WEST VIRGINIA
SECRETARY OF STATE
KEN HECHLER
ADMINISTRATIVE LAW DIVISION

Form #2

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NOTICE OF A COMMENT PERIOD ON A PROPOSED RULE

AGENCY: West Virginia Board of Pharmacy TITLE NUMBER: 15

RULE TYPE: Legislative ; CITE AUTHORITY Chapter 30-5-19

AMENDMENT TO AN EXISTING RULE: YES X NO ___

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

TITLE OF RULE BEING AMENDED: 15-1-5, 5.1 Application; 15-1-6, 6.2 Application; 15-1-11 Drug product selection regulations; 15-1-18 Automated data processing system

IF NO, SERIES NUMBER OF NEW RULE BEING PROPOSED: ___

TITLE OF RULE BEING PROPOSED: ___

IN LIEU OF A PUBLIC HEARING, A COMMENT PERIOD HAS BEEN ESTABLISHED DURING WHICH ANY INTERESTED PERSON MAY SEND COMMENTS CONCERNING THESE PROPOSED RULES. THIS COMMENT PERIOD WILL END ON November 10, 1988 AT 5:00 p.m. . ONLY WRITTEN COMMENTS WILL BE ACCEPTED AND ARE TO BE MAILED TO THE FOLLOWING ADDRESS.

WV Board of Pharmacy
150 Rockdale Road
Follansbee, WV 26037

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

Dolores Prantil
Acting Office Administrator

ATTACH A **BRIEF** SUMMARY OF YOUR PROPOSAL

Copy #1

SERIES 1

RULES AND REGULATIONS OF THE BOARD OF PHARMACY

INDEX

TITLE 15
LEGISLATIVE RULES
BOARD OF PHARMACY

SERIES 1
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. -- June 13, 1985

1.4. Effective Date. -- June 13, 1985

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 there

in.

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)~~ set by the West Virginia Board of Pharmacy 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 ap-

plicant 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).~~ the West Virginia Board of Pharmacy with a fee set by the West Virginia Board of Pharmacy.

(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 type-

written 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. ~~Negative Formulary.~~

~~(a) 1. Aminophylline~~

~~2. Dicumarol~~

~~3. Digoxin~~

~~4. Digitoxin~~

insertion on back.

15-1-11. Drug product selection regulations.

11.1 The Board of Pharmacy of the State of West Virginia adopts the Approved Drug Products with Therapeutic Equivalence Evaluations, "The Orange Book", and its additional supplements as published by the Food & Drug Administration.

11.2 The Board may remove a drug product from the formulary, after opportunity for public comment that the Board determines is therapeutic nonequivalent.

11.3 Same as on original

~~5. Furosemide.~~

~~6. Isosorbide Dinitrate.~~

~~7. Nitroglycerin.~~

~~8. Phenytoin.~~

~~9. Prednisone.~~

~~10. Prednisolone.~~

~~11. Quinidine.~~

~~12. Tolbutamide.~~

~~13. Warfarin.~~

~~The pharmacist may not substitute:~~

~~(b) (1) An erythromycin base when an erythromycin salt or ester is prescribed.~~

~~(2) An erythromycin salt or ester when an erythromycin base is prescribed.~~

~~(3) A different erythromycin salt or ester from the salt or ester, or base is prescribed.~~

~~(c) Exceptions to negative formulary.~~

~~Any product not in violation of F.D.A. requirements and holding a valid NDA or ANDA approved applications, and determined by the F.D.A. to be acceptable in both bio equivaleney and bio availability, and so published as approved by the F.D.A. shall be interchangeable for the purpose of generic substitution, notwithstanding the products listed on the Negative Formulary (Part a and b above). A list of F.D.A. and Board approved exceptions to the Negative Formulary shall be published annually by the Board on the first day of July of every year or as soon thereafter as practical, and bulletins will be issued periodically during the year as such products meet F.D.A. approval. This list shall be the only accepted list by which products on the Negative Formulary may be substituted.~~

~~(d) Procedure for revisions.~~

~~Any manufacturer or person aggrieved by the exclusion or inclusion of any product on the Negative Formulary (Part a and b above) or on the list of exceptions to the Negative Formulary (Part c above), may petition the Board for a determination of bioequivaleney / bioavailability and possible revision of said formulary or list. The expense of any such determination shall, if the Board so decides, be borne by the party seeking said determination and the burden of proof shall also be on said party~~.

~~(e)~~ Any pharmacist, or other person, firm, corporation or copartnership who after public notice of section (e), article seventeen of the West Virginia Code, shall be subject to the provisions of subsection (L), section twelve-b, article five, chapter thirty of the West Virginia Code of 1931 as amended.

§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 person-

nel 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 prescriptions.

(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.

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

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

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 Regulations:

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 inquiry 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 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 the 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.

New Section to be added - See following insertion

Board of Pharmacy
Leg. Rule, 30-5
Series I

New Section to be added

15-1-18. Automated data processing systems.

18.1. Definitions.

(a) Automated Data Processing System (ADP): A system utilizing computer software and hardware for the purposes of recordkeeping.

(b) CRT: Cathode Ray Tube used to impose visual information on a screen.

(c) Computer: Programmable electronic device capable of multifunctions including but not limited to storage, retrieval and processing of information.

(d) Downtime: That period of time when a computer is not operable.

(e) Printout: A hard-copy produced by computer that is readable without the aid of any special device.

(f) Common Data Base: A file or data base created by ADP that enables authorized users to have common access to this file regardless of physical location.

(g) Computer Operator: The person charged with the responsibility of entry and retrieval ADP of Patient information.

18.2. Record of Dispensing.

Records of dispensing for original and refill prescriptions are to be made and kept by pharmacies for five years. Information must be immediately accessible for a period of not less than one year from the date of last entry. Information beyond one year but up to five years from the date of last entry may be maintained off-line but must be produced no later than forty-eight hours upon request from proper authorities. The information shall include, but not be limited to:

(a) Quantity dispensed

(b) Date of dispensing

(c) Serial Number (or equivalent if an institution)

(d) The identification of the pharmacist responsible for dispensing.

(e) Record of renewals to date

(f) Name and strength of medication

18.3. Record of Retrieval (Documentation of Activity)

(a) Any such ADP system must provide via CRT display and/or hard copy printout a current history of all authorized prescription activity. This information shall include but not be limited to:

(1) Serial number of prescription (or equivalent if an institution)

(2) Date of dispensing

(3) Quantity dispensed

(4) The identification of the pharmacist responsible for dispensing

(5) Medication dispensed

(b) An automated data processing system may be used for the storage and retrieval of refill information for prescription orders for controlled substances in Schedule III and IV, subject to the following conditions:

(1) Any such proposed computerized system must provide on-line retrieval (via CRT display or hard-copy printout) of original prescription, order information for those prescription orders which are currently authorized for refilling. This shall include, but is not limited to, data such as the original prescription number, date of issuance of the original prescription order by the practitioner, full name and address of the patient, name, address, and DEA registration number of the practitioner, and the name, strength, dosage form, quantity of the controlled substance prescribed (and quantity dispensed if different from the quantity prescribed), and the total number of refills authorized by the prescribing practitioner.

(2) Any such proposed computerized system must also provide on-line retrieval (via CRT display or hard-copy printout) of the current refill history for Schedule III or IV controlled substance prescription orders (those authorized for refill during the past six months.) This refill history shall include, but is not limited to, the name of the controlled substance, the date of refill, the quantity dispensed, the identification code, or name or initials of the dispensing pharmacist for each refill and the total number of refills dispensed to date for that prescription order.

(3) Documentation of the fact that the refill information entered into the computer each time a pharmacist refills an original prescription order for a Schedule III or IV controlled substance is correct must be provided by the individual pharmacist who makes the use of such a system. If such a system provides a hard-copy printout of each day's controlled substance prescription order refill data, that printout shall be verified, dated, and signed by the individual pharmacist who refilled such a prescription order. The individual pharmacist must verify that the data indicated is correct and then sign this document in the same manner as he would sign a check or legal document (e.g., J. H. Smith or John H. Smith). This document shall be maintained in a separate file at that pharmacy for a period of two years from the dispensing date. This printout of the day's controlled substance prescription order refill data must be provided to each pharmacy using such a computerized system within 72 hours of the date on which the refill was dispensed. It must be verified and signed by each pharmacist who is involved with such dispensing. (In lieu of such a printout, the pharmacy shall maintain a bound log book, or separate file, in which each individual pharmacist involved in such dispensing shall sign a statement [in the manner previously described] each day, attesting to the fact that the refill information entered into the computer that day has been reviewed by him/her and is correct as shown. Such a book or file must be maintained at the pharmacy employing such a system for a period of two years after the date of dispensing the appropriately authorized refill).

(4) Any such computerized system shall have the capability of producing a printout of any refill data which the user pharmacy is responsible for maintaining under the Act and its implementing regulations. For example, this would include a refill-by-refill audit trail for any specified strength and dosage form of any controlled substance (by either brand or generic name or both). Such a printout must include name of the prescribing practitioner, name and address of the patient, quantity dispensed on each refill, date of dispensing for each refill, name or identification code of the dispensing pharmacist, and the number of the original prescription order. In any computerized system employed by a user pharmacy, the central recordkeeping location must be capable of sending the printout to the pharmacy within 48 hours, and if a DEA Special Agent or Compliance Investigator requests a copy of such printout from the user pharmacy, it must, if requested to do so by the Agent or Investigator, verify the printout transmittal capability of its system by documentation (e.g., postmark).

(5) In the event that a pharmacy which employs such a computerized system experiences system down-time, the pharmacy must have an auxiliary procedure which

will be used for documentation of refills of Schedule III and IV controlled substance prescription orders. This auxiliary procedure must insure that refills are authorized by the original prescription order, that the maximum number of refills has not been exceeded, and that all of the appropriate data is retained for on-line data entry as soon as the computer system is available for use again.

(c) When filing refill information for original prescription orders for Schedule III or IV controlled substances, a pharmacy may use only one of the two systems described in paragraphs of this CFR 21, CH II, SEC 1306.22.

18.4. Auxiliary Recordkeeping System

An auxiliary recordkeeping system shall be established for the documentation of renewals if the ADP is inoperative for any reason. When the ADP is restored to operation, the information regarding prescriptions dispensed and renewed during the inoperative period shall be entered into the automated data processing system within 72 hours.

18.5. Common Data Base

Two or more pharmacies may establish and use a common data file or base to maintain required or pertinent dispensing information. Pharmacies using such a common file are not required to transfer prescriptions or information for dispensing purposes between or among pharmacies participating in the same common prescription file or data base; provided however any such common file must contain complete and adequate records of each prescription and renewals dispensed.

18.6. Operating the ADP System

A registered pharmacist shall view and interpret all computer functions relative to filling and refilling prescriptions.

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