WEST VIRGINIA
SECRETARY OF STATE
KEN HECHLER
ADMINISTRATIVE LAW DIVISION

Form #6

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OFFICE OF WEST VIRGINIA SECRETARY OF STATE

NOTICE OF FINAL FILING AND ADOPTION OF A LEGISLATIVE RULE AUTHORIZED BY THE WEST VIRGINIA LEGISLATURE.

AGENCY: Board of Pharmacy TITLE NUMBER: 15

AMENDMENT TO AN EXISTING RULE: YES ✓, NO ___

IF YES, SERIES NUMBER OF RULE BEING AMENDED: 1

TITLE OF RULE BEING AMENDED: Rules & Regulations of the Board of Pharmacy

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

TITLE OF RULE BEING PROPOSED: ___

THE ABOVE RULE HAS BEEN AUTHORIZED BY THE WEST VIRGINIA LEGISLATURE.

AUTHORIZATION IS CITED IN (house or senate bill number) 100

SECTION 64-9-206, PASSED ON 5/26/93.

THIS RULE IS FILED WITH THE SECRETARY OF STATE. THIS RULE BECOMES EFFECTIVE ON THE FOLLOWING DATE: June 14, 1993

Betty Jo Payne

(d) The legislative rules filed in the state register on the eleventh day of March, one thousand nine hundred ninety-one, modified by the board of pharmacy to meet the objections of the legislative rule-making review committee and refiled in the state register on the twenty-fourth day of May, one thousand nine hundred ninety-one, relating to the board of pharmacy (computer regulations), are authorized.

(e) The legislative rules filed in the state register on the twenty-eighth day of August, one thousand nine hundred ninety-one, modified by the board of pharmacy to meet the objections of the legislative rule-making review committee and refiled in the state register on the eighth day of January, one thousand nine hundred ninety-two, relating to the board of pharmacy (licensure of wholesale drug distributors), are authorized.

(f) The legislative rules filed in the state register on the twenty-eighth day of August, one thousand nine hundred ninety-one, modified by the board of pharmacy to meet the objections of the legislative rule-making review committee and refiled in the state register on the eighth day of January, one thousand nine hundred ninety-two, relating to the board of pharmacy (mail order house), are authorized.

(g) The legislative rules filed in the state register on the fifteenth day of September, one thousand nine hundred ninety-two, modified by the board of pharmacy to meet the objections of the legislative rule-making review committee and refiled in the state register on the twenty-eighth day of January, one thousand nine hundred ninety-three, relating to the board of pharmacy (board of pharmacy), are authorized with the amendments set forth below:

On page forty-nine, subsection (f), after the words 'who presents a' by inserting the word 'new';

And,

On page fifty, subdivision (1), after the words 'who presents a' by inserting the word 'new'".

§64-9-21. Board of examiners of psychologists.

Title 15
Legislative Rules
Board of Pharmacy

Series 1
Rules of the Board of Pharmacy

S15-1-1. General

1.1. Scope -- West Virginia Code, S30-5-19 mandates that the Board of Pharmacy shall make such Rules, not inconsistent with law, as necessary, to carry out the purposes and enforce the provisions of Article five.

1.2 Authority. -- W.Va. Code S30-5-19

1.3 Filing Date.

1.4. Effective Date.

S15-1-2. Definitions.

The following words and phrases as used in this Rule 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 subdivisions (a), (b) or (c) of this subsection. 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.

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 West Virginia Code S60A-2-1 et seq. (Uniform Controlled Substances Act).

2.7. The term "Prescription" means an order for drugs or medicines or combinations or mixtures thereof, written or signed by a duly licensed physician, an authorized physician assistant at the direction of his or her supervising physician in accordance with the provisions West Virginia Code S30-3-16 of dentist, optometrist, as authorized by West Virginia Code S30-8-2, veterinarian or other medical practitioner licensed to write prescription written or signed by an authorized physician assistant shall be printed with the name of the physician assistant, and a list of drugs approved under the physician assistant's job description, in accordance with the provision of West Virginia Code S30-3-16. The term "Prescription" also includes 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 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 made by the pharmacist constitutes 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 physician assistant shall require a copy of the list of drugs approved under the job description of the physician assistant prior to accepting such orders. All descriptions shall be preserved on file for a period of five (5) years, subject to inspection by the proper officer of the law. The requirements of this subsection apply except for narcotic prescriptions, when all narcotic laws and regulations must be complied with.

2.8. The term "Cosmetic" which includes "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 the term shall not include soap.

2.9. The term "Pharmacy" or "Drug Store" or "Apothecary" means any place where the practice of pharmacy is conducted and includes 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 similar or like import; or (d) 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 includes the proper and safe storage of the drugs, the maintenance of proper records regarding dispensing 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 West Virginia Code S60-A-2.

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 whose license 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 the Uniform Controlled Substances Act West Virginia Code S60A-2-1 et seq. 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 "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 where:

(a) the pharmacy, drug store or apothecary is a new business;

(b) An established business is transferred to a successor;

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

(d) A transfer of ownership results in controlling interest being acquired by one (1) or more persons; or

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

Only pharmacy or drug store permits issued under West Virginia Code §30-11-14 are considered a renewal.

2.20. The term "Person" means an 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 licensed 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. In this rule the word "apprentice" to refer to individuals registered with the Board

to obtain the practical experience required under West Virginia Code S15-1-2.

2.23. The term "Internship describes the practical experience requirement, and "Nine (9) months practical experience" means an average work week of not less than forty (40) hours for a period of one (1) calendar year, except as provided in this rule 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 or her of reasonable self-control.

2.26. "Act" or "Uniform Controlled Substances Act" when used in this rule means and refers to chapter sixty-a of the West Virginia Code.

§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 and two public members who shall be appointed by the governor, by and with the advice and consent of the Senate. Each pharmacist member of the Board, at the time of his appointment, shall be a citizen and a licensed pharmacist of the State of West virginia and actively engaged in the practice of

pharmacy. The public members shall be residents of this state who have attained the age of majority and may not be a past or present member of the profession of pharmacy, the spouse of a member of the profession of pharmacy, a person who has ever had any material financial interest in the providing of pharmacy service or who is engaged in any activity directly related to the practice of pharmacy.

3.2. Officers of the Board.--The members of the board shall annually elect as officers of the Board one (1) member to serve for a period on one (1) member to serve for a period of one (1) year as President of the Board; one (1) member to serve for a period on one (1) year as vice president of the Board; and, one (1) member to serve for a period of one (1) year as Secretary of the Board, all of whom shall hold their offices for one (1) year and until their successors are elected. The Board shall hold the election 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 the 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 consider appropriate. In addition thereto, it may hold such additional meetings as may be necessary and which shall be called by the Secretary at the direction of the President or upon the written request of any three (4) 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 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 West Virginia Code S30-1-1 et seq. and 30-5-1 et seq. and shall pay the moneys into the State Treasury monthly on or before the tenth day of the month in which the moneys are received. He or she 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 moneys received by him or her during the preceding six (6) months.

3.8. Compensation of members; expenses.--Every member of the Board shall receive one hundred fifty dollars ($150.00) 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 Board shall prescribe the Secretary's salary and in proceedings relative to the fixing of his or her salary, the Secretary has 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 proceedings and a register of all applicants for license or registration, showing for each, the date of his or her application, his or her name, age, and educational and other qualifications, place of residence, whether an examination was required, whether the applicant was rejected or a certificate of license or certificate of registration granted, the date of the action, the

license or registration number, if required, and any suspension or revocation of a license or registration. 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, is prima facie evidence of all matters recorded therein.

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

3.10. Roster of licensed pharmacists and licensed pharmacies.--The Secretary of the Board shall also prepare and maintain a complete roster of licensed pharmacies within this State and licensed pharmacists practicing within or without this State. The pharmacy and pharmacists names must be arranged alphabetically. The Board may call for and require a registration whenever it considers it necessary or expedient to secure an accurate roster.

S15-1-4. Apprenticeship; Requirements For Certificate.

4.1. The principal purpose of serving an apprenticeship 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. An apprencticeship is required under West

Virginia Code S30-5-5 for licensure.

The Board shall certify apprenticeship, except as provided in this subsection only for an individual:

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

(b) For whom the licensed pharmacist or other employer has notifed the Board within ninety days of the employment of the apprentice.

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

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

4.2. No apprentice 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. Apprentice receives experience for any period of time that is concurrent with enrollment in a recognized school of pharmacy. The Board may grant an additional four (4) months experience time for apprentices participating or enrolled in a supervised apprenticeship or clinical pharmacy concurrent with the last year of the professional pharmacy curriculum.

4.4. No apprenticeship 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 West Virginia Code S30-5-2.

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

4.6. The Board may accept apprenticeship 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 apprenticeship experience.

S15-1-5. Licensure and Annual Renewal; Requirement For.

5.1. Application.

All applicants for examination shall apply in writing to the Secretary of the Board at lest fifteen (15) days before the date the examination is to be conducted and shall transmit with his or her application a fee of one hundred twenty-five dollars ($125) which sum the Board is authorized to charge for an examination or investigation into the 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 or she is a person of good moral character and not addicted to drunkenness or the use of controlled substances and that he or she has not ben convicted of violating the provisions of any law relating to the practice of pharmacy and that he or she has not been convicted of a crime involving moral turpitude: Provided, that an applicant, who has been arrested pursuant to West Virginia Code S30A-4-401, and who has later been discharged pursuant to West Virginia Code S60A-4-407 may, upon otherwise having satisfied the requirements of this section, be considered by the Board to have fully satisfied its requirements.

(c) Education.

The applicant shall present to the board satisfactory evidence that he or she is a graduate of a recognized school of pharmacy as defined in section one of this rule.

(d) Apprenticeship.

The applicant shall have acquired at least nine (9) months of apprenticeship experience under the supervision of a licensed pharmacist preceptor as defined in Sections 2.22 and 4 of this Rule.

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. The Board shall give notice of the examination 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 West Virginia Code §30-1-13, 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 examination, including the written, oral and practical portions of the examination.

(c) An applicant must pass a written examination in subjects determined by the Board as being reasonable, in testing his or her 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 or her 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%) is necessary for an applicant to pass the examination.

An applicant failing to pass the examination satisfactorily to the Board is entitled at either the first or second succeeding examination conducted by the Board, to a reexamination without further cost but one reexamination exhausts his or her privilege for examination under his or her 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 or her the right to practice pharmacy in the

State of West Virginia until such time as the permanent certificate as a licensed pharmacist may be prepared for him or her. The permanent certificate of registration which 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 the certificate or duplicate is issued. No certificate is assignable.

5.5. Annual renewal of registration.

(a) Annual renewal.

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

(c) Failure to renew.

If any pharmacist fails for a period of thirty (30) days after the first day of July to apply to the Board for a renewal of his or

her registration, the Boad shall erase his or her name from the register of registered pharmacists.

Such person, in order to again become registered, shall 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 or her qualifications to practice the profession, the Board shall reinstate him or her upon payment of a reinstatement fee of two hundred fifty dollars plus the renewal fee of thirty dollars.

S15-1-6. 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) The applicant is at least eighteen (18) years of age.

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

(c) The applicant is in good standing in the state of original licensing.

(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 or

her license suspended or revoked for violation of pharmacy, liquor, narcotic or food and drug laws.

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

(h) Applicants who registered since 1945 graduated from a recognized school of pharmacy and in addition thereto, 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 evidenced 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 shall not 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) The applicant shall complete a preliminary application form obtained from the Secretary of the National Association of Boards of Pharmacy informing the Secretary which state or states the applicant has previously registered and in what state he or she wishes to register and submit the form with a required fee of one hundred twenty-five dollars ($125) to the Secretary of the National Association of Boards of Pharmacy, O'Hare Corporate Center, 1300 Higgins Road, Suite 103, Park Ridge, Illinois, 60068.

On receiving the application for licensing by reciprocity, the National Association of Boards of Pharmacy contacts authorities in states where the applicant may have been licensed to secure verification, and, in addition, runs a character check on all applicants. The Board shall supply an applicant who possesses the necessary qualifications 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 two hundred fifty dollars ($250) unless the applicant desires to be examined other than at a regular meeting of the Board. In that case, the applicant shall pay an additional fee of one hundred fifty dollars ($150).

(b) The application must include the following:

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

in which he or she is registered.

(2) A recent bust photograph with a statement thereon, signed by the applicant, affirming that it is a photograph of the 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 the checking of credentials, an interview, and such questions 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.

S15-1-7. 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 for registration, a statement of the charges against the licensee and a notice of the time and place of hearing shall be served upon the licensee as a notice is served under West Virginia Code S56-2-1 at least thirty (30) days prior to the hearing and he or she 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 licensee charged as it may consider advisable.

7.3. The Board has 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 have the power to administer oaths.

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

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

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

(1) Any person may initiate proceedings before the Board, for the revocation, cancellation or suspension of a license or permit before the Board by filing charges with the Board in writing and under oath.

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

(3) Representation: At any hearing the licensee or permitee has the right to appear either personally or by counsel, or both, to produce witnesses or evidence in his or her 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 is the duty of the deputy to require an orderly presentation in accordance with this rule.

(b) Order of presentation.

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

(2) The absence of a licensee or permittee in no way affects 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 this rule, the President of the Board or the Board's appointee shall commence the hearing by causing the charges to be read, and thereafter receiving the answer of the licensee or permittee to the charges, if any. The licensee or permittee may plead either guilty or not guilty to the charges.

(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 or her attorney. The testimony shall be given under oath.

(5) After the presentation of evidence in support of the

charges, the licensee or permittee or his or her 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 licensee or permittee shall give direct testimony and immediately thereafter, are subject to cross-examination by the Board or its duly authorized appointee. All 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 charges and evidence in opposition of the charges, the licensee or permitee or his or her attorney may present an 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. The 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 order or act. An appeal from the action of the Board does not stay the Board's action unless specifically directed

as a stay by the Board.

(c) Application for reissuance of license.

Upon application, the Board may reissue a license to a person whose license has been suspended or revoked. The application, in the case of suspension or revocation, shall not be made prior to one (1) year after the suspension or revocation.

Upon application, the Board may reinstate a license which has been suspended. The 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 receives an invitation to appear before the Board, the 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 invited.

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

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

(e) Hearings by Board upon complaint.

(1) Any person aggrieved by the Rules promulgated by the Board is entitled to have his or her complaint set down for hearing by the Board.

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

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

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

C) The complaint shall specify reasonable evidence that the rule is inconsistent with the law governing the practice of pharmacy in West Virginia.

(3) The Board shall hold hearings for the complaint ten (10) days from the date of receipt of the 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

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

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

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

§15-1-9. Refilling Prescriptions.

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

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

9.3. The refilling of prescriptions is limited by the provisions of the Uniform Controlled Substances Act, West Virginia Code, S60A-3-308.

(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.

S15-1-10. 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.

S15-1-11. Drug Product Selection Regulations.

11.1. The Board of Pharmacy of the State of West Virginia

adopts the Food and Drug Administration's approved Drug Products and Legal Requirements Publication, the 1989 Ninth Edition and its supplements, as published by the United States Pharmacopeia Drug Product.

S15-1-12. 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 is 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 partnership 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 place of business 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 a 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 the permit, as well as the location of the 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. The 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 is required to operate with not less than two (2) licensed pharmacists.

(d) All pharmacies or drug stores, as defined, must have on file a recent edition of the United State 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 this rule.

(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 is seventy-five dollars ($75) annually.

(f) Any pharmacy, prior to engaging in parenteral/enteral compounding, shall obtain a parenteral/enteral compounding permit as provided in this rule.

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 an 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 licensed 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 who is not a licensed pharmacist, the Board will issue the permit jointly to the licensed pharmacist in charge and to the person owning the pharmacy, as defined in section one of this rule.

(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 is seventy-five ($75). Permits issued under this section are not transferable and 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 lapses and becomes null and void. To renew a lapsed permit the Board must inspect the pharmacy and the permittee must pay a fee of one hundred fifty dollars ($150) and one hundred fifty dollars ($150) for the inspection.

12.5. Surrender of permit.

(a) Where a licensed pharmacist in whose name a permit has

been issued leaves the employment of the pharmacy or drug store he or she is responsible for notifying the Board of the termination of his or her services, and also for the surrender of the permit in his or her name. Neglect on the part of the pharmacist to notify the Board may prevent him or her from 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 licensed pharmacist in whose name a pharmacy permit has been issued for any reason ceases to be actually the licensed pharmacist who has responsible supervision over the 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) is charged for issuing the permit.

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

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 shall be present on duty during all hours of product preparation. Changes in the pharmacist manager shall be reported to the Board of Pharmacy office within then (10) days by the permit holder and pharmacist manager of record. A pharmacist manager of a 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 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.

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 a patient, a person picking up the prescription for the patient, or a person delivering the prescription to the patient at his or her 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 the forms adopted by the Board and the pharmacy shall publicly display the forms 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 determined that an approved generic equivalent means the established name of a prescription drug or drug product designated by an official compendium of the United States and recognized by the Board in the list of prescription drugs or drug products to be posted by price, strength, manufacturer and quantity in every licensed pharmacy.

(c) The forms shall bear a title across the top portion reading, "Prescription Price List and Services." The pharmacist

issuance of a new permit is forbidden by law and each day of operation considered a separate offense.

12.6. Violations.

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

(b) All licensed pharmacists must notify the Board immediately of any change in employment and change of address. Failure to notify the Board is sufficient cause for suspension.

(c) It is the duty of any person who employs any licensed pharmacist to immediately notify the Board of any discharge, termination or change of place of employment of the licensed pharmacist. Failure to notify the Board is sufficient cause for suspension of any permit or license held by that person.

12.7. Security.

In the event that a prescription area is to be operated for a period less than the regular business hours of the entire store, the following requirements apply.

(a) The pharmacy 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 designed so that only a pharmacist with a key has 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. The owner of the pharmacy shall submit the plans and specifications of the permanent barrier to the Board for approval showing that it affords adequate security. Plans shall be submitted prior to proceedings with any construction, which plan shall indicate the pharmacy area which shall be of adequate space. Before a pharmacy permit is 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: Each pharmacy area shall have a separate phone (listing) which may be answered only in the 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. If no pharmacist is present when the prescription order (s) must be deposited the patient or his or her agent shall deliver the prescription order into a "Mail Slot" or "Drug Box". The times that the pharmacy is open for business must be displayed so that they are prominently visible to the person depositing the

shall designate the prices, and the 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 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 priced as required by West Virginia Code, §30-5-12a.

(f) The owner of the pharmacy, a member of firm, or an officer of corporation shall certify on the forms provided by the Board that a list of current prices and other information as required by West Virginia Code, §30-5-12a is available to the public as required this rule.

(g) Any pharmacy that does not comply with West Virginia Code, §30-5-12a and this rule is subject to the penalties as prescribed in the West Virginia Code, §30-5-19 on revocation of permits.

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

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

13.1. The Board will not issue a permit 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 which 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) Mortar and pestles, spatulas, ointment pads, funnels, stirring rods, etc., to meet the current needs for extemporaneous compounding.

(e) For pharmacies compounding ophthalmic preparations, IV additives or other pharmaceuticals requiring more sophisticated techniques, 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.

S15-1-14. Parenteral/enteral compounding.

14.1. A pharmacy engaged in the practice of parenteral/enteral compounding shall comply with the following regulations:

(1) 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, 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 S30-5-1 (6), 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.

(2) Pharmacy environment.

(a) The compounding and dispensing of sterile parenteral/enteral prescription preparations shall be accomplished

(c) The pharmacy shall maintain a patient profile for each patient. The 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. The Policy and Procedure Manual shall set forth in detail the objectives and operational guidelines of the permittee. It shall include a Quality Assurance Program which monitors personnel qualifications, training and performance, equipment facilities and random product sampling consistent with recommended standards for compounding and dispensing intravenous admixtures and a comprehensive patient drug profile and other parenteral medication as set forth by the Joint Commission on Accreditation of Hospitals, the National Coordinating Committee and Large Volume Parenterals and as provided by the West Virginia Board of Pharmacy. The Manual shall be kept current. The pharmacy shall provide a copy of the Policy and Procedure Manual 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 the 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. A Type A or B VLAP hood should be used 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) A completed Board of Pharmacy permit application form.

(2) A copy of the Policy and Procedure Manual.

(3) The 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 requirement 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 of adequate size to accommodate other equipment required by this section and sufficient space to allow pharmacists and other employees working in the room, 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 this section.

(4) Appropriate waste containers for:

A) Used needles and syringes.

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

(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 Pharmacopeia 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.

S15-1-15. Sanitary Regulation of Pharmacies.

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

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

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

15.4. Upon the completion of compounding a prescription the pharmacist shall clean the prescription counter and place the refuse or waste materials in a closed receptacle, and all

instruments used in the compounding of the prescriptions shall be thoroughly cleaned and placed in a clean cabinet or storage place.

15.5. 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 cleaning of the hands of those preparing and compounding prescriptions.

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

15.7. 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.

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

§15-1-16. Sale of Drugs By Mechanical Devices, Sharing Compensation.

16.1. The sale of drugs and medicines by mechanical devices or vending machines is prohibited.

16.2. Sharing compensation.--The independent judgment of a pharmacist is a public trust, and his or her first allegiance is to the patient whom he or she serves. No pharmacist shall, except with a person licensed to practice pharmacy, or in the course of his or her employment with a duly licensed institution, clinic or foundation, directly or indirectly share compensation arising out

of or incidental to his or her professional employment with, or accept professional employment from any person or persons who for compensation prescribe drugs used in the compounding or dispensing prescriptions.

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 or her 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 or herself to the highest standards of professional conduct.

In order that the citizens of West Virginia receive the best possible pharmaceutical services, and that the public health, welfare and safety is fully protected, the following rules of professional conduct have been adopted by the West Virginia Board of Pharmacy as authorized by W.Va. Code S30-5-2.

17.1. 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 or she 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 the

professional judgment and skill of a pharmacist. He or she shall at all times practice his or her profession in conformity with federal and state laws and regulations and the regulations of the West Virginia State Board of Pharmacy.

17.2. Uncertain prescription orders.

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

17.3. Refusal of prescription.

It is the duty of a pharmacist to make his or her 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 or her inability to fill the prescription order.

17.4. 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 or

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

17.5. Diagnosis or treatment.

No pharmacist shall attempt to diagnose, treat or prescribe for any disease, illness or organic disorder. A pharmacist may advise 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.

17.6. 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.

17.7. 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.

17.8. 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 the drugs to be used in excess of the requirements established in a legitimate physician-patient relationship.

No pharmacist shall purchase, accept, compound or dispense any medicinal preparation, whether by prescription order or otherwise, which in his or her 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.

17.9. 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 the order with the date, time and method of ascertaining the approval.

17.10. 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.

17.11. 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.

17.12. 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 any agreement or arrangement for the payment or acceptance or compensation in any form or type for the recommending or professional services of either; nor shall he or she 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.

17.13. Duties.

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

(a) To accept all new prescriptions transmitted by oral communication.

(b) To affix typed prescription labels to prescription containers.

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

medications.

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

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

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

(f) To counsel patients. An offer to counsel shall be made by the pharmacist or the pharmacist's designee in a oral communication with the patient or caregiver or agent who presents a prescription, unless, in the professional judgment of the pharmacist it is considered inappropriate. In such instances, it is permissible for the offer to counsel to be made in a written communication, by telephone, in person, or in a manner determined by the pharmacist to be appropriate. The requirements in this section constitute an acceptable offer to provide counseling to all parties including recipients of Medicaid and other third party programs or plans in the state.

(1) In those cases, when the offer to counsel, as described in this sub-section, has been accepted, a pharmacist who provides prescription services to patients, shall discuss with the

patient or caregiver or agent who presents a prescription, any matter which in the exercise of the pharmacist's professional judgment the pharmacist considers significant, which may or may not include any of the following:

(a) The name and description of the medication;

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

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

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

(e) Techniques for self-monitoring drug therapy;

(f) Proper storage;

(g) Prescription refill information; and

(h) Any action to be taken in the event of a missed dose.

(2) Nothing in this sub-section requires a pharmacist to provide consultation if the patient or caregiver or agent does not

accept the offer to counsel. The refusal may be noted whether manually or electronically in the patient's profile.

(3) To make a reasonable effort to obtain, record, and maintain at least the following information at the individual pharmacy:

(a) The patients name, address, telephone number, date of birth or age, and gender.

(b) The patient's individual history when significant, including disease state and states, known allergies and drug reactions, and a comprehensive list of medications and relevant devices; and

(c) The pharmacist's comments relevant to the patient's drug therapy.

(4) Patient counseling, is not required for inpatients of a hospital or institution where other licensed health care practitioners are authorized to administer the drug(s).

(g) To perform any of the functions in this section except, nothing shall restrict registered interns from performing any and all of the functions in this section under the supervision of a registered pharmacist.

(h) To perform any other functions of any nature or kind which require the knowledge, ability or skill of a registered pharmacist.

17.14. Evasion or violation of the rules of professional conduct.

These rules of professional conduct are intended to govern all pharmacists licensed to practice in West Virginia by the State Board of Pharmacy and their employees or agents. A violation of any provision of this rule constitutes unprofessional conduct.

Any pharmacist who knowingly accepts professional employment from any person, firm or corporation who violates or evades this rule is guilty of a violation of the rule the same as if he or she had personally engaged in the evasion or violation.

17.15. 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 the rules shall be posted in the prescription department of every such establishment where it can be seen by all persons entering the department.

15-1-18. **Pharmacist Consultants And Coordinators Of Pharmaceutical Services.**

The requirements in this section apply to pharmacists who 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.

18.1. Requirements.

(a) The Board of Pharmacy shall maintain a roster of all pharmacist consultants and coordinators of pharmaceutical services. All pharmacists serving as consultants or coordinators shall be licensed 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 with the West Virginia Board of Pharmacy on forms provided by the Board. The forms shall specify the service which the pharmacist is providing and the location where the service is being provided. The forms must be signed by the pharmacist and the administrator of the facility. The pharmacist must register annually with the West Virginia Board of Pharmacy.

(d) All applicants certified as pharmacist consultants or coordinators of pharmaceutical services shall meet such additional educational and experienced backgrounds as required by the Board and comply with this rule.

(e) Pharmacist consultants or coordinators of pharmaceutical services shall document by time and date their activities consistent with the level of institutional care requirements.

18.2. Responsibilities.

(a) The pharmacist consultant or coordinator of pharmaceutical services is responsible for initiating and maintaining 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 of pharmaceutical services shall cause to be developed, issued and implemented a "Policy and Procedures" manual for pharmaceutical services. This manual shall be open to inspection 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) In-service drug education.

(7) Procedures 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 is responsible for maintaining an adequate professional library of pharmaceutical references within the facility.

(d) The pharmacist consultant or coordinator shall insure compliance with the rules of professional conduct as adopted by the Board of Pharmacy under West Virginia Code, §30-5-2

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

(f) Nothing under this rule precludes a patient in a skilled nursing facility or intermediate care facility from free choice of pharmaceutical supplies and drugs.

SENATE BILL NO. 231

(By Senator Manchin

[Introduced March 1, 1993; referred to the Committee on Health and Human Resources; and then to the Committee on the Judiciary.]

A BILL to amend and reenact section twenty, article nine, chapter sixty-four of the code of West Virginia, one thousand nine hundred thirty-one, as amended, relating to authorizing the board of pharmacy to promulgate legislative rules relating to the board.

Be it enacted by the Legislature of West Virginia:

That section twenty, article nine, chapter sixty-four of the code of West Virginia, one thousand nine hundred thirty-one, as amended, be amended and reenacted, to read as follows:

ARTICLE 9. AUTHORIZATION FOR MISCELLANEOUS AGENCIES AND BOARDS TO PROMULGATE LEGISLATIVE RULES.

§64-9-20. Board of pharmacy.

(a) The legislative rules filed in the state register on the second day of October, one thousand nine hundred eighty-four, modified by the board of pharmacy to meet the objections of the

legislative rule-making review committee and refiled in the state register on the ninth day of January, one thousand nine hundred eighty-five, relating to the board of pharmacy (parenteral/enteral compounding), are authorized.

(b) The legislative rules filed in the state register on the twelfth day of September, one thousand nine hundred eighty-nine, modified by the board of pharmacy to meet the objections of the legislative rule-making review committee and refiled in the state register on the fifteenth day of November, one thousand nine hundred eighty-nine, relating to the board of pharmacy (board of pharmacy), are authorized.

(c) The legislative rules filed in the state register on the sixth day of May, one thousand nine hundred ninety, modified by the board of pharmacy to meet the objections of the legislative rule-making review committee and refiled in the state register on the fifth day of June, one thousand nine hundred ninety, relating to the board of pharmacy (continuing education for the licensure of pharmacists), are authorized.

(d) The legislative rules filed in the state register on the eleventh day of March, one thousand nine hundred ninety-one, modified by the board of pharmacy to meet the objections of the legislative rule-making review committee and refiled in the state register on the twenty-fourth day of May, one thousand nine hundred ninety-one, relating to the board of pharmacy (computer regulations), are authorized.

(e) The legislative rules filed in the state register on the twenty-eighth day of August, one thousand nine hundred ninety-one, modified by the board of pharmacy to meet the objections of the legislative rule-making review committee and refiled in the state register on the eighth day of January, one thousand nine hundred ninety-two, relating to the board of pharmacy (licensure of wholesale drug distributors), are authorized.

(f) The legislative rules filed in the state register on the twenty-eighth day of August, one thousand nine hundred ninety-one, modified by the board of pharmacy to meet the objections of the legislative rule-making review committee and refiled in the state register on the eighth day of January, one thousand nine hundred ninety-two, relating to the board of pharmacy (mail order house), are authorized.

(g) The legislative rules filed in the state register on the fifteenth day of September, one thousand nine hundred ninety-two, modified by the board of pharmacy to meet the objections of the legislative rule-making review committee and refiled in the state register on the twenty-eighth day of January, one thousand nine hundred ninety-three, relating to the board of pharmacy (board of pharmacy), are authorized.

NOTE: The purpose of this bill is to authorize the Board of Pharmacy to promulgate legislative rules relating to the Board.

Strike-throughs indicate language that would be stricken from the present law, and underscoring indicates new language that would be added.

KEN HECHLER
Secretary of State

MARY P. RATLIFF
Deputy Secretary of State

A. RENEE COE
Deputy Secretary of State

CATHERINE FREROTTE
Executive Assistant

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

STATE OF WEST VIRGINIA

SECRETARY OF STATE

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

WILLIAM H. HARRINGTON
Chief of Staff

JUDY COOPER
Director, Administrative Law

DONALD R. WILKES
Director, Corporations

(Plus all the volunteer help we can get)

FAX: (304) 558-0900

May 28, 1993

Betty Jo Payne
Pharmacy, Bd. of
236 Capitol Street
Charleston, WV 25301

HB 100 authorizing, **Title 15, Series 1, Rules & Regulations of the Board of Pharmacy**, passed the Legislature on **May 26, 1993.** It is now awaiting the Governor's signature.

You have sixty (60) days after the Governor signs HB 100, to final file the legislative rule with the Secretary of State's office. To final file your legislative rule, fill in the blanks on the enclosed form #6, the "Final Filing" form and file the form with our office. Authorization for your legislative rule is cited in **HB 100** section **64-9-20(g).** The agency may set the effective date of the legislative rule up to ninety (90) days from the date the legislative rule is final filed with the Secretary of State's office. Please have an authorized signature on the bottom line.

***IMPORTANT: IF YOUR AGENCY HAS COMPLETED THE LEGISLATIVE RULE ON A COMPUTER SYSTEM THAT USES A 3 1/2" OR 5 1/4" DISK, **PLEASE SUBMIT A CLEAN COPY, WITH ALL UNDERLINING AND STRIKE-THROUGHS TAKEN OUT,** TO OUR OFFICE WHEN FINAL FILING THE RULE. STATE ON THE DISK THE FORMAT THE RULE IS IN AND THE TITLE IT IS FILED UNDER. THIS WILL MAKE IT QUICKER FOR US TO ENTER YOUR RULES ON THE LEGISLATIVE DATA BASE. REMEMBER THE TEXT OF THE COMPUTER FILED RULE **MUST** BE IDENTICAL - WORD FOR WORD, COMMA FOR COMMA, **WITH ALL UNDERLINING AND STRIKE-THROUGHS TAKEN OUT,** AS THE HARD COPY AUTHORIZED BY THE LEGISLATURE.

After the final rule is entered into the legislative data base, the rule will be sent to the agency for review and proofing. Following confirmation or corrections, as the case may be, the Secretary of State shall submit to the agency a final version of the rule for their records.

If you have any questions or need any assistance, please do not hesitate to call our office.

Thank You
Administrative Law Division

KEN HECHLER
Secretary of State

MARY P. RATLIFF
Deputy Secretary of State

A. RENEE COE
Deputy Secretary of State

CATHERINE FREROTTE
Executive Assistant

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

STATE OF WEST VIRGINIA

SECRETARY OF STATE

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

WILLIAM H. HARRINGTON
Chief of Staff

JUDY COOPER
Director, Administrative Law

DONALD R. WILKES
Director, Corporations

(Plus all the volunteer help we can get)

FAX: (304) 558-0900

TO: Betty Jo Payne

AGENCY: Pharmacy

FROM: JUDY COOPER, DIRECTOR, ADMINISTRATIVE LAW DIVISION

DATE: January 28, 1994

THE ATTACHED RULE FILED BY YOUR AGENCY HAS BEEN ENTERED INTO OUR COMPUTER SYSTEM. PLEASE REVIEW, PROOF AND RETURN IT WITH ANY CORRECTIONS. IF THERE ARE NO CORRECTIONS, PLEASE SIGN THIS MEMO AND RETURN IT TO THIS OFFICE. YOU WILL BE SENT A FINAL VERSION OF THE RULE FOR YOUR RECORDS.

PLEASE RETURN EITHER THE CORRECTED RULE OR THIS FORM WITHIN TEN (10) WORKING DAYS OF THE DATE YOU RECEIVED THIS REQUEST. CALL IF YOU HAVE ANY QUESTIONS.

SERIES: 1 TITLE: 15 Pharmacy

* THE ATTACHED RULE HAS BEEN REVIEWED AND IS CORRECT.

SIGNED: Harold Craig III

TITLE OF PERSON SIGNING: Executive Director

DATE: 2/14/94

****

* THE ATTACHED RULE HAS BEEN REVIEWED AND NEEDS CORRECTING. THE CORRECTIONS HAVE BEEN MARKED.

SIGNED: _____

TITLE OF PERSON SIGNING: _____

DATE: _____

NOTE: IF YOU ARE NOT THE PERSON WHO HANDLES THIS RULE, PLEASE FORWARD TO THE CORRECT PERSON.