WEST VIRGINIA SECRETARY OF STATE

MAC WARNER

ADMINISTRATIVE LAW DIVISION

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Office of West Virginia
Secretary Of State

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

AGENCY: Pharmacy TITLE-SERIES: 15-01

RULE TYPE: Legislative Amendment to Existing Rule: Yes Repeal of existing rule: No

RULE NAME: Licensure and Practice of Pharmacy

CITE STATUTORY AUTHORITY: §30-5-7

The above rule has been authorized by the West Virginia Legislature.

Authorization is cited in (house or senate bill number) 4079

Section NA Passed On 3/9/2018 12:00:00 AM

This rule is filed with the Secretary of State. This rule becomes effective on the following date:

April 2, 2018

This rule shall terminate and have no further force or effect from the following date:

04/02/2028

BY CHOOSING 'YES', I ATTEST THAT THE PREVIOUS STATEMENT IS TRUE AND CORRECT.

Yes

Michael L Goff -- By my signature, I certify that I am the person authorized to file legislative rules, in accordance with West Virginia Code §29A-3-11 and §39A-3-2.

TITLE 15
LEGISLATIVE RULE
WEST VIRGINIA BOARD OF PHARMACY

SERIES 1
LICENSURE AND PRACTICE OF PHARMACY

§15-1-1. General.

1.1. Scope. -- Licensure and practice of pharmacist care.

1.2. Authority -- W. Va. Code §§ 30-5-7.

1.3. Filing date -- April 2, 2018

1.4. Effective date -- April 2, 2018

1.5. Sunset Date -- This legislative rule shall terminate April 2, 2028 unless renewed prior to that date.

§15-1-2. Definitions.

2.1. The following words and phrases as used in this Rule mean:

2.1.1. "Accredited School of Pharmacy" means a school of pharmacy accredited by the American Council on Pharmaceutical Education (ACPE), or a recognized school of pharmacy located outside of the United States or its territories (a foreign school of pharmacy) which pharmacy education is found by the Board to be equivalent to an ACPE accredited school by a graduate from the foreign school of pharmacy obtaining a Foreign Pharmacy Graduate Examination Committee Certificate (FPGEC) from the National Association of Boards of Pharmacy (NABP).

2.1.2. "Act" or "Uniform Controlled Substance Act" means West Virginia Code § 60A-1-1, et seq.

2.1.3. "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.

2.1.4. "Automated pharmacy system" means mechanical systems which perform operations or activities, other than compounding or administration, relative to the storage, packaging, dispensing, or distribution of medications, and which collect, control, and maintain all transaction information.

2.1.5. "Board" means the West Virginia Board of Pharmacy.

2.1.6. "Board authorization" means a license, registration or permit issued under West Virginia Code Chapter 30, Article 5, and this rule.

2.1.7. "Compounding" means:

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

(1) 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

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

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

2.1.8. "Confidential information" means patient-identifiable information maintained by any person in connection with the practice of pharmacist care 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 person providing pharmacist care.

2.1.9. "Controlled Substance" means a drug, substance, or immediate precursor in Schedule I through Schedule V of either the Federal Controlled Substances Act, 21 USC Section 801, et seq., or the West Virginia Uniform Controlled Substances Act, W. Va. Code § 60A-1-1, et seq.

2.1.10. "Cosmetic" means:

(a) articles intended to be rubbed, poured, sprinkled or sprayed on, introduced into, or otherwise applied to the human body, or any part of the human body for cleansing, beautifying, promoting attractiveness or temporarily altering the appearance;

(b) articles intended for use as a component of those articles, except that the term shall not include soap; and

(c) shall be held to include "dentifrice" and "toilet articles"

2.1.11. "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.

2.1.12. "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.

2.1.13. "Direct supervision" means that a licensed pharmacist is physically present in the pharmacy and is available to verify the accuracy of a prescription before it is dispensed.

2.1.14. "Dispense" or "dispensing" means the interpretation, evaluation, and

implementation of a prescription drug order, including the preparation, verification and delivery of a drug or device to a patient or patient's agent in a suitable container appropriately labeled for subsequent administration to, or use by, a patient.

2.1.15. Distribute" or "Distribution" means to sell, offer to sell, deliver, offer to deliver, broker, give away, or transfer a drug, whether by passage of title, physical movement, or both. The term does not include:

(a) To dispense or administer;

(b) (i) Delivering or offering to deliver a drug by a common carrier in the usual course of business as a common carrier; or providing a drug sample to a patient by a practitioner licensed to prescribe such drug;

(ii) A health care professional acting at the direction and under the supervision of a practitioner; or the pharmacy of a hospital or of another health care entity that is acting at the direction of such a practitioner and that received such sample in accordance with the Prescription Drug Marketing Act and regulations to administer or dispense;

(iii) Intracompany sales.

2.1.16. “Distributor" means a person licensed as a wholesaler or third-party logistics provider.

2.1.17. "Drug" means:

(a) Articles recognized as drugs by the United States Food and Drug Administration, or in any official compendium, or supplement;

(b) An article, designated by the board, for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or other animals;

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

(d) Articles intended for use as a component of any articles specified in paragraph (a), (b) or (c) of this subdivision.

2.1.18. "Drug regimen review" includes, but is not limited to, the following activities:

(a) Evaluation of the prescription drug orders and, if available, patient records for:

(i) Known allergies;

(ii) Rational therapy-contraindications;

(iii) Reasonable dose and route of administration; and

(iv) Reasonable directions for use.

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

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

(i) Drug-drug;

(ii) Drug-food;

(iii) Drug-disease; and

(iv) Adverse drug reactions.

(d) Evaluation of the prescription drug orders and if available, patient records for proper use, including overuse and underuse and optimum therapeutic outcomes.

2.1.19. "Electronic data intermediary" means an entity that provides the infrastructure to connect a computer system, hand-held electronic device or other electronic device used by a prescribing practitioner with a computer system or other electronic device used by a pharmacist to facilitate the secure transmission of:

(a) An electronic prescription order;

(b) A refill authorization request;

(c) A communication; or

(d) Other patient care information.

2.1.20. "E-prescribing" means the transmission, using electronic media, of prescription or prescription-related information between a practitioner, pharmacist, pharmacy benefit manager or health plan as defined in 45 CFR §160.103, either directly or through an electronic data intermediary. E-prescribing includes, but is not limited to, two-way transmissions between the point of care and the pharmacist. E-prescribing may also be referenced by the terms "electronic prescription" or "electronic order".

2.1.21. "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.

2.1.22. "Inspector" means an agent of the Board, who is a licensed pharmacist, appointed by the Board to conduct periodic inspections of board authorization holders and perform other duties as designated by the Board.

2.1.23. "Institutional facility" means any organization whose primary purpose is to provide

a physical environment for patients to obtain health care services, including but not limited to a hospital, convalescent home, nursing home, extended care facility, mental health facility, rehabilitation center, psychiatric center, developmental disability center, drug abuse treatment center, family planning clinic, correctional facility, hospice, public health facility, or athletic facility.

2.1.24. "Institutional pharmacy" means that physical portion of an institutional facility that is engaged in the compounding, dispensing, and distribution of drugs, devices, and other materials used in the diagnosis and treatment of injury, illness, and disease and which holds a pharmacy license from the Board.

2.1.25. "Intern" or "pharmacy intern" means an individual who is currently licensed by the board to engage in the practice of pharmacist care while under the supervision of a pharmacist.

2.1.26. "Labeling" means the process of preparing and affixing a label to a drug container exclusive, however, of a labeling by a manufacturer, packer or distributor of a nonprescription drug or commercially packaged prescription drug or device.

2.1.27. "Mail order pharmacy" means a pharmacy, regardless of its location, which dispenses greater than twenty-five percent (25%) prescription drugs via the mail or other delivery services.

2.1.28. "Manufacturer" means any person who is engaged in manufacturing, preparing, propagating, processing, packaging, repackaging or labeling of a prescription drug, whether within or outside this state.

2.1.29. "Manufacturing" means the production, preparation, propagation or processing of a 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 or substances or labeling or relabeling of its contents and the promotion and marketing of the drugs or devices. Manufacturing also includes the preparation and promotion of commercially available products from bulk compounds for resale by pharmacies, practitioners or other persons.

2.1.30. "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.

2.1.31. "Nuclear pharmacist" means a pharmacist who has been certified in the specialty of nuclear pharmacy.

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

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

(a) the applicant is a new business;

(b) the applicant is an established business that is transferred to a successor;

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

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

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

2.1.34. "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 pharmacist care is provided; and any place outside of this state where drugs are dispensed and the practice of pharmacy and pharmacist care is provided to residents of this state.

2.1.35. "Over-the counter drug" or "OTC drug" means any drug that is not a prescription drug or prescription drug.

2.1.36. "Patient counseling" means the communication by the pharmacist of information, as prescribed further in the rules of the board, to the patient to improve therapy by aiding in the proper use of drugs and devices.

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

2.1.38. "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.

2.1.39. "Pharmacist care" means the provision by a pharmacist of patient care activities, with or without the dispensing of drugs or devices, intended to achieve outcomes related to the cure or prevention of a disease, the elimination or reduction of a patient's symptoms, or the arresting or slowing of a disease process, and as provided in West Virginia Code § 30-5-10.

2.1.40. "Pharmacist" means an individual currently licensed by this state to engage in the practice of pharmacist care.

2.1.41. "Pharmacist-in-charge" means a pharmacist currently licensed in this state who:

(a) accepts responsibility for the operation of a pharmacy in conformance with all state and federal laws and rules pertinent to the practice of pharmacist care and the distribution of drugs;

(b) has the responsibility for the practice of pharmacist care, as defined in this rule, at the pharmacy for which he or she is pharmacist-in-charge. The pharmacy permit holder has responsibility for all other functions, administrative and operational, of the pharmacy. The pharmacist-in-charge may advise the pharmacy permit holder in writing of administrative and operational matters. The pharmacist-in-charge is not legally responsible if the permit holder does

not follow the written advice;

(c) works at least 30 hours a week, with the pharmacist-in-charge working at least three days per week, in that pharmacy, including the use of any accrued annual or sick leave; Provided That, in any pharmacy which is open on average less than 40 hours per week in a calendar year, he or she must work in the pharmacy a majority of the hours that the pharmacy is open (e.g., if open 20 hours per week, the pharmacist-in-charge must work 11 hours per week within the pharmacy); and

(d) with regard to a pharmacist-in-charge in a Charitable Clinic Pharmacy, this position may be filled by a committee of up to three (3) pharmacists who accept as a group the responsibilities of the required pharmacist-in-charge. Further notwithstanding the requirements of subsection c, above, with regard to a Charitable Clinic Pharmacy, if the pharmacy is open an average of more than 40 hours per week, the pharmacist-in-charge or pharmacist-in-charge committee must work at least 8 hours per calendar month; if the pharmacy is open on average at least 30 and up to 40 hours per week, the pharmacist-in-charge or pharmacist-in-charge committee must work in the charitable clinic pharmacy at least 6 hours per calendar month; if the pharmacy is open on average at least 15 and up to 30 hours per week, the pharmacist-in-charge or pharmacist-in-charge committee must work in the charitable clinic pharmacy at least 4 hours per calendar month; if the charitable clinic pharmacy is open on average at least 5 and up to 15 hours per week, the pharmacist-in-charge or pharmacist-in-charge committee must work in the charitable clinic pharmacy at least 2 hours per calendar month; and, if the charitable clinic pharmacy is open less than 5 hours per week, the pharmacist-in-charge or pharmacist-in-charge committee must work in the charitable clinic pharmacy the lesser of 2 hours per month or 50% of the hours the charitable clinic pharmacy is open.

Charitable Clinic Pharmacy hours per week	Hours required by PIC per month
More than 40:	8
30 to 40:	6
15 to 30:	4
5 to 15:	2
Less than 5:	The lesser of 2 or 50% of hours open

2.1.42. "Pharmacy technician" means registered supportive personnel who work under the direct supervision of a pharmacist, and who have passed an approved training program; Provided That, in a Charitable Clinic Pharmacy, when no pharmacist is on-site, a pharmacy technician may work under the direct supervision of a prescribing practitioner who is licensed as a prescribing practitioner who is licensed as such in the State of West Virginia.

2.1.43. “Pharmacy technician trainee” means registered supportive personnel currently engaged in a pharmacy technician training program which has been approved by the Board and who is under the direct supervision of a pharmacist.

2.1.44. "Practitioner" or “prescribing practitioner” means an individual authorized by a jurisdiction of the United States to prescribe drugs in the course of professional practices, as

allowed by law.

2.1.45. "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.

2.1.46. "Prescription drug" means any human drug required by federal law or regulation to be dispensed only by prescription, including finished dosage forms and active ingredients subject to section 503(b) of the federal food, drug and cosmetic act.

2.1.47. "Prescription" or "Prescription order" means a lawful order from a practitioner for a drug or device for a specific patient, including orders derived from collaborative pharmacy practice, where a valid patient-practitioner relationship exists, that is communicated to a pharmacist in a pharmacy.

2.1.48. "President" means the President of the West Virginia Board.

2.1.49. "Refill" means a subsequent dispensing of the medicine ordered by the practitioner in the original prescription order, based upon the practitioner's authorization for the subsequent dispensings in that original prescription order.

2.1.50. "Renewal" means a new prescription drug order for the same medication previously prescribed for a patient, authorized by the practitioner without change or modification from the original prescription order after the authorized number of refills of the original prescription order has been exhausted.

2.1.51. "Sample" means a package of a prescription drug provided by a manufacturer on the request of a practitioner or charitable clinic to be given to a patient without charge in accordance with federal law.

2.1.52. "Secretary" means the Secretary of the West Virginia Board.

2.1.53. "Vendor" means a private vendor which produces or supplies official state prescription paper.

2.1.54. "Vice-President" means the Vice-President of the West Virginia Board.

2.1.55. "West Virginia Official Prescription Paper" means prescription paper which meets the following criteria:

(a) Prevention of unauthorized copying;
(b) Prevention of erasure or modification; and
(c) An ability to prevent counterfeit prescriptions or prescription pads.

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

§ 15-1-3. General Provisions.

3.1. 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.

3.2. 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 in it '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 to it.

3.3. Disposition of moneys; report to auditor. – The Secretary shall receive and account for, all moneys derived by virtue of the provisions of W.Va. Code §§ 30-1-1 et. seq. and 30-5-1 et. seq., and shall pay such moneys into the State Treasury monthly on or before the tenth day of each month in which the monies are received.

3.4. Record of proceedings; registration of applicant; certified copies of records prima facie evidence, report to governor. – The Secretary of the Board shall keep a record of its proceedings and a register of all applicants for license or registration, showing for each, the date of his or her application, 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 the books and register, or a copy of any part of them, certified by the Secretary and attested by the seal of the Board, is prima facie evidence of all matters recorded by the Board.

3.5. Roster of licensed or registered persons. – The Secretary shall prepare and maintain a complete roster of all persons, granted a board authorization, alphabetically and by class or type and by whether within or without the state.

3.6. Power of Inspection and Investigation – The authorized agents of the Board may inspect and investigate in a lawful manner and during regular business hours all places or persons holding a board authorization. The 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. The board authorization holder shall allow access to selling prices only when needed for a specific investigation or inquiry by the Board regarding a particular drug.

3.7. During the course of any inspection or investigation by an agent of the Board the agent may temporarily close any holder of a board authorization upon the discovery of any of the following:

3.7.1. the ability of the pharmacist to practice pharmacist care with reasonable skill, competency, or safety to the public is impaired because the board authorization holder's cognitive,

interpersonal, or psychomotor skills are affected by psychiatric, psychological, or emotional problems, or excessive alcohol or drug use or addiction; or

3.7.2. the absence of valid board authorization issued by the Board or by the absence of an available pharmacist to be on duty.

3.8. When a board authorization holder is closed under subsection 3.7.1 of this section they shall remain closed until an unimpaired pharmacist arrives on the premises or when a board authorization holder is closed under subsection 3.7.2 of this section, the permittee shall remain closed until a valid permit is obtained and on display as required by law.

3.9. Agents of the Board when acting in good faith and without malice are immune from individual civil liability while acting within the scope of their duties as such agents of the Board.

§ 15-1-4. Internship Requirements.

4.1.1. No person may practice as a pharmacy intern without being licensed by the board.

4.1.2. To be eligible to practice as a pharmacy intern, an applicant must:
(a) make application to the board on a form provided by the Board;
(b) pay the required application fee;
(c) meet all other requirements for licensure; and
(d) complete a criminal history records check as prescribed in § 29.

4.1.3. A pharmacy intern license expires on the 30th day of June of each year, and, upon proper application, may be renewed annually up to four years from the date of issue.

4.1.4. A legible copy of the original internship certificate of licensure shall be displayed at the place of internship.

4.1.5. The pharmacy intern must have the original with him or her in a readily retrievable location at any pharmacy or other practice site where he or she is practicing as an intern. An intern shall produce the original intern certificate upon request of an appropriate official or agent of the board or proper law enforcement.

4.2. The Board may certify internship credit for an individual:

4.2.1. When a preceptor holds a current, valid license as a pharmacist from the board and the pharmacy intern has been issued an intern certificate;

4.2.2. When the pharmacy intern has notified the Board within 10 days of the employment as an intern;

4.2.3 When the pharmacy intern notifies the Board within 10 days subsequent to termination of any internship under a specific preceptor; and

4.2.4 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.

4.3. No pharmacy intern shall be certified by the Board unless the intern is enrolled in or is a graduate of an accredited school of pharmacy, or has met the requirements for educational equivalency by obtaining a Foreign Pharmacy Graduate Examination Committee Certification.

4.4. A pharmacy intern may receive experience credit for any period of time during which he or she is enrolled in an accredited school of pharmacy and the Board may accept and certify up to 1,500 hours of internship credit for interns participating or enrolled in a supervised internship as part of the school of pharmacy experiential education curriculum.

4.5. A pharmacy intern shall earn internship hours only for hours obtained in the practice of pharmacist care in the role of a pharmacist and in a licensed pharmacy. Hours worked in the role of a pharmacy technician will not be certified or accepted.

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 pharmacy intern acquired internship experience or from the recognized school of pharmacy from which the intern acquired internship experience. Up to one third of the internship hours may be fulfilled by an internship in a foreign country either through an accredited school of pharmacy experiential education program or as certified on a letter of credit or certification from the Board of Pharmacy or other regulatory body of the foreign state, province, or country responsible for regulation of the practice of pharmacy in the foreign location.

§ 15-1-5. Examination for Licensure and Registration and Annual Renewal Requirements.

5.1. Application – An applicant for examination to become a licensed pharmacist shall apply in writing to the Board at least 15 days before the date of examination is to be conducted and shall transmit with the application the prescribed fee of $125.00. The application shall be made on a form provided by the Board.

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

5.2.1. An applicant shall be 18 years of age or older, proof of which shall be shown by birth certificate or other acceptable document.

5.2.2. An 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.

5.2.3. An applicant shall present to the Board satisfactory evidence that he or she is a graduate of an approved school of pharmacy, or has met the requirements for educational equivalency by obtaining a Foreign Pharmacy Graduate Examination Committee Certification through the program administered by the National Association of Boards of Pharmacy (NABP).

5.2.4. An applicant shall have acquired 1500 hours of internship in a licensed pharmacy.

5.2.5. An applicant shall complete a criminal history records check as prescribed in § 29.

5.3. Examinations.

5.3.1. State and national examinations required for licensure are administered on behalf of the Board by NABP.

5.3.2. Examinations for the North American Pharmacist Licensure Examination (NAPLEX), the Multistate Pharmacy Jurisprudence Examination for West Virginia (MPJE), and as part of the Foreign Pharmacy Graduate Examination Committee Certification shall be done in accordance with the processes and procedures required by NABP.

5.3.3. An applicant for licensure as a pharmacist shall pass the NAPLEX and the MPJE, administered by NABP.

5.3.4. An applicant failing to achieve the required grades may repeat the failed examination or examinations one time without re-applying to the board within 6 months of the date of the original application, but one re-examination exhausts the applicant's privilege to sit for the examinations under the current application.

5.3.5. An applicant failing to achieve the required grade on each examination a second time may apply for licensure a second time, and again have two chances to pass the examinations.

5.3.6. An applicant failing to achieve the required grade on each examination a third time must petition the board before making reapplication a third or any subsequent time. At this time the board may require the applicant to complete a remediation evaluation and/or program before the applicant may reapply for licensure and sit for the examinations.

5.4. Certificate of licensure– 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) member of the Board, and attested by the President and Secretary. For any duplicate of this certificate the Board shall charge $25.00. A certificate is not assignable.

5.5. License and registration renewal.

5.5.1. The board shall charge and collect the following fees:

(a) Biennial renewal of license of pharmacist: $100.00;
(b) License of pharmacy intern: $10.00 for the original license; $5.00 for each renewal for the remaining periods of his or her internship;
(c) Registration of a consultant pharmacist: $20.00 for each application; and
(d) Registration of a pharmacy technician: $25.00 for the original registration; $20.00 for each biennial renewal

5.5.2. All licenses of pharmacists and registrations of pharmacy technicians expire on the thirtieth day of June, 2002. After the thirtieth day of June, 2002, one half of all licenses for

pharmacists and registrations for pharmacy technicians shall be renewed for a period of one year to expire on the thirtieth day of June, and shall be biennially thereafter. The Board shall renew one half of all licenses for pharmacists and registrations for pharmacy technicians for a period of two years, to expire on the thirtieth day of June, and shall renew those licenses and registrations biennially thereafter: Provided That, registrations of pharmacy interns shall continue to be renewed annually. Every licensed pharmacist, pharmacy intern or pharmacy technician who desires to renew his or her license or registration shall apply to the state board of pharmacy for renewal of his or her license or registration, and shall transmit with his or her application the fee prescribed. The renewal application may be sent by the board at least thirty days prior to expiration of the license or permit. The notification may be sent electronically to an e-mail or be mailed to the last known address of each pharmacist, pharmacy intern or pharmacy technician, in the discretion of the board and as shown on record with the Board. The Board has until August 31 of each year to issue the license or registration and no license or registration shall be considered lapsed until September 1. It is the responsibility of the applicant to make timely application for renewal, and if he or she has not received an application by June 1 of the year in which his or her authorization expires, the applicant should request one from the Board. Applications for renewal received in the office after June 30 of the year in which his or her authorization expires will require the payment of a late fee equal to the amount of the renewal application fee, as well as the regular renewal fee. If the applicant submitted a renewal application by June 30, and has not received his or her license or registration by July 31, the applicant should contact the Board.

5.5.3. If any pharmacist, pharmacy intern, or pharmacy technician whose license or registration has expired fails to apply to the board for a renewal of his or her license or registration by August 31 of the year in which his or her authorization expires, the Board shall remove his or her name from the register of pharmacists, pharmacy interns, and pharmacy technicians.

5.5.4. In order for any pharmacist, pharmacy intern, or pharmacy technician whose name has been removed from the register of the board to again become licensed or registered, the pharmacist, pharmacy intern or pharmacy technician shall petition the board, or an authorized committee of the board, for reinstatement, in writing, to show cause for permitting the license or registration to lapse. If his or her license or registration has been expired for one year or less (i.e., the petition for reinstatement is received on or before June 30 of the year after his or her authorization expired), and if the board finds the person otherwise eligible and qualified to practice, the Board shall reinstate that person upon payment of reinstatement fee of $250.00 for a pharmacist plus the renewal fee of $100.00, or upon payment of a reinstatement fee of $50.00 for a pharmacy technician plus the renewal fee of $20.00. If the pharmacist license or pharmacy technician registration has been expired for more than one year (i.e., the petition is received after June 30 of the year after his or her authorization expired), the board finds the person has submitted to the board satisfactory reasons for allowing the license or registration to lapse, and satisfies the board as to his or her qualifications to practice the profession by successfully passing the examinations administered or otherwise required by the board for reinstatement, the Board shall reinstate that person upon payment of reinstatement fee of $250.00 for a pharmacist plus the renewal fee of $100.00, or upon payment of a reinstatement fee of $50.00 for a pharmacy technician plus the renewal fee of $20.00. If a pharmacy intern's license has been expired for more than a year, he or she must make new application as an intern and pay the required application fee for an initial pharmacy intern license.

§ 15-1-6. Reciprocity; Licensure of Pharmacists From Other States or Countries.

6.1. The Board may license and admit to practice pharmacists in this state that have been legally licensed or registered as pharmacists in other states or countries if:

6.1.1. The applicant is at least 18 years of age;

6.1.2. The applicant is in good standing in the state or country from which he is seeking to transfer his or her licensure or registration;

6.1.3. The applicant is in fact, competent and physically and mentally qualified to function as a pharmacist;

6.1.4. The applicant is of good moral character and not addicted to alcohol or a controlled substances;

6.1.5. The applicant has not been convicted, or had his or her license in any other state or country suspended or revoked for violation of pharmacy, liquor, controlled substance, or food and drug laws;

6.1.6. 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; and

6.1.7. The applicant passes the West Virginia MPJE.

6.1.9. The applicant must complete a criminal history records check as prescribed in § 29

6.2. 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. In order to receive credit for that service an affidavit shall be signed by the supervising pharmacist and attested by the secretary of the board of pharmacy of the state or country where the internship was served.

6.3. Applicants for licensure by reciprocity shall not work as pharmacists until they receive a certificate of licensure from the board.

6.4. A foreign pharmacy graduate whose undergraduate pharmacy degree was conferred by a school of pharmacy outside of the United States, and its territories, 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 MPJE examinations provided he or she has completed 1500 hours of internship, of which 500 hours may have been earned in a foreign country, as certified on a letter of credit or certification from the Board of Pharmacy or other regulatory body of the foreign state, province, or country responsible for regulation of the practice of pharmacy in the foreign location, and must complete a criminal history records check as prescribed in § 29.

6.5. Application.

6.5.1. 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 to that effect, the Board shall supply the applicant who possesses the necessary qualifications with application forms. An applicant must complete the forms and submit a fee of $250.00.

6.5.2. The application shall include the following provided by the applicant:

(a) 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;
(b) A recent head shot photograph with a statement signed by the applicant that it is a photograph of the applicant and has been made within the previous twelve (12) months; and
(c) A signed waiver from the applicant allowing the Board to obtain a certified criminal records check on the applicant.

6.6. Appearance before the Board – Applicants for licensure by reciprocity shall appear before the Board or its designated agent at the time specified, for checking of credentials, an interview and examination as may be necessary to determine the fitness of the applicant to practice in West Virginia. The Board may revoke any applicant who misrepresents himself or herself to the Board.

§ 15-1-7. Proceedings for Disciplinary Action.

7.1. Contested case hearings shall be held as provided in W. Va. Code §§29A-5-1. et. seq., and 30-1-1. et. seq.

7.2. The Board may amend the charges set forth in a statement of charges as it considers proper.

7.3. Motions for a continuance of a hearing may be granted upon a showing of good cause. Motions for continuance shall 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, the Board shall give consideration to the ability of the party requesting the continuance to proceed effectively without a continuance. The Board shall deny a motion for continuance filed less than seven (7) days from the date of the hearing 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. The Board member or the hearing examiner presiding over the hearing shall rule on all other motions for continuance.

7.4. 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 the prehearing conference or at the hearing prior to the commencement of testimony. The Board Member or the hearing examiner presiding at the hearing shall hear the motions and the response from the non-moving party and shall rule on the motions

accordingly.

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

7.6. Conferences; Informal Disposition of Cases.

7.6.1. 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:

(a) To dispose of procedural requests, prehearing motions or similar matters;
(b) To simplify or settle issues by consent of the parties; of
(c) To provide for informal disposition of cases by stipulation or agreement.

7.6.2. The Board or its duly appointed hearing examiner may cause the conferences to be held on the Board's or the hearing examiner's own motion or by the request of a party.

7.6.3. The Board may also initiate or consider stipulation or agreement proposals with regard to the informal disposition of cases and may enter into the stipulations or agreements without conference.

7.7. Subpoenas

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.

§ 15-1-8. Confidential Information.

Confidential 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 judgment, such release is necessary to the patient's health and well-being; to health plans, as that term is defined in 45 CFR § 160.103, for payment; 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. Appropriate disclosure, as permitted by this rule, may occur by the pharmacist either directly or through an electronic data intermediary.

§ 15-1-9. Transfer of Prescription Drugs.

9.1. No prescription drug may be transferred except by the following methods:

9.1.1. Transfer of drugs without prescription.

(a) Prescription drugs without a prescription may be transferred only to a permittee or practitioner and the transaction shall be recorded and the gross dollar value of the transfers shall not exceed five percent (5%) of the total prescription drug sales revenue of either the transferor or the transferee pharmacy during any twelve (12) consecutive month period.

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

(1) the name of the drug and its quantity;
(2) the date of transaction;
(3) the permittee or practitioner to whom the prescription drug was transferred; and
(4) the selling price.

(c) The record of the transfer shall be kept in the pharmacy and be immediately accessible within one year from the date of transfer, and available within forty-eight (48) hours if between one year and five years from the date of transfer.

(d) Any pharmacy with transfers of prescription drugs that exceed the five percent restriction set forth in paragraph 9.1.1a of this section shall obtain a permit to be a wholesaler. Intracompany sales and transfers of drugs by a retail pharmacy to another retail pharmacy to alleviate a temporary shortage shall not be included in calculation of the drug sales revenue.

9.1.2. Transfer of drugs with a Prescription.

(a)Prescription drugs transferred by a practitioner's prescription order are dispensed. A prescription shall contain at least the following elements:

(1) The patient's name and address and the date the prescription is written, Provided that, if the prescription is for expedited partner therapy as permitted by West Virginia Code Chapter 16, Article 4F, then the words "Expedited Partner Therapy" or the designation "EPT" may be written for the name of the patient;
(2) The drug's name and quantity; and
(3) Directions for use.

(A) If the prescription is written on a practitioner's date prescription blank, the order shall contain the following:

1. The practitioner's printed name, address, professional designation and practitioner identifier number; and
2. The practitioner's signature.

(B) If the prescription is written on an institutional prescription blank, the order shall contain the following:

1. The printed name of the practitioner and DEA number with suffix; and
2. The practitioner's signature.

(C) No sticker or other substance shall be allowed to obliterate or cover any of the information required by this subdivision.

9.2. Samples

9.2.1. Samples are the property of a practitioner and may only be received upon a signed request from the practitioner to the drug manufacturer.

9.2.2. Samples are not allowed in a pharmacy except that institutional pharmacies may receive, store, and dispense prescription drug samples without charge to patients of a practitioner that is affiliated with the institution, provided that the following requirements met:

(a) All prescription drug samples received by the pharmacy are obtained pursuant to a written, signed request of a licensed practitioner affiliated with that institution. For the purposes of this subsection "Affiliated" is interpreted to mean that the requesting practitioner treats patients at the facility;
(b) the pharmacy retains a copy of all written, signed prescription drug sample requests;
(c) prescription drug samples are stored separately from the prescription drug products held for sale (retail stock);
(d) records of prescription drug sample receipt or dispensing are maintained separately from records of prescription drug products held for sale and sold (retail stock);
(e) a relationship exists between the health care entity and the pharmacy which is evidenced by a written documentation;
(f) prescription drug samples are dispensed by the pharmacy to patients in the manufacturer's or distributor's original packaging; and
(g) 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. A pharmacist may not refill any prescription order containing a drug if 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; if an Automated Data Processing System is used to document the refill, a daily printout of all prescription orders filled shall be made and verified and signed by each pharmacist responsible for that day's work or a log may be kept of each refill number and this log shall be signed by each pharmacist.

10.3. No prescription order may be refilled after twelve (12) months from the date of issuance by the practitioner.

10.4. The refilling of prescription orders for controlled substances is limited by provisions of the Uniform Controlled Substances Act, W. Va. Code § 60A-3-308.

§ 15-1-11. Transferring Prescription Orders Between Pharmacies.

11.1. 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:

11.2.1. The transferring pharmacist:

(a) Writes the word "VOID" on the face of the original prescription order; for electronic prescriptions, information that the prescription has been transferred must be added to the prescription record;
(b) Records on the reverse of the original prescription the name, address, and Drug Enforcement Administration (DEA) registry number of the pharmacy to which the prescription was transferred and the name of the pharmacist receiving the prescription information; for electronic prescriptions, information that the prescription has been transferred must be added to the prescription record; and
(c)Records the date and time of the transfer and his or her first and last name;

11.2.2. The pharmacist receiving the transferred prescription order information:

(a) Writes the word "TRANSFER" on the face of the transferred prescription; and
(b) Provides all the information required to be on a prescription and includes:

(1) Date of issuance of the original prescription;
(2) Number of refills on the original prescription;
(3) The date the original prescription was dispensed;
(4) The number of valid refills remaining and date of last refill;
(5) The pharmacy's name, address, DEA registry number and the original prescription number from which the prescription was transferred; and
(6) The first and last name of the transferring pharmacist;

11.2.3. A pharmacist may give a copy of a prescription clearly marked "For Information Only" to a patient; and

11.2.4. 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 in this subsection.

11.3. No pharmacy shall refuse to transfer information about a previously dispensed prescription to another pharmacy when requested by a patient. A pharmacy shall transfer prescription information 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 the use by the patient. Pharmacies shall maintain original and transferred prescription drug orders for a period of five (5) years from the

date of the last refill; maintained on-site for a period of twelve (12) months from last 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, the common electronic file or database shall contain complete records of each prescription drug order and refill dispensed, and the system shall have the capability at the pharmacy refilling the prescription drug order or at the pharmacy where the prescription is transferred to generate a hard copy record of each prescription drug order transferred or accessed for purposes of refilling.

§ 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:

12.1.1. The returned drugs are in a manufacturer's original, sealed and visibly tamperproof container;

12.1.2. 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

12.1.3. All drugs are identified as to lot and control number and expiration date.

12.2. No controlled substance that has been dispensed may be returned and placed in stock for reuse or resale under any circumstances. However, any entity registered pursuant to Title 15, Series 2, of these rules which is properly registered with the DEA as an authorized collector to receive the transfer from ultimate users of any unwanted and unused pharmaceutical controlled substances in their lawful possession for safe, secure, and responsible disposal, may receive returns of controlled substances for such disposal.

12.3. Any drugs returned within or by an institution shall be recorded in a log which lists the name of the patient, the name and strength of the drug with the name of its manufacturer, the 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 shall 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 W. Va. Code § 30-5-12b.The Board may approve drug products not listed in the Orange Book as acceptable products for generic substitution upon submission of a written request to the Board.

§ 15-1-14. Regulations Governing Pharmacy Permits.

14.1. A pharmacy shall first secure a registration from the Board and comply fully with W. Va. Code § 30-5-22 before it may lawfully conduct a pharmacy.

14.2. 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 registration to do so. No registration will be issued unless a pharmacy is operated or pharmacist care is provided. Not more than one registration may be issued in any one name in more than one location. Every registered pharmacy shall be under the direct charge of a pharmacist, designated the Pharmacist-in-charge, and shall operate in compliance with the state and federal laws and rules and regulations.

14.2.1. The application for a new registration shall be made on a form prescribed and furnished by the Board, which when properly executed shall include, but not be limited to the following information:

(a) identification of the owner that is applying for the registration;
(b) the name under which the business will be operated and which will be used in advertising;
(c) the physical location of the pharmacy including;

1. Its street number; and
2. The city and county;

(d) The mailing address of the pharmacy if different from its physical location;
(e) The name and license number of the pharmacist-in-charge;
(f) The name and license numbers of other pharmacists regularly employed at the pharmacy;
(g) The name and registration numbers of pharmacy technicians and pharmacy technician trainees regularly employed at the pharmacy;
(h) The pharmacy's hours of operation; and
(i) detailed floor plans for the pharmacy made to scale.

14.2.2. Each pharmacy shall make a separate application and a separate registration shall be issued for each pharmacy.

14.2.3. A pharmacy shall have available in the pharmacy, in either print or electronic media, a current edition of a drug information and reference compendium such as Elsevier Gold Standard/Clinical Pharmacology, Facts & Comparisons, or other appropriate compendium approved by the board, and shall have the necessary equipment to render service dictated by public health, and as required by other sections of this rule.

14.2.4. An initial application for a pharmacy registration shall be accompanied by a fee of $150.00.

14.2.5. A pharmacy compounding parenteral/enteral drugs shall also apply for a compounding permit as required by section 16 of this rule.

14.3. Issuance of permit.

14.3.1. The Board shall issue a registration to conduct a pharmacy to the applicant after a satisfactory inspection of the facility.

14.3.2. The registration registers the pharmacy to which it is issued and is not transferrable. 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.

14.3.3. A registration shall be posted in a visibly conspicuous place. The registration may not be in a location that is out of sight of the dispensing area.

14.4. Renewal of registration.

14.4.1. The annual renewal of a registration takes place on the first day of July of each year. The fee for the annual renewal is $75.00. Registrations expire on the thirtieth day of June of each calendar year. Renewal applications shall be delivered to the Board office by the fifteenth day of June to allow time for processing. Pharmacies shall have a grace period for renewal until July 31 of the year in which the permit expires; however, renewal applications received in the Board office after June 30 of the year in which the registration expires shall require the payment of a late fee in the amount of $75.00 in addition to the application fee of $75.00, for a total amount of $150.00.

14.4.2. If a pharmacy does not make application for renewal by the first day of August each year, to renew an expired registration the Board shall re-inspect the pharmacy and the permittee shall pay the required renewal fee and late fee totaling $150.00 for the registration, and $150.00 for the re-inspection , for a total amount of $300.00.

14.5. Surrender of registration.

14.5.1. When a pharmacist-in-charge in whose name a pharmacy registration has been issued leaves the full time employment of that pharmacy; or for any other reason ceases to be in complete and actual charge of the pharmacy, he or she shall immediately notify the Board, in writing, of the termination or change of his or her services, and return the original pharmacy registration to the Board office with the date of the change and the name and registration number of the newly designated pharmacist-in-charge written on the registration in indelible ink . A copy of the registration as modified shall be made and posted in the pharmacy. For the purposes of this subsection 'full time employment' means working at least 30 hours per week, 3 days per week at one pharmacy. If the pharmacist-in-charge fails to notify the Board and return the pharmacy registration the Board may take disciplinary action against the offending pharmacist.

14.5.2. A pharmacy owner shall notify the Board, immediately and in writing, of the termination of the full time employment of the pharmacist-in-charge; as shown on the registration, or any other action which causes the pharmacist-in- charge to cease being in complete and actual charge of the pharmacy. The pharmacy registration holder shall immediately designate a new pharmacist-in-charge and write the name on a copy of the pharmacy registration in indelible ink

and post it in the pharmacy. An interim pharmacist-in-charge may be designated for a period not to exceed sixty days. The Board may permit in its discretion an additional period of time for an interim pharmacist-in-charge based upon a request in writing detailing the circumstances which warrant the extension. The original pharmacy registration shall be returned to the Board office with the date of the change and the name and registration number of the newly designated pharmacist-in-charge written on the original registration in indelible ink. A copy of the registration as modified shall be made and posted in the pharmacy. Until a pharmacist-in-charge is designated and written in indelible ink on the pharmacy registration, the pharmacy shall not operate. Each day of operation in the absence of a designated pharmacist-in-charge is considered a separate offense. The pharmacy registration holder shall notify the Board of the replacement in writing within 30 days upon a form provided by the Board with a fee of $10.00 for the new registration reflecting the new pharmacist-in-charge. Upon receipt of this notification, the Board shall provide a newly printed registration to the pharmacy. If an interim pharmacist-in-charge is designated who is not the permanent pharmacist-in-charge, the name of the interim pharmacist-in-charge and the period of time that pharmacist served as interim pharmacist-in-charge shall be noted on the form, and a fee will not be charged and a newly printed registration will not be issued until a permanent pharmacist-in-charge is designated. An interim pharmacist-in-charge is not required to be employed the minimum number of hours as is the permanent pharmacist-in-charge.

14.5.3. A pharmacy that moves to a new address or a different location within the current building shall apply for a new registration and submit the appropriate fees. The Board shall inspect the facility before a new registration may be issued.

14.5.4. When a pharmacy changes ownership the registration expires and a new registration must be obtained from the Board.

14.6. Violations.

14.6.1. The violation of any of these rules shall be considered cause of disciplinary action.

14.6.2. A pharmacist shall 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.

14.6.3. A person who employs a licensed pharmacist shall notify the Board within 7 days, in writing, of any discharge or termination of the licensed pharmacist or change of the status of the pharmacist-in-charge. A pharmacy registration holder who fails to notify the Board is subject to disciplinary action.

14.6.4. A person who employs a licensed pharmacist shall immediately notify the Board, in writing, of any complaints registered against a pharmacist regarding the violation of any pharmacy laws or rules.

14.7. Security.

14.7.1. If a pharmacy is to be operated for a period less than 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. The Board may approve plans, on a case by case basis, for non-physical barriers . If the pharmacist is always present when other persons are in the store or institution, the pharmacy area need not to be enclosed by a physical barrier. The barrier shall be designated 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 shall be of sufficient strength and thickness that it may not be easily removed and must be equipped with keyed locks; or

(2) If the barrier is of a movable material it shall be constructed of material strong enough to prevent breakage and shall have openings or interstices small enough to prohibit removal of any items in the protected area and be equipped with keyed locks;

14.7.2. 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 are subject to the following conditions:

(a) The device shall be maintained in operating order and shall have an auxiliary source of power;

(b) The device shall fully protect the prescription department and shall be capable of detecting breaking and/or entering by any means when activated;

(c) 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. The pharmacy registration holder may deactivate the system for security or surveillance purposes as long as the reason for the deactivation, the person deactivating the system, and time and date of deactivation are documented and immediately available to the Board; and

(d) This subsection does not apply to pharmacies which are open and staffed by pharmacists twenty four (24) hours a day;

14.7.3. The door keys are alarm activation and de-activation codes to the prescription areas are subject to the following:

(a) Only pharmacists practicing at the pharmacy and authorized by the pharmacist-in-charge may possess any keys to the locks on the doors of the prescription area;

(b) The pharmacist-in-charge 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;

(c) During times that an institutional pharmacy may be unattended by a pharmacist, arrangements shall be made in advance by the pharmacist-in-charge for provision of drugs to the medical staff and other authorized personnel of the institution by use of night cabinets and, in emergency circumstances, by access to the pharmacy. A pharmacist shall be 'on call' during all absences. In the absence of a pharmacist, drugs shall be stored in a locked cabinet or other enclosure constructed and located outside the pharmacy area, to which only specifically authorized personnel may obtain access by key or combination, and which is sufficiently secure to deny access to unauthorized persons. The pharmacist-in-charge shall, in conjunction with the appropriate committee of the institution, develop inventory listings of those drugs to be included in the cabinets and determine who may have access, and shall ensure that:

(1) drugs are properly labels;
(2) only prepackaged drugs are available, in amounts sufficient for immediate therapeutic requirements;
(3) whenever access to the cabinet occurs, written practitioner's orders and proof-of-use are provided;
(4) all drugs in the cabinet are inventoried no less than once per week;
(5) a complete audit of all activity concerning the cabinet is conducted no less than once per month; and
(6) written policies and procedures are established to implement the provisions of this subdivision; and

(d) Whenever any drug is not available from floor supplies or night cabinets, and the drug is required to immediately treat a life-threatening situation of a patient, the drug may be obtained from the pharmacy by a supervisory nurse in accordance with the requirements of this subdivision. The pharmacist-in-charge shall, in conjunction with the appropriate committee of the institution, designate in writing one supervisory nurse in any given eight hour shift who is responsible for obtaining drugs from the pharmacy during any emergency situation. Removal of any drug from the pharmacy by an authorized nurse shall be recorded on a suitable form showing the patient's name, and location within the institution, the name of the drug, its strength and amount, and date and time, and the signature of the nurse. The form shall be left with the container from which the drug was removed and the supervisory nurse shall contact the pharmacist "on call";

14.7.4. 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;

14.7.5. Except as provided in Title 15, Series 14, for central prescription filling, ~~C~~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, the patient's authorized designee picking up the prescription for the patient, or person delivering the prescription to the patient at his or her residence or other place designated by the patient or the patient's authorized designee. If the patient or the patient's designee is unknown to the pharmacist then his or her identity shall be established by photo identification card;

14.7.6. Dispensing has not occurred until the drug is actually picked up by or delivered to the patient or patient's representative. Mobile pharmacy units and remote dispensing are prohibited. Completed prescriptions must be picked up at or delivered from the same pharmacy at which they were prepared, except that this subsection does not apply to a mail order pharmacy licensed by the Board, or to transfers of prescription drugs by a retail pharmacy to alleviate a temporary shortage; and

14.7.7. 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

14.8.1. No pharmacist may work more than 12 hours within a 24 hour period without at least 8 hours off duty in that 24 hours, except in a case of emergency when a pharmacist calls off work, the pharmacist on duty may work more than 12 hours in order to keep the pharmacy open. The pharmacists would have to document and date and amount of time worked beyond the 12 hour limit along with the reason for the extended hours of work and make it available to the Board.

14.8.2. Any pharmacy dispensing more than 15 prescriptions per hour on average during a day shall have a registered pharmacy technician or a pharmacy technician trainee assisting the pharmacist. The pharmacist-in-charge shall determine the work schedule for pharmacy technicians and pharmacy technician trainees based upon prior dispensing records.

14.8.3. The pharmacist on duty or the pharmacy registrant shall notify the pharmacist-in-charge whenever a prescription error, loss of drugs, or a violation of any statute or rule occurs and the pharmacist-in-charge is not present.

§ 15-1-15. Equipment, Facilities and Record Systems.

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

15.1.1. The pharmacy shall have a separate area available for patient counseling which will ensure the privacy and confidentiality of the discussions; and which has adequate space to use any equipment, visual aids, and publications, if necessary, to provide proper counseling. This subdivision does not apply to pharmacies which have been granted a registration prior to the effective date of this provision of May 1, 1999.

15.1.2. All standards set by the United States Pharmacopeial Convention ("USP")are the minimum standards followed by all licensed pharmacists and pharmacies during the course of the professional practice of pharmacist care.

15.2. A pharmacy shall continually possess the following:

15.2.1. A sanitary method of measuring and dispensing between 5 and 250 milliliters of liquids;

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

15.2.3. For a pharmacy 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;

15.2.4. 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;

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

15.2.6. An acceptable system of keeping records of prescriptions dispensed as required by the Uniform Controlled Substance Act and any Rules and Regulations pertaining to the Act;

15.2.7. A system of keeping patient profiles as required by Title 15, Series 4; and

15.2.8. The most currently available Pharmacy Law Book and book of Rules and Regulations published by the Board.

§ 15-1-16. Sterile Pharmaceutical Compounding.

16.1. Permitting and Control.

16.1.1. 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 Board shall issue a permit after a satisfactory inspection of the completed facilities.

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

16.1.3. 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.

16.1.4. This section shall not apply to pharmacies which were granted a parenteral-enteral compounding permit prior to the effective date of this rule; if the current compounding

environment meets the requirements of the rule in effect prior to this rule and the public health, safety, and welfare is not jeopardized.

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

16.2.1. A completed Board application form;

16.2.2. A copy of the Policy and Procedure Manual required under subsection 16.5 of this section;

16.2.3. Statement and plans showing how the applicant meets the minimum requirements regarding space, equipment, supplies and publications.

16.3. The compounding 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:

16.3.1. Separation from other areas by a 'clean' entry room or vestibule;

16.3.2. Adequate space for at least one certified air flow hood in each sterile admixture compounding room along with other necessary equipment and supplies; and

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

16.4. General Requirements.

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

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

(a) The drug's expiration date;
(b) The date of preparation; and
(c) The drug's control number.

16.4.3. A pharmacy with a Sterile Pharmaceutical Compounding Permit shall provide a twenty four (24) hour telephone number to allow its patients or other health care providers who may be administering its prescriptions to contact its pharmacists.

16.5. A pharmacy with a Sterile Pharmaceutical Compounding Permit shall comply with the following requirements:

16.5.1. 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:

(a) A statement in detail of the objectives and operational guidelines of the permittee;
(b) A Description of a Quality Assurance Program which monitors:

(1) personnel qualifications,
(2) Continuing training and performance of staff;
(3) Equipment and facilities requirements;
(4) Standards for compounding and dispensing; and
(5) Any other requirements of this Board; and

16.5.2. The pharmacy shall provide protection for its personnel involved in the handling of cytotoxic agents by:

(a) Utilizing the proper equipment and supplies; and
(b) Having a special section of the Policy and Procedure Manual devoted to handling procedures, including:

(1) A statement that compounding shall be conducted within a properly certified vertical airflow hood;
(2) A discussion of the proper use of protective garb;
(3) A description of the proper techniques to prevent all contamination of the prescription and chemical contamination of the person preparing the prescription; and
(4) Disposal procedures of cytotoxicagents in accordance with accepted professional standards and applicable law.

16.6. Space, Equipment, Supplies, and Reference Works.

16.6.1. A pharmacy operating under a Sterile Pharmaceutical Permit shall meet the minimum requirements for space, equipment, supplies and reference materials, which are in addition to those required for a regular pharmacy 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 site 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 shall be located in the "clean" anteroom adjoining the buffer room according to United States Pharmacopeia standards.
(4) The compounding area shall 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) At least the following equipment shall be available and shall be maintained in working order:

(1) Properly certified airflow hood;
(2) Adequate refrigerator and freezer space;
(3) A sink and wash area in the anteroom as provided for in this section; and
(4) Appropriate waste containers for:

(A) Used needles and syringes;
(B) All cytotoxic waste including disposable apparel used in its preparation;

(c) 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) Minimum reference works required in a pharmacy with a Sterile Pharmaceutical Compounding permit are:

(1) A current edition, in either print or electronic media, of a drug information and reference compendium such as Elsevier Gold Standard/Clinical Pharmacology, Facts & Comparisons, or other appropriate compendium approved by the board; and
(2) Handbook of Injectable Drugs published by the American Society of Hospital Pharmacists, or its equivalent.

§ 15-1-17. Licensure and Control of Nuclear Pharmacies.

17.1. General Requirements.

17.1.1. A pharmacy providing radiopharmaceutical services, and compounding or mixing prescription orders for radiopharmaceuticals shall obtain a Nuclear Pharmacy registration 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.

17.1.2. Pharmacies providing regular pharmacist care in addition to radiopharmaceutical services shall comply with all sections of this rule applicable to pharmacies in general.

17.2. Space.

17.2.1. The nuclear pharmacy area shall be separate from all other pharmacy areas for non-radioactive drugs and shall be secured from unauthorized personnel.

17.2.2. A pharmacy handling radiopharmaceuticals shall provide a radioactive storage and

product decay area which meets the requirements of the appropriate federal agency.

17.3. Dispensing and labeling.

17.3.1. 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.

17.3.2. 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:

(a) the standard radiation symbol;
(b) The words "CAUTION-Radioactive Material";
(c) the name of the radio nucleotide;
(d) the chemical form;
(e) The amount of radioactive material contained in millicuries or microcuries;
(f) The volume in milliliters, if the material is a liquid;
(g) The requested calibration time for the amount of radioactivity contained; and
(h) The practitioner's name and the assigned lot number.

17.3.3. The immediate inner container shall be labeled with:

(a) The standard radiation symbol;
(b) The words "CAUTION-Radioactive Material"; and
(c) The prescription number

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

17.4. 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 that a licensed pharmacist may divide the product into individual doses.

§ 15-1-18. Sanitary Regulation of Pharmacies.

18.1. The pharmacist-in-charge of a pharmacy shall maintain the prescription room and equipment in the prescription room in a clean and orderly condition and in good operating order at all times.

18.2. The prescription counter 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 pharmacist and pharmacy interns when providing pharmacist care, shall wear a clean

white coat or jacket with a name tag identifying the individual and showing their job designation, and are required to keep themselves and their apparel in clean condition. All pharmacy technicians and pharmacy technician trainees shall wear a name tag identifying the individual and showing their job designation and shall wear clean attire and a coat, jacket, or apron of a color other than white.

18.5. Any area used for providing pharmacist care 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 pharmacists, pharmacy interns, pharmacy technicians, pharmacy technician trainees, and agents of the Board may be present in the prescription area when pharmacist care is being provided, unless the pharmacist on duty considers the presence of another individual appropriate. The pharmacy permit holder may enter the pharmacy without a pharmacist present for immediate security or surveillance purposes as long as the reason for entry, the name of the person entering, and the time and date of entry are documented and immediately available to the Board.

§ 15-1-19. Rules of Professional Conduct.

19.1. Statement of purpose

19.1.1. 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 practice pharmacy. The pharmacist recognizes his or her responsibility to the public in providing pharmacist care, providing safe storage and handling of drugs, in dispensing drugs and devices 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.

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

19.2. Freedom of practice.

19.2.1. No person practicing pharmacist care 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 pharmacist care or offer pharmaceutical services under any terms or conditions which tend to impair the free and complete exercise of the professional skill and judgment of another pharmacist. A person practicing pharmacist care shall at all times practice his or her profession in conformity with federal and state laws and regulations and the rules of this Board.

19.2.2. Every pharmacist, pharmacy intern, and pharmacy technician, when practicing the profession of pharmacy, shall provide pharmacist care as defined in this rule.

19.3. Uncertain Prescription orders.

19.3.1. No pharmacist, pharmacy intern, or pharmacy technician, shall compound or dispense any prescription order which, in his or her judgment and/r professional opinion, contains any error, irregularity or ambiguity. The pharmacist shall hold a conference with the prescriber before dispensing, if there is any doubt that the prescription order is not legal or correct or issued for a legitimate medical purpose.

19.4. Professional services – 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 pharmacist care, including the compounding and dispensing of all prescription orders which may reasonably be expected to be compounded or dispensed by pharmacists.

19.5. Confidential information.

19.5.1. No person practicing pharmacist care shall exhibit, discuss or reveal any patient-specific confidential information as defined in this rule with any person other than:

(a) Agents of the Board engaged in the performance of their official duties;
(b) Another pharmacist or pharmacy technician when necessary;
(c) The patient or his or her authorized representative;
(d) The prescriber or other members of the health care team treating the patient; or
(e) Any person authorized by law to receive the information.

19.6. Diagnosis or treatment – No pharmacist, pharmacy intern, or pharmacy technician shall attempt to diagnose any disease, illness or organic disorder. This does not preclude evaluation of a patient after a diagnosis is made by a practitioner. A pharmacist may advise individuals on the merits and quality of over-the-counter (OTC) products.

19.7. Coded prescription orders – No pharmacist, pharmacy intern, or pharmacy technician 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.

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

19.9. Promotion of and reliability of drugs.

19.9.1. No person practicing pharmacist care 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 the drugs to be used in excess of the requirements established in a legitimate physician-patient-pharmacist relationship.

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

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

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

19.12. Physician agreements – No pharmacist or pharmacy shall enter into or engage in any agreement or arrangement with any practitioner which may tend to exploit the patient, nor shall he or she enter into an agreement of any kind where in any way a patient's free choice of pharmacist or pharmacy is limited in any manner.

19.13. Duties and responsibilities – It is the duty and responsibility of the pharmacist in every pharmacy to perform, at the minimum, the following duties:

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

(a) the name of the caller;
(b) the time and date of transmission; and
(c) the hand-written initials of the receiver.

19.13.2. To dispense, deliver, or distribute a prescription drug order accurately as prescribed. For the purposes of this paragraph "accurately as prescribed" means:

(a) To the correct patient (or agent of the patient) for whom the drug or devise was prescribed;
(b) with the correct drug in the correct strength, quantity, and dosage form ordered by the practitioner; a pharmacist may substitute a generic drug pursuant to W. Va. Code § 30-5-12b; and
(c) With correct labeling (including directions for use) as ordered by the practitioner;

19.13.3. 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;

19.13.4. 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;

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

19.13.6. To counsel or inform patients about their drugs, which may include supplemental media according to the pharmacist's professional judgment, to the patient, care giver, or agent. 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 judgment of the pharmacist 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 this judgment 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.

(a) In those cases, when the offer to counsel, as described in this subsection, has been accepted, a pharmacist who provides pharmacist 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 judgment he or she considers significant, which may or may not include the following:

(1) The name of and a description of the medication;
(2) the dosage form, route of administration, degree, and duration of drug therapy;
(3) Special directions and precautions for preparation, administration, and use by the patient;
(4) 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;
(5) Techniques for self-monitoring drug therapy;
(6) Proper storage and handling;
(7) Prescription refill information; and
(8) Any action to take in the event of a missed dose.

(b) 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 drugs;

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

(a) The patients name, address, telephone number, date of birth or age, and gender;
(b) The patient's individual history including disease states, known allergies and drug reactions, and a comprehensive list of medications and relevant devices; and
(c) The pharmacist's comments regarding the patient's therapy;

19.13.8. To perform all of the functions in this section;

19.13.9. To adequately supervise all pharmacy interns, registered pharmacy technicians and pharmacy technician trainees; and

19.13.10. To perform any other functions of any nature or kind which:

(a) Require the knowledge, ability or skill of a licensed pharmacist and
(b) Attempt to improve the therapeutic outcome to the patient of the pharmacist care provided by the pharmacist.

19.14. Violation of the rules of professional conduct.

19.14.1. The rules of professional conduct in this section are intended to govern all pharmacists, pharmacy interns, pharmacy technicians, and pharmacies licensed or registered by the Board and improve the pharmacist care provided to the citizens of West Virginia.

19.14.2. The violation of the provisions of this section by a licensed pharmacist, pharmacy intern, pharmacy technician, or person with a permit to operate a pharmacy shall result in disciplinary action. To the extent not otherwise provided, pharmacy interns and pharmacy technicians must comply with the requirements of subsection 19.13 of this section to the extent permitted by his or her scope of practice.

19.14.3. Any pharmacist who knowingly accepts and continues employment with any permittee who violates the rules of the Board is guilty of a violation of the rule the same as if he or she had personally engaged in the violation.

19.15. Publication and posting of rules – The Board shall make a copy of the Rules of Professional Conduct in this section available to every pharmacy and pharmacist licensed by the Board. Every pharmacy shall visibly post a copy of the rules in the prescription area.

§15-1-20. Duties and Responsibilities of the Pharmacist-in-Charge.

3.1. A pharmacy may not operate without a pharmacist-in-charge (hereinafter "PIC"), who shall be designated on the application for a pharmacy license, and in each license renewal. 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; Provided that, he or she may volunteer as the pharmacist-in-charge at a charitable clinic pharmacy while serving as a PIC in another pharmacy.

3.2. The pharmacist-in-charge has the following responsibilities:

3.2.1. The pharmacist-in-charge shall be responsible for the practice of pharmacy, as defined in this rule, at the pharmacy for which he or she is the pharmacist-in-charge. The pharmacy permit holder shall be responsible for all other functions, administrative and operational, of the pharmacy. The pharmacist-in-charge may advise the pharmacy permit holder in writing of administrative and operational matters. The pharmacist-in-charge is not legally responsible if the permit holder does not follow the written advice;

3.2.2. The pharmacist-in-charge shall notify the pharmacy permit holder of potential violations of any statute, rule or court order existing within the pharmacy. If appropriate action has not been taken within a reasonable amount of time the pharmacist-in-charge shall reduce to writing the above and submit to the pharmacy permit holder with a copy to the Board. No pharmacist-in-charge shall be sanctioned by the Board for any violation of any statute, rule or court order if they have previously given this written notice to the pharmacy permit holder. The pharmacy permit holder shall be responsible for such violations;

3.2.3. Implementing 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;

3.2.4. The PIC shall 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 maintain 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;

3.2.5. Implementing policies and procedures for the procurement, storage, security, and disposition of drugs and devices;

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

3.2.7. 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;

3.2.8. Making or filing any reports required by state or federal laws, rules, and regulations;

3.2.9. Responding to the board regarding any warning notice issued by the Board. The Board shall provide notification of the issuance of the warning notice to the pharmacy permit holder;

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

3.2.11. Providing the board with prior written notice of the installation or removal of an Automated Pharmacy System. The notice shall 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.

3.3. 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.

3.3.1. 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.

3.3.2. The PIC shall 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.

§15-1-21. Manner of Issuance of a Prescription.

21.1. A prescription to be valid, shall be issued for a legitimate medical purpose by a practitioner acting within the course of legitimate professional practice, and shall bear the preprinted, stamped, typed, or manually printed name, address and telephone number of the prescribing practitioner. If it is a prescription for a controlled substance listed in Schedules II through V, then it shall also contain the prescriber's DEA registration number, including any suffix. The National Provider Identification (NPI) number shall be required on all valid prescriptions beginning January 1, 2012.

21.1.1. A pharmacist shall receive the communication of a prescription. A pharmacist may accept a prescription, including that for a controlled substance listed in Schedules II through V, that is communicated in written form or by E-prescribing. A pharmacist may accept 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, that is communicated orally (including telephone voice communication) or by way of electronic transmission other than E-prescribing.

21.1.2. If communicated orally or by way of electronic transmission other than E-prescribing, the pharmacist shall immediately reduce the prescription to a form that may be maintained for the time period required by any applicable federal and State of West Virginia laws and rules.

21.1.3. A prescription blank for a controlled substance shall not contain the preprinted name of a controlled substance or the written, typed or rubber-stamped name of a controlled substance until the prescription blank is signed, dated and issued to a patient.

21.1.4. A prescription for a Schedule II controlled substance may be communicated orally or by way of electronic transmission other than E-prescribing only in the following situations and with the following restrictions. Otherwise, a prescription for a Schedule II controlled substance shall be communicated in written form or by E-prescribing.

(a) 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 prescription, signed by the practitioner, 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:

(1) 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;

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

(3) 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 shall note on the prescription that the patient is a hospice patient.

21.1.6. 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 if the prescribing practitioner is not known to the pharmacist, he or she shall 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 other good faith efforts to insure his identity; and:

(a) 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);

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

(c) within seven (7) days after authorizing an emergency oral prescription, the practitioner has a written prescription for the emergency quantity prescribed 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.

21.1.7. A prescribing practitioner may authorize his or her agent to communicate a prescription orally or by way of electronic transmission either directly or through an electronic data intermediary to a pharmacist in a licensed pharmacy, provided:

(a) the identity of the transmitting agent is included in the order;

(b) the prescription is transmitted either directly or through an electronic data intermediary to a pharmacist in a licensed pharmacy of the patient's choice with no unauthorized person having access to the prescription;

(c) the prescription identifies 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;

(d) the pharmacist exercises professional judgment regarding the accuracy, validity, and authenticity of the prescription communicated by way of electronic transmission; and

(e) all electronic equipment for receipt of prescriptions communicated by way of electronic transmission is maintained so as to ensure against unauthorized access.

21.1.8 Electronic Data Intermediaries.

(a) Electronic data intermediaries may transmit electronic prescriptions, prescription refill authorization requests, communications, and other patient care information using a secure infrastructure between an authorized prescribing practitioner and a pharmacy of the patient's choice.

(b) Electronic data intermediaries shall meet the following requirements for electronically transmitted prescription orders, refill authorization requests, communications and other transmitted patient care information:

(1) Maintain the confidentiality and security of transmitted information as required by applicable federal and state laws.

(2) Transmit prescriptions to the pharmacy of the patient's choice.

(3) Maintain the integrity, privacy, and security of archived copies of the electronic information related to the transmissions as required by applicable state and federal laws, including maintaining them as confidential information.

§ 15-1-22. Labeling.

22.1. All drugs dispensed by a licensed pharmacy shall be labeled according to the requirements of this section, and shall include all information required by federal law or regulation or state law or rule.

22.1.1. All drugs dispensed for use by inpatients of a hospital or other health care facility, where the drug is not in the possession of the ultimate user prior to administration, shall meet the following requirements:

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

(1) the name of the drug;
(2) the route of administration, if other than oral;
(3) the strength and volume, where appropriate, expressed in the metric system whenever possible;
(4) the control number and expiration date;
(5) special storage conditions, if required; and

(b) Identification of the repackager by name or by license number shall be clearly distinguishable from the rest of the label.
(c) 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:

(1) identification of the dispensing pharmacy;
(2) the patient's name;
(3) the date of dispensing;
(4) then name of the drug dispensed; and
(5) the strength, expressed in the metric system whenever possible.

22.1.2. All drugs dispensed to inpatients for self-administering shall be labeled in accordance with subdivision 22.1.4 of this section.

22.1.3. Whenever any drugs are added to parental solutions, the admixtures shall bear a distinctive label indicating:

(a) the name of the solution, the lot number, and the volume of the solution;
(b) the patient's name;
(c) the infusion rate;
(d) the bottle sequence number or other system control number;
(e) the name and quantity of each additive;
(f) the date of the preparation;
(g) the beyond-use date and time of parental admixture; and
(h) ancillary precaution labels.

22.1.4. All drugs dispensed to ambulatory or outpatients shall have a label affixed to the container in which the drug is dispensed, including:

(a) the name (including store number, if any), address, and telephone number of the pharmacy dispensing the drug;
(b) the name of the patient for whom the drug is prescribed; or, if the patient is an animal, the last name of the owner, name and species of the animal; Provided that, if the prescription is for expedited partner therapy as permitted by West Virginia Code Chapter 16, Article 4F, then the words "Expedited Partner Therapy" or the designation "EPT" may be written for the name of the patient;
(c) the name of the prescribing practitioner;
(d) directions stated on the prescription order, and medication purpose/indication if included on the prescription order;
(e) the date filled;
(f) any cautions which may be required by federal or state law;
(g) the prescription number of the prescription drug order;
(h) the name or initials of the dispensing pharmacist;
(i) the proprietary or generic name of the drug dispensed, and its strength;

(1) when dispensing an equivalent drug product, the word 'substitution" or the letters 'sub" shall appear on the label affixed to the container in which the drug is dispensed, followed by the generic name and manufacturer, or reasonable abbreviation, and/or distributor of the chosen product. This requirement only applies to single-entity, multiple-course drugs;
(2) 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;
(3) 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 labeling, and is the approved abbreviation for identifying the combination product dispensed;

(j) drug quantity;
(k) number of remaining refills;
(l) auxiliary information;
(m) the name of the manufacturer or distributor of the drug; and
(n) the beyond-use date.

22.1.5. No radiopharmaceutical may be dispensed unless a label is affixed to the immediate container bearing the following information:

(a) the standard radiation symbol;
(b) the words "Caution- Radioactive Material; and
(c) the prescription number.

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

a. the standard radiation symbol;

b. the words "Caution- Radioactive Material";
c. the radionuclide and chemical form;
d. the activity and date and time of assay;
e. the volume, if in liquid form;
f. the requested activity and the calibrated activity;
g. the prescription number;
h. the patient's name or space for the patient's name. When 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 pharmacist shall obtain the patient's name and it shall become a part of the prescription to be retained for a period of five years;
i. the name and address of the nuclear pharmacy;
j. the name of the practitioner; and
k. the lot number of the prescription.

§ 15-1-23. Pharmacist Consultants.

23.1. Places needing consultants.

23.1.1. 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 here 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.

23.2. Requirements and registration.

23.2.1. 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.

23.2.2. Every pharmacist providing pharmacy consulting services shall apply annually on the prescribed form, to register with the Board as follows:

(a) The consultant pharmacist shall file an application with the Board for each institution, place or person to whom consulting services are provided;
(b) The application shall contain, but is not limited to:

(1) The name, address and phone number of the applying consultant and his or her license number;
(2) The name, address, phone number and type of institution, entity or person receiving the consulting services;
(3) A description of the services to be provided by the consultant; and
(4) The name and signature of the facility administrator.

23.2.3. The consultant pharmacist shall immediately report to the Board any change in the data previously placed on the application for registration as a consultant. If the consulting

arrangement is discontinued the consultant pharmacist shall immediately return the consulting permit to the Board.

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

23.3. Education – All pharmacist registered as consultants shall have three (3) hours of continuing education in the subjects of consulting practice each year. These three (3) hours may be included in the mandatory fifteen (15) hours of continuing education required for license renewal as a pharmacist.

23.4. Responsibilities.

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

23.4.2. 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:

(a) Prescriptions;
(b) Floor stock;
(c) Emergency boxes or kits;
(d) Investigational drugs;
(e) Samples; and
(f) Outdated or discontinued drugs.

23.4.3. 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:

(a) Transcribing drug orders and prescription ordering;
(b) Prescription delivery system and in-house verification;
(c) Drug recall;
(d) Automatic stop orders;
(e) Formulary or standards for drug quality;
(f) Systematic review of drug orders;
(g) Reconciliation of controlled substances;
(h) Disposition by the following means of prescriptions not totally consumed by the patient:

    (1) Return to pharmacy for credit; and
    (2) Destruction by the pharmacist in the presence of a registered nurse; and

(i) In-serving drug education for other personnel.

23.4.4. The pharmacist consultant shall maintain an appropriate drug reference library for use by other health care personnel.

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

23.4.6. 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.

(a) The pharmacist or his or her employer shall receive remuneration directly from the facility to which he or she is proving the service.
(b) If the pharmacist consultant has any financial interest in the pharmacy providing drugs or devices to the facility he or she may not provide consulting service in order to obtain an agreement to be the supplier.

23.4.7. 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.

§ 15-1-24. Specialized Dispensing Systems.

24.1. Definition.

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

24.2. Types.

24.2.1. 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 shall be labeled with the following:

(a) The name and strength of the drug;
(b) The name of the manufacturer or the packager;
(c) The lot number; and
(d) The expiration date.

24.2.2. A unit of use system is a system in which all doses containing different medications to be administered at a given time are placed together in a single package, or packet, which is 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 shall be labeled with the following:

(a) The name and strength of each drug contained in the unit of use packet;

(b) The name of the manufacturer or the packager of each drug in the unit of use packet;
(c) The lot number of each drug in the unit use packet; and
(d) The expiration date of each drug in the unit of use packet;

24.2.3. Punch card packaging is a system, which does not constitute unit does packaging, 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 shall be labeled with the following:

(a) The name and strength of the drug contained in the punch card;
(b) The name of the manufacturer or packager of the drug contained in the punch card;
(c) The lot number of the drug contained in the punch card;
(d) The expiration date of the drug contained in the punch card; and
(e) All other information required to be on the label of a completed prescription order.

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

24.3.2. Expiration dates may 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.

24.3.3. 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.

24.4. Methods of supplying drugs and devices.

24.4.1. Institutions may not have drugs supplied in floor stock quantities unless a controlled substance permit is held by the institution.

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

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

(a) Drugs in emergency kits are to be administered only by those persons licensed to administered drugs;
(b) The drugs in the emergency kit are of such nature that their absence would threaten the survival of the patients or intended recipients;
(c) The contents of the emergency kit are determined by the pharmacist consultant and the medical director and the nursing director;
(d) The emergency kit is sealed so that it is obvious if it has been opened and it is stored under secure conditions;

(e) Administration of drugs from the kit is ordered by a practitioner and a record kept of administration;
(f) Drugs stocked in the emergency kit are unit dose packaged;
(g) Any drug used from the kit is replaced only upon a prescription or physician institution order form for the patient to which the dose was administered; and
(h) Any emergency kit containing controlled substances is kept only at a facility holding a controlled substance permit from the Board.

§ 15-1-25. Institutions and Other Places Needing a Controlled Substance Permit.

25.1. Any facility, including 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, shall have a permit to handle controlled substances on hand at the facility. A practitioner whose office is his or her primary place of practice is not required to obtain a permit for the office but shall obtain a permit for any satellite offices or clinics with controlled substances on the premises.

25.2. The Board shall issue a controlled substance permit to those persons required by W. Va. Code §§60A-3-301, 302 to possess a permit.

25.3. Fees –The fees for a controlled substance permit are as follows unless changed by statute:

25.3.1. Manufacturer and wholesaler $50.00

25.3.2. Hospital or Clinic $50.00

25.3.3. Extended care facility or nursing home $25.00

25.3.4. Non-government training institution $25.00

25.3.5. Non-government researcher $25.00

25.3.6. Pharmacy $10.00

25.3.7. Non-government jails and correctional facilities . . $25.00

25.3.8. Non-government rescue or emergency squads $25.00

25.3.9. Non-government humane societies $25.00

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

§15-1-26. Emergency Dispensing by Pharmacists.

26.1. A pharmacist may dispense an emergency supply refill of life-sustaining prescription drugs to a patient without a prescription when, in the professional judgment of the pharmacist, the emergency supply is appropriate and the prescribing practitioner is not available. The emergency

supply may not be more than a ten (10) days supply and the pharmacist shall immediately document the dispensing indicating the patient name, drug and its strength and amount, date filled, the name of the dispensing pharmacist, and the reasons for emergency dispensing. The dispensing pharmacist shall contact the prescribing practitioner as soon as possible subsequent to the drugs being dispensed.

15-1-27. West Virginia Official Prescription Paper Program Rules.

27.1. The purpose of this section is to establish rules for the West Virginia official prescription paper program set forth at West Virginia Code Section 30-5-7(a)(32) for use in writing prescriptions by practitioners.

27.2. Minimum Requirements of West Virginia Official Prescription Paper. The prescription paper shall contain the following security features:

(a) shall meet all requirements issued by the Center for Medicare and Medicaid Services for a written prescription for controlled substances as required by Section 2002(b) of PL. 110-28 of the Iraq War Supplemental Appropriations Bill enacted by the United States Congress in 2007;

(b) shall contain six (6) quantity check-off boxes printed on the form and in the following quantities shall appear:

(1) 1-24;
(2) 25-49;
(3) 50-74;
(4) 75-100;
(5) 101-150; and
(6) 151 and over:

Provided That, if the blank has the quantity prescribed electronically printed in both numeric and word format, then the quantity check-off boxes shall not be necessary;

(c) shall contain space for the prescriber to indicate number of refills, if any, or to indicate no refills;

(d) shall provide space for the patient's name and address, the prescribing practitioner's signature;

(e) shall provide space for the preprinted, stamped, typed, or manually printed name, address and telephone number of the prescribing practitioner, and the practitioner's DEA registration number and NPI number; Provided that, if a practitioner does not have authority to prescribe controlled substances, then no DEA number shall be required, and, instead, the following statement shall be printed: "No Controlled Substances Authority"; and, Provided further that, if a practitioner is a veterinarian, no NPI number shall be required;

(f) shall contain the following statement printed on the bottom of the prescription blank: "This prescription may be filled with a generically equivalent drug product unless the words 'Brand Medically Necessary' are written in the practitioner's own handwriting, on this prescription form.".

27.3. Practitioners licensed to practice in this State may purchase West Virginia Official Prescription Paper as per individual orders from any vendor(s) which produces or supplies compliant West Virginia Official Prescription Paper.

27.4. On and after July 1, 2016, every written prescription written in West Virginia by a practitioner shall be written on West Virginia Official Prescription Paper. A pharmacist may not fill a written prescription from a West Virginia practitioner unless issued upon West Virginia Official Prescription Paper, except that a pharmacist may provide emergency supplies in accordance with the relevant laws and rules for emergency dispensing or other insurance contract requirements. Nothing in this section shall be construed to impact regulations regarding verbal, facsimile, electronic, or out-of-state prescription practices.

27.5. Practitioners; control and reporting of West Virginia Official Prescription Paper.

(a) Adequate safeguards and security measures shall be undertaken by practitioners holding West Virginia Official Prescription Paper to assure against the loss, destruction, theft or unauthorized use of the forms. The forms may be used only by the practitioner to whom they are issued and are not transferable.

(b) The Practitioner must also notify the vendor of any failure to receive West Virginia Official Prescription Paper within a reasonable time after ordering it. Further, practitioners must immediately notify the Board and vendor in writing of the loss through destruction, theft or loss, or unauthorized use of any Official Prescription Paper blanks, including:

(1) Estimated number of blanks affected;
(2) Control numbers if available; and
(3) Suspected reason for destruction, theft, or loss.

(c) West Virginia Official Prescription Paper does not have to come pre-printed from a vendor, but may also be created at the point of prescribing with software-generated prescriptions by printing on plain paper with secure technology accessible only by the prescriber and his or her authorized agent that results in a tamper resistant prescription as required by subsection 27.3 of this section.

§ 15-1-28. Practice of Telepharmacy.

Except as otherwise provided specifically herein, the practice of telepharmacy is permitted only as follows:

(a) for a pharmacist to provide direct patient-care activities of patient counseling and medication therapy management, when the patient is unable to be present in the pharmacy for a personal, face-to-face interaction, provided the pharmacist is:

(1) licensed to practice pharmacist care in West Virginia; or,

(2) licensed to practice pharmacist care in the state where the mail order pharmacy is located if dispensing prescription drugs to a patient in this State from a non-resident mail order pharmacy properly permitted as a mail order pharmacy to dispense into this State;

(b) for after-hours drug regimen review of prescription orders for a patient in an institutional facility when the institutional pharmacy is closed, for the pharmacist to authorize the dispensing and administration, provided the pharmacist is licensed to practice pharmacist care in West Virginia;

~~(c) for remote-order-entry or remote-order-review of prescription orders received at one in-state pharmacy, but~~

~~(1) for purpose of data entry, entered by a licensed pharmacist, pharmacy intern, or registered pharmacy technician who is located at another in-state pharmacy which shares a common automated data processing system, and such system creates an audit trail of which pharmacist, pharmacy intern, or pharmacy technician entered the data; and~~

~~(2) for purpose of drug regimen review, reviewed by a licensed pharmacist or pharmacy intern who is located at another in-state pharmacy which shares a common automated data processing system, and such system creates an audit trail of which pharmacist or pharmacy intern provided the drug regimen review.~~

§ 15-1-29. Criminal History Record Check.

29.1 Beginning July 1, 2017, and in addition to all the requirements for licensure, all applicant for an initial license to practice as a pharmacist, intern, pharmacy technician, or pharmacy technician trainee in West Virginia shall request and submit to the Board the results of a state and national criminal history record check.

29.2. The purpose of the criminal history record check is to assist the Board in obtaining information that may relate to the applicant's fitness for licensure.

29.3. In addition to the State Police, the Board may contract with and designate a company specializing in the services required by this section instead of requiring the applicant to apply directly to the West Virginia State Police or similar out-of-state agency for the criminal history records checks. Provided that any such company must utilize protocols consistent with standards established by the Federal Bureau of investigation and the National Crime Prevention and Privacy Compact.

29.4 The applicant shall furnish to the State Police, or other organization duly designated by the Board, a full set of fingerprints and any additional information required to complete the criminal history record check.

29.5. The applicant is responsible for any fees required by the State Police, or other organization duly designated by the Board, for the actual costs of the fingerprinting and the actual costs of conducting a complete criminal history record check.

29.6. The Board may require the applicant to obtain a criminal history records check from a similar Board approved agency or organization in the state of the applicant's residence if outside of West Virginia.

29.7. The applicant shall authorize the release of all records obtained by the criminal history record check to the Board.

29.8. A criminal history record check submitted in support of an application for licensure must have been requested by the applicant no earlier than twelve (12) months immediately prior to the Board's receipt of the applicant's application for licensure.

29.9. An initial licensure application is not complete until the Board receives the results o9f a state and criminal history record check conducted by the State Police or another entity duly

authorized by the Board. The Board shall not grant an application for licensure submitted by any applicant who fails or refuses to submit the criminal history record check required by this section.

29.10. Should criminal offenses be reported on an applicant's criminal history record check, the Board will consider the nature, severity, and recency of offenses, as well as rehabilitation and other factors on a case by case basis for licensure. Criminal history record checks shall be verified by a source acceptable to the Board, other than the applicant.

29.11 The results of the state and national criminal history record check may not be released to or by a private entity except:

29.11.a. To the individual who is the subject of the criminal history record check;

29.11.b. With written authorization of the individual who is the subject of the criminal history record check; or

29.11.c. Pursuant to a court order.

29.12. Criminal history record checks and related records are not public records for the purposes of chapter twenty-nine-b of the West Virginia Code.