

SECRETARY OF STATE

KEN HECHLER

ADMINISTRATIVE LAW DIVISION

Form #2

FILED

JUN 22 2 40 PM '98

OFFICE OF WEST VIRGINIA SECRETARY OF STATE

NOTICE OF A COMMENT PERIOD ON A PROPOSED RULE

AGENCY: West Virginia Board of Pharmacy TITLE NUMBER: 15

RULE TYPE: Legislative; CITE AUTHORITY Sections 29A-3-9, 30-5-2

AMENDMENT TO AN EXISTING RULE: YES X NO Repeal and Replace

IF YES, SERIES NUMBER OF RULE BEING AMENDED: 1

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

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 July 23, 1998 AT 4:00 P.M.

ONLY WRITTEN COMMENTS WILL BE ACCEPTED AND ARE TO BE MAILED TO THE FOLLOWING ADDRESS.

West Virginia Board of pharmacy
232 Capitol Street
Charleston, West Virginia 25301

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

William S. Douglas Jr.

Authorized Signature Executive Director

ATTACH A BRIEF SUMMARY OF YOUR PROPOSAL

\$17.40

APPENDIX B

FISCAL NOTE FOR PROPOSED RULES

Rule Title: Rules and Regulations

Type of Rule: Legislative Interpretive Procedural

Agency: West Virginia Board of Pharmacy

Address: 232 Capitol Street
Charleston, WV 25301

1. Effect of Proposed Rule

	ANNUAL FISCAL YEAR				
	INCREASE	DECREASE	CURRENT	NEXT	TERRAFTER
ESTIMATED TOTAL COST	\$ N/A	\$	\$ N/A	\$	\$
PERSONAL SERVICES					
CURRENT EXPENSE					
REPAIRS & ALTERNATIONS					
EQUIPMENT					
OTHER					

2. Explanation of above estimates:

Proposed rule will not change operating costs of Board except the addition of processing authority to administer immunizations permits. The volume and costs unable to be determined.

3. Objectives of these rules:

Repeals and replaces the current Title 15.Series 1 of the Board's Legislative rules. Updates rules in order to apply to modern practice of pharmacy.

Rule Title: Rules and Regulations

4. Explanation of Overall Economic Impact of Proposed Rule.

A. Economic Impact on State Government.

N/A

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

Only change is to add \$25.00 fee for pharmacists who apply for and obtain an Authority to Administer Immunizations permit.

C. Economic Impact on Citizens/Public at Large.

N/A

Date: 6/22/98

Signature of Agency Head or Authorized Representative

William J. Douglas Jr.

Executive Director

SUMMARY OF PROPOSED RULE

Title 15

Legislative Rules

Series 1

Rules and Regulations

This rule repeals and replaces the current Series 1, entitled “Rules and Regulations of the Board of Pharmacy.” This rule provides definitions of many terms and establishes general provisions for Board operation. The rule establishes internship requirements. The rule provides the requirements for application as a pharmacist, including examination requirements, renewals, and reinstatement of lapsed licenses. The rule establishes the qualifications for obtaining a license by reciprocity, including requirements for a foreign pharmacy graduate. The rule establishes proceedings for disciplinary action. The rule establishes how drugs may be transferred and the restrictions on refilling and transferring of prescription orders. The rule establishes how drugs and devices may be returned. The rule states the requirements for drug product selection and substitution. The rule establishes the requirements for pharmacy permits, including the minimum requirements, security, and professional work environment. The rule states the required equipment, facilities, and record systems required by a pharmacy. The rule establishes the requirements for a permit to conduct sterile pharmaceutical compounding. The rule establishes licensure and control of nuclear pharmacies. The rule establishes the sanitary

requirements in a pharmacy. The rule establishes rules of professional conduct for pharmacists. The rule establishes the duties and responsibilities of a pharmacist-in-charge. The rule establishes the manner of issuance of a prescription. The rule states different labeling requirements. The rule establishes the requirements and responsibilities of a consultant pharmacist. The rule establishes different types of specialized dispensing systems, including the use of emergency kits. The rule states the requirement for places that need to obtain a controlled substance permit, including the fees for such permit. The rule establishes the authority of pharmacists to administer immunizations after certain training.

STATEMENT OF CIRCUMSTANCES

Title 15 Legislative Rules Series 1 Rules and Regulations

Title 15, Series 1, Rules and Regulations of the Board of Pharmacy went into effect June 14, 1993. Since that time the practice of pharmacy has evolved and there have been dramatic changes affecting how drugs are dispensed, in what settings the drugs are dispensed, and the role of the pharmacist. The current regulations do not cover these many facets of the modern day practice of pharmacy and make it difficult to apply to current situations and enforce. Therefore, it is necessary to update the regulations so that the Board can effectively regulate the practice of pharmacy in order to protect the public.

TITLE 15
LEGISLATIVE RULES

SERIES 1
RULES AND REGULATIONS

FILED
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OFFICE OF WEST VIRGINIA
SECRETARY OF STATE

§15-1-1 GENERAL

1.1 Scope-W. Va. Code §30-5-19 et. seq. mandates that the Board of Pharmacy shall make such Rule, not inconsistent with law, as necessary, to carry out the purposes and enforce the provisions of Article five.

1.2 Authority.--W. Va. Code §30-5-19.

1.3 Filing date _____.

1.4 Effective date _____.

1.5 Repeal of former rule- This legislative rule repeals and replaces WV 15CSR1 "Rules and Regulations of the Board of Pharmacy" filed June 11, 1993 and effective June 14, 1993.

§15-1-2. DEFINITIONS.

2.1 The following words and phrases as used in this Rule have the following meanings, unless the context otherwise requires:

(a) "Act" or "Uniform Controlled Substance Act" means and refers to chapter 60A of the West Virginia Code.

(b) "Administer" means the direct application of a drug to the body of a patient or research subject by injection, inhalation, ingestion or any other means.

(c) "Board of Pharmacy" or "Board" means the West Virginia state board of pharmacy.

(d) "Compounding" means:

(1) The preparation, mixing, assembling, packaging, or labeling of a drug or device:

(A) As the result of a practitioner's prescription drug order or initiative based on the practitioner/patient/pharmacist relationship in the course of professional practice for sale or dispensing, or

(B) For the purpose of, or as an incident to, research, teaching or chemical analysis and not for sale or dispensing, or

© The preparation of drugs or devices in anticipation of prescription drug orders based on routine, regularly observed prescribing patterns.

(e) The term "Cosmetic" which shall be held to include "Dentifrice" and "Toilet articles" means:

(1) 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 temporarily altering the appearance.

(2) Articles intended for use as a component of any such articles, except that the term shall not include soap.

(f) "Confidential information" means information maintained by the pharmacist in the patient record or which is communicated to the patient as part of patient counseling, or which is communicated by the patient to the pharmacist. This information is privileged and may be released only to the patient or to other members of the health care team and other pharmacists where, in the pharmacist's professional judgement, such release is necessary to the patient's health and well-being; to such other persons or governmental agencies authorized by law to receive such privileged information; as necessary for the limited purpose of peer review and utilization review; and as authorized by the patient or required by court order.

(g) "Controlled Substance" means a drug, substance, or

immediate precursor in Schedule I through Schedule V of either the Federal Controlled Substances Act or the West Virginia Uniform Controlled Substances Act.

(h) "Deliver" or "delivery" means the actual, constructive or attempted transfer of a drug or device from one person to another, whether or not for a consideration.

(i) "Device" means an instrument, apparatus, implement or machine, contrivance, implant or other similar or related article, including any component part or accessory, which is required under federal law to bear the label, "Caution: Federal or state law requires dispensing by or on the order of a physician" or the language or symbol as determined by the U. S. Food and Drug Administration.

(j) "Dispense" or "dispensing" is that aspect of the practice of pharmacy concerned with the preparation and delivery of a drug or device in an appropriately labeled and suitable container to a patient or a patient's representative or surrogate pursuant to a lawful order of a practitioner for subsequent administration to, or use by, a patient.

"Dispensing" shall not be construed to include the prescribing and administering of controlled substances as is included in the definition of "Dispensing" controlled substances found in W. Va. Code §60A-1-101(h.)

(k) "Distribute" means the delivery of a drug or device other than by administering or dispensing.

(l) "Distributor" means a person licensed as a wholesaler.

(m) "Drug" means:

(1) Articles recognized as drugs in the USP-NF, Facts and Comparisons, Physicians Desk Reference or supplements thereto, for use in the diagnosis, cure, mitigation, treatment or prevention of disease in human or other animals;

(2) Articles, other than food, intended to affect the structure or any function of the body of human or other animals; and

(3) Articles intended for use as a component of any articles specified in subsection (1) or (2) of this section.

(n) "Drug regimen review" includes, but is not limited to, the following activities:

(1) Evaluation of prescription orders and patient records for:

(A) Known allergies;

(B) Rational therapy-contraindications;

© Reasonable dose and route of administration; and

(D) Reasonable directions for use.

(2) Evaluation of the prescription drug orders and patient records for duplication of therapy.

(3) Evaluation of the prescription drug for interactions and/or adverse effects which may include, but are not limited to, any of the following:

(A) Drug-drug;

(B) Drug-food;

© Drug-disease; and

(D) Adverse drug reactions.

(4) Evaluation of the prescription drug orders and patient records for proper utilization, including over utilization, under utilization and optimum therapeutic outcomes.

(o) "Inspector" means an agent of the Board, who is a licensed

pharmacist, appointed by the Board to conduct periodic inspections of permittees and perform other duties as designated by the Board.

(p) "Investigator" means an agent of the Board appointed to conduct official inquiries and perform other duties as designated by the Board.

(q) "Intern" means an individual who is:

(1) Currently licensed by the Board to engage in the practice of pharmacy while under the supervision of a licensed pharmacist and is satisfactorily progressing toward meeting the requirements for licensure as a pharmacist; or

(2) A graduate of an approved college of pharmacy or a graduate who has established educational equivalency by obtaining a Foreign Pharmacy Graduate Examination Committee certificate, who is currently licensed by the Board for the purpose of obtaining practical experience as a requirement for licensure as a pharmacist; or

(3) A qualified applicant who is licensed by the Board and is awaiting examination for licensure, or

(4) An individual participating in a residency or fellowship program.

(r) "Labeling" means the process of preparing and affixing a label and the affixing of auxiliary labels to a drug container exclusive, however, of a labeling by a manufacturer, packer or distributor of a nonprescription drug or commercially packaged legend drug or device. Any such label shall include all information required by federal law or regulation or state law or rule.

(s) "Manufacturer" means a person engaged in the manufacturing of drugs or devices.

(t) "Manufacturing" means production, preparation, propagation or processing of any drug or device, either directly or indirectly, by extraction from substances of natural origin or independently by means of chemical or biological synthesis and includes any packaging or repackaging of the substance(s) or labeling or relabeling of its contents and the promotion and marketing of such drugs or devices. Manufacturing also includes the preparation or repackaging, and promotion of commercially available products from bulk compounds for resale by pharmacies, practitioners or other persons.

(u) "Nonprescription drug" means a drug which may be sold without a prescription and which is labeled for use by the consumer in accordance with the requirements of the laws and rules of this state and the federal government.

(v) "Nuclear pharmacist" means a pharmacist that has been certified in the specialty of nuclear pharmacy.

(w) "Patient counseling" means the oral communication by the pharmacist of information, as defined in the rules of the board, to the patient or care giver, to improve therapy by aiding in the proper use of drugs and devices.

(x) "Permit" means any license, registration, or other privilege granted or issued by the board to any person for the purpose of providing a business or service to individuals or the public and the holder of the permit is the "permittee". No permit will be issued unless a business is operated or a service is provided. Not more than one permit may be issued in any one name in more than one location.

(y) "Person" means an individual, corporation, partnership, association or any other legal entity, including government.

(z) "Person Addicted" means one who has acquired the habit of using alcoholic beverages or controlled substances or other agents to such an extent as to deprive him or her of reasonable self-control.

(aa) "Pharmaceutical care" is the dispensing of drugs and devices

prescribed by a practitioner, or otherwise used by a patient, including proper counseling, and any other pharmaceutical care services, to achieve an outcome related to:

- (1) The cure of a disease, or
- (2) Arresting or slowing a disease process, or
- (3) Elimination or reduction of symptoms of a disease process, or
- (4) Elimination or reduction of pain.

(bb) "Pharmacist" or "registered pharmacist" means an individual currently licensed by this state to engage in the practice of pharmacy and pharmaceutical care.

(cc) "Pharmacist-in-charge" means a pharmacist currently licensed in this state who;

1. Accepts responsibility for the operation of a pharmacy in conformance with all state and federal laws and rules pertinent to the practice of pharmacy and the distribution of drugs.
2. Is personally in full and actual charge of such pharmacy and personnel.
3. Works at least fifty percent (50%) of the time when employed in a pharmacy that is open 72 hours per week or less.
4. Works at least 36 hours a week in a pharmacy open more than 72 hours per week.

(dd) . "Mail order pharmacy" means a pharmacy, regardless of its location, which dispenses drugs or medicines through the United States Mail or otherwise from any point outside the state of West Virginia to any point within the state of West Virginia or from any point within the state of West Virginia to any point outside the state and is registered with the board.

(ee) "Outpatient pharmacy" means any pharmacy, apothecary, or place within this state where drugs are dispensed and sold at

retail or displayed for sale at retail and where the practice of pharmacy is conducted and pharmaceutical care is provided; and anyplace outside of this state where drugs are dispensed and the practice of pharmacy and pharmaceutical care is provided to residents of this state.

(ff) "Inpatient pharmacy" means the area within a licensed institution; i.e., a hospital, or other place where patients stay at least one night, where drugs are stored and dispensed to other areas of the institution for administration to the patients by other licensed health care providers.

(gg) "Institutional pharmacy" means a place where drugs are dispensed primarily in unit dose form for residents in an institutional setting; not a private residence.

(hh) "Nuclear pharmacy" means a place where radioactive drugs are prepared and dispensed and which operates under specialized rules.

(ii) "Pharmacy technician" means registered supportive personnel who work under the direct supervision of a pharmacist, and who have passed an approved training program.

(jj) "The practice of pharmacy" is the personal health service concerned with the preparing, compounding and dispensing of drugs and medical devices used in the diagnosis, treatment or prevention of disease, dispensed on the prescription of a practitioner, or otherwise legally dispensed or sold and shall include the proper and safe storage of drugs, the maintenance of proper records and the dissemination of information to other health care professionals and proper counseling to the patient concerning the therapeutic value and proper use of drugs and devices.

(kk) "Practitioner" means an individual currently licensed, registered or otherwise authorized by the jurisdiction in which he or she practices to prescribe and administer drugs in the course of professional practices, including allopathic and osteopathic physicians, dentists, physician's assistants, optometrists, veterinarians, podiatrists and nurse practitioners,

as allowed by law.

The term "Practitioner" shall not be construed to be persons and places, as defined in W.V. Code §60A-1-101 (v) (1) and (2), that handle controlled substances.

(ll) "Preceptor" means an individual who is currently licensed as a pharmacist by the board, meets the qualifications as a preceptor under the rules of the board, and participates in the instructional training of pharmacy interns.

(mm) "Prescription drug" or "legend drug" means a drug which, under federal law, is required, prior to being dispensed or delivered, to be labeled with any of the following statements or the language or symbol as determined by the U. S. Food and Drug Administration.

(1) "Caution: Federal law prohibits dispensing without prescription".

(2) "Caution: Federal law restricts this drug to use by, or on the order of, a licensed veterinarian"; or a drug which is required by any applicable federal or state law or rule to be dispensed pursuant to a prescription drug order or is restricted to use by practitioners only.

(nn) "Prescription" or "Prescription order" means a lawful order from a properly licensed practitioner to a pharmacist for a drug or device for a specific patient and transmitted by:

(1) Written order, or

(2) Oral order to a pharmacist who must immediately:

(A) Reduce it to writing which becomes the original order, and

(B) Hand initial it to identify the receiver, and

© Show the date, time and name of person transmitting the order, or

(3) Electronic transmission which produces a printed copy.

All other methods of transmission are prohibited.

(oo) The term "Poisonous Drug" means any drug likely to be destructive to adult human life in quantities of 300 mg or less.

(pp) The term "Deleterious Drug" means any drug likely to be destructive to adult human life in quantities of 3.5 Grams or less.

(qq) "Over-the counter drug" or "OTC drug" means any drug that is not a prescription drug or legend drug.

(rr) "President" means the President of the West Virginia Board of Pharmacy.

(ss) "Sample" means a package of a legend drug provided by a manufacturer on the request of a practitioner to be given to a patient without charge.

(tt) The term "Secretary" means the Secretary of the West Virginia Board of Pharmacy

(uu) The term "Vice-President" means the Vice-President of the West Virginia Board of Pharmacy

vv. "Original License" means a license issued by the Board to an applicant when:

(1) the applicant is a new business.

(2) the applicant is an established business that is transferred to a successor.

(3) the applicant is an established business in which fifty percent (50%) ownership or more is transferred to a new owner.

(4) the applicant is an established business in which control of pharmaceutical services is transferred; not including a change in pharmacist-in-charge.

(5) the applicant is an established business which moves to a new location.

(ww) An "approved" or "recognized" "School of Pharmacy" means a school of pharmacy accredited by the American Council on Pharmaceutical Education.

(xx) A "Wholesaler" is a person or entity licensed by the Board to distribute, by sales or otherwise, prescription legend drugs to persons other than a consumer or patient.

§15-1-3 GENERAL PROVISIONS

- 3.1 Board in general. -- The Board of Pharmacy shall consist of five (5) practicing pharmacists and two (2) public members 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 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 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 as President of the Board, one (1) to serve as Vice-president and one (1) to serve as Secretary, all to serve a one (1) year term or until their successors are elected. The election is to be held in June each year.
- 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 Meetings of the Board -- The Board shall hold at least two (2)

meetings a year for the purpose of examining applicants for licensure to practice pharmacy in West Virginia and for the transaction of such other business as may legally come before it. It may hold additional meetings for any legitimate purpose it may consider appropriate, which shall be called by the Secretary at the direction of the President or upon the written request of any three (3) members. "Roberts Rules of Order" shall control conduct of all meetings.

- 3.5 Quorums -- Four (4) members must be present at the time and place set for the meeting before any action can be taken by the Board. A majority vote of the members in attendance is required before any motion may be passed.
- 3.6 Location of Office -- The Board shall determine the location of its office.
- 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 the monies 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 Every member of the board shall be paid a per diem for each day actually spent in attending sessions of the Board or of its committees and the necessary travel, as set by West Virginia Code §30-50-2(c), 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.

- 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\her application, name, age, educational and other qualifications, place of residence, whether an examination was required, whether the applicant was rejected or a certificate of licensure or registration granted. the license or registration number, if required, and any suspension or revocation of any 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.
- 3.10 Roster of licensed or registered persons. -- The Secretary of the Board shall prepare and maintain a complete roster of all persons, licensed and registered by it, alphabetically and by class or type and by whether within or without the state.
- 3.11 Power of Inspection and Investigation-- The duly authorized agents of the Board shall have the power to inspect and investigate in a lawful manner and during regular business hours all places or persons with permits. Such inspection and/or investigation may include, but not be limited to, all inventories, invoices for prescription drugs, selling prices, and other records required by law, acts of individuals and facilities, but shall not extend to financial data or sales data other than shipment data or pricing data; unless the owner, operator or agent in charge of the controlled premises consents in writing.
- 3.12 During the course of any inspection or investigation by an agent of the Board the agent shall have the authority to temporarily close any permittee upon the discovery of any of the following:

(a) the ability of the pharmacist to practice pharmacy with reasonable skill, competency, or safety to the public is impaired because the permittee's cognitive, interpersonal, or psychomotor skills are affected by psychiatric, psychological, or emotional problems or excessive alcohol or drug use or addiction, or

(b) the absence of a valid permit issued by the Board or by the lack of presence of a pharmacist.

3.13 When a permittee is closed under § 15-1-3.12

(a) of this Rule they shall remain closed until a competent pharmacist arrives on the premises or when closed under § 15-5-3.12 © they shall remain closed until a valid permit is obtained and on display as required by law.

3.14 Agents of the Board when acting in good faith and without malice shall enjoy immunity from individual civil liability while acting within the scope of their duties as such agents of the Board.

§15-1-4 INTERNSHIP REQUIREMENTS

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

The Board shall certify internship for an individual in this section only:

(a) When a preceptor holds a current, valid license as a pharmacist from the board and the intern has been issued an intern certificate which expires three (3) years from the date of issue. The internship certificate shall be displayed at the place of internship, and

b. When the intern has notified the Board within ten (10) days of the employment as an intern, and

c. When the intern notifies the Board within ten (10) days subsequent to termination of any internship under a specific preceptor, and

d. When the internship is certified by the submission of a

"Certification by Preceptor as to Internship" form immediately after termination of the internship. (Forms are available from the board office.)

- 4.2 No intern shall be certified by the Board unless the intern is enrolled in or is a graduate of a recognized school of pharmacy.
- 4.3 An intern may receive experience credit for any period of time during which he or she is enrolled in a recognized school of pharmacy and the Board may accept up to 640 hours credit for interns participating or enrolled in a supervised internship as part of the pharmacy curriculum.
- 4.4 All internship will be obtained in the practice of pharmacy and certified in a pharmacy in which the volume of prescription dispensing is more than ten thousand (10,000) prescription orders per year, unless a particular or extenuating situation warrants deviation from this figure in the judgement and discretion of the Board.
- 4.5 Any preceptor supervising the internship shall be a qualified preceptor and employ the training concepts outlined in "A Guide for Preceptors and Interns" available through the Board office.
- 4.6 The Board may accept internship hours gained outside West Virginia on a letter of credit or certification from the Board of Pharmacy of the state in which the intern acquired internship experience. Up to one third of the internship hours may be fulfilled by an internship in a foreign country.

§15-1-5 EXAMINATION FOR LICENSURE AND REGISTRATION AND ANNUAL RENEWAL REQUIREMENTS

5.1 Application.

All applicants for examination shall apply in writing to the Board at least fifteen (15) days before the date the examination is to be conducted and shall transmit with the application the prescribed fee. The application shall be made on a form provided by the Board.

5.2 The requirements for application as a pharmacist are as follows:

(a) Age.

The applicant must be not less than eighteen (18) years of age, proof of which must be shown by birth certificate or other acceptable document.

(b) Moral Character.

Every applicant shall present to the Board satisfactory evidence that he or she is a person of good moral character and has not been convicted of a felony involving controlled substances or violent crime and has not been addicted to alcohol or controlled substances.

© Education.

1. The applicant for licensure as a pharmacist shall present to the Board satisfactory evidence that he or she is a graduate of an approved school of pharmacy.

2. Applicants for registration shall have a high school diploma or General Educational Development (GED) Certificate.

(d) Internship.

The applicant shall have acquired one thousand five hundred (1500) hours of internship in a licensed pharmacy.

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.

b. A maximum of two (2) days shall be allowed for all portions of the examination.

c. An applicant for licensure as a pharmacist must pass the NAPLEX examination administered by NABP and one or more examinations in subject determined by the Board as being reasonable, in testing his or her knowledge.

d. For the purpose of grading or rating, answers to the questions shall be valued by marks or points based upon their importance as determined by the Board. An individual test grade

of seventy percent (70%) and an average of seventy five percent (75%) on all the examinations created and administered by the Board is necessary for an applicant to be passed for licensure.

e. An applicant failing to achieve the required grade may repeat the examination one time with out further cost within six (6) months, but one re-examination exhausts the privilege to sit for examination under the current application.

5.4 Certificate of licensure or registration.

a. An applicant for licensure who has successfully passed all the required examinations may receive a letter signed by the Secretary prior to preparation of a permanent certificate, or a permanent certificate evidencing that he or she is a licensed pharmacist. The permanent certificate of licensure shall bear a serial number, the full name of the applicant, the date of its issuance, the seal of the Board, and shall be signed by at least four (4) members of the Board and shall be attested by the President and Secretary. For any duplicate of this certificate the Board shall charge a fee of twenty five dollars (\$25.00) paid before issuance. No certificate is assignable.

5.5 Annual license renewal.

(a) Every licensed pharmacist who desires to continue in the practice of pharmacy, shall on or before the first day of July annually apply to the Board for a renewal of his or her license, and shall transmit with the application the prescribed fee.

. If the Board finds that the applicant has been legally licensed and is entitled to a renewal, it shall issue a renewal certificate attesting to that fact.

(b) Every registered pharmacy technician who desires to continue registration, shall on or before the first day of July annually apply to the Board for a renewal of his or her registration and shall transmit with the application the prescribed fee. If the Board finds that the applicant has been legally registered and is entitled to a renewal, it shall issue a renewal certificate attesting to that fact.

© Notification of the need to renew licensure shall be given by the Board at least thirty (30) days prior to the first of July.

(d) Failure to renew.

If any pharmacist or pharmacy technician fails for a period of sixty (60) days after the first of July of each year to apply to the Board for a renewal of his or her license, the Board shall send a second notification of the required annual renewal to the last known address of the pharmacist by certified mail, return receipt requested. If the pharmacist or pharmacy technician fails to apply for renewal of licensure within thirty (30) days after receipt of the second notification, his or her name shall be erased from the register of pharmacists and pharmacy technicians.

(e) Re-instatement.

In order for any pharmacist or pharmacy technician whose name has been erased from the register of the Board pursuant to subsection (d) of this section to again become licensed, such pharmacist or pharmacy technician shall personally appear before the Board, or an authorized committee of the Board, to show cause for permitting the license to lapse.

1. If such pharmacist submits to the Board satisfactory reasons for failing to renew their license and satisfies the Board as to his or her qualifications to practice the profession by successfully passing the examinations administered by the Board such person shall be reinstated upon payment of a fee of two hundred fifty dollars (\$250.00) plus the appropriate annual renewal fee.

2. If such pharmacy technician submits to the Board satisfactory reasons for failing to renew their certificate and pays an appropriate late fee plus the prescribed renewal fee and demonstrates their competency to work as a pharmacy technician by successfully passing the pharmacy technician examination they shall be reinstated.

§15-1-6 RECIPROCITY; LICENSURE OF PHARMACISTS FROM OTHER STATES OR COUNTRIES

6.1 Qualifications.

The Board may license and admit to practice pharmacists in this state, such persons that have been legally licensed or registered as pharmacists in other states or countries: PROVIDED, that;

- a. The applicant is at least eighteen (18) years of age.
- b. The original state in which the applicant is licensed or registered accords similar recognition to licensed pharmacists of West Virginia.
- c. The applicant is in good standing in the state or country of original licensure or registration.
- 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 not addicted to alcohol or a controlled substance(s).
- f. The applicant has not been convicted, or had his or her license suspended or revoked for violation of pharmacy, liquor, controlled substance, or food and drug laws.
- g. The applicant originally passed a written examination in subjects determined by the Board as being reasonable. The applicant also originally 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.
- h. The applicant is familiar with West Virginia Laws and Rules and Regulations governing the practice of pharmacy and must demonstrate such by examination.
- I. An applicant may serve all or part of his or her internship in another state and up to one-third (1/3) of his or her internship in another country and shall be given credit for the same when an affidavit of such is signed by the pharmacist under whom served and when the affidavit is attested by the secretary of the board of pharmacy of the state or country where the internship was served.

j. Applicants for reciprocity and others coming into West Virginia from other states and counties shall not accept positions as pharmacists or attempt to work as pharmacists until they receive a certificate of licensure from the state of West Virginia.

6.2 Foreign pharmacy graduate

a. A foreign pharmacy graduate whose undergraduate pharmacy degree was conferred by a recognized school of pharmacy outside of the fifty (50) United States, the District of Columbia, and Puerto Rico, may establish educational equivalency by obtaining a Foreign Pharmacy Graduate Examination Committee Certificate (FPGEC) from the National Association of Boards of Pharmacy (NABP). An applicant for licensure who receives FPGEC certification meets the educational requirement for licensure and may sit for the NAPLEX and state examinations provided he or she has obtained 1500 hours of internship; of which 500 hours may have been earned in a foreign country.

6.3 Application.

a. The applicant shall complete a preliminary application form obtained from the National Association of Boards of Pharmacy and return it to that organization.

After the preliminary application data has been verified by the National Association of Boards of Pharmacy and the Board receives notification the Board shall supply the applicant who possesses the necessary qualifications with application forms. These forms must be completed and submitted with a fee of two hundred fifty-five dollars (\$255.00). In the event the applicant desires to take the examination at a time other than at the next scheduled examination the applicant shall submit to the Board an additional fee of one hundred fifty dollars (\$150.00).

b. The application must include the following provided by the applicant:

1. A certified copy of proof of experience, or the original pharmacist preceptor's affidavit proving experience, that was filed by the applicant when he or she took the examination in the state or country in which he or she is licensed or registered.

2. A recent bust photograph with a statement thereon, signed

by the applicant that it is a photograph of the applicant and has been made within the previous twelve (12) months.

3. A certified criminal records check from the state or country of original licensure, made within thirty (30) days of the date of application.

6.3 Appearance before the Board.

Applicants for licensure by reciprocity are required to appear before the Board or its designated agent at such time as directed, for checking of credentials, an interview and examination as may be necessary to determine the fitness of the applicant to practice in West Virginia. Misrepresentation shall serve to void any licensure that may be granted.

§15-1-7 PROCEEDINGS FOR DISCIPLINARY ACTION

7.1 Definitions

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

- (a) "Board" means the West Virginia Board of Pharmacy.
- (b) The term "demanding party" means an individual, pharmacy or any other permittee of the Board who has had a license or certificate denied, suspended, or revoked by the Board and who, as a result, demands that a hearing be held before the Board on the issue of such denial.

© The term "charged Party" means an individual, pharmacy or other permittee of the Board who holds a license or certificate issued by the Board and who has been charged by the Board as described in this rule.

7.2 Hearing Procedures.

- (a) Any person who has had a permit denied, suspended, or revoked by the Board, and believes such action was in violation of W. Va. Code § 30-1-1, et. seq. and/or §30-5-1, et. seq., shall be entitled to a hearing on the action denying, suspending, or revoking such permit.

- (b) Any person who desires a hearing for the reason described in subsection (a) must present a written demand for the hearing to the Board.
- © When the president of the Board or his or her authorized designee is presented with such a demand for a hearing, he or she shall schedule a hearing within thirty (30) days of receipt by him or her of such written demand, unless postponed to a later date by mutual agreement.
- (d) Charges may be instituted against any person who has a permit issued by the Board when reasonable cause exists for believing that the person may have engaged in conduct or be in such condition the permit should be suspended, revoked or otherwise disciplined for one or more of the grounds set forth in W. Va. Code §30-5-1, et. seq. or the Board's legislative rules. Charges may be based upon information received by way of a verified written complaint filed with the Board and further information gathered by the Board in the process of investigating such complaint. Charges may also be based on information received solely through inspection or investigative activities undertaken by the Board.
- (e) Charges instituted against a person holding a permit as described shall be set forth in a Complaint and Notice of Hearing issued in the name of the Board as the agency of the State regulating the practice of pharmacy and related activities. Such Complaint and Notice of Hearing shall designate the Board as the "Complainant" and shall designate the permittee involved in the proceedings as the "Respondent"; shall set out the substance of each offense charged with sufficient particularity to reasonably apprise the Respondent of the nature, time and place of the conduct or condition complained of therein; shall state the date, time and place for the hearing; and shall contain a statement of intention of the Board to appoint a hearing examiner.
- (f) The Board may amend the charges set forth in a Complaint and Notice of Hearing as it deems proper.
- (g) A Complaint and Notice of Hearing shall be served upon the demanding or charging party at least thirty (30) days prior to the

date of the hearing.

- (h) Upon written motion received by the Board no later than twenty (20) days prior to the date of hearing, a more definite statement of the matters charged or the reasons stated for denial of licensure shall be provided to the demanding or charged party or his or her counsel, at least fifteen (15) days prior to the hearing date.

7.3 Hearings shall be conducted as follows:

- (a) Any party to the hearing shall have the right to be represented by an attorney-at-law, duly qualified to practice law in the State of West Virginia.

- (b) Upon request by the Board, it shall be represented by the West Virginia Attorney General's Office.

- © Irrelevant, immaterial, or unduly repetitious evidence shall be excluded from the hearing. Furthermore, the rules of evidence as applied in civil cases in the circuit courts of this State shall be followed. However, when necessary to ascertain facts not reasonably susceptible of proof under those rules, evidence not admissible thereunder may be admitted, except where precluded by statute, if it is of a type commonly relied upon by reasonable prudent persons in the conduct of their affairs.

- (d) The rules of privilege recognized by the law of this State shall be followed.

- (e) Objections to evidentiary offers shall be noted in the record. Any party to the hearing may vouch the record as to any excluded testimony or evidence.

- (f) Any party to a hearing may appear with witnesses to testify on his or her behalf; may be heard in person, by counsel or both; may present such other evidence in support of his or her position as deemed appropriate by the Board or its designated hearing examiner; and, when appropriate, may cross-examine witnesses called by the Board in support of

charges or in defense of its decision to deny licensure.

(g) The hearing shall be held at such time and place as is designated by the Board but no hearing shall be conducted unless and until at least thirty (30) days written notice thereof has been served upon the charged or demanding party and/or his or her attorney. Such notice shall be given either by personal delivery thereof to the person to be notified, or by depositing such notice in the United States Mail, postage prepaid, in an envelope addressed to such person at the last known address of such person.

(h) The hearing shall be open to the general public.

(I) Members of the Board and its officers, agents and employees shall be competent to testify at the hearing as to material and relevant matters: Provided, that no member of the Board who testifies at such hearing shall thereafter participate in the deliberations or decisions of the Board with respect to the case in which he or she testified.

(k) A record of the hearing, including the complaint(s), if applicable, the notice of the hearing, all pleadings, motions, rulings, stipulations, exhibits, documentary evidence, evidentiary depositions and the stenographic report of the hearing, shall be made and a transcript shall be furnished to any party at his or her expense.

(l) Documentary evidence may be received in the form of copies or excerpts or by incorporation by reference.

(m) Where a hearing is held upon instance of the Board after charges have been brought against a licensee pursuant to this rule, the board shall have the burden of proof and shall present its evidence and/or testimony in support of the charges first.

(n) Where a hearing is held upon demand under the provisions of this section, the demanding party shall have the burden of proof and shall present its evidence and/or testimony in support of the charges first..

(o) Following the conclusion of the Board's presentation of evidence in accordance with subsection (m) of this section, the Respondent or charged party shall have the right to submit his or her evidence in defense.

(p) Following the conclusion of the demanding party's presentation of evidence in accordance with subsection (n) of this section, The Board shall have the right to submit its evidence in defense.

(q) The Board shall call witnesses to testify in support of its decision to deny a permit or in support of the charges instituted against a permittee; may present such other evidence to support its position; and, may cross-examine witnesses called by the demanding party or charged party in support of his or her position.

(r) All parties shall have the right to opening and closing arguments, not to exceed ten (10) minutes for each presentation.

(s) Hearings held by the Board as a result of charges instituted against a permittee may be continued or adjourned to a later date or to a different place by the Board or its designee by appropriate notice to all parties.

(t) Motions for a continuance of a hearing may be granted upon a showing of good cause. Motions for continuance must be in writing and received in the office of the Board no later than seven (7) days prior to the hearing date. In determining whether good cause exists, consideration will be given to the ability of the party requesting the continuance to proceed effectively without a continuance. A motion for continuance filed less than seven (7) days from the date of the hearing shall be denied unless the reason for the motion could not have been ascertained earlier. Motions for continuance filed prior to the date of the hearing may be ruled on by the officer of the Board to preside or the designated hearing examiner. All other motions for continuance shall be ruled on by the Board member (s) or the hearing examiner presiding over the hearing.

(u) All motions related to a case set for hearing before the

Board, except motions for continuance shall be received in the office of the Board at least ten (10) days before the hearing. Prehearing motions shall be heard at a prehearing conference or at the hearing prior to the commencement of testimony. The Board Member (s) or the hearing examiner presiding at the hearing shall hear the motions and the response from the non-moving party and shall rule on such motions accordingly.

7.4 Transcription of Testimony and Evidence.

- (a) All testimony, evidence, arguments and rulings on the admissibility of testimony and evidence shall be recorded by stenographic notes and characters or by mechanical means.
- (b) All recorded materials shall be transcribed. The Board shall have the responsibility to make arrangements for the transcription of the recorded testimony and evidence.
- © Upon the motion of the Board or any party assigning error or omission in any part of any transcript, the Board or its appointed hearing examiner shall settle all differences arising as to whether such transcript truly discloses what occurred at the hearing and shall direct that the transcript be corrected and/or revised as appropriate so as to make it conform to the truth.
- (d) A transcript of the hearing shall be provided to all members of the Board for review at least ten (10) days before the vote is taken on its decision in any licensure or licensure disciplinary matter.

7.5 Any party may submit proposed findings of fact and conclusions of law at a time and manner designated by the Board or its duly appointed hearing examiner.

7.6 Hearing Examiner

- (a) The Board may appoint a hearing examiner who shall be empowered to administer oaths and affirmations, examine witnesses under oath, rule on evidentiary matters, hold conferences for the settlement or simplification of issues by consent of parties, cause to be prepared a record of the hearing so that the Board is able to discharge its functions and otherwise conduct hearings.

- (b) Hearing examiners appointed by the Board are not authorized or empowered to grant, suspend, revoke or otherwise discipline any license.
- © The hearing examiner shall prepare recommended findings of fact and conclusions of law for submission to the Board. The Board may adopt, modify or reject such findings of fact and conclusions of law.

7.7 Conferences; Informal Disposition of Cases.

- (a) At any time prior to the hearing or thereafter, the Board, its designee or its duly appointed hearing examiner may hold conferences for the following purposes:
 - (1) To dispose of procedural requests, prehearing motions or similar matters; or
 - (2) To simplify or settle issues by consent of the parties; or
 - (3) To provide for the informal disposition of cases by stipulation or agreement.
- (b) The Board or its duly appointed hearing examiner may cause such conferences to be held on its own motion or by the request of a party.
- © The Board may also initiate or consider stipulation or agreement proposals with regard to the informal disposition of cases and may enter into such stipulations and/or agreements without conference.

7.8 Evidentiary depositions may be taken and read or otherwise included into evidence as in civil actions in the circuit courts of this State.

7.9 Subpoenas

- (a) Subpoenas to compel the attendance of witnesses and subpoenas duces tecum to compel the production of documents may be issued by any member of the Board or its executive director.

- (b) Written requests by a party for the issuance of subpoenas or subpoenas duces tecum must be received by the Board no later than ten (10) days before a scheduled hearing. Any party requesting the issuance of subpoenas or subpoenas duces tecum shall see that they are properly served in accordance with W. Va. Code §29-5-1 (b).

7.10 Orders

- (a) Any final order entered by the Board following a hearing conducted pursuant to these rules shall be made pursuant to the provisions of W. Va. Code §29A-5-3 and §30-1-8 (d). Such orders shall be entered within forty-five (45) days following the submission of all documents and materials necessary for the proper disposition of the case, including transcripts, and shall contain findings of fact and conclusions of law.
- (b) The findings of fact and conclusions of law must be approved by a majority of the Board either by a poll or vote at a regular meeting, before the final order is entered. A copy of the final order approved by a majority of the Board shall be served upon the demanding or charged party and/or his attorney of record, if any, within five (5) days after entry by the Board by personal service or by registered or certified mail.

7.11 Appeal.

An appeal from any final order entered in accordance with these rules shall comply with the provisions of W. Va. Code §30-1-9.

§15-1-8 REVIEW BY CIRCUIT COURT AND SUPREME COURT OF BOARD'S REFUSAL TO ISSUE, OR SUSPEND OR REVOKE PERMIT

- 8.1 Any person who has been refused a license for any cause other than failure to pass any examination given by the Board or whose 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, petitioner shall mail copies of the petition to the Board.
- 8.3 Upon receipt of the petition copy, the Secretary shall transmit to the clerk of the court, the record of the hearing proceedings.

§15-1-9 TRANSFER OF DRUGS

- 9.1 No legend drug may be transferred except by the following methods:

(a) Transfer of drugs without prescription.

(1) Legend drugs without a prescription may be transferred only to a permittee or practitioner and must be recorded in a book kept for that purpose and have a total cumulative value of less than five thousand dollars (\$5000.00) at the selling price for the year or less than two thousand five hundred (2,500) doses for the year, whichever is greater.

(2) The record book showing transfers of drugs without a prescription shall contain:

(A) name of drug and quantity, and

(B) date of transaction, and

(C) permittee or practitioner to whom transferred, and

(D) selling price.

(3) Any pharmacy with transfers of prescription drugs without a prescription that amounts to sales in excess of five thousand dollars (\$5000.00) per year or in excess of two thousand five hundred (2,500) doses per year, whichever is greater, shall obtain a permit to be a wholesaler.

(b) Transfer of drugs with a Prescription.

Legend drugs transferred by a practitioner's prescription order must be dispensed. A prescription order must contain at least the following elements:

- (1) Patients name and address and the date written, and
 - (2) Drug name and quantity, and
 - (3) Directions for use.
- A. If the prescription is written on a practitioner's prescription blank, the order must contain the following:
- (a) The practitioner's printed name, address, professional designation and DEA number, and
 - (b) Signature.
- B. If the prescription is written on an institutional prescription blank, the order must contain the following:
- (a) The printed name of the practitioner with professional designation and DEA number with suffix, and
 - (b) Signature.
- © No sticker or other substance shall be allowed to obliterate or cover any of the above information.

9.2 Samples

- (a) Samples are the property of a practitioner and may only be received upon a signed request from the practitioner to the manufacturer.
- (b) Samples are not allowed in a pharmacy except that in-patient and clinic pharmacies may receive, store, and dispense prescription drug samples without charge to patients of a practitioner that is affiliated with the clinic or institution, provided that the following requirements are met:
 - (1) All prescription drug samples received by the pharmacy are obtained pursuant to a written, signed request of a licensed practitioner affiliated with that institution or clinic. "Affiliation is interpreted to mean that the requesting practitioner sees patients at that facility, and
 - (2) the pharmacy retains a copy of all written, signed prescription drug sample requests,

and

(3) prescription drug samples are stored separately from the prescription drug products held for sale (retail stock), and

(4) records of prescription drug sample receipt and dispensing are maintained separately from records or prescription drug products held for sale and sold (retail stock), and

(5) a relationship exists between the health care entity and the pharmacy which is evidenced by a written business or contractual agreement, or other written documentation, and

(6) prescription drug samples are dispensed by the pharmacy to patients in the manufacturer's or distributor's original packaging, and

(7) the pharmacy and its employees do not sell, purchase, or trade or offer to sell, purchase, or trade any prescription drug sample.

§15-1-10 REFILLING PRESCRIPTION ORDERS

10.1 It is unlawful for a pharmacist or technician to refill any prescription order containing a drug wherein the label of the original container bears the statement, "CAUTION: Federal Law Prohibits Dispensing Without Prescription", or "RX Only", unless the practitioner has authorized the refill by written notation on the original prescription order. Subsequent refill authorization shall be treated as a new prescription order.

10.2 If a prescription order is refillable, the date of the refill and the hand written initials of the pharmacist shall be recorded upon the original written prescription order or if electronic recording is used a daily printout of all prescription orders filled must be made and verified and signed by each pharmacist responsible for that days work or a log may be kept of each refill number and this log must be signed by each pharmacist.

10.3 No prescription order may be refilled after fourteen (14) months from the original dispensing.

10.4 The refilling of prescription orders for controlled

substances is limited by provisions of the Uniform Controlled Substances Act, West Virginia Code Chapter 60A, article 3 section 308.

§15-1-11 TRANSFERRING PRESCRIPTION ORDERS BETWEEN PHARMACIES.

11.1 In the event that a pharmacy is not able to provide the medication when needed by the patient pursuant to an authorized refill, the pharmacist shall, upon the request of the patient, transfer the prescription information to the pharmacy designated by the patient.

11.2 The transfer of original prescription order information for the purpose of refilling the prescription order is permissible between pharmacies if the transfer is communicated directly between two pharmacists, and the following occurs:

a. The transferring pharmacist:

1. Writes the word "VOID" on the face of the original prescription order, and
2. Records on the reverse of the original prescription the name, address, Drug Enforcement Administration (DEA) registry number of the pharmacy to which it was transferred and the name of the pharmacist receiving the prescription information, and
3. Records the date and time of the transfer and the name of the pharmacist transferring the information.

b. The pharmacist receiving the transferred prescription order information:

1. Writes the word "TRANSFER" on the face of the transferred prescription, and
2. Provides all the information required to be on a prescription and includes:
 - A. Date of issuance of the original prescription, and

- B. Number of refills on the original prescription, and
- C. Date of original dispensing, and
- D. Number of valid refills remaining and date of last refill, and
- E. Pharmacy name, address, DEA registry number and the original prescription number from which the prescription information was transferred; and
- F. Name of transferring pharmacist.

c. Nothing in this rule shall prevent the giving of a copy of a prescription clearly marked "For Information Only" to a patient.

d. A computer record may be used if it reflects the fact that the original prescription order has been voided and shall contain all the other information required above.

11.3 No pharmacy shall refuse to transfer information about a previously dispensed prescription to another pharmacy when requested by the patient. Prescription information shall be transferred in accordance with this rule as soon as possible in order to assure that the patient's drug therapy is not interrupted.

11.4 Information on a prescription is the property of the patient and is intended to authorize the dispensing of a specific amount of medication for use by the patient. Original and transferred prescription drug orders shall be maintained for a period of five (5) years from the date of last refill; maintained on-site for a period of twelve (12) months from date of last refill, and available within 48 hours of request if date of last refill is between one (1) and five (5) years.

11.5 Pharmacies accessing a common electronic file or database used to maintain required dispensing information are not required to transfer prescription drug orders or information for dispensing purposes between or among pharmacies participating in the same common prescription file, provided, however, that any such common file shall contain complete records of each prescription drug order and refill dispensed, and, further, that a hard copy record of each prescription drug order transferred or accessed for purposes of refilling shall be generated and maintained at the pharmacy refilling the prescription drug order or to which the prescription is transferred.

§15-1-12 RETURNING DRUGS AND DEVICES.

12.1 No pharmacist or pharmacy shall accept from a patient or other

person, except for the purpose of destruction, any part of any unused prescription drug unless:

- (a) The returned drugs are in a manufacturer's original, sealed and visibly tamper-proof container, or
- (b) The returned drugs are in extemporaneously prepared unit dose packaging, as defined in this rule, and are returned within an institution or by an institution, and

© all drugs are identified as to lot and control number and expiration date.

12.2 No controlled substance may be returned and placed in stock for reuse or resale under any circumstances.

12.3 Any drugs returned must be recorded in a log which lists the name of the patient, the name and strength of the drug with name of manufacturer, prescription number (if applicable), the amount of the drug returned and the date of the return. The log shall contain the signatures of the receiving pharmacist and a registered nurse employed by the facility and the log must be retained for at least two (2) years.

§15-1-13 DRUG PRODUCT SELECTION AND SUBSTITUTION

13.1 The Board adopts the drug products in the Approved Drug Products with Therapeutic Equivalence Evaluations published by the Food and Drug Administration, Center for Drug Evaluation and Research, (commonly called the "Orange Book") with "AA", "AB", "AN", "AO", "AP" or "AT" ratings as acceptable products for generic substitution as required by West Virginia Code §30 -5- 12b.

13.2 The Board establishes the following formulary of drugs which it finds have no therapeutic equivalents, unless a substitutable drug is published in the Orange Book:

a. Dilantin

b. Synthroid

c. Lanoxin.

d. Premarin

§15-1-14. REGULATIONS GOVERNING PHARMACY PERMITS.

14.1 Pharmacy license and annual registration.

A pharmacy opening for business must first secure a license from the Board and comply fully with WV Code §30-5-14 before it may lawfully conduct a pharmacy . The annual registration for renewal of permits is effective on the

first day of July of each year and expires on the thirtieth day of June of each year.

14.2 Application for permits.

The Board shall require and provide for the annual registration of every pharmacy doing business in this state. Any person desiring to operate, maintain, open or establish a pharmacy in West Virginia, shall apply to the Board for a permit to do so. Every place so registered shall be under the direct charge of a pharmacist, designated the Pharmacist-in-charge, and shall operate in compliance with state and federal laws and rules and regulations.

a. The application for a new permit shall be made on a form prescribed and furnished by the Board, which when properly executed shall indicate, but not be limited to the following;

1. identification of the owner that is applying for the permit, and

2. the name under which the business will be operated and which will be used in advertising, and

3. the physical location of the pharmacy including;

A. Street and number.

B. City and County, and

4. mailing address of the pharmacy if different from physical location, and

5. name and license number of the pharmacist-in-charge, and

6. name and license number(s) of other pharmacist(s) regularly employed at the pharmacy, and

7. name and registration number(s) of pharmacy technician(s) employed at the pharmacy, and

8. hours of operation, and

9. detailed floor plans for the pharmacy made to scale.

b. Separate applications shall be made and separate permits shall be issued for each individual pharmacy.

c. Pharmacies renewing permits must have the current edition of the three volume set of the USP-DI and its supplements or appropriate text(s) approved by the board and shall have such equipment as may be necessary to render such service as public needs dictate, or the proper protection of the public health may require, and as required by other sections of this rule. If the United States Pharmacopeial Convention, Inc. discontinues publication of the USPDI, then the Board shall choose appropriate text(s) to replace the USPDI.

d. Each initial application for a pharmacy permit shall be accompanied by a fee of one hundred fifty dollars (\$150.00), or an amount as set by statute.

e. Any pharmacy compounding parenteral, enteral or ophthalmic preparations shall first obtain a parenteral/enteral compounding permit.

14.3 Issuance of permit.

a. A permit to conduct a pharmacy will be issued to the applicant by the Board after a satisfactory inspection of the facility.

b. The permit registers the pharmacy to which it is issued and is not transferable. It is issued on the joint application of the owner and the pharmacist-in-charge, on the sworn statement that it will be conducted in accordance with the provisions of the federal and state laws and attendant Rules and Regulations.

c. Permits must be posted in a visibly conspicuous place; the permits may not be in a location that is out of sight of the dispensing area.

14.4 Renewal of permit.

a. The annual renewal of permits takes place on the first day of July of each year. The fee for annual renewal is seventy five dollars (\$75.00) or an amount as set by statute. Permits issued under this section are not transferable and expire on the thirtieth day of June of each calendar year. Renewal applications should be delivered to the Board office by the fifteenth day of June to allow time for processing.

b. If application for renewal is not made by the first day of August each year, the license becomes null and void. To renew a lapsed permit the Board must re-inspect the pharmacy and the

permittee must pay a fee of one hundred fifty dollars (\$150.00) or an amount as set by statute for the permit and one hundred fifty dollars (\$150.00) or an amount as set by statute.

14.5 Surrender of permit.

a. When a pharmacist-in-charge in whose name a permit has been issued leaves the full time employment of that pharmacy; i.e. at least thirty -six (6) hours per week, or for any other reason ceases to be in complete and actual charge of the pharmacy, he or she is responsible to immediately notify the Board, in writing, of the termination or change of his or her services and to return the original pharmacy permit to the Board office with the date of the change noted on the permit. A copy of the permit shall be made and posted in the pharmacy with the newly designated pharmacist-in-charge written on the permit in indelible ink. Failure by the pharmacist-in-charge to notify the Board and return the pharmacy permit shall result in disciplinary action being taken by the Board against the offending pharmacist.

b. It is the duty of a pharmacy owner to notify the Board, immediately and in writing, of the termination of the full time employment of the pharmacist-in-charge; i.e. at least thirty-six (36) hours per week, as shown on the

permit, or any other action which causes the pharmacist-in-charge to cease being in complete and actual charge of the pharmacy. A new pharmacist-in-charge must immediately be designated and written on the pharmacy permit in indelible ink. Until a pharmacist-in-charge is designated and written in indelible ink on the pharmacy permit, the pharmacy shall not operate. The further operation of the pharmacy, in the absence of a designated pharmacist-in-charge is forbidden. Each day of operation in the absence of a designated pharmacist-in-charge is considered a separate offense. Notification of the replacement must be reported to the Board in writing within thirty (30) days upon a form provided by the Board with the appropriate fee. Upon receipt of this notification, the Board will provide a newly printed permit to the pharmacy.

c. Whenever a pharmacy is moved to a new address or different location within the current building, an application for a new permit must be made with the appropriate fees being paid and the facility must be inspected before issuance of a new permit.

d. When a pharmacy changes ownership the permit becomes null and void and a new permit must be obtained from the Board.

14.6 Violations.

a. The violation of any of these rules or regulations shall be considered cause for disciplinary action.

b. All pharmacists must notify the Board immediately, in writing, of any change in employment or change of address. Failure to notify the Board shall be sufficient cause for disciplinary action.

c. It shall be the duty of any person who employs any licensed pharmacist to immediately notify the Board, in writing, of any discharge, termination, or change in the place of employment of the licensed pharmacist or change in the status of the pharmacist-in-charge. Failure to notify the Board is sufficient cause for disciplinary action.

d. It shall be the duty of any person who employs any licensed pharmacist to immediately notify the Board, in writing, of any complaints registered against a pharmacist regarding his or her practice of pharmacy, and to report any knowledge or suspicion that a pharmacist has violated any pharmacy law or regulation.

14.7 Security.

In the event that a pharmacy is to be operated for a period less than the regular business hours of the entire store or institution, the following requirements apply:

a. The pharmacy area shall be separated from other departments of the store or institution by a floor to ceiling, physical barrier or partition, with entry doors that can be securely locked. If the pharmacist is always present when other persons are in the store or institution, the pharmacy area need not be enclosed by a physical 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, prepared and/or dispensed.

b. Physical barriers may be either of solid material or movable curtain type;

1. If the barrier is of a solid material it must be of sufficient strength and thickness that it may not be easily removed and must be equipped with keyed locks.

2. If the barrier is of a movable material it must be

constructed of material strong enough to prevent breakage and must have openings or interstices not large enough to permit removal of any items in the protected area and be equipped with keyed locks.

c. A device for the detection of breaking and/or entering shall be installed in each prescription department in each pharmacy. The installation and the device shall be based on accepted burglar alarm industry standards, and shall be subject to the following conditions:

1. The device shall be a sound, microwave, photoelectric, ultrasonic, or other accepted and suitable device.
2. The device shall be maintained in operating order and shall have an auxiliary source of power.
3. The device shall fully protect the prescription department and shall be capable of detecting breaking and/or entering by any means when activated.
4. Deactivation of the alarm system for the prescription department shall be restricted to the pharmacists working at

the pharmacy, and the system shall be activated whenever a pharmacist is not on duty.

5. This rule shall not apply to pharmacies which have been granted a permit prior to the effective date of this regulation provided that a previously installed security system is in place, that no structural changes are made in the prescription department, that no changes are made in the security device, that the prescription department is not closed while the rest of the business remains open, and provided further that a breaking and loss of drugs does not occur.

6. This section does not apply to pharmacies which are open and staffed by pharmacists twenty four (24) hours a day.

d. The door keys and alarm activation and de-activation codes to the prescription areas shall be subject to the following:

1. Only pharmacists practicing at this pharmacy and authorized by the pharmacist-in-charge shall have possession of any keys to the locks on the doors of the prescription

area.

2. The pharmacist may place a key and the alarm access code, if required, in a sealed envelope or other container with the pharmacist's signature across the seal in a vault or safe within the store or other secured place.

e. In the absence of a pharmacist, a sign with a minimum of four (4) inch letters shall be prominently displayed stating:

"Pharmacy Closed. No Pharmacist On Duty", and the pharmacist shall secure the pharmacy by implementing any barriers and security devices prior to leaving the pharmacy.

f. Each outpatient pharmacy area shall have a separate phone listing with separate number and which may only be answered in the pharmacy area. No extensions of this number are allowed outside of this area.

g. Written prescription and refill requests may be delivered to a pharmacy at any time. If no pharmacist is present the orders must be deposited in 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 prescription

order(s).

h. Completed prescription orders shall be bagged and kept in the pharmacy and cannot be removed from the pharmacy unless the pharmacist is present and the removal is for the immediate delivery to the patient, person picking up the prescription(s) for the patient, or person delivering the prescription(s) to the patient at his residence or similar place. If such person is unknown to the pharmacist then his or her identity shall be established by photo identification card.

i. Mobile pharmacy units are prohibited. Completed prescriptions must be picked up at or delivered from the same pharmacy at which they were prepared.

j. Emergency facilities to provide pharmaceutical services during emergency conditions or natural disasters may be approved by the Board for a period not to exceed 180 days.

14.8 Professional Work Environment

a. Any pharmacy operating in excess of twelve (12) hours shall be required to operate with two (2) pharmacists working each day. No pharmacist may work more than twelve (12) hours within a twenty-four (24) hour period.

b. Any pharmacy dispensing more than fifteen (15) prescriptions per hour must have a registered pharmacy technician assisting the pharmacist during that hour. The pharmacist-in-charge shall determine the work schedule for pharmacy technicians based upon prior dispensing records.

§15-1-15. EQUIPMENT, FACILITIES AND RECORD SYSTEMS

15.1 The Board shall not issue a permit to operate a pharmacy unless the necessary professional, physical, and technical equipment requirements have been fulfilled.

(a) The pharmacy shall have a separate area for patient counseling which will ensure the privacy and confidentiality of such discussions; and which has adequate space to use any equipment, visual aids, and publications to provide proper counseling. This rule does not apply to pharmacies which have been granted a permit prior to the effective date of this rule.

(b) All standards set by the United States Pharmacopeial Convention are the minimum standards to be followed by all licensed pharmacists and pharmacies during the course of the professional practice of pharmacy.

15.2 Every pharmacy shall continually possess the following:

a. A sanitary method of measuring and dispensing between five (5) and 250 milliliters

of liquids.

b. Mortars and pestles, spatulas, ointment pads, typewriter, counting trays, balance and weights, and any other equipment or supplies necessary to satisfy the requirements of this rule.

c. For pharmacies compounding ophthalmic preparations, IV additives, enteral nutritional products or other pharmaceuticals requiring more sophisticated techniques, the proper equipment and facilities to prepare sterile products and meet the requirements of good compounding practice are required.

d. Adequate facilities for the proper storage of pharmaceuticals; all areas where drugs and devices are stored shall be dry, well-lighted, well-ventilated, and maintained in a clean and orderly condition; storage areas shall be maintained at temperatures which will ensure the integrity of the drugs prior to their dispensing as stipulated by the USP and/or the manufacturer's or distributor's labeling unless otherwise indicated by the Board.

e. Facilities for the safe storage of controlled substances if the dispersion method is not used.

f. An acceptable system of keeping records of prescriptions

dispensed as required by the Uniform Controlled Substance Act,
and any Rules and Regulations pertaining thereto.

g. A system of keeping patient profiles which allows immediate
review of at least the following data about individuals;

1. Patient biographical data, and

2. Patient medications, and

3. Patient disease state(s), and

4. Pharmacist's notes, and

5. Any other data necessary to make rational judgements about
pharmaceutical care.

h. The most currently available Pharmacy Law Book and book of
Rules and Regulations as published by this Board.

§15-1-16. STERILE PHARMACEUTICAL COMPOUNDING

16.1 Permitting and control.

- a. A pharmacy compounding or mixing prescription orders for sterile solutions or suspensions to be administered parenterally, enterally, by irrigation or ophthalmic drops shall obtain a Sterile Pharmaceutical Compounding Permit from the Board in addition to a pharmacy license. The permit will be issued after a satisfactory inspection of the completed facilities.

- b. The compounding and preparation of sterile prescription orders shall be accomplished in a pharmacy environment subject to the West Virginia Code and the Rules and Regulations of this Board and all Federal laws and regulations.

- c. Sterile compounding or mixing shall be under the supervision and control of a pharmacist who shall be present on duty during all hours of prescription preparation.

16.2 Application for permit

An applicant for a Sterile Pharmaceutical Compounding Permit shall provide the Board with the following:

- a. A completed Board application form, and
- b. A copy of the Policy and Procedure Manual, and
- c. Statement and plans showing how the applicant meets the minimum requirements regarding space, equipment, supplies and publications.

16.3 Compounding environment.

The environment for this practice shall be separate rooms set apart from all other activities. The environment shall facilitate controlled aseptic conditions and meet all standards of the United States Pharmacopeial Convention (USP) including:

- a. Separation from other areas by a 'clean' entry room or vestibule, and
- b. Adequate space for at least one certified air flow hood in each sterile admixture compounding room along with other necessary equipment and supplies, and

c. Sufficient space to allow pharmacists and other employees room to work to safely and accurately fulfill their duties.

16.4 General requirements.

a. Special handling and packaging shall be available to maintain stability of the prepared prescription orders during delivery to the patient.

b. All prescriptions shall include labeling, in addition to that required by other state or federal law or rule, showing:

1. Expiration date, and
2. Date of preparation, and
3. Control number.

© A pharmacy with a Sterile Pharmaceutical Compounding Permit shall provide a twenty four (24) hour telephone number to contact its pharmacist(s) for use by its patients or other health care providers who may be administering its prescriptions.

16.5 Operating requirements.

A pharmacy with a Sterile Pharmaceutical Compounding Permit shall comply with the following requirements;

a. A Policy and Procedure Manual shall be maintained either separately or as a section of the Pharmacy Policy and Procedure Manual, and shall contain at least the following:

1. A statement in detail of the objectives and operational guidelines of the permittee, and

2. A Description of a Quality Assurance Program which monitors:

A. personnel qualifications,

B. Continuing training and performance of staff,

C. Equipment and facilities requirements,

D. Standards and sampling for compounding and dispensing, and

E. Any other requirements of this Board or the USP.

b. The pharmacy shall provide protection for its personnel

involved in the handling of cytotoxic agents by:

1. Utilizing the proper equipment and supplies, and

2. Having a special section of the Policy and Procedure

Manual devoted to handling procedures, including:

A. Statement that Compounding shall be conducted within a properly certified vertical airflow hood,

B. Discussion of the proper use of protective garb,

C. Description of proper techniques to prevent all contamination of the prescription and chemical contamination of the person preparing the prescription, and

D. Disposal procedures of cytotoxic agents in accordance with accepted professional standards and applicable law.

16.5 Space, Equipment, Supplies and Reference Works.

The minimum requirements for space, equipment, supplies and reference works, which are in addition to those required for a regular pharmacy permit, shall be met by a pharmacy operating under a Sterile Pharmaceutical Compounding Permit and include the following:

a. Space.

1. The area for preparing sterile preparations, as provided for in this rule and referred to as the sterile admixture room, shall be set apart from general work and storage areas.
2. Adequate air conditioning or positive air pressure must be maintained to prevent easy entry of outside air.
3. An operating sink with hot and cold running water must be located in the “clean” anteroom adjoining the buffer room according to USP standards.
4. The compounding area must be large enough to allow working room for all personnel

to be in the room at one time without interference with each other.

5. The buffer room must contain at least one certified airflow hood, vented if necessary.

b. Equipment.

At least the following equipment shall be available and shall be maintained in working order:

1. Properly certified airflow hood(s),

2. Adequate refrigerator and freezer space,

3. Sink and wash area in the anteroom as provided in this section, and

4. Appropriate waste containers for:

A. Used needles and syringes, and

B. All cytotoxic waste including disposable apparel used in its preparation.

c. Supplies

Minimum supplies on hand shall include but not be limited to:

1. Gloves, masks, and disposable gowns,
2. Disposable syringes and needles in necessary sizes,
3. Disinfectant cleaning material for equipment surfaces,
4. Disposable towels,
5. Liquid bactericidal cleanser for hand washing, and
6. Spill kits for cytotoxic agent spills.

d. Reference works.

Minimum reference works required in a pharmacy with a Sterile Pharmaceutical Compounding permit shall be:

1. A current edition of the three volume set of the USP-DI with supplements, or

referenced text(s) designated by the Board.

2. Handbook of Injectable Drugs published by the American Society of Hospital Pharmacists, or its equivalent, and

3. Procedures for Handling Cytotoxic Drugs by the American Society of Hospital Pharmacists, or its equivalent.

§15-1-17. LICENSURE AND CONTROL OF NUCLEAR PHARMACIES

17.1 General Requirements.

a. A pharmacy providing radiopharmaceutical services, and compounding or mixing prescription orders for radiopharmaceuticals shall obtain a Nuclear Pharmacy license from the Board. The license will be issued after satisfactory inspection of the completed facilities. The license will be issued only when the pharmacist-in-charge is a qualified nuclear pharmacist and the pharmacy has been approved by the appropriate federal agency.

b. Pharmacies providing regular pharmaceutical care in addition to radiopharmaceutical services shall comply with all

regulations applicable to pharmacies in general. Pharmacies providing only radiopharmaceutical services shall comply with all regulations relating to sanitary conditions, security, record keeping, and pharmaceutical care not directly related to dispensing non-radioactive drugs.

17.3 Space.

- a. The nuclear pharmacy area shall be separate from all other pharmacy areas for non-radioactive drugs and shall be secured from unauthorized personnel.
- b. A pharmacy handling radiopharmaceuticals shall provide a radioactive storage and product decay area which meets the requirements of the appropriate federal agency.

17.4 Dispensing and labeling.

- a. A prescription order for a radiopharmaceutical shall be dispensed in a package that is properly labeled.. A pharmacy may furnish radiopharmaceuticals only to practitioners for administration to patients and for the occasional transfer to another pharmacist.

b in addition to any label requirements of the Board for nonradioactive drugs, the immediate outside container of a radiopharmaceutical to be dispensed shall also be labeled with:

1. the standard radiation symbol,
2. The words "CAUTION--Radioactive Material",
3. the name of the radio nucleotide,
4. the chemical form,
5. The amount of radioactive material contained, in millicuries or microcuries,
6. The volume in milliliters, if the material is a liquid,
7. The requested calibration time for the amount of radioactivity contained, and
8. The practitioner's name and the assigned lot number.

c. The immediate inner container shall be labeled with:

1. The standard radiation symbol,
2. The words "CAUTION--Radioactive Material", and
3. The prescription number.

d. The amount of radioactivity shall be determined by radiometric methods for each dose immediately prior to dispensing.

17.5 Distribution.

Nuclear pharmacies may distribute approved radioactive drugs to any receiving pharmacy if the receiving pharmacy does not process the radioactive drugs in any manner nor violate or change the product packaging except dividing the product into individual doses by a licensed pharmacist.

§15-1-18. SANITARY REGULATION OF PHARMACIES.

- 18.1 The pharmacist-in-charge of a pharmacy is responsible to maintain the prescription room and equipment therein in a clean and orderly condition and in good operating order at all times.
- 18.2 The prescription counter, which includes any area used for providing pharmaceutical care, shall be used for no other purpose than for the compounding and dispensing of prescriptions and shall be maintained free from dust and in orderly condition.
- 18.3 The sink, with hot and cold running water, in the pharmacy shall be used for no other purpose than the cleaning of equipment and articles used in the preparation of prescriptions and the cleaning of hands of those preparing and dispensing prescriptions.
- 18.4 All pharmacists and interns, when providing pharmaceutical care, shall wear a clean white coat or jacket with an identifying tag showing name and job designation, and are required to keep themselves and their apparel in a clean and sanitary condition. All pharmacy technicians and pharmacy technician trainees shall wear an identifying tag showing name and job designation and sanitary attire and a coat, jacket, or apron of a color other than white.

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

18.6 The prescription room and anywhere drugs are stored shall be well ventilated, temperature controlled, free from obnoxious odors and equipped with adequate lighting.

18.7 Only persons who are licensed or registered by the Board or are pharmacy technician trainees, except agents of the Board, may be present in the prescription area when dispensing and pharmaceutical care is being provided.

§15-1-19 SHARING COMPENSATION.

19.1 The independent judgement 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 permittee, 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 of prescriptions.

§15-1-20 RULES OF PROFESSIONAL CONDUCT.

20.1 Statement of purpose.

a .The practice of pharmacy is a profession dedicated to the service of public health which requires knowledge, skill and integrity. The practice of pharmacy is restricted to persons who possess special education and qualifications and licenses to them privileges which are denied to others. The pharmacist recognizes his or her responsibility to the public in providing pharmaceutical care, providing safe storage and handling of drugs, in dispensing drugs and devises and the dissemination of information on drugs and devices to other health care specialists. For these reasons he or she is obligated to the highest standards of professional conduct.

b. In order that the citizens of West Virginia shall receive the best possible pharmaceutical care, and that the public health, welfare and safety be fully protected, the following rules of professional conduct shall be followed at all times..

20.2 Freedom of practice.

a. 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 interfere in the provision of pharmaceutical care or offer pharmaceutical services under any terms or conditions which tend to impair the free and complete exercise of the professional skill and judgement of another pharmacist. He or she shall at all times practice this profession in conformity with federal and state laws and regulations and the rules of this Board.

b. Every pharmacist, when practicing the profession of pharmacy, shall provide pharmaceutical care as defined in Rule 15-1-2.1

(x).

20.3 Uncertain Prescription orders.

a. No pharmacist shall compound or dispense any prescription order which, in his or her judgement and/or professional opinion, contains any error, irregularity or ambiguity. A conference with the prescriber is mandatory before dispensing, if there is any doubt that the prescription order is not legal or correct or issued for a legitimate medical purpose.

20.4 Professional services.

a. It is the duty of a practicing pharmacist to make his or her professional services available to the public. Every licensed pharmacy, except for a nuclear pharmacy, shall provide pharmaceutical care, including the compounding and dispensing of all prescription orders which may reasonably be expected to be compounded or dispensed by pharmacists.

20.5 Confidential information.

a. No pharmacist shall exhibit, discuss or reveal any confidential information as defined in this rule with any person other than:

1. Agents of the Board engaged in the performance of their official duties,
2. Another pharmacist or pharmacy technician when necessary,
3. The patient or his or her authorized representative,
- 4 The prescriber or other members of the health care team treating the patient,
5. Any person authorized by law to receive the information.

20.6 Diagnosis or treatment.

a. No pharmacist shall attempt to diagnose any disease, illness or organic disorder. This does not preclude evaluation after a diagnosis is made by a practitioner.

20.7 Coded prescription orders.

a. No pharmacist shall 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 use, other than those normal letters, numbers, words or symbols recognized by the profession of

pharmacy as a means of conveying information by prescription order.

20.8 False or misleading advertising.

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

20.9 Promotion of and reliability of drugs.

a. No pharmacist 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 tends to cause such drugs to be used in excess of the requirements established in a legitimate physician-patient-pharmacist relationship.

b. No pharmacist shall purchase, accept, compound or dispense any medicinal preparation, whether by prescription order or otherwise, which in his or her professional judgement is not therapeutically reliable.

20.10 Prescription order forms.

No pharmacist shall provide any practitioner with prescription order forms imprinted with any reference to a pharmacy or pharmacist.

20.11 Place of practice.

No place of practice or location shall be maintained to solicit, accept or dispense prescription orders other than a pharmacy for which a permit has been issued by the Board.

20.12 Physician agreements.

No pharmacist shall enter into or engage in any agreement or arrangement with any 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 another; nor shall he or she enter into an agreement of any kind whereby in any way a patient's free choice of pharmacist or pharmacy is limited.

20.13 Duties and responsibilities.

It is the duty and responsibility of a pharmacist in every pharmacy to perform, at the minimum, the following duties:

a. To accept all new prescription orders transmitted by oral communication, immediately reduce them to writing and document the same by entering on the prescription order form:

1. the name of the caller,
2. the time and date of transmission, and
3. the hand -written initials of the receiver.

b. To dispense, deliver, or distribute a prescription drug order accurately as prescribed; accurately as prescribed meaning:

1. To the correct patient (or agent of the patient) for whom the drug or device was prescribed,
2. with the correct drug in the correct strength, quantity, and dosage form ordered by the practitioner, and
3. With correct labeling (including directions for use) as ordered by the practitioner; provided, however, that nothing herein shall prohibit generic

substitution by the pharmacist.

- c. To ensure that his or her initials are on all prescription labels dispensed while he or she is on duty, whether prepared by him or her or prepared by a pharmacy technician under his or her supervision.

- d. To ensure that his or her initials are on all prescription order forms dispensed while he or she is on duty, whether prepared by him or her or prepared by a pharmacy technician under his or her supervision.

- e. To possess a list of the drugs which may be prescribed by a physician's assistant with prescriptive privileges and also to possess the written list of drugs excluded from the prescriptive authority of nurse practitioners prior to dispensing prescription orders from such prescribers.

- f. To counsel or inform patients about their drug(s). An offer to counsel shall be made by the pharmacist or designee in an oral communication with the patient, care giver or agent who presents a new prescription order, unless in the professional judgement 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 exercise of and reasons for such judgement shall be documented including the hand- written pharmacist's initials. An offer to counsel has not been made by a mere question of whether the patient has any questions.

1. In those cases, when the offer to counsel, as described in this subsection, has been accepted, a pharmacist who provides pharmaceutical care to patients shall discuss with the patient or care giver or agent who presents a new prescription order, any matter which in the exercise of the pharmacist's professional judgement the pharmacist considers significant, which may or may not include the following:

A. The name of and a description of the medication,

B. the dosage form, route of administration, dosage, 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 actions required if they occur,

E. Techniques for self-monitoring drug therapy,

F. Proper storage,

G. Prescription refill information; and

H. Any action to take in the event of a missed dose.

2. Nothing in this sub-section requires a pharmacist to provide consultation if the patient, care giver, or agent does not accept the offer to counsel. If counseling is refused it shall be documented, followed by the initials of the recording pharmacist.

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

g. To make a reasonable effort to obtain, record, and maintain at least the following information at the individual

pharmacy:

1. The patient's name, address, telephone number, date of birth or age, and gender,
 2. The patient's individual history including disease state and states, known allergies and drug reactions, and a comprehensive list of medications and relevant devices; and
 3. The pharmacist's comments regarding the patient's drug therapy.
- h. To perform all of the functions in this section,
- I. To adequately supervise all interns, registered pharmacy technicians and pharmacy technician trainees,
- j. To perform any other functions of any nature or kind which:
1. Require the knowledge, ability or skill of a licensed

pharmacist, and

2. Improve the therapeutic outcome to the patient of the pharmaceutical care provided by the pharmacist.

20.14 Evasion or violation of the rules of professional conduct.

- a. These rules of professional conduct are intended to govern all pharmacists licensed by this Board and improve the pharmaceutical care provided to the citizens of West Virginia.
- b. The evasion or violation of any of the parts of this rule by a licensed pharmacist or person with a permit to operate a pharmacy shall result in disciplinary action.
- c. Any pharmacist who knowingly accepts and continues employment with any permittee 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.

20.15 Publication and posting of rules.

The Board shall make a copy of these Rules of Professional Conduct available to every pharmacy and pharmacist licensed by the Board. A copy of the rules shall be visibly posted in the prescription area of every pharmacy.

§15-1-21 Duties and Responsibilities of the Pharmacist-in-Charge

21.1 (a) A pharmacy may not operate without a pharmacist-in-charge(PIC), who shall be designated on the application for a pharmacy license, and in each renewal thereof. A pharmacist may not serve as PIC unless he or she is physically present in the pharmacy a sufficient amount of time to provide supervision and control. A pharmacist may not serve as PIC for more than one pharmacy at any one time.

(b) The pharmacist-in-charge has the following responsibilities:

1. developing quality assurance programs for pharmacy services designed to objectively and systematically monitor and evaluate the quality and appropriateness of patient care, pursue opportunities to improve patient care, and resolve identified problems. Quality assurance programs shall be designed to prevent and detect drug diversion.

2. The PIC shall develop or adopt, implement, and maintain a Pharmacy Technician Training Manual for the specific practice setting of which he or she is

in charge. He or she shall supervise a training program conducted pursuant to the training manual for all individuals employed by the pharmacy who will assist in the practice of pharmacy. The PIC shall be responsible for maintaining a record of all technicians successfully completing the pharmacy's technician training program and shall attest to the Board, in a timely manner, those persons who, from time to time, have met the training requirements necessary for registration with the Board.

3. Establishing policies and procedures for the procurement, storage, security, and disposition of drugs and devices.

4. Assuring that all pharmacists and interns employed at the pharmacy are currently licensed and that all pharmacy technicians employed at the pharmacy are currently registered with the board.

5. Notifying the board immediately of any of the following changes:

- A. Change of employment or responsibility as the PIC,
- B. Change of ownership of the pharmacy,
- C. Change of address of the pharmacy, or
- D. Permanent closing of the pharmacy.

6. Making or filing any reports required by state or federal laws and rules.

7. Responding to the board regarding any minor violations brought to his or her

attention.

8. Establishing policies and procedures for maintaining the integrity and confidentiality of prescription information and patient health care information, or verifying the existence thereof and ensuring that all employees of the pharmacy read, sign, and comply with the established policies and procedures.

9. Providing the board with prior written notice of the installation or removal of an Automated Pharmacy System. Such notice must include, but is not limited to:

- A. The name and address of the pharmacy,
- B. The location of the automated equipment, and
- C. The identification of the responsible pharmacist.

c. The PIC shall be assisted by a sufficient number of pharmacists and pharmacy technicians as may be required to competently and safely provide pharmacy services.

1. The PIC shall maintain and file with the Board, on a form provided by the Board, a current list of all pharmacy technicians assisting in the provision of pharmacy services.

2. The PIC shall develop and implement written policies and procedures to specify the duties to be performed by pharmacy technicians. The duties and responsibilities of these personnel shall be consistent with their training and experience. These policies and procedures shall specify that pharmacy technicians are to be personally and directly supervised by a pharmacist stationed within the same work area who has the ability to control and who is responsible for the

activities of pharmacy technicians, and that pharmacy technicians are not assigned duties that may be performed only by a pharmacist.

§15-1-22 Manner of Issuance of a Prescription

22.1 A prescription, to be effective, must be issued for a legitimate medical purpose by a practitioner acting within the course of legitimate professional practice.

(a) A prescription must be communicated directly to a pharmacist in a licensed pharmacy. A prescription, including that for a controlled substance listed in Schedules II through V, may be communicated in written form. A prescription, including that for a controlled substance listed in Schedules III through V, and, in certain situations, that for a controlled substance listed in Schedule II, may be communicated orally (including telephone voice communication) or by way of electronic transmission.

(b) If communicated orally or by way of electronic transmission, the prescription shall be immediately reduced to a form by the pharmacist that may be maintained for the time required by laws and rules.

© A prescription for a Schedule II controlled substance may be communicated orally and/or by way of electronic transmission only in the following situations and/or with the following restrictions. Otherwise, a prescription for a Schedule II controlled substance

must be communicated in written form.

(1) A prescription for a Schedule II controlled substance may be communicated by the practitioner or the practitioner's agent by way of electronic transmission, provided the original written, signed prescription is presented to the pharmacist for review prior to the actual dispensing of the controlled substance, except the hard copy of the electronic transmission may serve as the original, written prescription in the following instances:

(A) the prescription for a Schedule II narcotic substance is to be compounded for the direct administration to a patient by parenteral, intravenous, intramuscular, subcutaneous, or intraspinal infusion, or

(B) the prescription for a Schedule II controlled substance is for a resident of a Long Term Care Facility, or

(C) the prescription for a Schedule II controlled substance is for a patient under the care of a hospice certified by Medicare or licensed by the state.

The practitioner or Practitioner's agent must note on the prescription that the patient is a hospice patient.

(d) In the case of an emergency situation, a prescription for a Schedule II controlled substance may be communicated by the practitioner orally or by way of electronic transmission, provided that:

(1) the quantity prescribed and dispensed is limited to the amount adequate to treat the patient during the emergency period (dispensing beyond the emergency period must be pursuant to a written prescription signed by the prescribing

practitioner);

(2) the orally communicated prescription shall be immediately reduced to writing by the pharmacist, or, if necessary, the prescription communicated by way of electronic transmission shall be immediately reduced to a hard copy;

(3) if the prescribing practitioner is not known to the pharmacist, he or she must make a reasonable effort to determine that the oral authorization came from a registered practitioner, which may include a callback to the practitioner using the practitioner's phone number as listed in the telephone directory and/or other good faith efforts to insure his identity; and

(4) within seven (7) days after authorizing an emergency oral prescription, the practitioner shall cause a written prescription for the emergency quantity prescribed to be delivered to the dispensing pharmacist. The prescription shall have written on its face "Authorization for Emergency Dispensing" and the date of the orally or electronically transmitted prescription. The written prescription may be delivered to the pharmacist in person or by mail, but if delivered by mail, it must be postmarked within the seven (7) day period. Upon receipt, the dispensing pharmacist shall attach this written prescription to the emergency oral prescription which had earlier been reduced to writing or to the hard copy of the electronically transmitted prescription. The pharmacist shall notify the nearest office of the U.S. Drug Enforcement Administration if the prescribing practitioner fails to deliver a written prescription.

(e) A prescribing practitioner may authorize his or her agent to communicate a

prescription orally or by way of electronic transmission to a pharmacist in a licensed pharmacy, provided:

- (1) the identity of the transmitting agent is included in the order,
- (2) the prescription is transmitted directly to a pharmacist in a licensed pharmacy of the patient's choice with no intervening person having access to the prescription,
- (3) the prescription shall identify the transmitter's phone number for verbal confirmation, the time and date of transmission, and the identity of the pharmacy intended to receive the transmission, as well as any other information required by federal or state law,
- (4) the pharmacist shall exercise professional judgement regarding the accuracy, validity, and authenticity of the prescription communicated by way of electronic transmission, and
- (5) all electronic equipment for receipt of prescriptions communicated by way of electronic transmission shall be maintained so as to ensure against unauthorized access.

§15-1-23 Labeling

23.1 All drugs dispensed by a licensed pharmacy shall be labeled according to the requirements of this rule.

- (a) All drugs dispensed for use by inpatients of a hospital or other health care

facility, whereby the drug is not in the possession of the ultimate user prior to administration, shall meet the following requirements:

(1) the label of a single-unit package of an individual-dose or unit-dose system of packaging of drugs shall include:

- (A) the non-proprietary or proprietary name of the drug;
- (B) the route of administration, if other than oral;
- © the strength and volume, where appropriate, expressed in the metric system whenever possible;
- (D) the control number and expiration date;
- (E) identification of the repackager by name or by license number shall be clearly distinguishable from the rest of the label; and
- (F) special storage conditions, if required.

(2) When a multiple-dose drug distribution system is utilized, including dispensing of single unit packages, the drugs shall be dispensed in a container to which is affixed a label containing the following information:

- (A) identification of the dispensing pharmacy;
- (B) the patient's name;
- © the date of dispensing;
- (D) the non-proprietary and/or proprietary name of the drug dispensed; and
- (E) the strength, expressed in the metric system whenever possible.

(b) All drugs dispensed to inpatients for self-administration shall be labeled in accordance with subsection (d) of this rule.

© Whenever any drugs are added to parenteral solutions, such admixtures shall bear a distinctive label indicating:

- (1) name of solution, lot number, and volume of solution;
- (2) patient's name;
- (3) infusion rate;
- (4) bottle sequence number or other system control number;
- (5) name and quantity of each additive;
- (6) date of preparation;
- (7) beyond-use date and time of parenteral admixture; and
- (8) ancillary precaution labels.

(d) All drugs dispensed to ambulatory or outpatients shall contain a label affixed to the container in which such drug is dispensed including:

- (1) the name and address of the pharmacy dispensing the drug;
- (2) the name of the patient for whom the drug is prescribed; or, if the patient is an animal, the name of the owner and species of the animal;
- (3) the name of the prescribing practitioner;
- (4) such directions as may be stated on the prescription;
- (5) the date of dispensing;
- (6) any cautions which may be required by federal or state law;
- (7) the serial number of the prescription drug order;

(8) the name or initials of the dispensing pharmacist;

(9) the proprietary or generic name of the drug dispensed and its strength, if more than one strength of the drug is marketed;

(A) when dispensing an equivalent drug product, the word “substitution” or letters “sub” must appear on the label affixed to the container in which such drug is dispensed, followed by the generic name and manufacturer, or reasonable abbreviation, and/or

distributor of the chosen product; provided this only applies to single-entity, multiple-source drugs;

(B) when dispensing a single-entity, single-source drug, the trade name of the prescribed drug may also appear on the label, and the generic name of the prescribed drug may also appear on the label;

© when dispensing a fixed combination product, the United States Pharmacopeia’s publication of Pharmacy Equivalent Names (PEN) for fixed combination products is the official list of

abbreviations for such labeling, and will be the approved abbreviation for identifying the combination product dispensed.

(10) the name of the manufacturer or distributor of the drug; and

(11) the beyond- use date.

(e) No radiopharmaceutical may be dispensed unless a label is affixed to the immediate container bearing the following information:

(1) the standard radiation symbol,

(2) the words "Caution- Radioactive Material", and

(3) the prescription number.

(f) No radiopharmaceutical may be dispensed unless a label is affixed to the outer or delivery container bearing the following information:

(1) the standard radiation symbol,

(2) the words "Caution - Radioactive Material",

(3) the radionuclide and chemical form;

(4) the activity and date and time of assay,

(5) the volume, if in liquid form,

(6) the requested activity and the calibrated activity,

(7) the prescription number,

(8) patient name or space for patient name; where the patient's name is not available at the time of dispensing, a 72 hour exemption is allowed to obtain the name of the patient; no later than 72 hours after dispensing the radiopharmaceutical, the patient's name shall become a part of the

prescription to be retained for a period of five years;

(9) the name and address of the nuclear pharmacy,

(10) the name of the practitioner, and

(11) the lot number of the prescription.

§15-1-24 Pharmacist Consultants.

24.1 Places needing consultants.

The requirements of this section apply to pharmacists serving as pharmacy consultants to, hospitals, skilled nursing facilities, intermediate nursing facilities, nursing homes, rest homes, personal care centers, governmental agencies, jails, correctional facilities, clinics; and any other place where a pharmacy permit is not held, but a controlled substance permit is required; or any place where a pharmacist's expertise is needed to increase or improve patient care and safety in the use of drugs and devices or where the expertise is needed to ensure proper storage conditions and safeguards.

24.2 Requirements and registration.

- a. A pharmacist providing consulting services shall be registered as a consultant pharmacist with the Board and shall be licensed to practice pharmacy in West Virginia.

- b. Every pharmacist providing pharmacy consulting services to any of the facilities mentioned in this rule, or to any other type of place or person, shall make application annually on the prescribed form, to register with the Board as follows:

1. An application must be filed with the Board, by the consultant pharmacist, for each institution, place or person to whom consulting services are provided.

2. The application shall contain, but is not limited to:

A. Name, address and phone number of applying consultant and license number,

B. Name, address, phone number and type of institution, entity or person receiving the consulting services,

C. A description of the services to be provided by the consultant, and

D. The name and signature of the facility administrator.

c. Any change in the data previously placed on the application for registration as a consultant shall be immediately reported to the Board. If the consulting arrangement is discontinued the consulting permit shall be immediately returned to the Board.

d. The fee for registration as a consultant is twenty dollars (\$20.00) for each registration.

24.3 Education

All pharmacists registered as consultants shall have ten (10) hours of continuing education in the subjects of consulting practice each year. These ten (10) hours are in addition to the fifteen (15) hours of continuing education required each year for a pharmacist to be licensed.

24.4 Responsibilities.

a. A pharmacist consultant shall document by date and time, in a permanent log book, his or her activities for each place where he or she is registered.

1. This log book must be present in each facility for which the consultant pharmacist is registered and must be available for inspection by the Board at any time.

b. The pharmacist consultant shall initiate and maintain, in each

facility, appropriate records and procedures for the receipt,
storage and disposition of all drugs including but not limited to:

1. Prescriptions,
2. Floor stock,
3. Emergency boxes or kits,
4. Investigational drugs,
5. Samples, and
6. Outdated or discontinued drugs.

c. The pharmacist consultant shall maintain a Policy and Procedures Manual for pharmaceutical services. The Manual shall be available to all inspectors and available to patient care providers for their guidance in drug handling. The manual shall include, but not be limited to, provisions for the following:

1. Transcribing drug orders and prescription ordering,

2. Prescription delivery system and in-house verification,
3. Drug recall,
4. Automatic stop orders,
5. Formulary or standards for drug quality,
6. Systematic review of drug orders,
7. Reconciliation of controlled substances,
8. Disposition by the following means of prescriptions not totally consumed by the patient:
 - A. Return to pharmacy for credit; and
 - B. Destruction by pharmacist in presence of a registered nurse.
9. In-service drug education of other personnel.

c. The pharmacist consultant shall be responsible for maintaining an appropriate drug reference library for use by other health care personnel.

d. The pharmacist consultant shall insure compliance with all applicable laws and regulations, both state and federal.

e. The pharmacist consultant shall make every effort to separate consulting duties from dispensing duties. Remuneration shall be comparable to that charged by a pharmacist consultant not associated with the supplier of drugs or devices.

1. Remuneration must be received by the pharmacist directly from the facility to which he or she is providing the service.

2. If the pharmacist consultant has any financial interest in the pharmacy providing drugs and/or devices to the facility he or she may not provide the consulting service in order to obtain an agreement to be the supplier.

f. Nothing in this rule precludes a patient in a skilled or intermediate nursing facility, or other voluntarily entered facility, from free choice of pharmacy services.

§15-1-25 Specialized dispensing systems.

25.1 Definition.

a. Specialized dispensing systems are those systems used to provide controlled administration of drugs, for oral administration, to patients and residents of health institutions other than traditional bottle systems.

25.2 Types.

a. A unit dose dispensing system is a system in which each individual unit of medication dosage form is in a separate container, which is intended to be placed in a larger prescription container which is complete with prescription labeling and contains several unit doses. Each individual unit-dose container must be labeled with the following:

1. Name and strength of drug,
2. Name of manufacturer or packager,

3. Lot number, and

4. Expiration date.

b. A unit of use system; which does not constitute unit dose packaging is a system in which all doses to be administered at a given time are placed together in a single package, or packet, which are intended to be placed in a larger prescription container which is complete with prescription labeling and contains several unit of use packets. Each unit of use packet must be labeled with the following:

1. Name and strength of each drug contained therein,

2. Name of manufacturer or packager of each drug therein,

3. Lot number of each drug therein, and

4. Expiration date of each drug therein.

c. Punch card packaging is a system in which several doses of the same drug

are packaged in a card, which is a prescription container, in which each dose has its own space and may be removed without disturbing the packaging for the remaining doses. A Punch card must be labeled with the following:

1. Name and strength of the drug contained therein,
2. Name of manufacturer or packager of the drug therein,
3. Lot number of the drug therein,
4. Expiration date of the drug therein, and
5. All other information required to be on the label of a completed prescription order.

25.3 Preparation.

- a. All extemporaneous unit dose, unit of use, punch card or any other specialized packaging must be done by pharmacists, interns or pharmacy technicians or pharmacy technician trainees under the direct supervision of a pharmacist.

b. Expiration dates must be no more than twenty five percent (25%) of the time between the day of packaging and the expiration date on the stock bottle, not to exceed twelve (12) months in any case.

c. These specialized packaging systems may not be used without the required prescription labeling being on the package that is intended to hold several doses for an individual patient.

25.4 Methods of supplying drugs and devices.

a. Drugs may not be supplied to institutions in floor stock quantities unless a controlled substance permit is held by the institution.

b. Drugs may be supplied by prescription for individual patients.

c. Drugs, other than by prescription, may be stocked in emergency kits when the following conditions are met:

1. Drugs in emergency kits are to be administered only by

those persons licensed to administer drugs,

2. The drugs in the emergency kit shall be of such nature that their absence would threaten the survival of the patient(s) or intended recipients,

3. The contents of the emergency kit shall be determined by the pharmacist consultant and the medical director and the nursing director,.

4. The emergency kit shall be sealed so that it is obvious if it has been opened and it shall be stored under secure conditions,

5. Administration of drugs from the kit must be ordered by a practitioner and a record kept of administration,

6. Drugs stocked in the emergency kit shall be unit dose packaged,

7. Any drug used from the kit shall be replaced only upon a prescription or physician institution order form for the patient to which the dose

was administered, and

8. Any emergency kit containing controlled substances may only be kept at a facility holding a controlled substance permit from the Board.

§30-5-26. PRESCRIBING BY PRACTITIONERS WITH PRESCRIPTIVE AUTHORITY.

26.1 All practitioners are authorized to prescribe within their medical specialty only for a legitimate medical purpose where a practitioner-patient relationship exists. Licensing boards, by statute and legislative rule, have defined and limited prescriptive authority of individuals licensed by those boards and the Board of Pharmacy requires all its permit holders to adhere to those limitations placed by other licensing boards.

§30-5-27. INSTITUTIONS AND OTHER PLACES NEEDING A CONTROLLED SUBSTANCE PERMIT.

27.1 Any Institution (which means any hospital, skilled nursing facility, intermediate nursing facility, personal care home, jail, correctional institution, emergency organization, clinic or any other place which is responsible to administer drugs to in-patients or out-patients which, may or may not, hold a permit

from this Board to operate a pharmacy) must have a permit to handle controlled substances from the Board of Pharmacy if the institution keeps controlled substances on hand at the facility. A practitioner's office that is his or her primary place of practice is not required to obtain this permit but any satellite offices or clinics with controlled substances on the premises must obtain the permit.

b. The Board shall issue a controlled substance permit to those persons required by West Virginia Code §§60A-3-301, 302 to possess such a permit.

27.2 FEES.

The fees for a controlled substance permit are as follows unless changed by statute:

- a. Manufacturer and wholesaler-----\$50.00

- b. Hospital or clinic-----\$50.00

- c. Extended care facility or nursing home----\$25.00

- d. Non-government training institution-----\$25.00

e. Non-government researcher-----\$25.00

f. Pharmacy-----\$10.00

g. Jails and correctional facilities-----\$25.00

h. Non-government rescue or emergency squads--\$25.00

I. Non-government humane societies-----\$25.00

j. All government agencies or employees are exempt from paying the fee.

§30-5-28 ADMINISTRATION OF IMMUNIZATIONS BY PHARMACISTS

28.1 Pharmacists registered in the state of West Virginia may administer vaccines after receiving an Authority to Administer Immunizations from the Board and being properly trained in the following:

- (a) disease epidemiology,
- (b) vaccine characteristics,
- © injection technique, and
- (d) emergency responses to adverse events.

28.2 Pharmacists may administer vaccines only in settings equipped with epinephrine and related supplies. Prior to immunization, a pharmacist shall question patients and/or their families about contraindications and inform them in specific terms about the risks and benefits of immunization and document any patient education provided.

28.3 An applicant for an Authority to Administer Immunizations permit shall:

(a) successfully complete an immunization training program recognized by the Board. The course of study must include current guidelines and recommendations of the Center for Disease Control and Prevention for pediatric, adolescent and adult patients and the American Pharmaceutical Association Guidelines for Pharmacy-based Immunization Advocacy. The training program shall include, at a minimum, the following:

1. basic immunology, including the human immune response;
2. the mechanism of immunity, adverse effects, dose, administration schedule of available vaccines, and approved medications for immunizations;
3. how to handle an emergency situation in the event one should occur as a result of the administration of the immunization;
4. how to persuade patients to be immunized and options for record-keeping for patients immunized;
5. how to administer subcutaneous, intradermal, and intramuscular injections;

6. record-keeping requirements for immunizations;
7. mechanisms of action for vaccines, contraindications, drug interactions, and monitoring after vaccine administration;
8. vaccine storage;
9. biohazard waste disposal and sterile techniques;
10. immunization coalitions and other community resources available;
11. mechanism for reporting adverse events to the Vaccine Adverse Event Reporting System (VAERS).

(b) obtain supervised instructions on the physical administration of immunizations during the course of study; and

© obtain and maintain current certification in Cardiopulmonary Resuscitation (CPR) or Basic Cardiac Life Support (BCLS).

28.4 Upon completion of a recognized immunization training program the Board may issue an Authority to Administer Immunizations permit to a licensed pharmacist who submits an application with a fee of twenty-five (\$25) dollars. The permit shall contain the following:

- (a) name of the pharmacist to whom the permit is issued;
- (b) the West Virginia license number of the pharmacist;
- © date of issue; and
- (d) expiration date.

28.5 The Authority to Administer Immunizations permit shall be renewed annually by the pharmacist with a renewal fee of twenty-five (\$25) dollars.

28.6 Pharmacists authorized by the West Virginia Board of Pharmacy to administer immunizations must maintain continuing competency by completing a minimum of three (3) contact hours of continuing education dedicated to the subject of immunization and/or vaccination. Those three (3) hours may be included in the mandatory fifteen (15) hours of continuing education required for license renewal as a pharmacist. Failure to comply with continuing competency shall be reason for revoking the Authority to Administer Immunizations permit.

28.7 Pharmacists authorized to administer immunizations shall maintain perpetual immunization records and offer a personal immunization record to each patient and their primary care provider whenever possible.