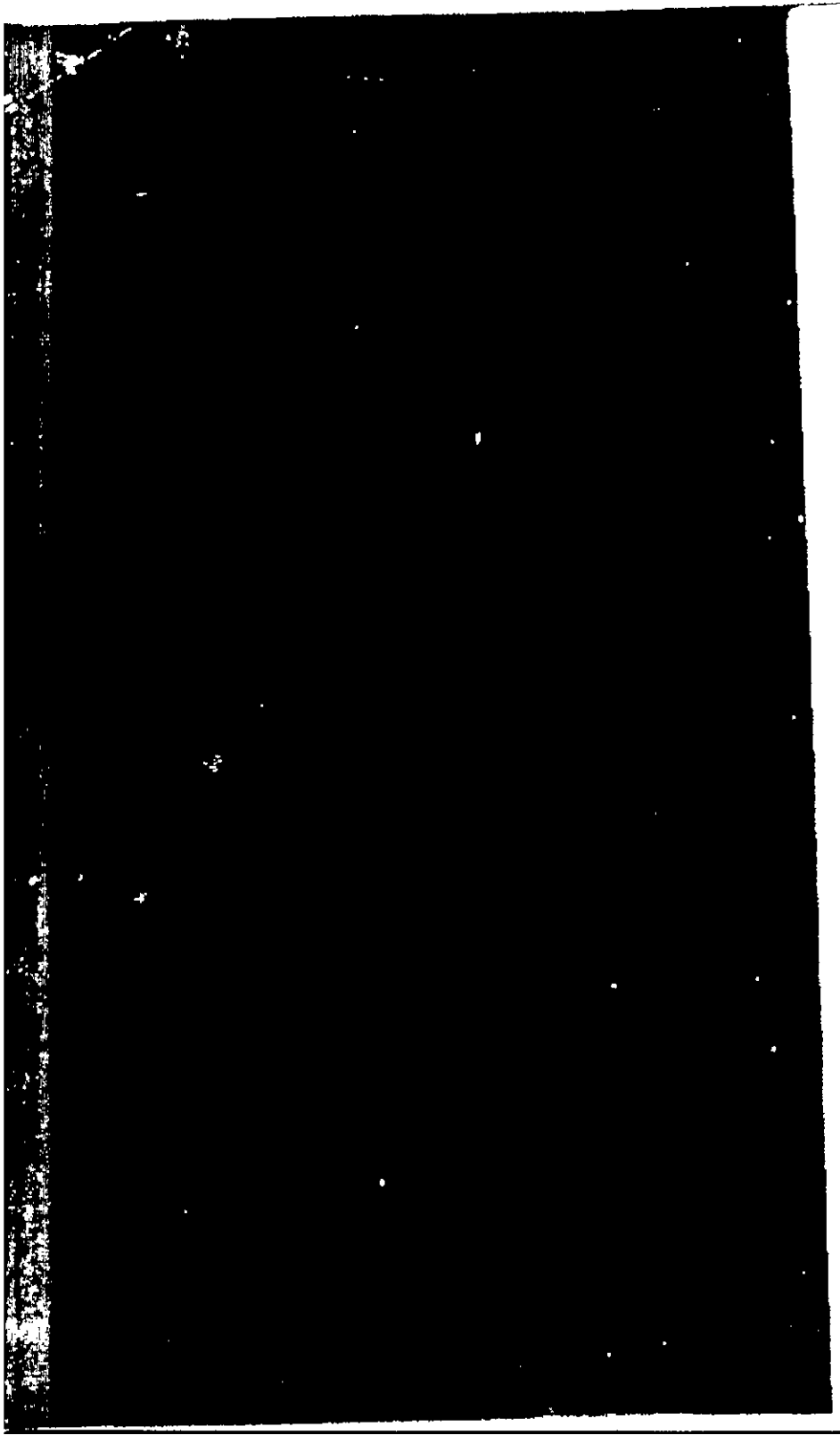
HEALTH INSURANCE ASSOCIATION OF AMERICA

BY: Spilman, Thomas, Battle & Klostermeyer, Its West Virginia counsel

T. Randolph Cox

TRC/lb

bcc: Ms. Jane Majcher



Offer to Counsel
See Page 152

OMNIBUS BUDGET RECONCILIATION ACT OF 1990

(304) Paul
342-1471
PDJ
Paul - See pg.
104 Stat. 1388-151
OBRA Omnibus 52

PART 1—REDUCTIONS IN SPENDING

SEC. 4401. REIMBURSEMENT FOR PRESCRIBED DRUGS.

(a) IN GENERAL.—

(1) DENIAL OF FEDERAL FINANCIAL PARTICIPATION UNLESS REBATE AGREEMENTS AND DRUG USE REVIEW IN EFFECT.—Section 1903(i) (42 U.S.C. 1396b(i)) is amended—

(A) by striking the period at the end of paragraph (9) and inserting "; or", and

(B) by inserting after paragraph (9) the following new paragraph:

"(10) with respect to covered outpatient drugs of a manufacturer dispensed in any State unless, (A) except as provided in section 1927(a)(3), the manufacturer complies with the rebate requirements of section 1927(a) with respect to the drugs so dispensed in all States, and (B) effective January 1, 1993, the State provides for drug use review in accordance with section 1927(g).".

(2) PROHIBITING STATE PLAN DRUG ACCESS LIMITATIONS FOR DRUGS COVERED UNDER A REBATE AGREEMENT.—Section 1902(a) of such Act (42 U.S.C. 1396a(a)) is amended—

(A) by striking "and" at the end of paragraph (52),

(B) by striking the period at the end of paragraph (53) and inserting "; and", and

(C) by inserting after paragraph (53) the following new paragraph:

"(54)(A) provide that, any formulary or similar restriction (except as provided in section 1927(d)) on the coverage of covered outpatient drugs under the plan shall permit the coverage of covered outpatient drugs of any manufacturer which has entered into and complies with an agreement under section 1927(a), which are prescribed for a medically accepted indication (as defined in subsection 1927(k)(6)), and

"(B) comply with the reporting requirements of section 1927(b)(2)(A) and the requirements of subsections (d) and (g) of section 1927.".

(3) REBATE AGREEMENTS FOR COVERED OUTPATIENT DRUGS, DRUG USE REVIEW, AND RELATED PROVISIONS.—Title XIX of the Social Security Act is amended by redesignating section 1927 as section 1928 and by inserting after section 1926 the following new section: 42 USC 1396

"PAYMENT FOR COVERED OUTPATIENT DRUGS

"SEC. 1927. (a) REQUIREMENT FOR REBATE AGREEMENT.— 42 USC 1396

"(1) IN GENERAL.—In order for payment to be available under section 1903(a) for covered outpatient drugs of a manufacturer, the manufacturer must have entered into and have in effect a rebate agreement described in subsection (b) with the Secretary, on behalf of States (except that, the Secretary may authorize a State to enter directly into agreements with a manufacturer). Any agreement between a State and a manufacturer prior to April 1, 1991, shall be deemed to have been entered into on January 1, 1991, and payment to such manufacturer shall be retroactively calculated as if the agreement between the manufacturer and the State had been entered into on January 1, 1991. If a manufacturer has not entered into such an agreement

before March 1, 1991, such an agreement, subsequently entered into, shall not be effective until the first day of the calendar quarter that begins more than 60 days after the date the agreement is entered into.

"(2) EFFECTIVE DATE.—Paragraph (1) shall first apply to drugs dispensed under this title on or after January 1, 1991.

"(3) AUTHORIZING PAYMENT FOR DRUGS NOT COVERED UNDER REBATE AGREEMENTS.—Paragraph (1), and section 1903(i)(10)(A), shall not apply to the dispensing of a single source drug or innovator multiple source drug if (A)(i) the State has made a determination that the availability of the drug is essential to the health of beneficiaries under the State plan for medical assistance; (ii) such drug has been given a rating of 1-A by the Food and Drug Administration; and (iii)(I) the physician has obtained approval for use of the drug in advance of its dispensing in accordance with a prior authorization program described in subsection (d), or (II) the Secretary has reviewed and approved the State's determination under subparagraph (A); or (B) the Secretary determines that in the first calendar quarter of 1991, there were extenuating circumstances.

"(4) EFFECT ON EXISTING AGREEMENTS.—In the case of a rebate agreement in effect between a State and a manufacturer on the date of the enactment of this section, such agreement, for the initial agreement period specified therein, shall be considered to be a rebate agreement in compliance with this section with respect to that State, if the State agrees to report to the Secretary any rebates paid pursuant to the agreement and such agreement provides for a minimum aggregate rebate of 10 percent of the State's total expenditures under the State plan for coverage of the manufacturer's drugs under this title. If, after the initial agreement period, the State establishes to the satisfaction of the Secretary that an agreement in effect on the date of the enactment of this section provides for rebates that are at least as large as the rebates otherwise required under this section, and the State agrees to report any rebates under the agreement to the Secretary, the agreement shall be considered to be a rebate agreement in compliance with the section for the renewal periods of such agreement.

"(b) TERMS OF REBATE AGREEMENT.—

"(1) PERIODIC REBATES.—

"(A) IN GENERAL.—A rebate agreement under this subsection shall require the manufacturer to provide, to each State plan approved under this title, a rebate each calendar quarter (or periodically in accordance with a schedule specified by the Secretary) in an amount specified in subsection (c) for covered outpatient drugs of the manufacturer dispensed under the plan during the quarter (or such other period as the Secretary may specify). Such rebate shall be paid by the manufacturer not later than 30 days after the date of receipt of the information described in paragraph (2) for the period involved.

"(B) OFFSET AGAINST MEDICAL ASSISTANCE.—Amounts received by a State under this section (or under an agreement authorized by the Secretary under subsection (a)(1) or an agreement described in subsection (a)(4)) in any quarter shall be considered to be a reduction in the amount expended under the State plan in the quarter for medical assistance for purposes of section 1903(a)(1).

"(2) STATE PROVISION OF INFORMATION.—

"(A) STATE RESPONSIBILITY.—Each State agency under this title shall report to each manufacturer not later than 60 days after the end of each calendar quarter and in a form consistent with a standard reporting format established by the Secretary, information on the total number of dosage units of each covered outpatient drug dispensed under the plan during the quarter, and shall promptly transmit a copy of such report to the Secretary.

"(B) AUDITS.—A manufacturer may audit the information provided (or required to be provided) under subparagraph (A). Adjustments to rebates shall be made to the extent that information indicates that utilization was greater or less than the amount previously specified.

"(3) MANUFACTURER PROVISION OF PRICE INFORMATION.—

"(A) IN GENERAL.—Each manufacturer with an agreement in effect under this section shall report to the Secretary—

"(i) not later than 30 days after the last day of each quarter (beginning on or after January 1, 1991), on the average manufacturer price (as defined in subsection (k)(1)) and, (for single source drugs and innovator multiple source drugs), the manufacturer's best price (as defined in subsection (c)(2)(B)) for covered outpatient drugs for the quarter, and

"(ii) not later than 30 days after the date of entering into an agreement under this section on the average manufacturer price (as defined in subsection (k)(1)) as of October 1, 1990 [1] for each of the manufacturer's covered outpatient drugs.

"(B) VERIFICATION SURVEYS OF AVERAGE MANUFACTURER PRICE.—The Secretary may survey wholesalers and manufacturers that directly distribute their covered outpatient drugs, when necessary, to verify manufacturer prices reported under subparagraph (A). The Secretary may impose a civil monetary penalty in an amount not to exceed $100,000 on a wholesaler, manufacturer, or direct seller, if the wholesaler, manufacturer, or direct seller of a covered outpatient drug refuses a request for information about charges or prices by the Secretary in connection with a survey under this subparagraph or knowingly provides false information. The provisions of section 1128A (other than subsections (a) (with respect to amounts of penalties or additional assessments) and (b)) shall apply to a civil money penalty under this subparagraph in the same manner as such provisions apply to a penalty or proceeding under section 1128A(a).

"(C) PENALTIES.—

"(i) FAILURE TO PROVIDE TIMELY INFORMATION.—In the case of a manufacturer with an agreement under this section that fails to provide information required under subparagraph (A) on a timely basis, the amount of the penalty shall be increased by $10,000 for each day in which such information has not been provided and such amount shall be paid to the Treasury, and, if such

[1] So in original. Probably should be "1990,".

information is not reported within 90 days of the deadline imposed, the agreement shall be suspended for services furnished after the end of such 90-day period and until the date such information is reported (but in no case shall such suspension be for a period of less than 30 days).

"(ii) FALSE INFORMATION.—Any manufacturer with an agreement under this section that knowingly provides false information is subject to a civil money penalty in an amount not to exceed $100,000 for each item of false information. Such civil money penalties are in addition to other penalties as may be prescribed by law. The provisions of section 1128A (other than subsections (a) and (b)) shall apply to a civil money penalty under this subparagraph in the same manner as such provisions apply to a penalty or proceeding under section 1128A(a).

"(D) CONFIDENTIALITY OF INFORMATION.—Notwithstanding any other provision of law, information disclosed by manufacturers or wholesalers under this paragraph is confidential and shall not be disclosed by the Secretary or a State agency (or contractor therewith) in a form which discloses the identity of a specific manufacturer or wholesaler, prices charged for drugs by such manufacturer or wholesaler, except as the Secretary determines to be necessary to carry out this section and to permit the Comptroller General to review the information provided.

"(4) LENGTH OF AGREEMENT.—

"(A) IN GENERAL.—A rebate agreement shall be effective for an initial period of not less than 1 year and shall be automatically renewed for a period of not less than one year unless terminated under subparagraph (B).

"(B) TERMINATION.—

"(i) BY THE SECRETARY.—The Secretary may provide for termination of a rebate agreement for violation of the requirements of the agreement or other good cause shown. Such termination shall not be effective earlier than 60 days after the date of notice of such termination. The Secretary shall provide, upon request, a manufacturer with a hearing concerning such a termination, but such hearing shall not delay the effective date of the termination.

"(ii) BY A MANUFACTURER.—A manufacturer may terminate a rebate agreement under this section for any reason. Any such termination shall not be effective until such period after the date of the notice as the Secretary may provide (but not beyond the term of the agreement).

"(iii) EFFECTIVENESS OF TERMINATION.—Any termination under this subparagraph shall not affect rebates due under the agreement before the effective date of its termination.

"(C) DELAY BEFORE REENTRY.—In the case of any rebate agreement with a manufacturer under this section which is terminated, another such agreement with the manufacturer (or a successor manufacturer) may not be entered into until a period of 1 calendar quarter has elapsed since the date of the termination, unless the Secretary finds good cause for an earlier reinstatement of such an agreement.

"(c) AMOUNT OF REBATE.—

"(1) BASIC REBATE FOR SINGLE SOURCE DRUGS AND INNOVATOR MULTIPLE SOURCE DRUGS.—With respect to single source drugs and innovator multiple source drugs, each manufacturer shall remit a basic rebate to the State medical assistance plan. Except as otherwise provided in this subsection, the amount of the rebate to a State for a calendar quarter (or other period specified by the Secretary) with respect to each dosage form and strength of single source drugs and innovator multiple source drugs shall be equal to the product of—

"(A) the total number of units of each dosage form and strength dispensed under the plan under this title in the quarter (or other period) reported by the State under subsection (b)(2); and

"(B)(i) for quarters (or periods) beginning after December 31, 1990, and before January 1, 1993, the greater of—

"(I) the difference between the average manufacturer price (after deducting customary prompt payment discounts) and 87.5 percent of such price for the quarter (or other period), or

"(II) the difference between the average manufacturer price for a drug and the best price (as defined in paragraph (2)(B)) for such quarter (or period) for such drug (except that for calendar quarters beginning after December 31, 1990, and ending before January 1, 1992, the rebate shall not exceed 25 percent of the average manufacturer price, and for calendar quarters beginning after December 31, 1991, and ending before January 1, 1993, the rebate shall not exceed 50 percent of the average manufacturer price); and

"(ii) for quarters (or other periods) beginning after December 31, 1992, the greater of—

"(I) the difference between the average manufacturer price for a drug and 85 percent of such price, or

"(II) the difference between the average manufacturer price for a drug and the best price (as defined in paragraph (2)(B)) for such quarter (or period) for such drug.

"(C) For the purposes of this paragraph, the term 'best price' means, with respect to a single source drug or innovator multiple source drug of a manufacturer, the lowest price available from the manufacturer to any wholesaler, retailer, nonprofit entity, or governmental entity within the United States (excluding depot prices and single award contract prices, as defined by the Secretary, of any agency of the Federal Government). The best price shall be inclusive of cash discounts, free goods, volume discounts, and rebates (other than rebates under this section) and shall be determined without regard to special packaging, labeling, or identifiers on the dosage form or product or package, and shall not take into account prices that are merely nominal in amount; [32]

"(D) In the case of a covered outpatient drug approved for marketing after October 1, 1990, any reference in this paragraph to 'October 1, 1990' shall be a reference to the first day of the first month during which the drug was marketed.

[32] So in original. Probably should be "".

"(2) ADDITIONAL REBATE FOR SINGLE SOURCE AND INNOVATOR MULTIPLE SOURCE DRUGS.—(A) Each manufacturer shall remit an additional rebate to the State medical assistance plan in an amount equal to:

"(i) For calendar quarters (or other periods) beginning after December 31, 1990 and ending before January 1, 1994—

"(I) the total number of each dosage form and strength of a single source or innovator multiple source drug dispensed during the calendar quarter (or other period); multiplied by

"(II)(aa) the average manufacturer price for each dosage form and strength, minus

"(bb) the average manufacturer price for each such dosage form and strength in effect on October 1, 1990, increased by the percentage increase in the Consumer Price Index for all urban consumers (U.S. average) from October 1, 1990, to the month before the beginning of the calendar quarter (or other period) involved; [33]

"(ii) For calendar quarters (or other periods) beginning after December 31, 1993—

"(I) the total number of each dosage form and strength of a single source or innovative multiple source drug dispensed during the calendar quarter (or other period); multiplied by

"(II) the amount, if any, by which the weighted average manufacturer price for single source and innovator multiple source drugs of a manufacturer exceeds the weighted average manufacturer price for the manufacturer as of October 1, 1990, increased by the percentage increase in the Consumer Price Index for all urban consumers (U.S. average) from October 1, 1990, to the month before the beginning of the calendar quarter (or other period) involved.

"(B)(i) For the purposes of subparagraph (A)(ii), the term 'weighted average manufacturer price' means (with respect to a calendar quarter or other period) the ratio of—

"(I) the sum of the products (for all covered drugs of the manufacturer purchased under a State program under this title) of—

"(aa) the average manufacturer price for each such covered drug; and

"(bb) the number of units of the covered drug sold to any State program under this title during such period, to

"(II) the total number of units of all such covered drugs sold under a State program under this title in such period, except that the Secretary may exclude certain new drugs from the calculation of the weighted average if the inclusion of any such drug in such calculation has the effect of—

"(aa) reducing the rebate otherwise calculated pursuant to subparagraph (A)(ii); or

"(bb) increasing the rebate otherwise calculated pursuant to subparagraph (A)(ii) (in cases where such calculation under the conditions outlined in clause (ii).[34]

[33] So in original. Probably should be ";".
[34] So in original. Probably should be "(iii)".

"(ii)(I) The Secretary may exclude drugs approved by the Food and Drug Administration on or after October 1, 1990, from the calculation of weighted average manufacturer price if inclus [35] manufacturer demonstrates through a petition, in a form and manner prescribed by the Secretary, undue hardship on such manufacturer as a result of the inclusion of such drug in such calculation).[36]

"(II) The Secretary may promulgate guidelines to restrict the conditions under which the Secretary may consider such petitions.

"(C) For each of 8 calendar quarters beginning after December 31, 1991, the Secretary shall compare the aggregate amount of the rebates under subparagraph (A)(i) to the aggregate amount of rebates under subparagraph (A)(ii). Based on any such comparison, the Secretary may propose and utilize an alternative formula for the purpose of calculating an aggregate rebate.

"(3) REBATE FOR OTHER DRUGS.—The amount of the rebate to a State for a calendar quarter (or other period specified by the Secretary) with respect to covered outpatient drugs (other than single source drugs and innovator multiple source drugs) shall be equal to the product of—

"(A) the applicable percentage (as described in paragraph (4) [37] of the average manufacturer price for each dosage form and strength of such drugs (after deducting customary prompt payment discounts) for the quarter (or other period), and

"(B) the number of units of such form and dosage dispensed under the plan under this title in the quarter (or other period) reported by the State under subsection (b)(2).

"(4) For the purposes of paragraph (3), the applicable percentage is—

"(A) with respect to calendar quarters beginning after December 31, 1990, and ending before January 1, 1994, 10 percent; and

"(B) with respect to calendar quarters beginning on or after December 31, 1993, 11 percent.

"(d) LIMITATIONS ON COVERAGE OF DRUGS.—

"(1) PERMISSIBLE RESTRICTIONS.—(A) Except as provided in paragraph (6), a State may subject to prior authorization any covered outpatient drug. Any such prior authorization program shall comply with the requirements of paragraph (5).

"(B) A State may exclude or otherwise restrict coverage of a covered outpatient drug if—

"(i) the prescribed use is not for a medically accepted indication (as defined in (k)(6));

"(ii) the drug is contained in the list referred to in paragraph (2); or

"(iii) the drug is subject to such restrictions pursuant to an agreement between a manufacturer and a State authorized by the Secretary under subsection (a)(1) or in effect pursuant to subsection (a)(4).

"(2) LIST OF DRUGS SUBJECT TO RESTRICTION.—The following drugs or classes of drugs, or their medical uses, may be excluded from coverage or otherwise restricted:

"(A) Agents when used for anorexia or weight gain.

"(B) Agents when used to promo'e fertility.

[35] So in original. The "inclus" probably should be "the".
[36] So in original. Probably should be "calculation.".
[37] So in original. Probably should be "(4)".

"(C) Agents when used for cosmetic purposes or hair growth.

"(D) Agents when used for the symptomatic relief of cough and colds.

"(E) Agents when used to promote smoking cessation.

"(F) Prescription vitamins and mineral products, except prenatal vitamins and fluoride preparations.

"(G) Nonprescription drugs.

"(H) Covered outpatient drugs which the manufacturer seeks to require as a condition of sale that associated tests or monitoring services be purchased exclusively from the manufacturer or its designee.

"(I) Drugs described in section 107(c)(3) of the Drug Amendments of 1962 and identical, similar, or related drugs (within the meaning of section 310.6(b)(1) of title 21 of the Code of Federal Regulations ('DESI' drugs)).

"(J) Barbiturates.

"(K) Benzodiazepines.

"(3) UPDATE OF DRUG LISTINGS.—The Secretary shall (except with respect to new drugs approved by the FDA for the first 6 months following the date of approval of such drugs shall not be subject to being listed in paragraph (2) under the provisions of this paragraph), by regulation, periodically update the list of drugs described in paragraph (2) or classes of drugs, or their medical uses, which the Secretary has determined, based on data collected by surveillance and utilization review programs of State medical assistance programs, to be subject to clinical abuse or inappropriate use.

"(4) INNOVATOR MULTIPLE-SOURCE DRUGS.—Innovator multiple-source drugs shall be treated under applicable State and Federal law and regulation.

"(5) PRIOR AUTHORIZATION PROGRAMS.—A State plan under this title may not require, as a condition of coverage or payment for a covered outpatient drug for which Federal financial participation is available in accordance with this section, the approval of the drug before its dispensing for any medically accepted indication (as defined in subsection (k)(6)) unless the system providing for such approval—

"(A) provides response by telephone or other telecommunication device within 24 hours of a request for prior authorization; and

"(B) except with respect to the drugs on the list referred to in paragraph (2), provides for the dispensing of at least a 72-hour supply of a covered outpatient prescription drug in an emergency situation (as defined by the Secretary).

"(6) TREATMENT OF NEW DRUGS.—A State may not exclude for coverage, subject to prior authorization, or otherwise restrict any new biological or drug approved by the Food and Drug Administration after the date of enactment of this section, for a period of 6 months after such approval.

"(7) OTHER PERMISSIBLE RESTRICTIONS.—A State may impose limitations, with respect to all such drugs in a therapeutic class, on the minimum or maximum quantities per prescription or on the number of refills, provided such limitations are necessary to discourage waste. Nothing in this section shall restrict the ability of a State to address individual instances of fraud or abuse in any manner authorized under the Social Security Act.

"(8) DELAYED EFFECTIVE DATE.—The provisions of paragraph (5) shall become effective with respect to drugs dispensed under this title on or after July 1, 1991.

"(e) DENIAL OF FEDERAL FINANCIAL PARTICIPATION IN CERTAIN CASES.—The Secretary shall provide that no payment shall be made to a State under section 1903(a) for an innovator multiple-source drug dispensed on or after July 1, 1991, if, under applicable State law, a less expensive noninnovator multiple source drug (other than the innovator multiple-source drug) could have been dispensed.

"(f) PHARMACY REIMBURSEMENT.—

"(1) NO REDUCTIONS IN REIMBURSEMENT LIMITS.—(A) During the period of time beginning on January 1, 1991, and ending on December 31, 1994, the Secretary may not modify by regulation the formula used to determine reimbursement limits described in the regulations under 42 CFR 447.331 through 42 CFR 447.334 (as in effect on the date of the enactment of the Omnibus Budget Reconciliation Act of 1990) to reduce such limits for covered outpatient drugs.

(B) [**] During the period of time described in subparagraph (A), any State that was in compliance with the regulations described in subparagraph (A) may not reduce the limits for covered outpatient drugs described in subparagraph (A) or dispensing fees for such drugs.

"(2) ESTABLISHMENT OF UPPER PAYMENT LIMITS.—HCFA shall establish a Federal upper reimbursement limit for each multiple source drug for which the FDA has rated three or more products therapeutically and pharmaceutically equivalent, regardless of whether all such additional formulations are rated as such and shall use only such formulations when determining any such upper limit.

"(g) DRUG USE REVIEW.—

"(1) IN GENERAL.—

"(A) In order to meet the requirement of section 1903(i)(10)(B), a State shall provide, by not later than January 1, 1993, for a drug use review program described in paragraph (2) for covered outpatient drugs in order to assure that prescriptions (i) are appropriate, (ii) are medically necessary, and (iii) are not likely to result in adverse medical results. The program shall be designed to educate physicians and pharmacists to identify and reduce the frequency of patterns of fraud, abuse, gross overuse, or inappropriate or medically unnecessary care, among physicians, pharmacists, and patients, or associated with specific drugs or groups of drugs, as well as potential and actual severe adverse reactions to drugs including education on therapeutic appropriateness, overutilization and underutilization, appropriate use of generic products, therapeutic duplication, drug-disease contraindications, drug-drug interactions, incorrect drug dosage or duration of drug treatment, drug-allergy interactions, and clinical abuse/misuse.

"(B) The program shall assess data on drug use against predetermined standards, consistent with the following:

"(i) compendia which shall consist of the following:

[**] So in original. Probably should be "(B)".

"(I) American Hospital Formulary Service Drug Information;

"(II) United States Pharmacopeia-Drug Information; and

"(III) American Medical Association Drug Evaluations; and

"(ii) the peer-reviewed medical literature.

"(C) The Secretary, under the procedures established in section 1903, shall pay to each State an amount equal to 75 per centum of so much of the sums expended by the State plan during calendar years 1991 through 1993 as the Secretary determines is attributable to the statewide adoption of a drug use review program which conforms to the requirements of this subsection.

"(D) States shall not be required to perform additional drug use reviews with respect to drugs dispensed to residents of nursing facilities which are in compliance with the drug regimen review procedures prescribed by the Secretary for such facilities in regulations implementing section 1919, currently at section 483.60 of title 42, Code of Federal Regulations.

"(2) DESCRIPTION OF PROGRAM.—Each drug use review program shall meet the following requirements for covered outpatient drugs:

"(A) PROSPECTIVE DRUG REVIEW.—(i) The State plan shall provide for a review of drug therapy before each prescription is filled or delivered to an individual receiving benefits under this title, typically at the point-of-sale or point of distribution. The review shall include screening for potential drug therapy problems due to therapeutic duplication, drug-disease contraindications, drug-drug interactions (including serious interactions with nonprescription or over-the-counter drugs), incorrect drug dosage or duration of drug treatment, drug-allergy interactions, and clinical abuse/misuse. Each State shall use the compendia and literature referred to in paragraph (1)(B) as its source of standards for such review.

"(ii) As part of the State's prospective drug use review program under this subparagraph applicable State law shall establish standards for counseling of individuals receiving benefits under this title by pharmacists which includes at least the following:

OFFER TO COUNSEL

"(I) The pharmacist must offer to discuss with each individual receiving benefits under this title or caregiver of such individual (in person, whenever practicable, or through access to a telephone service which is toll-free for long-distance calls) who presents a prescription, matters which in the exercise of the pharmacist's professional judgment (consistent with State law respecting the provision of such information), the pharmacist deems significant including the following:

"(aa) The name and description of the medication.

"(bb) The route, dosage form, dosage, route of administration, and duration of drug therapy.

"(cc) Special directions and precautions for preparation, administration and use by the patient.

"(dd) Common severe side or adverse effects or interactions and therapeutic contraindications that may be encountered, including their avoidance, and the action required if they occur.

"(ee) Techniques for self-monitoring drug therapy.

"(ff) Proper storage.

"(gg) Prescription refill information.

"(hh) Action to be taken in the event of a missed dose.

"(II) A reasonable effort must be made by the pharmacist to obtain, record, and maintain at least the following information regarding individuals receiving benefits under this title:

"(aa) Name, address, telephone number, date of birth (or age) and gender.

"(bb) Individual history where significant, including disease state or states, known allergies and drug reactions, and a comprehensive list of medications and relevant devices.

"(cc) Pharmacist comments relevant to the individuals drug therapy.

Nothing in this clause shall be construed as requiring a pharmacist to provide consultation when an individual receiving benefits under this title or caregiver of such individual refuses such consultation.

"(B) RETROSPECTIVE DRUG USE REVIEW.—The program shall provide, through its mechanized drug claims processing and information retrieval systems (approved by the Secretary under section 1903(r)) or otherwise, for the ongoing periodic examination of claims data and other records in order to identify patterns of fraud, abuse, gross overuse, or inappropriate or medically unnecessary care, among physicians, pharmacists and individuals receiving benefits under this title, or associated with specific drugs or groups of drugs.

"(C) APPLICATION OF STANDARDS.—The program shall, on an ongoing basis, assess data on drug use against explicit predetermined standards (using the compendia and literature referred to in subsection (1)(B) as the source of standards for such assessment) including but not limited to monitoring for therapeutic appropriateness, overutilization and underutilization, appropriate use of generic products, therapeutic duplication, drug-disease contraindications, drug-drug interactions, incorrect drug dosage or duration of drug treatment, and clinical abuse/misuse and, as necessary, introduce remedial strategies, in order to improve the quality of care and to conserve program funds or personal expenditures.

"(D) EDUCATIONAL PROGRAM.—The program shall, through its State drug use review board established under paragraph (3), either directly or through contracts with accredited health care educational institutions, State medical societies or State pharmacists associations/societies or other organizations as specified by the State, and using data

provided by the State drug use review board on common drug therapy problems, provide for active and ongoing educational outreach programs (including the activities described in paragraph (3)(C)(iii) of this subsection) to educate practitioners on common drug therapy problems with the aim of improving prescribing or dispensing practices.

"(3) STATE DRUG USE REVIEW BOARD.—

"(A) ESTABLISHMENT.—Each State shall provide for the establishment of a drug use review board (hereinafter referred to as the 'DUR Board') either directly or through a contract with a private organization.

"(B) MEMBERSHIP.—The membership of the DUR Board shall include health care professionals who have recognized knowledge and expertise in one or more of the following:

"(i) The clinically appropriate prescribing of covered outpatient drugs.

"(ii) The clinically appropriate dispensing and monitoring of covered outpatient drugs.

"(iii) Drug use review, evaluation, and intervention.

"(iv) Medical quality assurance.

The membership of the DUR Board shall be made up at least ⅓ but no more than 51 percent licensed and actively practicing physicians and at least ⅓ * * * licensed and actively practicing pharmacists.

"(C) ACTIVITIES.—The activities of the DUR Board shall include but not be limited to the following:

"(i) Retrospective DUR as defined in section (2)(B).

"(ii) Application of standards as defined in section (2)(C).

"(iii) Ongoing interventions for physicians and pharmacists, targeted toward therapy problems or individuals identified in the course of retrospective drug use reviews performed under this subsection. Intervention programs shall include, in appropriate instances, at least:

"(I) information dissemination sufficient to ensure the ready availability to physicians and pharmacists in the State of information concerning its duties, powers, and basis for its standards;

"(II) written, oral, or electronic reminders containing patient-specific or drug-specific (or both) information and suggested changes in prescribing or dispensing practices, communicated in a manner designed to ensure the privacy of patient-related information;

"(III) use of face-to-face discussions between health care professionals who are experts in rational drug therapy and selected prescribers and pharmacists who have been targeted for educational intervention, including discussion of optimal prescribing, dispensing, or pharmacy care practices, and follow-up face-to-face discussions; and

"(IV) intensified review or monitoring of selected prescribers or dispensers.

The Board shall re-evaluate interventions after an appropriate period of time to determine if the intervention improved the quality of drug therapy, to evaluate the success of the interventions and make modifications as necessary.

"(D) ANNUAL REPORT.—Each State shall require the DUR Board to prepare a report on an annual basis. The State shall submit a report on an annual basis to the Secretary which shall include a description of the activities of the Board, including the nature and scope of the prospective and retrospective drug use review programs, a summary of the interventions used, an assessment of the impact of these educational interventions on quality of care, and an estimate of the cost savings generated as a result of such program. The Secretary shall utilize such report in evaluating the effectiveness of each State's drug use review program.

"(h) ELECTRONIC CLAIMS MANAGEMENT.—

"(1) IN GENERAL.—In accordance with chapter 35 of title 44, United States Code (relating to coordination of Federal information policy), the Secretary shall encourage each State agency to establish, as its principal means of processing claims for covered outpatient drugs under this title, a point-of-sale electronic claims management system, for the purpose of performing online, real time eligibility verifications, claims data capture, adjudication of claims, and assisting pharmacists (and other authorized persons) in applying for and receiving payment.

"(2) ENCOURAGEMENT.—In order to carry out paragraph (1)—

"(A) for calendar quarters during fiscal years 1991 and 1992, expenditures under the State plan attributable to development of a system described in paragraph (1) shall receive Federal financial participation under section 1903(a)(3)(A)(i) (at a matching rate of 90 percent) if the State acquires, through applicable competitive procurement process in the State, the most cost-effective telecommunications network and automatic data processing services and equipment; and

"(B) the Secretary may permit, in the procurement described in subparagraph (A) in the application of part 433 of title 42, Code of Federal Regulations, and parts 95, 205, and 307 of title 45, Code of Federal Regulations, the substitution of the State's request for proposal in competitive procurement for advance planning and implementation documents otherwise required.

"(i) ANNUAL REPORT.—

"(1) IN GENERAL.—Not later than May 1 of each year the Secretary shall transmit to the Committee on Finance of the Senate, the Committee on Energy and Commerce of the House of Representatives, and the Committees on Aging of the Senate and the House of Representatives a report on the the operation of this section in the preceding fiscal year.

"(2) DETAILS.—Each report shall include information on—

"(A) ingredient costs paid under this title for single source drugs, multiple source drugs, and nonprescription covered outpatient drugs;

"(B) the total value of rebates received and number of manufacturers providing such rebates;

"(C) how the size of such rebates compare with the size or rebates offered to other purchasers of covered outpatient drugs;

"(D) the effect of inflation on the value of rebates required under this section;

"(E) trends in prices paid under this title for covered outpatient drugs; and

"(F) Federal and State administrative costs associated with compliance with the provisions of this title.

"(j) EXEMPTION OF ORGANIZED HEALTH CARE SETTINGS.—(1) Covered outpatient drugs dispensed by * * * Health Maintenance Organizations, including those organizations that contract under section 1903(m), are not subject to the requirements of this section.

"(2) The State plan shall provide that a hospital (providing medical assistance under such plan) that dispenses covered outpatient drugs using drug formulary systems, and bills the plan no more than the hospital's purchasing costs for covered outpatient drugs (as determined under the State plan) shall not be subject to the requirements of this section.

"(3) Nothing in this subsection shall be construed as providing that amounts for covered outpatient drugs paid by the institutions described in this subsection should not be taken into account for purposes of determining the best price as described in subsection (c).

"(k) DEFINITIONS.—In this section—

"(1) AVERAGE MANUFACTURER PRICE.—The term 'average manufacturer price' means, with respect to a covered outpatient drug of a manufacturer for a calendar quarter, the average price paid to the manufacturer for the drug in the United States by wholesalers for drugs distributed to the retail pharmacy class of trade.

"(2) COVERED OUTPATIENT DRUG.—Subject to the exceptions in paragraph (3), the term 'covered outpatient drug' means—

"(A) of those drugs which are treated as prescribed drugs for purposes of section 1905(a)(12), a drug which may be dispensed only upon prescription (except as provided in paragraph (5)), and—

"(i) which is approved for safety and effectiveness as a prescription drug under section 505 or 507 of the Federal Food, Drug, and Cosmetic Act or which is approved under section 505(j) of such Act;

"(ii)(I) which was commercially used or sold in the United States before the date of the enactment of the Drug Amendments of 1962 or which is identical, similar, or related (within the meaning of section 310.6(b)(1) of title 21 of the Code of Federal Regulations) to such a drug, and (II) which has not been the subject of a final determination by the Secretary that it is a 'new drug' (within the meaning of section 201(p) of the Federal Food, Drug, and Cosmetic Act) or an action brought by the Secretary under section 301, 302(a), or 304(a) of such Act to enforce section 502(f) or 505(a) of such Act; or

"(iii)(I) which is described in section 107(c)(3) of the Drug Amendments of 1962 and for which the Secretary has determined there is a compelling justification for its medical need, or is identical, similar, or related (within the meaning of section 310.6(b)(1) of title 21 of the Code of Federal Regulations) to such a drug, and (II) for which the Secretary has not issued a notice of an opportunity for a hearing under section 505(e) of the Federal Food, Drug, and Cosmetic Act on a proposed order of the Secretary to withdraw approval of an application for such drug under such section because the Secretary has determined that the drug is less than effective for some or all conditions of use prescribed, recommended, or suggested in its labeling; and

"(B) a biological product, other than a vaccine which—

"(i) may only be dispensed upon prescription,

"(ii) is licensed under section 351 of the Public Health Service Act, and

"(iii) is produced at an establishment licensed under such section to produce such product; and

"(C) insulin certified under section 506 of the Federal Food, Drug, and Cosmetic Act.

"(3) LIMITING DEFINITION.—The term 'covered outpatient drug' does not include any drug, biological product, or insulin provided as part of, or as incident to and in the same setting as, any of the following (and for which payment may be made under this title as part of payment for the following and not as direct reimbursement for the drug):

"(A) Inpatient hospital services.

"(B) Hospice services.

"(C) Dental services, except that drugs for which the State plan authorizes direct reimbursement to the dispensing dentist are covered outpatient drugs.

"(D) Physicians' services.

"(E) Outpatient hospital services * * * * [39] emergency room visits.

"(F) Nursing facility sevices.

"(G) Other laboratory and x-ray services.

"(H) Renal dialysis.

Such term also does not include any such drug or product which is used for a medical indication which is not a medically accepted indication.

"(4) NONPRESCRIPTION DRUGS.—If a State plan for medical assistance under this title includes coverage of prescribed drugs as described in section 1905(a)(12) and permits coverage of drugs which may be sold without a prescription (commonly referred to as 'over-the-counter' drugs), if they are prescribed by a physician (or other person authorized to prescribe under State law), such a drug shall be regarded as a covered outpatient drug.

"(5) MANUFACTURER.—The term 'manufacturer' means any entity which is engaged in—

"(A) the production, preparation, propagation, compounding, conversion, or processing of prescription drug products, either directly or indirectly by extraction from substances of natural origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis, or

"(B) in the packaging, repackaging, labeling, relabeling, or distribution of prescription drug products.

Such term does not include a wholesale distributor of drugs or a retail pharmacy licensed under State law.

"(6) MEDICALLY ACCEPTED INDICATION.—The term 'medically accepted indication' means any use for a covered outpatient drug which is approved under the Federal Food, Drug, and Cosmetic Act, which appears in peer-reviewed medical lit-

[39] So in original. Probably should be "services emergency".

erature or which is accepted by one or more of the following compendia: the American Hospital Formulary Service-Drug Information, the American Medical Association Drug Evaluations, and the United States Pharmacopeia-Drug Information.

"(7) MULTIPLE SOURCE DRUG; INNOVATOR MULTIPLE SOURCE DRUG; NONINNOVATOR MULTIPLE SOURCE DRUG; SINGLE SOURCE DRUG.—

"(A) DEFINED.—

"(i) MULTIPLE SOURCE DRUG.—The term 'multiple source drug' means, with respect to a calendar quarter, a covered outpatient drug (not including any drug described in paragraph (5)) for which there are 2 or more drug products which—

"(I) are rated as therapeutically equivalent (under the Food and Drug Administration's most recent publication of 'Approved Drug Products with Therapeutic Equivalence Evaluations'),

"(II) except as provided in subparagraph (B), are pharmaceutically equivalent and bioequivalent, as defined in subparagraph (C) and as determined by the Food and Drug Administration, and

"(III) are sold or marketed in the State during the period.

"(ii) INNOVATOR MULTIPLE SOURCE DRUG.—The term 'innovator multiple source drug' means a multiple source drug that was originally marketed under an original new drug application approved by the Food and Drug Administration.

"(iii) NONINNOVATOR MULTIPLE SOURCE DRUG.—The term 'noninnovator multiple source drug' means a multiple source drug that is not an innovator multiple source drug.

"(iv) SINGLE SOURCE DRUG.—The term 'single source drug' means a covered outpatient drug which is produced or distributed under an original new drug application approved by the Food and Drug Administration, including a drug product marketed by any cross-licensed producers or distributers [40] operating under the new drug application.

"(B) EXCEPTION.—Subparagraph (A)(i)(II) shall not apply if the Food and Drug Administration changes by regulation the requirement that, for purposes of the publication described in subparagraph (A)(i)(I), in order for drug products to be rated as therapeutically equivalent, they must be pharmaceutically equivalent and bioequivalent, as defined in subparagraph (C).

"(C) DEFINITIONS.—For purposes of this paragraph—

"(i) drug products are pharmaceutically [41] equivalent if the products contain identical amounts of the same active drug ingredient in the same dosage form and meet compendial or other applicable standards of strength, quality, purity, and identity;

"(ii) drugs are bioequivalent if they do not present a known or potential bioequivalence problem, or, if they do present such a problem, they are shown to meet an appropriate standard of bioequivalence; and

"(iii) a drug product is considered to be sold or marketed in a State if it appears in a published national listing of average wholesale prices selected by the Secretary, provided that the listed product is generally available to the public through retail pharmacies in that State.

"(8) STATE AGENCY.—The term 'State agency' means the agency designated under section 1902(a)(5) to administer or supervise the administration of the State plan for medical assistance.".

(b) FUNDING.—

(1) DRUG USE REVIEW PROGRAMS.—Section 1903(a)(3) (42 U.S.C. 1936b(a)(3)) is amended— 42 USC 1396b

(A) by striking "plus" at the end of subparagraph (C) and inserting "and", and

(B) by adding at the end the following new subparagraph:

"(D) 75 percent of so much of the sums expended by the State plan during a quarter in 1991, 1992, or 1993, as the Secretary determines is attributable to the statewide adoption of a drug use review program which conforms to the requirements of section 1927(g); plus".

(2) TEMPORARY INCREASE IN FEDERAL MATCH FOR ADMINISTRATIVE COSTS.—The per centum to be applied under section 1903(a)(7) of the Social Security Act for amounts expended during calendar quarters in fiscal year 1991 which are attributable to administrative activities necessary to carry out section 1927 (other than subsection (g)) of such Act shall be 75 percent, rather than 50 percent; after fiscal year 1991, the match shall revert back to 50 percent. 42 USC 1396b note.

(c) DEMONSTRATION PROJECTS.— 42 USC 1396

(1) PROSPECTIVE DRUG UTILIZATION REVIEW.— note.

(A) The Secretary of Health and Human Services shall provide, through competitive procurement by not later than January 1, 1992, for the establishment of at least 10 statewide demonstration projects to evaluate the efficiency and cost-effectiveness of prospective drug utilization review (as a component of on-line, real-time electronic point-of-sales claims management) in fulfilling patient counseling and in reducing costs for prescription drugs.

(B) Each of such projects shall establish a central electronic repository for capturing, storing, and updating prospective drug utilization review data and for providing access to such data by participating pharmacists (and other authorized participants).

(C) Under each project, the pharmacist or other authorized participant shall assess the active drug regimens of recipients in terms of duplicate drug therapy, therapeutic overlap, allergy and cross-sensitivity reactions, drug interactions, age precautions, drug regiment compliance, prescribing limits, and other appropriate elements.

(D) Not later than January 1, 1994, the Secretary shall submit to Congress a report on the demonstration projects conducted under this paragraph.

(2) DEMONSTRATION PROJECT ON COST-EFFECTIVENESS OF REIMBURSEMENT FOR PHARMACISTS' COGNITIVE SERVICES.—

(A) The Secretary of Health and Human Services shall conduct a demonstration project to evaluate the impact on

[40] So in original. Probably should be "distributors".
[41] So in original. Probably should be "pharmaceutically".

quality of care and cost-effectiveness of paying pharmacists under title XIX of the Social Security Act, whether or not a drug is dispensed, for drug use review services. For this purpose, the Secretary shall provide for no fewer than 5 demonstration sites in different States and the participation of a significant number of pharmacists.

(B) Not later than January 1, 1995, the Secretary shall submit a report to the Congress on the results of the demonstration project conducted under subparagraph (A).

42 USC 1396r-8 note.

(d) STUDIES.—

(1) STUDY OF DRUG PURCHASING AND BILLING ACTIVITIES OF VARIOUS HEALTH CARE SYSTEMS.—

(A) The Comptroller General shall conduct a study of the drug purchasing and billing practices of hospitals, other institutional facilities, and managed care plans which provide covered outpatient drugs in the medicaid program. The study shall compare the ingredient costs of drugs for medicaid prescriptions to these facilities and plans and the charges billed to medical assistance programs by these facilities and plans compared to retail pharmacies.

(B) The study conducted under this subsection shall include an assessment of—

(i) the prices paid by these institutions for covered outpatient drugs compared to prices that would be paid under this section,

(ii) the quality of outpatient drug use review provided by these institutions as compared to drug use review required under this section, and

(iii) the efficiency of mechanisms used by these institutions for billing and receiving payment for covered outpatient drugs dispensed under this title.

(C) By not later than May 1, 1991, the Comptroller General shall report to the Secretary of Health and Human Services (hereafter in this section referred to as the "Secretary"), the Committee on Finance of the Senate, the Committee on Energy and Commerce of the House of Representatives, and the Committees on Aging of the Senate and the House of Representatives on the study conducted under subparagraph (A).

(2) REPORT ON DRUG PRICING.—By not later than May 1 of each year, the Comptroller General shall submit to the Secretary, the Committee on Finance of the Senate, the Committee on Energy and Commerce of the House of Representatives, and the Committees on Aging of the Senate and House of Representatives an annual report on changes in prices charged by manufacturers for prescription drugs to the Department of Veterans Affairs, other Federal programs, retail and hospital pharmacies, and other purchasing groups and managed care plans.

(3) STUDY ON PRIOR APPROVAL PROCEDURES.—

(A) The Secretary, acting in consultation with the Comptroller General, shall study prior approval procedures utilized by State medical assistance programs conducted under title XIX of the Social Security Act, including—

(i) the appeals provisions under such programs; and

(ii) the effects of such procedures on beneficiary and provider access to medications covered under such programs.

(B) By not later than December 31, 1991, the Secretary and the Comptroller General shall report to the Committee on Finance of the Senate, the Committee on Energy and Commerce of the House of Representatives, and the Committees on Aging of the Senate and the House of Representatives on the results of the study conducted under subparagraph (A) and shall make recommendations with respect to which procedures are appropriate or inappropriate to be utilized by State plans for medical assistance.

(4) STUDY ON REIMBURSEMENT RATES TO PHARMACISTS.—

(A) The Secretary shall conduct a study on (i) the adequacy of current reimbursement rates to pharmacists under each State medical assistance programs conducted under title XIX of the Social Security Act; and (ii) the extent to which reimbursement rates under such programs have an effect on beneficiary access to medications covered and pharmacy services under such programs.

(B) By not later than December 31, 1991, the Secretary shall report to the Committee on Finance of the Senate, the Committee on Energy and Commerce of the House of Representatives, and the Committees on Aging of the Senate and the House of Representatives on the results of the study conducted under subparagraph (A).

(5) STUDY OF PAYMENTS FOR VACCINES.—The Secretary of Health and Human Services shall undertake a study of the relationship between State medical assistance plans and Federal and State acquisition and reimbursement policies for vaccines and the accessibility of vaccinations and immunization to children provided under this title. The Secretary shall report to the Congress on the Study not later than one year after the date of the enactment of this Act.

(6) STUDY ON APPLICATION OF DISCOUNTING OF DRUGS UNDER MEDICARE.—The Comptroller General shall conduct a study examining methods to encourage providers of items and services under title XVIII of the Social Security Act to negotiate discounts with suppliers of prescription drugs to such providers. The Comptroller General shall submit to Congress a report on such study no later than 1 year after the date of enactment of this subsection.

SEC. 4402. REQUIRING MEDICAID PAYMENT OF PREMIUMS AND COST-SHARING FOR ENROLLMENT UNDER GROUP HEALTH PLANS WHERE COST-EFFECTIVE.

(a) IN GENERAL.—Title XIX (42 U.S.C. 1396 et seq.) is amended—

(1) in section 1902(a)(25) (42 U.S.C. 1396a(a)(25))—

(A) by striking "and" at the end of subparagraph (E),

(B) by adding "and" at the end of subparagraph (F), and

(C) by adding at the end the following new subparagraph:

"(G) that the State plan shall meet the requirements of section 1906 (relating to enrollment of individuals under group health plans in certain cases);"; and

(2) by inserting after section 1905 the following new section:

"ENROLLMENT OF INDIVIDUALS UNDER GROUP HEALTH PLANS

42 USC

"SEC. 1906. (a) For purposes of section 1902(a)(25)(G) and subject to subsection (d), each State plan—

KEN HECHLER
Secretary of State

MARY P. RATLIFF
Deputy Secretary of State

A. RENEE COE
Deputy Secretary of State

CATHERINE FREROTTE
Executive Assistant

Telephone: (304) 558-6000
Corporations: (304) 558-8000

STATE OF WEST VIRGINIA
SECRETARY OF STATE

Building 1, Suite 157-K
1900 Kanawha Blvd., East
Charleston, WV 25305-0770

WILLIAM H. HARRINGTON
Chief of Staff

JUDY COOPER
Director, Administrative Law

DONALD R. WILKES
Director, Corporations

(Plus all the volunteer help we can get)

October 21, 1992

NOTICE OF EMERGENCY RULE DECISION BY THE SECRETARY OF STATE

AGENCY: Board of Pharmacy

RULE: Series 1, Amended Rule Rules of the West Virginia Board of Pharmacy

DATE FILED AS AN EMERGENCY RULE: September 16, 1992

DECISION NO. 28-92

Following review under WV Code 29A-3-15a, it is the decision of the Secretary of State that the above emergency rule be approved with the following exception.

Section 15-1-16.14(f) states:

> The above requirement shall constitute an acceptable offer to provide counseling to all parties including recipients of Medicaid and other third-party programs or plans in this state.

The underlined portion above is not approved because it exceeds the scope of the agency's emergency authority.

A copy of the complete decision with required findings is available from this office.

OFFICE OF WEST VIRGINIA
SECRETARY OF STATE

OCT 21 3 38 PM '92

FILED

KEN HECHLER
Secretary of State

KEN HECHLER
Secretary of State

MARY P. RATLIFF
Deputy Secretary of State

A. RENEE COE
Deputy Secretary of State

CATHERINE FREROTTE
Executive Assistant

Telephone: (304) 558-6000
Corporations: (304) 558-8000

STATE OF WEST VIRGINIA
SECRETARY OF STATE

Building 1, Suite 157-K
1900 Kanawha Blvd., East
Charleston, WV 25305-0770

WILLIAM H. HARRINGTON
Chief of Staff

JUDY COOPER
Director, Administrative Law

DONALD R. WILKES
Director, Corporations

(Plus all the volunteer help we can get)

DECISION

EMERGENCY RULE DECISION
(ERD 28-92)

AGENCY: Board of Pharmacy
RULE: Series 1, Amended Rule Rules of the West Virginia Board of Pharmacy
FILED AS AN EMERGENCY RULE: September 16, 1992

par. 1 The Board of Pharmacy (Board) has filed the above amended rule as an emergency rule.

par. 2 West Virginia Code 29A-3-a requires the Secretary of State to review all emergency rules filed after March 8, 1986. This review requires the Secretary of State to determine if the agency filing such emergency rule: 1) has complied with the procedures for adopting an emergency rule; 2) exceeded the scope of its statutory authority in promulgating the emergency rule; or 3) can show that an emergency exists justifying the promulgation of an emergency rule.

par. 3 Following review, the Secretary of State shall issue a decision as to whether or not such an emergency rule should be disapproved [(29A-3-a(a)].

par. 4 (A) Procedural Compliance: WV Code 29A-3-15 permits an agency to adopt, amend or repeal, without hearing, any legislative rule by filing such rule, along with a statement of the circumstances constituting the emergency, with the Secretary of State and forthwith with the Legislative Rule-Making Review Committee (LRMRC).

par. 5 If an agency has accomplished the above two required filings with the appropriate supporting documents by the time the emergency rule decision is issued or the expiration of the thirty-five day review period, whichever is sooner, the Secretary of State shall rule in favor of procedural compliance.

par. 6 The Board filed this emergency rule with supporting documents with the Secretary of State September 16, 1992 and with the LRMRC September 16, 1992.

par. 7 It is the determination of the Secretary of State that the Board has complied with the procedural requirements of WV Code §29A-3-15 for adoption of an emergency rule.

par. 8 (B) Statutory Authority -- WV Code §30-5-19 reads:

> The Board of Pharmacy shall make such rules and regulations, not inconsistent with law, as necessary to carry out the purposes and enforce the provisions of this article and is hereby authorized to revoke any permit or license issued under the provisions of this article at any time when examination or inspection of the pharmacy or drugstore shall disclose that such place of business is not being conducted according to law.
> The board of pharmacy shall have the power and authority to employ field agents, chemist, clerical help and other qualified personnel, as may be necessary to carry out the purposes and enforce the provisions of this article.

par. 9 It is the determination of the Secretary of State that the Board has authority to promulgate an emergency rule if an emergency exists.

par. 10 (C) Emergency WV Code 29A-3-15(g) defines "emergency" as follows:

> (g) For the purposes of this section, an emergency exists when the promulgation of a rule is necessary for the immediate preservation of the public peace, health, safety or welfare or is necessary to comply with a time limitation established by this code or by a federal statute or regulation or to prevent substantial harm to the public interest.

par. 11 There are essentially three classes of emergency broadly presented with the above provision: 1) immediate preservation; 2) time limitation; and 3) substantial harm. An agency need only document to the satisfaction of the Secretary of State that there exists a nexus between the proposal and the circumstances creating at least one of the above three emergency categories.

par. 12 The facts and circumstances as presented by the Board are as follows:

> Omnibus Budget Reconciliation Act of 1990 (OBRA 90) is a Federal Law that will be implemented by the Health Care Financing Administration. The responsibility has been reserved to the State Board of Pharmacy. It must implement the OBRA 90

patient counseling requirements for medicaid patients by January 1, 1993. These regulations meet that requirement. Failure to implement these rules could cost the State Medicaid Program Federal funds.

par. 13 It is the determination of the Secretary of State that this proposal qualifies under the definition of an emergency as defined in §29A-3-15(g). . . "time limitation as set forth by the Omnibus Budget Reconciliation Act of 1990," with the exception noted on page 1 of this notice of an emergency rule decision.

par. 14 This decision shall be cited as Emergency Rule Decision 28-92 or ERD 28-92 and may be cited as precedent. This decision is available from the Secretary of State and has been filed with the Board of Pharmacy, the Attorney General and the Legislative Rule Making Review Commission.

KEN HECHLER
Secretary of State

Entered _____

FILED
OCT 21 3 38 PM '92
OFFICE OF WEST VIRGINIA SECRETARY OF STATE