PHARMACY LAWS AND LEGISLATIVE RULES OF WEST VIRGINIA

GOVERNING

THE PRACTICE OF PHARMACY

CONTROLLED SUBSTANCES ACT

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2017 EDITION

WEST VIRGINIA

BOARD OF PHARMACY

Reprinted from the West Virginia Code and Rules

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§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 28, 2017.

1.4. Effective date -- April 28, 2017.

1.5. Sunset Date -- This rule shall terminate and have no further force or effect on April 28, 2027.

§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 $125.00).

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

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;
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
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:

To dispose of procedural requests, prehearing motions or similar matters;
To simplify or settle issues by consent of the parties; of
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.

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.

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

the name of the drug and its quantity;
the date of transaction;
the permittee or practitioner to whom the prescription drug was transferred; and
the selling price.

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.

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.

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

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;
The drug's name and quantity; and
Directions for use.

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

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

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

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

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:

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;
the pharmacy retains a copy of all written, signed prescription drug sample requests;
prescription drug samples are stored separately from the prescription drug products held for sale (retail

stock);
records of prescription drug sample receipt or dispensing are maintained separately from records of prescription drug products held for sale and sold (retail stock);
a relationship exists between the health care entity and the pharmacy which is evidenced by a written documentation;
prescription drug samples are dispensed by the pharmacy to patients in the manufacturer's or distributor's original packaging; and
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:

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;
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
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:

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

Date of issuance of the original prescription;
Number of refills on the original prescription;
The date the original prescription was dispensed;
The number of valid refills remaining and date of last refill;
The pharmacy's name, address, DEA registry number and the original prescription number from which the prescription was transferred; and
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:

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

Its street number; and
The city and county;

The mailing address of the pharmacy if different from its physical location;
The name and license number of the pharmacist-in-charge;
The name and license numbers of other pharmacists regularly employed at the pharmacy;
The name and registration numbers of pharmacy technicians and pharmacy technician trainees regularly employed at the pharmacy;
The pharmacy's hours of operation; and
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:

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;

Physical barriers may be either of solid material or movable curtain type:

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
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:

The device shall be maintained in operating order and shall have an auxiliary source of power;
The device shall fully protect the prescription department and shall be capable of detecting breaking and/or entering by any means when activated;
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

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:

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

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. 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:

The drug's expiration date;
The date of preparation; and

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

personnel qualifications,
Continuing training and performance of staff;
Equipment and facilities requirements;
Standards for compounding and dispensing; and
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:

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

A statement that compounding shall be conducted within a properly certified vertical airflow hood;
A discussion of the proper use of protective garb;
A description of the proper techniques to prevent all contamination of the prescription and chemical contamination of the person preparing the prescription; and
Disposal procedures of cytotoxic agents 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:

Space.

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.
Adequate sit conditioning or positive air pressure must be maintained to prevent easy entry of outside air.
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.

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

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

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

Used needles and syringes;
All cytotic waste including disposable apparel used in its preparation;

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

Gloves, masks, and disposable gowns;
Disposable syringes and needles in necessary sizes;
Disinfectant cleaning material for equipment surfaces;
Disposable towels;
Liquid bactericidal cleanser for hand washing; and
Spill kits for cytotoxic agent spills;

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

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
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:

the standard radiation symbol;
The words “CAUTION-Radioactive Material”;
the name of the radio nucleotide;
the chemical form;
The amount of radioactive material contained in millicuries or microcuries;
The volume in milliliters, if the material is a liquid;
The requested calibration time for the amount of radioactivity contained; and
The practitioner’s name and the assigned lot number.

17.3.3. The immediate inner container shall be labeled with:

The standard radiation symbol;
The words “CAUTION-Radioactive Material”; and
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 stores 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.

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:

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

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

Identification of the repackager by name or by license number shall be clearly distinguishable from the rest of the label.

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:

identification of the dispensing pharmacy;
the patient's name;
the date of dispensing;
then name of the drug dispensed; and
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:

the name of the solution, the lot number, and the volume of the solution;
the patient's name;
the infusion rate;
the bottle sequence number or other system control number;
the name and quantity of each additive;
the date of the preparation;
the beyond-use date and time of parental admixture; and
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:

the name (including store number, if any), address, and telephone number of the pharmacy dispensing the drug;
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;
the name of the prescribing practitioner;
directions stated on the prescription order, and medication purpose/indication if included on the prescription order;
the date filled;
any cautions which may be required by federal or state law;
the prescription number of the prescription drug order;
the name or initials of the dispensing pharmacist;
the proprietary or generic name of the drug dispensed, and its strength;

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;
when dispensing a single-entity, single-source drug, the trade name of the prescribed drug may also appear on the label, and the generic name of the prescribed drug may also appear on the label;
when dispensing a fixed combination product, the United States Pharmacopeia's publication of Pharmacy Equivalent Names (PEN) for fixed combination products is the official list of abbreviations for labeling, and is the approved abbreviation for identifying the combination product dispensed;

drug quantity;
number of remaining refills;
auxiliary information;
the name of the manufacturer or distributor of the drug; and
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:

the standard radiation symbol;
the words "Caution- Radioactive Material; and
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:

the standard radiation symbol;
the words "Caution- Radioactive Material";
the radionuclide and chemical form;
the activity and date and time of assay;
the volume, if in liquid form;
the requested activity and the calibrated activity;
the prescription number;
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;
the name and address of the nuclear pharmacy;
the name of the practitioner; and
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 on the prescribed form, to register with the Board as follows:

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

The name, address and phone number of the applying consultant and his or her license number;
The name, address, phone number and type of institution, entity or person receiving the consulting services;
A description of the services to be provided by the consultant; and
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:

Prescriptions;
Floor stock;
Emergency boxes or kits;
Investigational drugs;
Samples; and
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:

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

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

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.

The pharmacist or his or her employer shall receive remuneration directly from the facility to which he or she is proving the service.
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:

The name and strength of the drug;
The name of the manufacturer or the packager;
The lot number; and
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:

The name and strength of each drug contained in the unit of use packet;
The name of the manufacturer or the packager of each drug in the unit of use packet;
The lot number of each drug in the unit use packet; and
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:

The name and strength of the drug contained in the punch card;
The name of the manufacturer or packager of the drug contained in the punch card;
The lot number of the drug contained in the punch card;
The expiration date of the drug contained in the punch card; and
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:

Drugs in emergency kits are to be administered only by those persons licensed to administered drugs;
The drugs in the emergency kit are of such nature that their absence would threaten the survival of the patients or intended recipients;
The contents of the emergency kit are determined by the pharmacist consultant and the medical director and the nursing director;
The emergency kit is sealed so that it is obvious if it has been opened and it is stored under secure conditions;
Administration of drugs from the kit is ordered by a practitioner and a record kept of administration;
Drugs stocked in the emergency kit are unit dose packaged;
Any drug used from the kit is replaced only upon a prescription or physician institution order form fir the patient to which the dose was administered; and
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.

WEST VIRGINIA
SECRETARY OF STATE
NATALIE E. TENNANT
ADMINISTRATIVE LAW DIVISION

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OFFICE WEST VIRGINIA SECRETARY OF STATE

Form#6

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

AGENCY: West Virginia Board of Pharmacy

TITLE NUMBER: 15

AMENDMENT TO AN EXISTING RULE: YES NO_

IF YES, SERIES NUMBER OF RULE BEING AMENDED: 2

TITLE OF RULE BEING AMENDED: RULES OF THE BOARD OF PHARMACY

FOR THE UNIFORM CONTROLLED SUBSTANCES ACT

IF NO, SERIES NUMBER OF RULE BEING PROPOSED: _

TITLE OF RULE BEING PROPOSED:

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

AUTHORIZATION IS CITED IN (house or senate bill number) ..:.S=en=a=te B=i=ll.:..10=1..:..7

SECTION ...§64-9-3 , PASSED ON June 14 2016

THIS RULE IS FILED WITH THE SECRETARY OF STATE. THIS RULE BECOMES EFFECTIVE ON THE FOLLOWING DATE: July 1, 2016

David E. Potters

Authored Signature

TITLE 15 LEGISLATIVE RULE BOARD OF PHARMACY

SERIES 2
RULES OF THE BOARD OF PHARMACY FOR THE UNIFORM CONTROLLED SUBSTANCES ACT

§ 15-2-1. General.

Scope. -- W. Va. Code §60A-3-301 mandates that the Board of Pharmacy shall promulgate rules relating to the registration and control of the manufacture and distribution of controlled substances within this State.

Authority. -- W. Va. Code §60A-3-301.

Filing Date. -- June 24, 2016.

Effective Date. -- July 1, 2016.

§ 15-2-2. Adoption of Federal Law.

The requirements of the federal regulations, Drug Enforcement Administration, Department of Justice, 21 CFR Parts 1300-1321, and the federal Controlled Substances Act, 21 U.S.C. 801, as revised, are adopted by the West Virginia Board of Pharmacy (hereinafter, the "Board") and all licensed pharmacists and licensed pharmacies shall comply with them.

The federal regulations are available on the internet at http://www.gpo.gov/fdsys/browse/collectionCfr.action?collectionCode=CFR.

§ 15-2-3. Controlled Substance Permits.

Persons required to register.

3.1.1 Every person who manufactures, distributes, including reverse distributing, or dispenses any controlled substance or who proposes to engage in the manufacture, distribution or dispensing of any controlled substance shall obtain annually a controlled substance permit unless exempted by law or pursuant to Section 3.2 of this rule. Only persons actually engaged in these activities are required to obtain a registration; related or affiliated persons who are not engaged in these activities are not required to be registered. For example, a stockholder or parent corporation of a corporation manufacturing controlled substances is not required to obtain a registration. A person who has obtained a controlled substance permit from the Board is a "registrant".

The Board shall exempt from payment of a fee for a controlled substance permit the following registrants:
Any official or agency of the United States Army, Navy, Marine Corps, Air Force, Coast Guard, Veterans' Administration or Public Health Service who is authorized to procure or purchase controlled substances for official use; and

Any official, employee or other civil officer or agency of the United States, of any state or any political subdivision or agency thereof, who is authorized to purchase controlled substances, to obtain the substances from official stocks, to dispense or administer the substances, to conduct research, instructional activities, or chemical analysis with the substances, or any combination thereof, in the course of his or her official duties or employment.

In order to claim exemption from payment of a fee, the applicant shall complete the certification on the appropriate application form, in which the registrant's superior certifies to the status and address of the registrant and to the authority of the registrant to acquire, possess or handle controlled substances.

Exemption from payment of a fee does not relieve the registrant of any other requirements or duties prescribed by law.

An applicant shall include all information called for in the form, unless the item is not applicable, in which case this fact shall be indicated.

An individual applicant shall sign each application, attachment, or other document filed as part of an application; the partners shall sign the application if the applicant is a partnership; by a partner of the applicant if a partnership; the officers shall sign the application if the applicant is a corporation, corporate division, association, trust or other entity. Another person may be authorized to sign for the applicant, if proof of authority (e.g., general power of attorney) accompanies the application.

If the applicant is a pharmacy, the pharmacist in charge of the pharmacy shall sign the application. If the owner of the pharmacy is a person, other than the practicing pharmacist, the other person, partnership, or corporation, corporate division, association, trust or other entity, shall sign the application form as provided in subsection 3.4 of this rule in addition to any other persons required to sign the application.

If the applicant is a rest home, nursing home, hospital, orphanage, clinic, home for the aged, governmental agency or institution or other place requiring the use of pharmacist consultants or coordinators of pharmaceutical services, the consultant or coordinator shall sign the application in addition to any other persons required to sign the application.

Filing of application; joint filings.

3.7.1 An applicant for registration shall submit the application to the office of the Board of Pharmacy for filing.

3.7.2. Any person required to obtain more than one (1) registration may submit all applications in one (1) package. Each application must be complete and should not refer to an accompanying application for required information.

Acceptance for filing; defective applications.

Upon receipt, the Board shall date applications submitted for filing. If found to be complete, the Board will accept the application for filing. The Board will not accept any application failing to comply with the requirements of this rule. If an application has minor defects as to completeness, the Board may accept the application for filing with a request to the applicant for additional information. The Board shall return a defective application to the applicant within ten
(10) days following its receipt with a statement of the reason for not accepting the application for filing. An applicant may correct a defective application and resubmit the application for filing at any time.

Additional information.

The Board may require an applicant to submit such documents or written statements of fact relevant to the application as it considers necessary to determine whether the application should be granted. The failure of the applicant to provide the documents or statements within a reasonable time after being requested to do so is considered a waiver by the applicant of an opportunity to present the documents or facts for consideration by the Board in granting or denying the application.

Amendments to and withdrawal of applications.

An applicant may amend or withdraw an application without permission of the Board at any time before the date on which the applicant receives an order to show cause, or before the date on which a notice of hearing on the application is published pursuant to W. Va. Code §60A- 3-305, whichever is sooner. An applicant may amend or withdraw an application with permission of the Board at any time where good cause is shown by the applicant or where the amendment or withdrawal is in the public interest.

3.10.2 After an application has been accepted by the Board for filing, the Board shall consider a request by the applicant that it be returned or failure of the applicant to respond to official correspondence regarding the application, when sent by registered or certified mail, as withdrawal of the application.

Administrative review generally.

The Board may inspect, or cause to be inspected, the establishment of an applicant or registrant, pursuant to W. Va. Code §60A-5-501. The West Virginia Board of Pharmacy shall

review the application for registration and other information gathered by the Board regarding an applicant in order to determine whether the applicable standards of. Va. Code §60A-3-303 have been met by the applicant.

Applications for research in Schedule I substances.

In the case of an application for registration to conduct research with controlled substances in Schedule I, the Board shall determine the qualifications and competency of the applicant as well as the merits of the research protocol. The Board, in determining the merits of a research protocol, shall confer as to effective procedures to safeguard adequately against diversion of the controlled substances from legitimate medical or scientific use. If the Board finds the applicant qualified and competent and the research protocol meritorious and adequately safeguarded, it shall register the applicant unless it finds registration should be denied for reasons set forth in W. Va. Code §60A-3-303.

If the Board is unable to find the applicant qualified or the Board finds that grounds exist for the denial of the application, it shall issue an order to show cause and, if requested by the applicant, shall hold a hearing on the application.

The controlled substance permit shall contain the name, address and registration number of the registrant, the activity authorized by the registration, the schedules of the controlled substances which the registrant is authorized to handle, and the expiration date of the registration. The registrant shall prominently display the controlled substance permit at the registered location.

Registration or any authority conferred may not be assigned or otherwise transferred except upon conditions specifically designated by the Board and then only pursuant to its written consent.

§ 15-2-4. Security Requirements.

Security requirements.

Security requirements generally.

All registrants shall provide effective controls and procedures to guard against theft and diversion of controlled substances. In order to determine whether a registrant has provided effective controls against diversion, the Board shall evaluate the overall security system and needs of the applicant or registrant.

Physical security controls shall be commensurate with the schedules and quantity of controlled substances in the possession of the registrant in normal business operations. If a controlled substance is transferred to a different schedule or a noncontrolled substance is listed on any schedule, or the quantity of controlled substances in the possession of the registrant in normal business operations significantly increases, physical security controls shall be expanded and extended accordingly.

All registrants who receive or transfer substantial quantities of controlled substances in normal business operations shall employ security procedures to guard against in-transit losses.

Before distributing a controlled substance to any person who the registrant does not know to be registered to possess the controlled substance, the registrant shall make a good faith inquiry either with the Board or with the appropriate state controlled substances registration agency, if any, to determine that the person is registered to possess the controlled substance.

The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Office of the Board of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.

The registrant shall notify the Office of the Board of any theft or significant loss of any controlled substances upon discovery of the theft or loss as provided in subsection 8.3.

Physical security controls

When a pharmacy is closed, controlled substances listed in Schedule II shall be stored in a securely locked narcotic cabinet made of 20 gauge metal or better or may be dispersed throughout the stock of noncontrolled substances in a manner as to obstruct the theft or diversion of the controlled substance. Any other method of storage of controlled substances listed in Schedule II is not allowed unless specifically approved by the Board for that particular pharmacy. Only pharmacists practicing at the pharmacy and authorized by the pharmacist-in-charge may possess any keys or combinations to the narcotic cabinet. Controlled substances listed in Schedule III, IV, or V may be stored in the narcotic cabinet or may be dispersed throughout the stock of noncontrolled substances in such a manner as to obstruct the theft or diversion of the controlled substance. A secure automated distribution system, approved by the Board, may contain controlled substances within an institutional setting in lieu of a narcotic cabinet.

The registrant shall not employ as an agent or employee who has access to controlled substances, any person who has been convicted of a felony offense relating to controlled substances or who, at any time, had an application for registration denied, or had his or her registration revoked.

§ 15-2-5. Definitions; Labeling And Packaging Requirements For Controlled Substances.

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

"Act" means the Uniform Controlled Substances Act (W. Va. Code §60A-1-101 et. seq.).

"Analogue" means a substance that, in relation to a controlled substance, has a substantially similar chemical structure.

"Commercial Container" means any bottle, jar, tube, ampule, or other receptacle in which a substance is held for distribution or dispensing to an ultimate user, and in addition, any box or package in which the receptacle is held for distribution or dispensing to an ultimate user. "Commercial Container" does not include any package liner, package insert or other material kept with or within a commercial container, nor any carton, crate, drug, or other package in which commercial containers are stored or are used for shipment of controlled substances.

"Immediate derivative" means a substance which is the principal compound or any analogue of the parent compound manufactured from a known controlled substance primarily for use and which has equal or similar pharmacologic activity as the parent compound which is necessary to prevent, curtail or limit manufacture.

"Immediate precursor" means a substance which is the principal compound commonly used or produced primarily for use and which is an immediate chemical intermediary used or likely to be used in the manufacture of a controlled substance, the control of which is necessary to prevent, curtail or limit manufacture.

"Individual Practitioner" means a physician, dentist, veterinarian or other individual licensed, registered or otherwise permitted, by the jurisdiction in which he or she practices, to dispense a controlled substance in the course of professional practice, but does not include a pharmacist, a pharmacy or an institutional practitioner.

5.1.7 "Institutional Practitioner" means a hospital or other person (other than an individual) licensed, registered or otherwise permitted, by the jurisdiction in which it practices, to dispense a controlled substance in the course of professional practice, but does not include a pharmacy.

"Label" means a display of written, printed, or graphic matter upon the immediate container of any drug or device.

"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.

"Manufacture" means the producing, preparation, propagation, compounding, conversion or processing of a controlled substance, either directly or indirectly or by extraction from substances of natural origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis, and includes any packaging or repackaging of the substance, or the labeling or relabeling of its container, except that this term does not include the preparation, compounding, packaging or labeling of a controlled substance:

By a practitioner as an incident to his or her administering or dispensing of a controlled substance in the course of his or her professional practice; or

By a practitioner, or by his or her authorized agent under his or her supervision, for the

purpose of, or as an incident to, research, teaching or chemical analysis and not for sale.

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

"Perpetual inventory" means an ongoing system for recording quantities of drugs received, dispensed or otherwise distributed by a pharmacy.

"Pharmacist" or "registered pharmacist" means an individual currently licensed by the jurisdiction in which he or she practices to engage in the practice of pharmacist care.

"Prescription" means an order for medication which is dispensed to or for an ultimate user but does not include the immediate administration to the ultimate user.

"Readily Retrievable" means that certain records are kept by automatic data processing systems or other electronic or mechanized record keeping systems in such a manner that they can be separated out from all other records in a reasonable time and/or records are kept on which certain items are asterisked, red-lined or in some other manner visually identifiable apart from other items appearing on the records.

"Registrant" means a person who has obtained a controlled substance permit from the Board.

Any term not defined in this rule has the definition set forth in W. Va. Code §60A-1- 101 and 60A-8-5.

Symbol required; exceptions.

Each commercial container of a controlled substance shall have printed on the label the symbol designating the schedule in which the controlled substance is listed. Each commercial container, if it otherwise has no label, shall bear a label complying with the requirement of this section.

Each manufacturer shall print upon the labeling of each controlled substance distributed the symbol designating the schedule in which the controlled substance is listed.

The following symbols shall designate the schedule corresponding thereto: Schedule I .....CI or C-I.
Schedule II .....CU or C-II.
Schedule III .....CIII or C-III.
Schedule IV.....CIV or C-IV.
Schedule V .....CV or C-V.

The word "Schedule" need not be used. No distinction need be made between narcotic and nonnarcotic substances.

The symbol is not required on a carton or wrapper in which a commercial container is held if the symbol is easily legible through the carton or wrapper.

The symbol is not required on a commercial container too small or otherwise unable to accommodate a label, if the symbol is printed on the box or package from which the commercial container is removed upon dispensing to an ultimate user.

The symbol is not required on a commercial container containing, or on the labeling of, a controlled substance being utilized in clinical research involving blind and double blind studies.

The symbol is not required on a commercial container containing, or on the labeling, of a controlled substance intended for export from the United States.

Location and size of symbol on label.

5.3.1 The symbol shall be prominently located on the right upper comer of the principal panel of the label of the commercial container and/or the panel of the commercial container normally displayed to dispensers of any controlled substance listed in Schedule I through V. The symbol shall be at least two (2) times as large as the largest type otherwise printed on the label.

5.3.2. In lieu of locating the symbol in the comer of the label, as prescribed in subsection

5.3.1 of this rule, the symbol may be overprinted on the label, in which case the symbol shall be printed at least one half (2) the height of the label and in a contrasting color providing clear visibility against the background color of the label.

5.3.3 In all cases, the symbol shall be clear and large enough to afford easy identification of the schedule of the controlled substance upon inspection without removal from the dispenser's shelf.

Location and size of symbol on labeling.

The symbol shall be prominently located on all labeling other than labels covered by subsection 5.3 of this rule. In all cases the symbol shall be clear and large enough to afford prompt identification of the controlled substance upon inspection of the labeling.

Effective dates of labeling requirements.

All labels on commercial containers of, and all labeling of, a controlled substance which either is listed in any schedule on June 15, 1971, and thereafter transferred to another schedule or is added to any schedule after June 15, 1971, and which is packaged more than one hundred eighty

(180) days following the date on which the transfer or addition becomes effective, shall comply with the requirements of subsection 5.2 of this rule.

The Board may, in the case of any controlled substance, require compliance with the requirements of subsection 5.2 of this rule, within a period of time shorter than required by this section if it finds that public health or safety necessitate an earlier effective date.

Sealing of controlled substances.

On each bottle, multiple dose vial, or other commercial container of any controlled substance, there shall be securely affixed to the stopper, cap, lid, covering or wrapper or other container, a seal to disclose upon inspection any tampering or opening of the container.

§ 15-2-6. Records And Reports Of Registrants.

All records required to be kept shall be readily retrievable.

Maintenance of records and inventories.

Every inventory and other record required to be kept shall be kept by the registrant and be available, for at least five (5) years from the date of the inventory or record, for inspecting and copying by authorized employees of the Board.

Each registered manufacturer, distributor, importer, and exporter shall maintain inventories and records of controlled substances as follows:

Inventories and records of controlled substances listed in Schedules I and II shall be maintained separately from all of the records of the registrant; and

Inventories and records of controlled substances listed in Schedules III, IV and V shall be maintained either separately from all other records of the registrant or in a form that the information required is readily retrievable from the ordinary business records of the registrant.

Each registered individual practitioner and institutional practitioner required to keep records shall maintain inventories and records of controlled substances in the manner prescribed in subdivision 6.2.2 of this rule.

Each registered pharmacy shall maintain the inventories and records of controlled substances as follows:

Inventories and records of all controlled substances listed in Schedules I and II shall be maintained separately from all other records of the pharmacy, and prescriptions for the substances shall be maintained in a separate prescription file. Each pharmacy shall maintain a perpetual inventory of all Schedule II drugs received, dispensed, or otherwise distributed, with reconciliation at least monthly. Electronic monitoring at the pharmacy or by another entity that provides alerts for

discrepancies between drugs received, drugs dispensed, or otherwise distributed is acceptable provided such alerts are reviewed at least monthly; and

Inventories and records of controlled substances listed in Schedules III, IV and V shall be maintained either separately from all other records of the pharmacy or in a form that the information required is readily retrievable from ordinary business records of the pharmacy, and prescriptions for the substances shall be maintained either in a separate prescription file for controlled substances listed in Schedules III, IV and V only, or in a form that they are readily retrievable from the other prescription records of the pharmacy. Prescriptions shall be considered readily retrievable if, at the time they are initially filed, the face of the prescription is stamped in red ink in the lower right corner with the letter "C" no less than 1 inch high and filed either in the prescription file for controlled substances listed in Schedules I and II or in the usual consecutively numbered prescription file for noncontrolled substances. However, if a pharmacy employs an automated data processing system or other electronic record-keeping system for prescriptions which permits identification by prescription number and retrieval of original documents by prescriber's name, patient's name, drug dispensed, and date filled, then the requirement to mark the hard copy prescription with a red "C" is waived.

General requirements for inventories.

Each inventory shall contain a complete and accurate record of all controlled substances on hand on the date the inventory is taken. Controlled substances are considered to be "On Hand" if they are in the possession of or under the control of the registrant, including substances returned by a customer, substances ordered by a customer but not yet invoiced, substances stored in a warehouse on behalf of the registrant and substances in the possession of employees of the registrant and intended for distribution as complimentary samples.

A registrant shall make a separate inventory for each registered location. In the event controlled substances are in the possession or under the control of the registrant at a location for which he or she is not registered, the substances shall be included in the inventory of the registered location to which they are subject to control or to which the person possessing the substance is responsible. Each inventory for a registered location shall be kept at the registered location.

A registrant shall make a separate inventory for each independent activity for which he or she is registered, except as provided in subsection 6.10 of this rule.

A registrant may take an inventory either as of the opening of business or as of the close of business on the inventory date. The registrant shall indicate on the inventory records whether the inventory is taken as of the opening or as of the close of business and the date the inventory is taken.

A registrant shall maintain an inventory in a written, typewritten or printed form. An inventory taken by use of an electronic or oral recording device shall be promptly transcribed.

Initial inventory date.

Every person required to keep records shall take an inventory of all stocks of controlled substances on hand on the date he or she first engages in the manufacture, distribution or dispensing of controlled substances, in accordance with subsections 6.4 through 6.7 of this rule, as applicable. In the event a person commences business with no controlled substances on hand, he or she shall record this fact as the initial inventory.

Biennial inventory date.

After the initial inventory is taken, the registrant shall take a new inventory of all stocks of controlled substances on hand at least every two years. The biennial inventory may be taken on any date which is within two years of the previous biennial inventory date.

Inventory date for new controlled substances.

On the effective date of a rule or statutory change by the Board or the DEA adding a substance to any schedule of controlled substances, when the substance was, immediately prior to that date, not listed on any such schedule, every registrant required to keep records who is manufacturing, distributing or dispensing that substance, shall take an inventory of all stocks of the substance on hand. Thereafter the substance shall be included in each inventory made by the registrant pursuant to subsection 6.5 of this rule.

Inventories of manufacturers.

Each registered manufacturer shall include the following information in the inventory:

For each controlled substance in bulk form to be used in (or capable of use in) the manufacture of the same or other controlled or noncontrolled substances in finished form:

The name of the substance; and

The total quantity of the substance to the nearest metric unit weight consistent with unit size.

For each controlled substance in the process of manufacture on the inventory date:

The name of the substance;

The quantity of the substance in each batch and/or stage of manufacture, identified by the batch number or other appropriate identifying number; and

The physical form which the substance is to take upon completion of the

manufacturing process (e.g. granulations, tablets, capsules or solutions), identified by the batch number or other appropriate identifying number, and if possible the finished form of the substance (e.g. ten (10) milligram tablet or ten (10) milligram concentration per fluid ounce of milliliter) and the number or volume of the substance.

For each controlled substance in finished form:

The name of the substance;

Each finished form of the substance (e.g., ten (10) milligram tablet or ten (10) milligram concentration per fluid ounce or milliliter);

The number of units or volume of each finished form in each commercial container (e.g., one hundred (100) tablet bottles or six (6) three (3) milliliter vials); and
The total quantity of the substance in all forms to the nearest metric unit weight.

For each controlled substance not included in Subdivisions (a), (b) or (c) of this subsection (e.g., damaged, defective or impure substances awaiting disposal, substances held for quality control purposes, or substances maintained for extemporaneous compoundings):

The name of the substance;

The total quantity of the substance to the nearest metric unit weight or the total number of units of finished form; and

The reason for the substance being maintained by the registrant and whether the substance is capable of use in the manufacture of any controlled substance in finished form.

Inventories of distributors.

Each registered distributor shall include in the inventory the same information required of manufacturers pursuant to subdivision 6.7.1 (c) and subdivision 6.7.1(d) of this rule.

Inventories of dispensers and researchers.

Each person registered to dispense or conduct research with controlled substances and required to keep records pursuant to section 6.4 of this rule, shall include in the inventory the same information required of manufacturers pursuant to subdivision 6.7.1 (c) and subdivision 6.7.1(d) of this rule. In determining the number of units of each finished form of a controlled substance in a commercial container which has been opened, the dispenser shall do as follows:

If the substance is listed in Schedule I or II, the dispenser shall make an exact count or measure of the content; and

If the substance is listed in Schedule III, IV or V, the dispenser shall make an estimated count or measure of the contents, unless the container holds more than one thousand (1,000) tablets or capsules in which case the dispenser shall make an exact count of the contents.

Inventories of importers and exporters.

Each registered importer or exporter shall include in the inventory the same information required of manufacturers pursuant to subdivision 6.7.1 (c) and subdivision 6.7.1(d) of this rule. Each registered importer and exporter who is also registered as a manufacturer or as a distributor shall include in the inventory as an importer or exporter only those stocks of controlled substances that are actually separated from the stocks as a manufacturer or as a distributor (e.g., in transit or in storage for shipment).

Inventories for chemical analysts.

Each analytical laboratory registered to conduct chemical analysis with controlled substances shall include in its inventory the same information required of manufacturers pursuant to subdivision 6.7.1 (c) and subdivision 6.7.1(d) of this rule, as to substances which have been manufactured, imported or received by the laboratory conducting the inventory. If less than one (1) kilogram of any controlled substance (other than a hallucinogenic controlled substance listed in Schedule I), or less than twenty (20) grams of a hallucinogenic substance listed in Schedule I, (other than lysergic acid diethylamide), or less than five tenths (0.5) gram of lysergic acid diethylamide, is on hand at the time of inventory, that substance need not be included in the inventory. Laboratories of the Board may possess up to one hundred fifty (150) grams of any hallucinogenic substance in Schedule I without regard to a need for an inventory of those substances.

General requirements for continuing records.

Every registrant required to keep records pursuant to subsection 6.3 of this rule, shall maintain on a current basis a complete and accurate record of each substance manufactured, imported, received, sold, delivered, exported or otherwise disposed of by the registrant.

A registrant shall maintain separate records for each registered location. In the event controlled substances are in the possession or under the control of a registrant at a location for which he or she is not registered, the registrant shall include the substances in the records of the registered location to which they are subject to control or to which the person possessing the substance isresponsible.

A registrant shall maintain separate records for each independent activity for which he or she is registered.

In recording dates of receipt, importation, distribution, exportation or other transfer, the registrant shall use the date on which the controlled substances are actually received, imported, distributed, exported or otherwise transferred as the date of receipt or distribution of any documents

of transfer (e.g., invoices or packing slips).

Records of manufacturers.

Each registered manufacturer shall maintain records with the following information to account for all controlled substances used in the manufacturing process:

For each controlled substance in bulk form to be used, or capable of use in, or being used in, the manufacture of the same or other controlled or noncontrolled substances in finished form:

The name of the substance;

The quantity manufactured in bulk form by the registrant, including the date, quantity and batch or other identifying number of each batch manufactured;

The quantity received from other persons, including the date and quantity of each delivery and the name, address and registration number of the other person from whom the substance was received;

The quantity imported directly by the registrant (under a registration as an importer) for use in manufacture by him or her, including the date, quantity and import permit or declaration number for each importation;

The quantity used to manufacture the same substance in finished form, including:

The date and batch or other identifying number of each manufacture;
The quantity used in the manufacture;

The finished form (e.g., ten (10) milligram tablets or ten (10) milligram concentration per fluid ounce or milliliter);

The number of units of finished form manufactured;

The quantity used in quality control;

The quantity lost during manufacturing and the causes therefore, if known;

The total quantity of the substance contained in the finished form;

The theoretical and actual yields; and

Any other necessary information;

The quantity used to manufacture other controlled and noncontrolled substances, including the name of each substance manufactured and the information required in subdivision 6.13.l(a)(5) of this rule;

The quantity distributed in bulk form to other persons, including the date and quantity of each distribution and the name, address and registration number of each person to whom a distribution was made;

The quantity exported directly by the registrant (under a registration as an exporter), including the date, quantity and export permit or declaration number of each exportation; and

The quantity distributed or disposed of in any other manner by the registrant (e.g., by distribution of complimentary samples or by destruction), including the date and manner of distribution or disposal, the name, address and registration number of the person to whom distributed and the quantity distributed or disposed.

For each controlled substance in finished form:

The name of the substance;

Each finished form (e.g., ten (10) milligram tablet or ten (10) milligram concentration per fluid ounce or milliliter) and the number of units or volume of finished form in each commercial container (e.g., one hundred (100) tablet bottle or three (3) milliliter vial);

The number of containers of each commercial finished form manufactured from bulk form by the registrant, including the information required pursuant to subdivision 6.13.1(a)(5) of this rule;

The number of units of finished forms and/or commercial containers received from other persons, including the date of and number of units and/or commercial containers in each delivery and the name, address and registration number of the person from whom the units were received;

The number of units of finished forms and/or commercial containers imported directly by the registrant (under a registration as an importer), including the date of and the number of units and for commercial containers in each importation;

The number of units and/or commercial containers manufactured by the registrant from units in finished form received from others or imported, including:

The date and batch or other identifying number of each manufacture;

The operation performed (e.g., repackaging or relabeling);

The number of units of finished form used in the manufacture, the number manufactured and the number lost during manufacture, with the causes therefore, if known; and

Any other information necessary to account for all controlled substances used in the manufacturing process;

The number of commercial containers distributed to other persons, including the date of and number of containers in each distribution, and the name, address and registration number of the person to whom the containers were distributed;

The number of commercial containers exported directly by the registrant (under a registration as an exporter), including the date, number of containers and export permit or declaration number for each exportation; and

The number of units of finished forms and/or commercial containers distributed or disposed of in any other manner by the registrant (e.g., by distribution of complimentary samples or by destruction), including the date and manner of distribution or disposal, the name, address and registration number of the person to whom distributed and the quantity in finished form distributed or disposed.

Records for distributors.

Each registered distributor shall maintain records with the following information for each controlled substance:

The name of the substance;

Each finished form (e.g., ten (10) milligram tablet or ten (10) milligram concentration per fluid ounce or milliliter) and the number of units or volume of finished form in each commercial container (e.g., one hundred (100) tablet bottle or three (3) milliliter vial);

The number of commercial containers of each finished form received from other persons, including the date of and number of containers in each delivery and the name, address and registration number of the person from whom the containers were received;

The number of commercial containers of each finished form imported directly by the registrant (under a registration as an importer), including the date of and the number of containers in each importation;

The number of commercial containers of each finished form distributed to other persons, including the date of and number of containers in each distribution and the name, address and registration number of the person to whom the containers were distributed;

The number of commercial containers of each finished form exported directly by the registrant (under a registration as an exporter), including the date of and the number of containers in each exportation; and

The number of units or volume of finished forms and/or commercial containers distributed or disposed of in any other manner by the registrant (e.g., by distribution as complimentary samples), including the date and manner of distribution or disposal, the name, address and registration number of the person to whom distributed and the quantity of the substance in finished form distributed or disposed.

Records for dispensers and researchers.

Each person registered to dispense or conduct research with controlled substances and required to keep records pursuant to section 6.3 of this rule, shall maintain records with the following information for each controlled substance:

The name of the substance;

Each finished form (e.g., ten (10) milligram tablet or ten (10) milligram concentration per fluid ounce or milliliter) and the number of units or volume of finished form in each commercial container (e.g., one hundred (100) bottle or three (3) milliliter vial);

The number of commercial containers of each finished form received from other persons, including the date of and number of containers in each delivery and the name, address and registration number of the person from whom the containers were received;

The number of units or volume of each finished form dispensed, including the name and address of the person to whom it was dispensed, the date of dispensing, the number of units or volume dispensed, and the written or typewritten name or initials of the individual who dispensed or administered the substance on behalf of the dispenser; and

The number of units or volume of each finished form and/or commercial container disposed of in any other manner by the registrant, including the date and manner of disposal and the quantity of the substance in finished form disposed.

Records for importers.

Each registered importer shall maintain records with the following information for each controlled substance:

The name of the substance;

The quantity (or number of units or volume in finished form) imported, including the date, quantity (or number of units or volume) and import permit or declaration number for each

importation;

The quantity (or number of units or volume in finished form) distributed to other persons, including the date and quantity (or number of units or volume) of each distribution and the name, address and registration number of each person to whom a distribution was made;

The quantity disposed of in any other manner by the registrant (except quantities used in manufacturing by an importer under a registration as a manufacturer, which is to be recorded pursuant to subdivision 6.13.l(a)(4) or subdivision 6.13.l(b)(5) of this rule, including the date and manner of disposal and the quantity disposed.

Records for chemical analysis.

Each person registered to conduct chemical analysis with controlled substances shall maintain records with the following information, to the extent known and reasonably ascertainable, for each controlled substance:

The name of the substance;

The form or forms in which the substance is received, imported or manufactured by the registrant (e.g., powder, granulation, tablet, capsule or solution) and the concentration of the substance in that form (e.g., C.P., U.S.P., N.F., ten (10) milligram tablet or ten (10) milligram concentration per milliliter);

The total number of the forms received, imported or manufactured (e.g., one hundred (100) tablets, thirty (30) one (1) milliliter vial, or ten (10) grams of powder), including the date and quantity of each receipt, importation or manufacture and the name, address and registration number, if any, of the person from whom the substance was received; and

The quantity distributed, exported or destroyed in any manner by the registrant (except quantities used in chemical analysis or other laboratory work), including the date, the manner of distribution, exportation or destruction and the name, address and registration number, if any, of each person to whom the substance was distributed or exported.

Order forms, import and export permits, import invoices and export declarations relating to controlled substances shall be maintained separately from all other records of the registrant.

Records of controlled substances used in chemical analysis are not required.

Records relating to known or suspected controlled substances received as samples for analysis are not required under this section.

§ 15-2-7. Prescriptions.

Rules governing the issuance, filling and filing of prescriptions for controlled substances are set forth generally in W. Va. Code §60A-3-308 and West Virginia Code of State Rules§ 15-1-21.

Reserved.

Persons entitled to issue prescriptions.

A prescription for a controlled substance may be issued only by an individual practitioner who is authorized to prescribe controlled substances in the jurisdiction in which he or she practices, and is strictly limited to the schedule(s), class(es) or specific substance(s) which he or she is permitted by that jurisdiction to prescribe.

A prescription issued by an individual practitioner except for Schedule II controlled substance, may be communicated to a pharmacist by an employee or agent of the individual practitioner.

Purpose of issue of prescription.

To be effective, an individual practitioner shall issue a prescription for a controlled substance for a legitimate medical purpose in the usual course of his or her professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription. An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription within the meaning and intent of the Uniform Controlled Substances Act and the person knowingly filling such a purported prescription, as well as the person issuing it, are subject to the penalties provided for violations of the provisions of law relating to controlled substances.

An individual practitioner shall not issue a prescription in order for the individual practitioner to obtain controlled substances for the purpose of general dispensing to patients; i.e. office use. A pharmacy may provide controlled substances to a practitioner for office use, but must do so by providing appropriate documentation through the use of an invoice or other federally required documentation or forms.

A practitioner shall not issue a prescription for the dispensing of narcotic drugs listed in any schedule to a narcotic drug dependent person for the purpose of continuing his or her dependence upon such drugs, except in the course of conducting an authorized clinical investigation in the development of a narcotic addict rehabilitation program.

Manner of issuance of prescriptions.

All prescriptions for controlled substances shall be dated as of, and signed on, the day when issued and shall bear the full name and address of the patient, and the name, address and

registration number of the practitioner. If the prescription is transmitted by e-prescribing, the signature may be an electronic signature. All paper prescriptions, including, but not limited to traditional paper prescription blanks, computer generated prescriptions that are printed out or faxed, and prescriptions received by the pharmacy as a fax prescription regardless of the method of transmission by the prescriber, must contain the prescriber's manual signature; an electronic signature, an electronic reproduction of the signature, signature stamp, or other form of signature is not a valid signature for a paper prescription. A practitioner may sign a prescription in the same manner as he or she would sign a check or legal document (e.g. J.H. Smith or John H. Smith). Where an oral order is not permitted, prescriptions shall be written, typed, or computer-generated and printed with ink, and shall be manually signed by the practitioner. The prescriptions may be prepared by a secretary or agent for the signature of a practitioner, but the prescribing practitioner is responsible in case the prescription does not conform in all essential respects to the law and legislative rules. A corresponding liability rests upon the pharmacist who fills a prescription not prepared in the form prescribed in this rule, Provided that: a pharmacist may make changes to a prescription order written for a controlled substance in accordance with the following:

the pharmacist may add or change the patient's address upon verification;
the pharmacist may add or change the dosage form, drug strength, drug quantity, directions for use, or issue date only after consultation with and agreement of the prescribing practitioner.
such consultations and corresponding changes should be noted by the pharmacist on the prescription; and
the pharmacist is never permitted to make changes to the patient's name, controlled substance prescribed (except for generic substitution permitted by state law) or the prescriber's signature.

Form of controlled substance prescription.

Each controlled substance prescription shall be written on a separate blank and no non-- controlled substance can be ordered on a blank with a controlled substance. This rule does not apply to prescriptions written for patients of an institutional facility as defined by West Virginia Code of State Rules § 15-1-2.1.21, 15 CSR 1. No more than one controlled substance may be written per prescription blank. A controlled substance prescription issued by a practitioner located outside the state of West Virginia that does not comply with this section may be accepted by the pharmacist if it is issued pursuant to the laws in the state in which the practitioner resides.

If a pharmacist receives a prescription with more than one controlled substance on the blank or a non-controlled substance on a blank with a controlled substance, then the pharmacist shall refuse to fill the prescription. If the pharmacist in his or her professional judgment determines the immediate necessity for the patient to receive his or her medication, then the prescriptions may be dispensed and the pharmacist shall document in a log the prescription numbers and drugs dispensed. This log shall be kept in the pharmacy and be available for inspection. The pharmacist shall contact the prescriber as soon as possible to inform them that the prescription was not written according this rule. If the pharmacist continues to receive prescriptions from the same practitioner that do not

comply with this rule, then the pharmacist shall inform the Board.

Every controlled substance prescription shall have the name of the practitioner stamped, typed, or printed legibly on the face of the prescription, as well as the signature of the practitioner. Institutional prescription blanks shall include the DEA number of the hospital or other institution and the special internal code number (suffix) assigned to him or her by the hospital or other institution, in lieu of the individual DEA number of the practitioner. If multiple practitioners are listed on a prescription blank, then the specific name of the prescriber shall be clearly distinguished upon the prescription. If a pharmacist receives a prescription that does not comply with this subsection, then the pharmacist shall refuse to fill the prescription. If the pharmacist in his or her professional judgment determines the immediate necessity for the patient to receive his or her medication, then the prescriptions may be dispensed and the pharmacist shall document in a log the date, patient name, practitioner name, prescription numbers, and drugs dispensed. This log shall be kept in the pharmacy and be available for inspection. The pharmacist shall contact the prescriber as soon as possible to inform them that the prescription was not written according to this rule. If the pharmacist continues to receive prescriptions from the same practitioner that do not comply with this rule, then the pharmacist shall inform the Board.

Persons entitled to fillprescriptions.

A prescription for controlled substances may only be filled by a pharmacist acting in the usual course of his or her professional practice and either registered individually or employed in a registered pharmacy or registered institutional practitioner (e.g., a hospital, nursing home, home for the aged, clinic, orphanage, governmental agency or institution or other place of similar character which dispenses controlled substances).

Dispensing of narcotic drugs for maintenance purposes.

7.8.1 The administering or dispensing directly, but not prescribing, of narcotic drugs listed in any schedule to a narcotic drug dependent person for "detoxification treatment" or "maintenance treatment" shall be considered to be within the meaning of the term "in the course of his or her professional practice or research.": Provided, that the practitioner is separately registered with the
U.S. Attorney General as required by section 303(g) of the federal Controlled Substances Act (21
U.S.C. 823(g)) and then thereafter complies with the regulatory standards imposed relative to treatment
qualification, security, records and unsupervised use of drugs pursuant to the Act.

A physician who is not specifically registered to conduct a narcotic treatment program may administer, but not prescribe, narcotic drugs to a person for the purpose of relieving acute withdrawal symptoms when necessary while arrangements are being made for referral for treatment. No more than one day's medication may be administered to the person or for the person's use at one time. The emergency treatment may be carried out for not more than three days and may not be renewed orextended.

This section is not intended to impose any limitations on a physician or authorized

hospital staff to administer or dispense narcotic drugs in a hospital to maintain or detoxify a person as an incidental adjunct to medical or surgical treatment of conditions other than addiction, or to administer or dispense narcotic drugs to persons with intractable pain in which no relief or cure is possible or none has been found after reasonable efforts.

Controlled substances listed in Schedule II.

Requirement of prescription.

A pharmacist may dispense a controlled substance listed in Schedule II, which is a prescription drug as determined under the Federal Food, Drug and Cosmetic Act, only pursuant to a paper prescription manually signed by the prescribing individual practitioner, or by electronic prescribing, except as allowed by subdivision 7.9.2 of this rule. A prescription for a Schedule II controlled substance may be transmitted by the practitioner or the practitioner's agent to a pharmacy via facsimile equipment or other electronic transmission other than electronic prescribing, provided that the original paper, manually signed prescription is presented to the pharmacist for review prior to the actual dispensing of the controlled substance, except as provided by West Virginia Code of State Rules § 15-1-21, 15 CSR 1. A prescription for a Schedule II controlled substance is valid for ninety (90) days from the date issued. A pharmacist may fill the prescription after ninety (90) days if the prescriber confirms to the pharmacist that he or she still wants the prescription filled and the pharmacist documents upon the prescription that the confirmation was obtained.

An individual practitioner may administer or dispense a controlled substance listed in Schedule II in the course of his or her professional practice without a prescription, subject to subsection 7.8.1 of this rule.

An institutional practitioner may administer or dispense directly, but not prescribe, a controlled substance listed in Schedule II only pursuant to a paper prescription manually signed by the prescribing individual practitioner, an electronic prescription, or an order for medication made by an individual practitioner which is dispensed for immediate administration to the ultimate user.

In the case of an emergency situation, a practitioner may communicate a prescription for a Schedule II controlled substance orally or by way of electronic transmission other than electronic prescribing, provided that if the prescribing practitioner is not known to the pharmacist, the pharmacist shall make a reasonable effort to determine that the oral authorization came from a registered practitioner, which may include a call-back to the practitioner using the practitioner's phone number as listed in the telephone directory and other good faith efforts to insure his or her identity; and:

the quantity prescribed and dispensed is limited to the amount adequate to treat the patient during the emergency period. Dispensing beyond the emergency period shall be pursuant to a prescription issued in the normal course of practice as permitted in subsection 7.9.1 of this rule.

the orally communicated prescription is immediately reduced to writing by the

pharmacist, or, if necessary, the prescription communicated by way of electronic transmission other than electronic prescribing is immediately reduced to a hard copy;

within seven (7) days after authorizing an emergency oral prescription, the practitioner delivers a valid paper or electronic prescription for the emergency quantity prescribed 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 paper prescription may be delivered to the pharmacist in person or by mail, but if delivered by mail, it shall be postmarked within the seven (7) day period; if sent by electronic prescription, it must be transmitted by the prescriber 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 and the Board if the prescribing practitioner fails to deliver a written prescription.

Refilling Schedule II prescriptions; issuance of multiple prescriptions.

The refilling of a prescription for a controlled substance listed in Schedule II is prohibited. However, a prescriber may issue multiple prescriptions authorizing the patient to receive a total of up to a 90-day supply of a Schedule II controlled substance provided each separate prescription provides instructions (other than the first prescription if the prescriber intends for that prescription to be filled immediately) indicating the earliest date on which each prescription may be dispensed. The signatures on such prescriptions must be dated as of the date they were actually signed, and may provide the instructions for when they may be filled by indicating "do not full until", "may not be filled before", or other similar language, followed by the earliest date on which it may be dispensed.

Partial filling of Schedule II prescriptions.

A pharmacist may dispense a partial filling of a prescription for a controlled substance listed in Schedule II, if the pharmacist is unable to supply the full quantity called for in a written or emergency oral prescription and he or she makes a notation of the quantity supplied on the face of the written prescription or written record of the emergency oral prescription. The remaining portion of the prescription may be filled within seventy-two (72) hours of the first partial filling, however, if the remaining portion is not or cannot be filled within the seventy-two (72) hour period, the pharmacist shall notify the prescribing individual practitioner. No further quantity of controlled substances may be supplied beyond seventy-two (72) hours without a new prescription.

Labeling of Schedule II prescriptions.

The pharmacist filling a written or emergency oral prescription for a controlled substance listed in Schedule II shall affix to the package a label showing date of filling, the pharmacy name and address, the serial number of the prescription, the name of the patient, the name of the prescribing practitioner and directions for use and cautionary statements, if any, contained in the

long as the total quantity prescribed is not exceeded. No refill may be provided more than three days prior to the date the prior dispensing would be exhausted unless special circumstances justifying the early refill exist. If an early refill is made, the pharmacist is encouraged to consult with the prescriber, and must document on the prescription record the special circumstances justifying the early dispensing.

Partial Filling of Schedule III, IV, or V prescriptions.

The partial filling of a prescription for a controlled substance listed in Schedule III, IV, or V is permissible provided that:

Each partial filling is recorded in the same manner as a refilling;

The total quantity dispensed in all partial fillings does not exceed the total quantity prescribed; and

No dispensing occurs after 6 months after the date on which the prescription was issued.

Labeling of Schedule III, IV, or V prescriptions.

The pharmacist filling a prescription for a controlled substance listed in Schedule III, IV, or V shall affix to the package a label showing the pharmacy name and address, the serial number and date of initial filling, the name of the patient, the name of the practitioner issuing the prescription, and directions for use and cautionary statements, if any, contained in the prescription as required by law.

Filing of Schedule III, IV, or V prescriptions.

All prescriptions for controlled substances listed in Schedules III, IV, or V shall be kept in accordance with section 6.15 of this rule.

Dispensing without prescription.

A pharmacist may dispense a controlled substance listed in Schedules II, III, IV, or V which is not a prescription drug as determined by the Federal Food, Drug, and Cosmetic Act, without a prescription to a purchaser at retail, unless:

The dispensing is made only by a pharmacist and not by a non-pharmacist employee even if under the direct supervision of a pharmacist. After the pharmacist has fulfilled his or her professional and legal responsibilities set forth in this section, the actual cash, credit transaction or delivery, may be completed by a non-pharmacist;

Not more than 240 cc. (8 ounces) of any controlled substance containing opium, nor

more than 120 cc. (4 ounces) of any other controlled substance nor more than 48 dosage units of any controlled substance containing opium, nor more than 24 dosage units of any other controlled substance may be dispensed at retail to the same purchaser in any given forty-eight (48) hour period;

The purchaser is at least eighteen (18) years of age;

The pharmacist requires every purchaser of a controlled substance under this section not known to him or her to furnish suitable identification, including proof of age where appropriate;

A bound record book for distributions of controlled substances under this section, other than by prescription, is maintained by the pharmacist. The book shall contain the name and address of the purchaser, the name and quantity of controlled substance purchased, the date of each purchase and the name or initials of the pharmacist who dispensed the substance to the purchaser. The book shall be maintained in accordance with the record keeping requirement of section 6.2 of this rule; and

A prescription is not required for distribution or dispensing of the substance pursuant to any other federal, state or local law.

§ 15-2-8. Miscellaneous.

Distribution upon discontinuance or transfer of business.

Any registrant desiring to discontinue or transfer business activities altogether or with respect to controlled substances shall notify the Board of Pharmacy immediately and shall submit with the notification a complete and detailed closing inventory of all controlled substances in the registrant's possession.

Disposal of controlled substances.

Compliance with federal law and regulations is considered in compliance with this section. A registrant shall document the destruction or disposal of all controlled substances on the appropriate form approved by the Board. The disposal of excessive amounts of residual and wasted controlled substances accrued by extemporaneous compounding in an institutional setting may be completed by two (2) registered or licensed health care professionals with a record of the destruction indicating the two witnesses with their signatures.

Registrants may become registered with the DEA as an authorized collector to receive the transfer from ultimate users any unwanted and unused pharmaceutical controlled substances in their lawful possession for safe, secure, and responsible disposal. Any authorized collector must comply fully with the DEA requirements for such an authorized collection program.

Reporting theft of drugs.

In the event of any controlled substances being lost or stolen, the registrant shall immediately submit a report of the drug theft or loss (DEA Form 106) to the Board of Pharmacy.

Ordering of Controlled Substances.

A registrant shall complete an order form (DEA Form 222) for each transfer of a Schedule II controlled substance to another registrant without a prescription.

A pharmacist shall verify the receipt within the pharmacy of all controlled substances listed in Schedule II-V by reviewing and countersigning the invoices or packing documents.

TITLE 15
LEGISLATIVE RULE
BOARD OF PHARMACY

SERIES 3
BOARD OF PHARMACY RULES FOR CONTINUING EDUCATION FOR LICENSURE OF PHARMACISTS

§15-3-1. General.

1.1. Scope. -- W. Va. Code §30-5-3A authorizes the Board of Pharmacy to promulgate rules which are necessary to perform the duties and responsibilities of the board as they relate to requiring pharmacists to meet certain continuing education requirements in order to maintain their license to practice pharmacy in the State of West Virginia.

1.2. Authority. -- This legislative rule is issued under the authority of W. Va. Code §30-5-7.

1.3. Filing Date. -- April 30, 2014.

1.4. Effective Date. -- May 30, 2014.

§15-3-2. Definitions.

2.1. "Accreditation Council for Pharmacy Education" ("ACPE") means the national accreditation organization for continuing pharmacy education.

2.2. "Chronic Pain" means pain that has persisted after reasonable medical efforts have been made to relieve the pain or cure its cause and that has continued, either continuously or episodically, for longer than three (3) continuous months. For purposes of this rule, "chronic pain" does not include pain associated with a terminal condition or illness, or with a progressive disease that, in the normal course of progression, may reasonably be expected to result in a terminal condition or illness.

2.3. "Continuing Pharmacy Education" ("CPE") means planned and accredited learning experiences beyond a formal degree program designed to promote the continual development of knowledge, skills, and attitudes on the part of the pharmacist or pharmacy technician.

2.4. "Continuing Pharmacy Education Committee" ("CPE Committee") means that committee appointed by the board responsible for approval of the content of each CPE program, which is not otherwise automatically approved by this rule for CPE credit, offered by a provider of CPE.

2.5. "Continuing Pharmacy Education Coordinator" ("CPE Coordinator") means that individual or organization who may be retained by the board for the purpose of coordinating CPE programming and licensure renewal requirements.

2.6. "Continuing Pharmacy Education Hour" ("CPE Hour") means one hour of participation in a board accredited continuing pharmacy education program under responsible sponsorship, capable direction and qualified instruction. For the purposes of this definition, an hour equals sixty (60) minutes of participation and represents 1.0 continuing pharmacy education hour.

2.7. "Continuing Pharmacy Education Number" (Number) means either the ACPE number or board-issued CPE number assigned to identify each approved program.

2.8. "Continuing Pharmacy Education Provider" (Provider) means an institution, organization, agency, corporation, company, or individual approved by the board for the purpose of direct provision of continuing pharmacy education programs.

2.9. "CPE Monitor" means the electronic CPE monitor created and maintained through the collaborative efforts of National Association of Boards of Pharmacy the Accreditation Council for Pharmacy Education (ACPE) to permit CPE providers, pharmacists, and pharmacy technicians to electronically keep track of CPE credits earned from CPE providers, by acting as a repository of this information maintained on licensees' behalf and reported by NABP to state boards of pharmacy which request verification of CPE.

2.10. "Reporting Period" means the two (2) year licensure period beginning on July 1 of a given year through June 30 two (2) years later which coincides with the licensee's renewal period.

2.11. "West Virginia Pharmacists Association" (Association) means a statewide professional organization whose members are pharmacists duly licensed by the board.

2.12. "West Virginia Society of Health System Pharmacists" means a statewide professional organization representing the interests of pharmacists duly licensed by the board who practice in hospitals, health maintenance organizations, long-term care facilities, home care, and other components of health care systems.

§15-3-3. Purpose.

3.1. The purpose of Continuing Pharmacy Education (CPE) is to maintain and enhance the professional proficiency of pharmacists licensed to practice in West Virginia for the benefit and health, safety and welfare of the people served by pharmacists in the State of West Virginia.

§15-3-4. Continuing Pharmacy Education Requirements.

4.1. A licensed pharmacist shall complete a minimum of thirty (30) CPE hours every two (2) years, inclusive of any CPE requirements for consultant pharmacist registration, pharmacist immunization

registration, and drug diversion training and best practice prescribing of controlled substances training, in order to renew his or her license to practice pharmacy in West Virginia, and each reporting period thereafter.

4.2. Hours earned may only be used to meet the requirements for one reporting period. Hours in excess of the number required at the end of each reporting period shall not be transferred or applied to future reporting periods to satisfy future CPE requirements. Hours earned in a new reporting period but used to meet the requirements of a prior reporting period may only be used for the prior reporting period.

4.3. Six (6) hours of the thirty (30) CPE hours required every two (2) years shall be obtained through a live presentation requiring the physical presence of the pharmacist at the CPE program.

4.4. Beginning July 1, 2014, unless a pharmacist has completed and timely provided to the board on the form to be provided by the board a waiver request attesting that he or she has not administered or dispensed a controlled substance during the entire previous reporting period, every pharmacist shall, as a prerequisite to license renewal, complete a minimum of three (3) hours of drug diversion training and best practice prescribing of controlled substances training during the previous reporting period.

4.4.a. Said three (3) hours of CPE shall be a part of the 30 hours of CPE required, and is not three (3) additional hours.

4.4.b. For purposes of this subsection, "drug diversion training and best practice prescribing of controlled substances training" means a training course of at least three (3) CPE hours which includes, at a minimum, all of the following:

4.4.b.1. Drug diversion, including West Virginia statistics on prescription drug abuse and resulting deaths;

4.4.b.2. Epidemiology of chronic pain and misuse of opioids;

4.4.b.3. Indication for opioids in chronic pain treatment including, at a minimum, general characteristics, toxicities, and drug interactions;

4.4.b.4. Patient evaluation and risk assessment and tools to assess risk and monitor benefits.

4.4.b.5. Initiation and ongoing-management of chronic pain in patients treated with opioid based therapies, including, at a minimum: treatment objectives; medication therapy management and collaborative practice; prescription of controlled substance agreements; urine screens and pill counts; patient education on safe use, storage and disposal of opioids; discontinuation of opioids; and documentation and medical records;

4.4.b.6. Case study of a patient with chronic pain;

4.4.b.7. Identification of diversion and drug seeking tactics and behaviors;

4.4.b.8. Best practice methods for working with patients, prescribers, law enforcement, and others as appropriate, concerning patients suspected of drug seeking behavior and diversion;

4.4.b.9. Compliance with controlled substances laws and rules; and

4.4.b.10. How to Register with and use the West Virginia Controlled Substances Monitoring Program established in West Virginia Code § 60A-9-1, *et seq*.

§15-3-5. Methods of Acquiring Continuing Pharmacy Education.

5.1. Continuing pharmacy education hours of credit may be earned by licensed pharmacists in the following manner if the provider grants the pharmacist a statement of credit or reports the credit to the CPE Monitor:

5.1.a. Live Programs, which means CPE activities that provide for a direct interaction between faculty and learners, and may include lectures, symposia, live teleconferences, live webinars, workshops, and other similar venues.

5.1.b. Home study by print, webinar, computer-based training, video, or other non-live approved programs or audio-visual presentations;

5.1.c. Credit earned from a United States accredited college/school or university for post-graduate courses in pharmaceutical sciences or other courses applicable to pharmacy practice;

5.1.d. Continuing pharmacy education programs granted credit by other states;

5.1.e. Any program approved by ACPE;

§15-3-6. Program Administration.

6.1. The board has the statutory responsibility for the oversight of CPE as required for licensure renewal and to appoint a Continuing Pharmacy Education Committee.

6.2. The CPE Committee shall:

6.2.a. perform necessary correspondence and communication with professional groups, organizations and individuals who have interest in CPE;

6.2.b. recommend to the board for its approval those providers of continuing pharmacy education programs who have been certified as meeting the criteria established for this purpose; and

6.2.c. recommend to the board for its approval those continuing pharmacy education programs which have met the criteria established for that purpose.

§15-3-7. Continuing Pharmacy Education Committee.

7.1. The Continuing Pharmacy Education Committee shall be composed of equal representation from the West Virginia Board of Pharmacy, each accredited school of pharmacy located in the State of West Virginia, the West Virginia Pharmacists Association, and the West Virginia Society of Health System Pharmacy Pharmacists.

7.2. The members of the CPE Committee shall be selected by the board and shall serve for a period of three (3) years, and may be reappointed.

7.3. The chairman of the CPE Committee shall be selected by the members of the committee.

7.4. The CPE Committee is responsible for approval of each program offered by a provider of CPE credit.

7.5. In all other matters concerning the approval of Continuing Pharmacy Education providers, the role of the CPE Committee is to advise and submit its recommendations to the board.

§15-3-8. Responsibilities of Providers.

8.1. CPE providers are responsible for submitting CPE programs to the board for approval.

8.2. Providers shall submit an application for approval of any CPE program in writing to the board at least thirty (30) days prior to their offering in order that potential participants will know whether the program is approved. The board may approve programs submitted later provided proper cause is shown for late submission.

8.3. The proposed CPE program shall contain all required information on forms provided by the board, including, but not limited to, the course name, provider name, proposed dates the program will be offered, agenda, content overview, learning objectives and faculty.

8.4. The board may revoke or suspend approval of providers for submission of fraudulent information concerning CPE.

8.5. Changes to the content of an ongoing approved program shall require the provider to submit a new application for the program.

8.6. Providers shall retain a file of participants of each accredited program for four (4) years.

8.7. Providers shall advise the board in writing of the date, location, and number of CPE hours of each program presented or made available along with the names and addresses of each participant successfully completing each program within thirty (30) days following the presentation or completion of an approved program.

8.8. Providers shall provide a statement of credit of participation to each participant or report course completion to the CPE Monitor for each participant who attends and successfully completes a program. The statement of credit shall include at a minimum, the course name, date completed, total CPE hours earned, and the provider's name, address, phone number, and CPE number.

§15-3-9. Responsibilities of Pharmacists.

9.1. Pharmacists shall keep valid records, receipts, and certifications of continuing pharmacy education programs completed for four (4) years and submit certifications of participation and completion to the board upon request. The records may be kept in whole or in part in the pharmacist's personal account in the CPE Monitor.

9.2. The board may take disciplinary action against a pharmacist for submission of fraudulent statements or certificates concerning CPE.

9.3. A Pharmacist shall submit, on forms provided by the board, a list of accredited CPE programs completed in the preceding reporting period with their renewal license application.

9.4. In the event a pharmacist fails to submit a list of completed CPE programs with his or her renewal application, the board shall notify the pharmacist at his or her last known address that disciplinary action shall be taken for failure to comply with CPE requirements.

9.5. A pharmacist may request a waiver from the board from the CPE requirements for reasons of illness, injury, incapacity, retirement, or other extenuating circumstances.

9.6. A pharmacist shall keep the board informed of his or her current mailing address.

9.7. A pharmacist may transfer CPE hours from another state to West Virginia if the other state accepts the transfer of West Virginia CPE hours.

9.8. A West Virginia licensed pharmacist who resides in another state requiring CPE and who does not practice in West Virginia may renew his or her West Virginia license by certifying on his or her CPE report form that he or she has a current and valid license to practice in the state in which he or she is residing. The following statement shall be placed on the form, and the form signed, dated, notarized, and returned to the West Virginia Board of Pharmacy with the renewal application and fee:

"I declare under penalties of falsification that I hold a current and valid pharmacist license, No. [___] in the State of [_____], and that I do not presently practice pharmacy in the State of West Virginia. I hereby agree to notify the West Virginia Board of Pharmacy if I return and commence practice in West Virginia."

9.9. A pharmacist may request CPE credit only once in a reporting period for each program attended or completed.

§15-3-10. Approval of Providers.

10.1. The board has established the policy that all CPE providers approved by ACPE are approved as providers of CPE in West Virginia.

10.2. All other providers shall make application for approval as a provider on the form provided by the board. Providers shall:

10.2.a. have a qualified director or coordinator of CPE program;

10.2.b. have qualified faculty to develop and present CPE programs, or shall have contracted or retained qualified people to develop and present programs;

10.2.c. have access to appropriate resources and materials, such as printing, projectors, and other suitable hardware and software for the development and presentation of programs;

10.2.d. have appropriate facilities and/or mechanisms to record, store, and retrieve data concerning attendance, credit, and other relevant data for individuals participating in the programs; and

10.2.e. demonstrate their ability and willingness to provide any and all information required by the board or the CPE Committee.

10.3. Providers approved in accordance with section 10.2 shall be reapproved as a provider every four (4) years from the date of approval. The board shall withdraw approval if a provider is found to be in violation of subsection 8.4 of this rule. The board may withdraw approval if a provider becomes unable to meet the requirements of section 10.2 at any time during the approval period. The provider may apply for re-approval if all applicable criteria are met. The application for re-approval shall be made within thirty (30) days after the notice of disapproval and the provider shall comply with the original procedure as prescribed in subsection 8.2 of this rule. The board at its discretion may impose a period of probation if it approves the application for re-approval.

§15-3-11. Approval of Continuing Pharmacy Programs.

11.1. Providers shall submit all CPE programs for approval by the board except as provided for in subsections 11.2 and 11.3 of this section.

11.2. The board has approved all programs developed and presented by ACPE approved providers.

11.3. Approval of a CPE program is valid for a three (3) year period if the content remains the same.

11.4. All programs shall meet the criteria utilized by ACPE and additionally shall meet the following criteria:

11.4.a. The program shall be within the scope of the following subjects:

11.4.a.1. Pharmaceutics: bioavailability, bioequivalence, product selection based on bioavailability and/or bioequivalence;

11.4.a.2. Pharmacognosy: drugs of natural origin as related to therapeutics;

11.4.a.3. Pharmacology: as related to therapeutics, dosage regimen, etc.;

11.4.a.4. Pharmaceutical Chemistry: chemistry of drugs as related to therapeutics;

11.4.a.5. Pharmacy Administration: as related to the managerial, behavioral, and social aspects of pharmacy practice;

11.4.a.6. Pharmacy Practice: as related to patient compliance, patient use and utilization of drugs, drug incompatibilities, proper selection and use of nonprescription drugs, and related topics; or

11.4.a.7. Public Health: as related to improving the pharmacist's role in public health and the health care system.;

11.4.b. The program shall be relevant, timely, and applicable to pharmacy practice;

11.4.c. The program content shall be well organized with stated objectives, and an orderly flow of material, with appropriate examples and/or illustrations; and

11.4.d. The program shall be appropriately presented, with the mode/method of presentation appropriate to the topic.

§15-3-12. Program Evaluation.

12.1. The provider or sponsor shall have an evaluation mechanism for the purpose of allowing the participant to assess achievement of personal objectives.

12.2. The provider or sponsor shall develop and employ evaluation techniques that will assess the effectiveness of the CPE activities and the level of fulfillment of the stated objectives, with the goal of continual provided or sponsor and CPE improvement.

12.3. The provider or sponsor shall compile the results of participants' evaluations and submit them to the board upon request.

§15-3-13. Credits and Records.

13.1. Credits and records of CPE shall be based on a CPE hour.

13.2. A pharmacist who develops and/or presents an approved CPE program shall receive credit for the number of continuing pharmacy education hours of that program for his or her initial presentation.

13.3. All providers and pharmacists shall retain their records for four (4) years in a manner that will enable their ready retrieval upon request of the board, its authorized agent or Committee.

13.4. Students providing documentation of enrollment in graduate programs of health related fields or participation in a residency program in a health related field are not required to provide additional documentation of participation in CPE. If a student discontinues his or her pursuit of graduate study, the prevailing CPE requirements apply for his or her continued licensure.

WEST VIRGINIA
SECRETARY OF STATE
FILED **NATALIE E. TENNANT**
ADMINISTRATIVE LAW DIVISION

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OFFICE WEST VIRGINIA SECRETARY OF STATE

Form#6

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

AGENCY: West Virginia Board of Pharmacy

TITLE NUMBER· 15

AMENDMENT TO AN EXISTING RULE: YES ..L NO_

IF YES, SERIES NUMBER OF RULE BEING AMENDED: 4

TITLE OF RULE BEING AMENDED: RECORD KEEPING AND AUTOMATED DATA PROCESSING SYSTEMS

IF NO, SERIES NUMBER OF RULE BEING PROPOSED: _

TITLE OF RULE BEING PROPOSED:

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

AUTHORIZATION IS CITED IN (house or senate bill number) _S__e_n=a=te"-B"""""il.1..1.._0_17

SECTION §64-9-13 , PASSED ON June 14, 2016

S RULE IS FILED WITH THE SECRETARY OF STATE. THIS RULE BECOMES EFFECTIVE ON THE FOLLOWING DATE: July 1,

2016

David E. Potters

Authorized Signature

TITLE 15
LEGISLATIVE RULE BOARD OF PHARMACY

SERIES4
RECORD KEEPING AND AUTOMATED DATA PROCESSING SYSTEMS

-4-1. General.

pe. -- Recordkeeping requirements, and outlining the proper use of an automated Data Processing System.

hority. -- W. Va. Code §30-5-7.

ng Date. -- June 24, 2016.

ective Date. -- July 1, 2016.

§15-4-2. Use of Automated Data Processing Systems -- General Provisions.

harmacy may establish and use an automated data processing system to keep records of prescription drugs which it penses.

o or more pharmacies may establish and use an automated data processing system as a common data file or database maintain required or pertinent prescription drug dispensing information. Pharmacies using a common file are not uired to transfer prescriptions or information for dispensing purposes between or among the pharmacies participating e same common prescription file or data base: Provided that any common file must contain complete and adequate rds of each prescription and renewal dispensed.

-4-3. Definitions.

ept as otherwise specifically stated in this rule, the definitions set forth in Title 15, Series 1, Section 2 are rporated by reference, and are fully applicable hereto.

tomated Data Processing System (ADP)" means a system utilizing computer software and hardware for the purpose of rdkeeping.

intout" means a readable printed copy of the output of a computer.

mmon database" means a file or collection of information created by the automated data processing system that bles authorized users to have common access to the file regardless of physical location.

n-line retrieval" means the producing of sight-readable documents on a suitable computer screen or monitor.

ardware" is the fixed components of a computer, server, or other such devices used for the electronic storage and ieval of data.

ftware" is a computer program used to direct the operation of a computer, as well as the documentation giving ructions on how to use it, and directs the storage of required data on the hardware.

5-4-4. Record of Dispensing Prescription Drugs.

cords of dispensing of prescription drugs for original and refill prescriptions are to be made and kept by pharmacies five (5) years. Information must be immediately accessible for a period of not less than one (1) year from the date of dispensing. Information beyond one (1) year but up to five (5) years from the date of dispensing may be intained other than on-line, but must be produced within forty-eight (48) hours upon request by proper authorities. e information contained in the records shall include, but not be limited to:

information required to be placed upon the label for the dispensed medication as set forth in Title 15, Series 1, tion 22;

full name of the pharmacist responsible for dispensing the drug; and

cord of renewals to date.

5-4-5. Record of Retrieval (Documentation of Activity)

e pharmacy must be able to provide a current history of all authorized prescription activity required to be kept by tion 4. In addition, this information must be capable of production on a patient-by-patient basis in the form of patient files which allows immediate review of at least the following data about the patient which may be reasonably ained by the pharmacist:

e patient's biographical data;
e patient's medications;
e patient's disease states and drug allergies;
e pharmacist's notes; and
y other data necessary to make rational judgments about pharmacist care.

ADP system, if used, must provide this information by a suitable computer screen or monitor display and be capable roviding a printout.

ADP system may be used for the storage and retrieval of refill information for

scription orders for controlled substances in Schedule III and IV, subject to the following conditions:

e ADP system shall provide on-line retrieval (via computer screen or monitor display or printout) of the original scription order information for those prescription orders which are currently authorized for refilling. Order ormation includes, but is not limited to: the original prescription number, the date of issuance of the original scription order by the prescribing practitioner, the full name and the address of the patient, the name, the address, the DEA registration number of the prescribing practitioner, and the name, the strength, the dosage form and ntity of the controlled substance prescribed and the quantity dispensed if different from the quantity prescribed, the total number of refills authorized by the prescribing practitioner.

e ADP system shall provide on-line retrieval (via computer screen or monitor display or printout) of the current ll history for Schedule III or IV controlled substance prescription order (those authorized for refill during the past (6) months). This refill history shall include, but not be limited to, the name of the controlled substance, the date of ll, the name of the controlled substance, the date of the refill, the quantity dispensed, the name or initials (or ntification code if used) of the dispensing pharmacist for each refill and the total number of refills dispensed to date that prescription order.

e ADP system shall contain documentation that an individual pharmacist has taken the responsibility for the accuracy he information entered into the system for original prescriptions and for refills of the original prescription for a hedule III or IV Controlled Substance. A printout of the day's controlled substance prescription order refill data must rovided to each pharmacy using the ADP system within seventy-two (72) hours of the date on which the refill was pensed. It must be verified and signed by each pharmacist who is involved with such dispensing. (In lieu of a printout, pharmacy shall maintain a bound log book, shall sign a statement (in the manner previously described) each day, sting to the fact that the refill information entered into the computer that day has been reviewed by him/her and is rect as shown. The book or file must be maintained at the pharmacy employing the system for a period of two (2) rs after the date of dispensing the appropriately authorized refill.

e ADP system shall have the capability of producing a printout of any refill data which the user pharmacy is ponsible for maintaining under W. Va. Code §30-5-1 et seq. and its implementing regulations. This includes a refill- refill audit trail for any specified strength and dosage form of any controlled substance (by either brand or generic me or both). The printout must include the name of the prescribing practitioner, the name and address of the ient, the quantity dispensed on each refill, the date of dispensing for each refill, the name or identification code of dispensing pharmacist, and the number of the original prescription order. Any recordkeeping location must be able of sending the Special Agent or Compliance Investigator a copy of the printout from the user pharmacy if uested to do so by the Agent or Investigator and must verify the printout transmittal capability of its system by umentation. (e.g., postmark).

he event that pharmacy which employs a computerized system experiences system

down-time, the pharmacy must have an auxiliary procedure which will be used for documentation of refills of Schedule III and IV controlled substance prescription order, that the maximum number of refills has not been exceeded, and that all of the appropriate data is retained for on-line data entry as soon as the computer system is available for use again.

When filing refill information for original prescription orders for Schedule III or IV Controlled Substances, a pharmacy may use the system described in Chapter 11, Drug Enforcement Administration, Department of Justice, as it relates to the Code of Federal Regulations under Section 1306.22, Titled, Refilling of Prescriptions.

§15-4-6. Auxiliary Recordkeeping System.

An auxiliary recordkeeping system shall be established by each pharmacy for the documentation of renewals if the ADP is inoperative. Information regarding prescriptions dispensed and renewed during the inoperative period shall be entered into the automated data processing system within seventy-two (72) hours.

§15-4-7. Operating the ADP System.

Only authorized pharmacy personnel licensed or registered by the Board may have access to the ADP.

§15-4-8. Records of Provision of Pharmacist Care Outside of a Licensed Pharmacy.

A pharmacist practicing pharmacist care services outside the premises of a licensed pharmacy shall maintain the records or other patient-specific information used in such activities in a readily retrievable form in a system that is secured and managed by the pharmacy with whom the pharmacist is providing such services; or, if acting independent of a pharmacy without the dispensing of prescription drugs to provide direct patient- care activities of patient counseling and medication therapy management, when the patient is unable to present to the pharmacy for a personal, face-to-face interaction, a secure system maintained by the pharmacist. The records or information shall:

provide accountability and an audit trail;

be provided to the Board upon request;

be preserved for a period of at least five years from the date relied upon or consulted for the purposes of performing any such function; and

secure from unauthorized access and use.

WEST VIRGINIA
SECRETARY OF STATE
NATALIE E. TENNANT
ADMINISTRATIVE LAW DIVISION

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SECRETARY OF STATE

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

AGENCY: West Virginia Board of Pharmacy

TITLE NUMBER· 15

AMENDMENT *TO* AN EXISTING RULE: YES.....!... NO_

IF YES, SERIES NUMBER OF RULE BEING AMENDED: S

TITLE OF RULE BEING AMENDED, LICENSURE OF WHOLESALE DRUG DISTRIBUTORS, THIRD PARTY LOGISTICS PROVIDERS, AND MANUFACTURERS

IF NO, SERIES NUMBER OF RULE BEING PROPOSED:,

TITLE OF RULE BEING PROPOSED:,

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

AUTHORIZATION IS CITED IN (house or senate bill number) ....:::S:.:::.enate:::..::B:::.:.ill..:...101.....7

SECTION 64-9-13

PASSED ON June 14,

2016

THIS RULE IS FILED WITH THE SECRETARY OF STATE. THIS RULE BECOMES EFFECTIVE ON THE FOLLOWING DATE: July 1, 2016

David E. Potters

Authorized Signature

ED

TITLE 15 LEGISLATIVE RULE BOARD OF PHARMACY

SERIES 5

LICENSURE OF WHOLESALE DRUG DISTRIBUTORS, THIRD PARTY£OGISTICS PROVIDERS, AND MANUFACTURERS

§15-5-1. General.

Scope. -- To establish rules for the federal Drug Quality and Security Act, and Prescription Drug Marketing Act, as amended, for the licensing by this state of persons who engage in wholesale distributions, provision of third-party logistics, and manufacturing, of prescription drugs in interstate commerce within and into this state.

Authority. -- W. Va. Code §60A-8-9.

Filing Date. -- June 24, 2016.

Effective Date. -- July 1, 2016.

§15-5-2. Definitions.

Except as otherwise specifically stated in this rule, the definitions set forth in Title 15, Series 1, Section 2 are incorporated by reference as if set forth fully herein, and are fully applicable hereto.

"Affiliate" means a business entity that has a relationship with a second business entity if, directly or indirectly:

one business entity controls, or has the power to control, the other business entity; or

a third party controls, or has the power to control, both of the business entities.

"Blood" means whole blood collected from a single donor and processed either for transfusion or further manufacturing.

"Blood component" means that part of blood separated by physical or mechanical means.

"Drug sample" means a unit of a prescription drug that is not intended to be sold and is intended to promote the sale of the drug.

"Healthcare entity" means any person or entity that provides diagnostic, medical, surgical, or dental treatment, or chronic or rehabilitative care, but does not include any retail pharmacy or any wholesale drug distributor. Except as provided in § 203.22(h) and (i) of Chapter 21 of the Code of Federal Regulations, a person cannot simultaneously be a "healthcare entity" and a retail pharmacy or wholesale drug distributor.

"Manufacturer" means anyone who is engaged in manufacturing, preparing, propagating, compounding, processing, packaging, repackaging, or labeling of a prescription drug.

"Outsourcing facility" means a facility engaged in manufacturing by compounding of sterile drugs which has registered with the Federal Food and Drug Administration as an outsourcing facility pursuant to Section 503B of the Federal Drug Quality and Security Act.

"Prescription drug" means any human drug required by Federal Law or regulation to be dispensed only by a prescription, including finished dosage forms and active ingredients subject to section 503(b) of the Federal Food, Drug and Cosmetic Act.

"Third-party logistics provider" means an entity that provides or coordinates warehousing, or other logistics services of a product in interstate commerce on behalf of a manufacturer, wholesale distributor, or dispenser of a product, but does not take ownership of the product, nor have responsibility to direct the sale or disposition of the product.

"Wholesale distribution" means distribution of prescription drugs, including directly or through the use of a third-party logistics provider or any other situation in which title, ownership, or control over the prescription drug remains with one person or entity but the prescription drug is brought into this state by another entity on their behalf, to persons other than a consumer or patient, but does not include:

Intracompany sales, (which include but are not limited to a transaction or transfer between any division, subsidiary, parent and/or affiliated or related company under the common ownership and control of a corporate entity;)

The sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug for emergency medical reasons; for purposes of this section, "emergency medical reasons" includes transfers of prescription drugs by a retail pharmacy to another retail pharmacy to alleviate a temporary shortage, (except that the gross dollar amount shall not exceed five (5) percent of the total prescription drug sales revenue of either the transferor or transferee pharmacy during any consecutive twelve (12) month period);

The distribution of drug samples by manufacturers' representatives or distributors' representatives;

The sale, purchase, or trade of blood and blood components intended for

transfusion;

The sale, purchase, or trade of a drug, an offer to sell, purchase, or trade a drug, or the dispensing of a drug pursuant to a prescription;

The purchase or other acquisition by a hospital or other health care entity that is a member of a group purchasing organization of a drug for its own use from the group purchasing organization or from other hospitals or health care entities that are members of such organization;

The sale, purchase or trade of a drug or an offer to sell, purchase, or trade a drug by a charitable organization described in Section 501(c)(3) of the United States Internal Revenue Code of 1954 to a nonprofit affiliate of the organization to the extent otherwise permitted by law;

The sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug among hospitals or other health care entities that are under common control; for purposes of this section, "common control" means the power to direct or cause the direction of the management and policies of a person or an organization, whether by ownership of stock, voting rights, by contract, or otherwise;

Drug returns, when conducted by a hospital, health care entity, or charitable institution in accordance with§ 203.23 of Title 21 of the Code of Federal Regulations; or

The sale of minimal quantities of drugs by retail pharmacies to licensed practitioners for office use (except that the gross dollar amount shall not exceed five (5) percent of the total prescription drug sales revenue of either the transferor or transferee pharmacy during any consecutive twelve (12) month period).

"Wholesale drug distributor" means any person or entity engaged in wholesale distribution of prescription drugs, including, but not limited to, manufacturers; repackers; own- label distributors; private-label distributors; reverse distributors, jobbers; brokers; warehouses, including manufacturers' and distributors' warehouses, chain drug warehouses, and wholesale drug warehouses; independent wholesale drug traders; prescription drug repackagers; physicians, dentists, veterinarians, birth control and other clinics, individuals, hospitals, nursing homes and/or their providers, health maintenance organizations and other health care providers, and retail and hospital pharmacies that conduct wholesale distributions. A wholesale drug distributor shall not include any for hire carrier or person or entity hired solely to transport prescription drugs.

§15-5-3. Wholesale Drug Distributor and Third-Party Logistics Provider Licensing and Manufacturer Permit Requirements.

Every wholesale distributor, wherever located, who engages in the wholesale distribution of drugs into, out of, or within the state must be licensed by the West Virginia Board of Pharmacy (hereinafter, the "Board") in accordance with the laws and regulations of this state

before engaging in the wholesale distribution of prescription drugs.

Any person operating as a manufacturer of prescription drugs must obtain a manufacturing permit issued by the Board in accordance with the laws and regulations of this state before engaging in manufacturing of prescription drugs in this state.

3.3 Notwithstanding any other provision to the contrary, each entity that meets the definition of a third-party logistics provider shall obtain a license as a third-party logistics provider and is not required to obtain a license as a wholesale distributor if the entity never assumes an ownership interest in the product it handles.

§15-5-4. Minimum Required Information For Wholesale Drug Distributor or Third-Party Logistics Provider Licensure, and Manufacturer Permit; Applications and Renewals.

A wholesale drug distributor or third-party logistics provider, and a manufacturer, including prescription drug manufacturers and outsourcing facilities, as part of the initial licensing procedure and as part of any renewal of license, shall provide on the application form as required by the Board:

(a). The name, full business address, and telephone number of the licensee; (b). All trade

or business names used by the licensee;

Addresses, telephone numbers, and the names of contact persons for the facility used by the licensee for the storage, handling, and distribution of prescription drugs;

The type of ownership or operation (i.e. partnership, corporation, or sole proprietorship) and

The name of the owner and/or operator of the licensee, including: (1). If a

person, the name of the person;

If a partnership, the name of each partner, and the name of the partnership;

If a corporation, the name and title of each corporate officer and director, the corporate names, and the name of the state of incorporation, and the name of the parent company, if any;

If a sole proprietorship, the full name of the sole proprietor and the name of the business entity.

Where operations are conducted at more than one (1) location by a single wholesale drug distributor, third-party logistics provider, or manufacturer, each location shall be licensed or permitted by the Board. However, the Board may provide for a single license or permit for a

business entity operating more than one facility within this state, or for a parent entity with divisions, subsidiaries, and/or affiliate companies within this state when operations are conducted at more than one (1) location and there exists joint ownership and control among all entities.

A wholesale drug distributor, third-party logistics provider, or manufacturer shall submit changes in any of the information required by this section to the Board within thirty (30) days after the change.

Applicants for an original wholesale drug distributor license or third-party logistics provider license shall pay an application fee of $750.00 which shall be submitted along with a satisfactory application for licensure. Each applicant for a wholesale drug distributor or third- party logistics provider license located in this state where prescription drugs will be handled, stored, or kept must complete an inspection satisfactory to the Board. Each applicant for a wholesale drug distributor or third-party logistics provider license located outside of this state must be properly licensed as such in that state or United States territory, of, if no such licensure is granted by that state or territory, then with the Federal Food and Drug Administration, and must supply proof of that authorization along with its application.

Applicants for an original manufacturer permit shall pay an application fee of Five Hundred Dollars ($500.00) which shall be submitted along with a satisfactory application for a permit. Each applicant for a manufacturer permit must be authorized to operate as a manufacturer with the Federal Food and Drug Administration, and must supply proof of that authorization along with its application. The manufacturer must supply proof of satisfactory inspection by the FDA within the previous 5-year period, or pay an additional fee of Four Hundred Dollars ($400.00) for inspection by the Board.

A wholesale drug distributor and third-party logistics provider license shall expire on June 30, of each calendar year. Applications for renewal of wholesale drug distributor and third- party logistics provider licenses shall be provided to each licensee at least thirty days before the first day of July of each calendar year by the Board. The notification may be sent electronically to an e-mail or be mailed to the last known address of the licensee. The fee for renewal is Seven Hundred Fifty Dollars (750.00).

If a completed application for renewal is not received in the Board office on or before June 30 of the year in which it expires, the license is expired. Renewal applications received after June 30 shall require the payment of a late fee in the amount of One Hundred Fifty Dollars ($150.00) in addition to the application fee of Seven Hundred Dollars ($750.00), for a total amount of Nine Hundred Dollars ($900.00).

If a completed application for renewal is not received in the Board office before the first day of August each year, then, in order to renew, the licensee shall pay a reinstatement fee of two hundred fifty dollars ($250.00), and pay the required renewal fee of Seven Hundred Fifty Dollars ($750.00), for a total amount of One Thousand Dollars ($1,000.00).

A manufacturer permit shall expire on June 30, of each calendar year. An application for renewal of a manufacturer permit shall be provided to each licensee at least thirty days before the first day of July of each calendar year by the Board. The notification may be sent electronically to an e-mail or be mailed to the last known address of the licensee. The fee for the annual renewal is Five Hundred Dollars ($500.00).

If a completed application for renewal is not received in the Board office on or before June 30 of the year in which it expires, the permit shall expire. Renewal applications received after June 30 shall require the payment of a late fee in the amount of One Hundred Fifty Dollars ($150.00) in addition to the application fee of Five Hundred Dollars ($500.00), for a total amount of Six Hundred Fifty Dollars ($650.00).

If an application for renewal is not received in the Board office before the first day of August each year, then, in order to, the manufacturer must supply proof of inspection by the FDA within the previous 5-year period, and the permittee shall pay a reinstatement fee of Two Hundred Fifty dollars ($250.00), in addition to the application fee of Five Hundred Dollars ($500.00), for a total amount of Seven Hundred Fifty Dollars ($750.00).

Licenses and permits issued under this section are not transferable, and become immediately expire upon change of ownership.

§15-5-5. Minimum Qualifications.

The Board shall consider, at a mm1mum the following factors in reviewing the qualifications of persons who engage in wholesale distribution of prescription drugs, act as a third-party logistics provider, or manufacturer prescription drugs within or into the state:

Any convictions of the applicant under any Federal, State, or local laws relating to drug samples, drug manufacturing, wholesale or retail drug distribution, or distribution of controlled substances;

Any felony convictions of the applicant under Federal, State, or local laws;

The applicant's past experience in the manufacture or distribution of prescription drugs, including controlled substances;

The furnishing by the applicant of false or fraudulent material in any application made in connection with drug manufacturing or distribution or acting as a third-party logistics provider;

Suspension or revocation by Federal, State, or local government of any license, permit, or other authorization currently or previously held by the applicant for the manufacture or distribution of, or acting as a third-party logistics provider related to, any drugs, including controlled substances;

Compliance with licensing requirements under previously granted licenses, if any;

Compliance with requirements to maintain and/or make available to the Board or to Federal, State, or local law enforcement officials those records required under this section;

5.18. An outsourcing facility must complete an initial inspection satisfactory to the board; and

5.1.9. Any other factors or qualifications the Board considers relevant to and consistent with the public health and safety.

The Board may deny a license to any applicant if it determines that the granting of a license would not be in the public interest. The Board shall base public interest considerations upon factors and qualifications that are directly related to the protection of the public health and safety.

§15-5-6. Personnel.

6.1. As a condition for receiving and retaining a wholesale drug distributor or third-party logistics provider license or manufacturer permit, the licensee or permittee shall require each person employed in any prescription drug wholesale distribution activity to have education, training, and experience, or any combination thereof, sufficient for that person to perform the assigned functions in such manner as to provide assurance that the drug product quality, safety and security will at all times be maintained as required by law.

§**15-5-7. Violations and Penalties.**

The Board may reprimand, suspend, restrict, or revoke any licenses or permits granted under this series upon conviction of violations of Federal, State, or local drug laws or regulations. Before any license or permit may be reprimanded, suspended, restricted, or revoked, a licensee or permittee under this series shall have a right to prior notice and a hearing pursuant to Chapter 29A, Administrative Procedures Act of the Code of West Virginia.

The Board may reprimand, suspend, restrict, or revoke any license or permit granted under this section for violations of theseregulations.

In any case where the Board finds that any licensee or permittee under this section shall be disciplined as set forth above, the Board may also levy an administrative penalty not to exceed one thousand dollars per day per violation, and may assess administrative costs against the licensee.

§15-5-8. Minimum Requirements for Wholesale Drug Distributors for the Storage and Handling of Prescription Drugs and for the Establishment and Maintenance of Prescription Drug Records.

The following constitutes the mm1mum requirements for the storage and handling of prescription drugs, and for the establishment and maintenance of prescription drug distribution records by wholesale drug distributors and their officers, agents, representatives, and employees.

Facilities. All facilities at which prescription drugs are stored, warehoused, handled, held, offered, marketed, or displayed shall:

Be of suitable size and construction to facilitate cleaning, maintenance, and proper operations;

Have storage areas designed to provide adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security conditions;

Have a quarantine area for storage of prescription drugs that are outdated, damaged, deteriorated, misbranded, or adulterated, or that are in immediate or sealed, secondary containers that have been opened;

Be maintained in a clean and orderly condition; and

Be free from infestation by insects, rodents, birds, or vermin of any kind.

Security.

All facilities used for wholesale drug distribution shall be secure from unauthorized entry.

Access from outside the premises shall be kept to a minimum and be well controlled.

The outside perimeter of the premises shall be well-lighted.

Entry into areas where prescription drugs are held shall be limited to authorized personnel.

All facilities shall be equipped with an alarm system to detect entry after hours.

All facilities shall be equipped with a security system that will provide suitable protection against theft and diversion. When appropriate, the security system shall provide protection against theft or diversion that is facilitated or hidden by tampering with computers or electronic records.

Storage. All prescription drugs shall be stored at appropriate temperatures and under appropriate conditions in accordance with requirements, if any, in the labeling of such drugs, or with requirements in the current edition of an official compendium, such as the United States Pharmacopeia/National Formulary (USP/NF).

If no storage requirements are established for a prescription drug, the drug may be held at "controlled" room temperature, as defined in an official compendium, to help ensure that its identity, strength, quality, and purity are not adversely affected.

Appropriate manual, electromechanical, or electronic temperature and humidity recording equipment, devices, and/or logs shall be utilized to document proper storage of prescription drugs.

The recordkeeping requirements in 8.6 of this section shall be followed for all stored drugs.

Examination of materials.

Upon receipt, each outside shipping container shall be visually examined for identity and to prevent the acceptance of contaminated prescription drugs or prescription drugs that are otherwise unfit for distribution. This examination shall be adequate to reveal container damage that would suggest possible contamination or other damage to the contents.

Each outgoing shipment shall be carefully inspected for identity of the prescription drug products and to ensure that there is no delivery of prescription drugs that have been damaged in storage or held under improper conditions.

The recordkeeping requirements in 8.6 of this section shall be followed for all incoming and outgoing prescription drugs.

Returned, damaged, and outdated prescription drugs.

Prescription drugs that are outdated, damaged, deteriorated, misbranded, or adulterated shall be quarantined and physically separated from other prescription drugs until they are destroyed or returned to their supplier.

Any prescription drugs whose immediate or sealed outer or sealed secondary containers have been opened or used shall be identified as such, and shall be quarantined and physically separated from other prescription drugs until they are either destroyed or returned to the supplier.

If the conditions under which a prescription drug has been returned cast doubt on the drug's safety, identity, strength, quality, or purity, then the drug shall be destroyed, or returned to the supplier, unless examination, testing, or other investigation proves that the drug meets appropriate standards of safety, identity, strength, quality, and purity. In determining whether the conditions under which a drug has been returned cast doubt on the drug's safety, identity, strength, quality, or purity, the wholesale drug distributor shall consider, among other things, the conditions under which the drug has been held, stored, or shipped before or during its return and the condition of the drug and its container, carton, or labeling, as a result of storage or

shipping.

The recordkeeping requirements in 8.6 of this section shall be followed for all outdate, damaged, deteriorated, misbranded, or adulterated prescription drugs.

Recordkeeping.

Wholesale drug distributors shall establish and maintain inventories and records of all transactions regarding the receipt and distribution or other disposition of prescription drugs. These records shall include the following information:

The source of the drugs, including the name and principal address of the seller or transferor, and the address of the location from which the drugs were shipped;

The identity and quantity of the drugs received and distributed or disposed of; and

The dates of receipt and distribution or other disposition of the drugs.

Inventories and records shall be made available for inspection and photocopying by authorized Federal, State, or local law enforcement agency officials for a period of two (2) years following disposition of the drugs.

Records described in this section that are kept at the inspection site or that can be immediately retrieved by computer or other electronic means shall be readily available for authorized inspection during the retention period. Records kept at a central location apart from the inspection site and not electronically retrievable shall be made available for inspection within two (2) working days of a request by an authorized official of a Federal, State, or local law enforcement agency.

Written policies and procedures. Wholesale drug distributors shall establish, maintain, and adhere to written policies and procedures, which shall be followed for the receipt, security, storage, inventory, and distribution of prescription drugs, including policies and procedures for identifying, recording, and reporting losses or thefts, and for correcting all errors and inaccuracies in inventories. Wholesale drug distributors shall include in their written policies and procedures the following:

A procedure whereby the oldest approved stock of a prescription drug product is distributed first. The procedure may permit deviation from this requirement if the deviation is temporary and appropriate.

A procedure to be followed for handling recalls and withdrawals of prescription drugs. The procedure shall be adequate to deal with recalls and withdrawals due to:

Any action initiated at the request of the Food and Drug Administration or

other Federal, State, or local law enforcement or other government agency, including the Board;

Any voluntary action by the manufacturer to remove defective or potentially defective drugs from the market; or

Any action undertaken to promote public health and safety by replacing of existing merchandise with an improved product or new package design.

A procedure to ensure that wholesale drug distributors prepare for, protect against, and handle any crisis that affects the security or operation of any facility in the event of a strike, fire, flood, or other natural disaster, or other situations of local, state, or national emergency.

A procedure to ensure that any outdated prescription drugs shall be segregated from other drugs and either returned to the manufacturer or destroyed. This procedure shall provide for written documentation of the disposition of outdated prescription drugs. This documentation shall be maintained for two (2) years after disposition of the outdated drugs.

Responsible persons. Wholesale drug distributors shall establish and maintain a list of officers, directors, managers, and other persons in charge of wholesale drug distribution, storage, and handling, including a description of their duties and a summary of their qualifications.

Compliance with Federal, State, and local law. Wholesale drug distributors shall operate in compliance with applicable Federal, State, and local laws and regulations.

Wholesale drug distributors shall permit the Board's authorized personnel and authorized Federal, State, and local law enforcement officials, to enter and inspect their premises and delivery vehicles, and to audit their records and written operating procedures, at reasonable times and in a reasonable manner, to the extent authorized by law. Such officials shall show appropriate identification prior to being permitted access to the wholesale drug distributors' premises and delivery vehicles.

Wholesale drug distributors that deal in controlled substances shall register with the Board and with the Drug Enforcement Administration (DEA), and shall comply with all applicable state, local, and DEA regulations.

Salvaging and reprocessing. Wholesale drug distributors are subject to the provisions of any applicable Federal, State, or local laws or regulations that relate to prescription drug product salvaging or reprocessing, including 21 CFR, 207, 210, and 211.

§ 15-5-9. Minimum Requirements for Third-Party Logistics Providers and Manufacturers for the Storage and Handling of Prescription Drugs and for the Establishment and Maintenance of Prescription Drug Records

9.1. Third-party logistics providers and manufacturers shall meet the mm1mum requirements for the storage and handling of prescription drugs, and for the establishment and

maintenance of prescription drug distribution records as required by the Federal Food and Drug Administration.

§15-5-10. The West Virginia Board of Pharmacy inspection powers and access to licensee and permittee records.

A person authorized by the board may inspect during normal business hours any premises being used by a wholesale drug distributor, third-party logistics provider, or manufacturer in this state in the course of its business.

Licensees and permittees under this series may keep records regarding purchase and sales transactions at a central location apart from the principal office of the licensee or permittee or the location at which the drugs were manufactured, housed, or stored by the licensee or permittee, and from which they were shipped: Provided, That such records shall be made available for inspection within two working days after a request to inspect by the board is made. Such records may be kept in any form permissible under federal law applicable to prescription drugs record keeping.

TITLE 15
LEGISLATIVE RULE
BOARD OF PHARMACY

SERIES 6
MAIL-ORDER AND NON-RESIDENT PHARMACIES

§15-6-1. General.

1.1. Scope. -- To establish rules for the Mail-order pharmacy and non-resident pharmacies.

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

1.3. Filing Date. -- April 28, 2017.

1.4. Effective Date. -- April 28, 2017.

1.5. Sunset Date -- This rule shall terminate and have no further force or effect on April 28, 2027.

§15-6-2. Definitions.

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

2.2. "Non-resident pharmacy" means a pharmacy outside of this state where drugs are dispensed and pharmacist care is provided to residents into this state.

2.3. "Pharmacy" means a place within this state where drugs are dispensed and pharmacist care is provided and a place outside of this state where drugs are dispensed and pharmacist care is provided to residents of this state.

2.4. "Prescription or prescription drug 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.

§15-6-3. Registrations for Mail-Order Pharmacies.

3.1. A mail-order pharmacy shall apply for a registration for authorization to dispense prescription drugs or medicines in West Virginia. A non-resident pharmacy shall be registered in this state in the same manner as a mail-order pharmacy pursuant to this Series by issuance of a mail order registration.

3.2. A mail-order pharmacy or non-resident pharmacy shall submit the application for the registration to the West Virginia Board of Pharmacy. The application shall contain the following information:

3.2.a. The owner of the mail-order pharmacy or non-resident pharmacy, whether an individual, a partnership, or a corporation.

3.2.b. The names and titles of all individual owners, partners or corporate officers.

3.2.c. The pharmacy manager.

3.2.d. The pharmacist-in-charge.

3.2.e. The complete address, telephone number and fax number of the mail-order pharmacy or non-resident pharmacy.

3.3. The mail-order pharmacy or non-resident pharmacy shall obtain separate registrations if it operates more than one pharmacy.

3.4. The mail-order pharmacy or non-resident pharmacy shall maintain a permit, registration, or license as required by the state where located.

3.5. The pharmacist-in-charge shall certify that the mail-order pharmacy or non-resident pharmacy is in compliance with the standards of care relative to the dispensing of prescription drug orders as required by the state where located.

3.6. The pharmacist in charge shall submit the names of all pharmacists employed at the mail-order pharmacy or non-resident pharmacy.

§15-6-4. Prescription record and reporting.

The mail-order pharmacy or non-resident pharmacy shall maintain prescription records which are available for review if required by the Board. The mail order pharmacy shall comply with the reporting requirements of the West Virginia Controlled Substances Monitoring Program as set forth in West Virginia Code § 60A-9-1 and the rules enacted in support thereof.

§15-6-5.

Mail-order pharmacies or non-resident pharmacies shall have a toll free accessible telephone for consumers to obtain counseling with a licensed pharmacist during regular working hours and the telephone number shall be prominently identified on the prescription container or on the prescription container label.

§15-6-6. Doing Business in West Virginia

Mail-order pharmacies or non-resident pharmacies soliciting, receiving, and dispensing and delivering orders comprising prescription drugs and scheduled controlled drug substances as defined in 21 USC 1 et seq., and 21 CFR 1 et seq., and delivered to ultimate consumers in West Virginia constitutes doing business in West Virginia.

§15-6-7. Resident Agent

Mail-order pharmacies or non-resident pharmacies doing business in West Virginia by dispensing and delivering prescription orders to West Virginia consumers shall designate a resident agent for purposes of service of process and notice.

§15-6-8. Pharmacist-In-Charge Licensure requirement

The pharmacist in charge or at least one designated pharmacist of the out-of-state mail order pharmacy or non-resident pharmacy shall be licensed to practice pharmacist care in West Virginia and act as the PIC of the registration, and any other pharmacist providing pharmacist care from the out-of-state mail order pharmacy or non-resident pharmacy shall be licensed in the state where the pharmacy is located.

REGISTRATION OF PHARMACY TECHNICIANS

§15-7-1. General.

1.1. Scope. -- To establish standards for the training and regulation of pharmacy technicians.

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

1.3. Filing Date. -- April 28, 2017.

1.4. Effective Date. -- April 28, 2017.

1.5. Sunset Date -- This rule shall terminate and have no further force or effect on April 28, 2027.

§15-7-2. Definitions.

2.1. “Certified Pharmacy Technician” or “CPhT” means a person who holds a current certification as a nationally certified pharmacy technician granted by NHA or PTCB.

2.2. “National Healthcareer Association” or “NHA” means the association which includes the ExCPT Certification Board, which develops, maintains, promotes, and administers a nationally accredited certification and recertification program for pharmacy technicians to become a CPhT, including its ExCPT Pharmacy Exam (ExCPT), which was originally established by the Institute for the Certification of Pharmacy Technicians.

2.3 "Pharmacy Technician" means a person registered with the board to practice certain tasks related to the practice of pharmacist care in this State within the scope of practice permitted by West Virginia Code Section 30-5-12, as provided, permitted, and limited by the laws and rules governing the practice of pharmacist care.

2.4. “Pharmacy Technician Certification Board” or “PTCB” means the entity established by its five governing organizations, the American Pharmacists Association, American Society of Health-System Pharmacists, Illinois Council of Health-System Pharmacists, Michigan Pharmacists Association, and National Association of Boards of Pharmacy, which develops, maintains, promotes, and administers a nationally accredited certification and recertification program for pharmacy technicians to become a CPhT, including its Pharmacy Technician Certification Exam (PTCE).

2.5. "Pharmacy Technician Trainee" means an individual currently engaged in a competency-based pharmacy technician education and training program which has been approved by the Board and who is performing the duties of a pharmacy technician under the direct supervision of a pharmacist.

§15-7-3. Qualifications For Registration as a Pharmacy Technician; 20 Hour Training Program.

3.1. To be eligible for registration as a pharmacy technician, an individual shall comply with West Virginia Code § 30-5-11, and shall submit an application on the forms provided by the board, together with the application fee of $25.00, evidencing that the individual:

(a) was registered as a pharmacy technician in the State of West Virginia prior to July 1, 2014, the registration was still active and in good standing through June 30, 2014, and he or she is otherwise eligible to renew his or her registration ; or

(b) for those obtaining registration beginning July 1, 2014, and forward:

(1) has either:

(A) graduated from a competency-based pharmacy technician education and training program of a learning institution or training center approved by the Board; or

(B) completed a pharmacy-provided, on-the-job, competency-based education and training program approved by the Board; and

(2) successfully passed the ExCPT national examination administered by NHA or the PTCE national examination administered by PTCB, and holds a current certification from NHA or PTCB, respectively, as a CPhT;

(3) completed a 20-hour training program as outlined in subsection 3.2 of this rule. The pharmacist-in-charge must submit to the Board certification in the form of an affidavit from the pharmacist-in-charge that the pharmacy technician trainee has adequately completed this training program; and

(4) request and submit to the board the results of a state and a national electronic criminal history records check by the West Virginia State Police. The applicant shall furnish to the State Police a full set of fingerprints and any additional information required to complete the criminal history records checks. The applicant is responsible for any fees required by the State Police in order to complete the criminal history records checks. The board may require the applicant to obtain an electronic criminal history records check from a similar agency in the state of the applicant's residence, if outside of West Virginia. In addition, the board may contract with a company specializing in the services required by this paragraph 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.

(A) The criminal history records must have been requested within the twelve (12) months immediately before the application is filed with the board.

(B) To be qualified for registration, the results of the criminal history records check must be unremarkable, and verified by a source acceptable to the board other than the applicant.

(C) The board may deny registration to any applicant who fails or refuses to submit the criminal history records checks required by this subsection.

3.2. The pharmacist-in-charge of each pharmacy shall create a 20-hour training program regarding the drug dispensing process in that pharmacy which shall include the following:

(a) the steps in receiving prescriptions;

(b) the creation of or updating of patient profiles;

(c) the entering of prescription information into the computer;

(d) the updating of files and the printing of labels;

(e) the pulling of stock packages from shelves;

(f) the checking of medications;

(g) the preparing of medications;

(h) refill procedures and regulations; and

(i) record keeping.

§15-7-4. Learning Institution or Training Center Provided and On-the-Job Pharmacy-Provided Competency-Based Training Program

4.1. In order for pharmacies to be able to train and hire competent pharmacy technicians, a pharmacy may employ an individual as a pharmacy technician trainee and provide on-the-job, competency-based pharmacy technician training for the individual to become qualified for registration as a pharmacy technician. A pharmacy shall submit its pharmacy technician training program to the Board for approval prior to its use, Provided that, all training programs currently approved for use by the Board on the effective date of this rule are hereby approved for continued use as previously approved. The training program shall be outlined in a training manual which shall be used throughout the program. A competency based pharmacy technician education and training program shall, at a minimum contain the following:

(a) written procedures and guidelines for the use and supervision of pharmacy technicians. The procedures and guidelines shall:

(1) specify the manner in which the pharmacist-in-charge responsible for the supervision of pharmacy technicians shall supervise the pharmacy technicians and verify the accuracy and completeness of all acts and functions performed by them; and

(2) specify duties which may and may not be performed by pharmacy technicians; and

(b) instruction in the following areas and any additional areas appropriate to the duties of pharmacy technicians in the pharmacy:

(1) Orientation;

(2) Job descriptions;

(3) Communication techniques;

(4) Legislative rules of the West Virginia Board of Pharmacy;

(5) Security and safety;

(6) Prescription drugs, including:

(A) Basic pharmaceutical nomenclature; and

(B) Dosage forms;

(7) Prescription drug orders, including:

(a) Prescribers;

(b) Directions for use;

(c) Commonly used abbreviations and symbols;

(d) Number of dosage units;

(e) Strengths and systems of measurement;

(f) Routes of administration;

(g) Frequency of administration;

(h) Interpreting directions for use; and

(8) Prescription drug order preparation, including:

(a) the creation or updating of patient medication records;

(b) the entering of prescription drug order information into the computer or typing the label in a manual system;

(c) the selection of the correct stock bottle and the accurate counting of or pouring of the appropriate quantity of drug product;

(d) the selection of the proper container; and

(e) the preparation of the finished drug product for inspection, labelling, and final check by pharmacists;

(9) Drug product prepackaging;

(10) the compounding of non-sterile pharmaceuticals; and

(11) Written policy and guidelines for the use of and supervision of pharmacy technicians.

4.2. A pharmacy technician trainee shall complete initial training at a pharmacy as outlined by the pharmacist-in-charge in the training manual, prior to the regular performance of his or her duties. Beginning July 1, 2014, the on-the-job, competency-based pharmacy technician training program shall consist of a minimum of 960 hours of employment within a 15-month period under the direct supervision of a pharmacist.

4.3. An individual may work as a pharmacy technician trainee only as a student enrolled in a competency-based pharmacy technician education and training program of a learning institution or training center approved by the Board as part of an experiential education component, or as an employee of a pharmacy in a 960-hour on-the-job, competency-based pharmacy technician training program. Prior to starting work in a pharmacy as a pharmacy technician trainee, the applicant shall submit an application on the forms provided by the board evidencing that he or she:

has graduated from a high school or obtained a Certificate of General Educational Development (GED) or its equivalent, or is currently enrolled in a high school competency based pharmacy technician education and training program;
is not an alcohol or drug abuser;
has not been convicted of a felony in any jurisdiction within ten years preceding the date of application;
has not been convicted of any misdemeanor or felony in any jurisdiction which bears a rational nexus to the practice of pharmacist care; and
has requested and submitted to the board the results of a state and a national electronic criminal history records check by the West Virginia State Police, as detailed in subdivision 3.1(b)(4) of this rule.

4.4. (a) If the pharmacy technician trainee leaves the competency-based pharmacy technician education and training program of a learning institution or training center identified in his or her application, the learning institution or training center shall notify the Board in writing within 30 days that the trainee is no longer enrolled in the program. Upon leaving, the trainee may not continue to work as a trainee.

(b) If the pharmacy technician trainee is transferring from the original pharmacy identified in his or her application as the pharmacy providing an on-the-job, competency-based pharmacy technician training program, the pharmacist-in-charge of that pharmacy shall notify the Board, in writing, within 30 days that the pharmacy technician trainee is no longer working there. The pharmacist-in-charge of the new pharmacy must notify the Board in writing within 30 days of the pharmacy technician trainee starting to work in the new pharmacy which is providing the on-the-job, competency-based pharmacy technician training program.

(c) Within 15 months of approval of his or her application to begin working as a pharmacy technician in a training program, the pharmacist-in-charge must submit to the Board a certification in the form of an affidavit from the pharmacist-in-charge that the pharmacy technician trainee has adequately completed the training program, or that he or she has failed to complete the training program, whichever is applicable.

(d) Any pharmacy technician trainee already participating in an ongoing training program prior to July 1, 2014, shall be given credit for any hours completed in that program, and will have until 2 years from the date he or she originally began that program, or until October 1, 2015, whichever occurs first, to complete the required topics covered in the training program, complete a minimum of 960 hours, and receive the certification of completion of the training program from the pharmacist-in-charge.

(e) A pharmacy technician trainee shall have 90 days from the date of graduation from the competency-based pharmacy technician education and training program of a learning institution or training center, or the date of the certification of completion of the training program by the pharmacist-in-charge, to successfully pass the ExCPT or PTCE national certification examination, obtain certification as a CPhT, and submit this information along with his or her application for registration in this State as a pharmacy technician.

(f) If the pharmacy technician trainee fails to complete the required training program and hours within the 15 months period, the pharmacy technician trainee must cease working in the pharmacy immediately. Provided that, the Board may, upon approval of a petition to the Board by a pharmacy technician trainee:

(1) provide an extension of time for completion of the training program upon a showing of special circumstances; or

(2) permit a pharmacy technician trainee to begin a training program again with no credit given for any previous hours.

(g) If the pharmacy technician trainee fails to successfully pass the ExCPT or PTCE national certification examination and obtain certification as a CPhT within 90 days from the date of graduation from the competency-based pharmacy technician education and training program of a learning institution or training center, or the date of the certification of completion of the training program by the pharmacist-in-charge, the pharmacy technician trainee shall cease working in the pharmacy immediately until he or she satisfies this requirement. Provided that, the Board may, upon approval of a petition to the Board by a pharmacy technician trainee:

(1) provide an extension of time for completion of a personal remediation or re-training program which is presented to the Board with the petition; or

(2) permit a pharmacy technician trainee to begin a training program again with no credit given for any previous hours by making a new application to become a pharmacy technician trainee as described in subsection 4.3 above.

4.5. The pharmacist-in-charge of the pharmacy providing on-the-job, competency-based pharmacy technician training program shall document whether or not the pharmacy technician trainee has completed the training program and certify the competency of each technician completing the training. The pharmacist-in-charge shall maintain a written record of the initial training of each pharmacy technician. The written record shall contain the following information:

(a) the name of the person receiving the training;

(b) the date of the training;

(c) a general description of the topics covered;

(d) a statement or statements that certify that the pharmacy technician is competent to perform the duties assigned;

(e) the name of the person supervising the training; and

(f) the signature of the pharmacy technician and the pharmacist-in-charge or other pharmacist employed by the pharmacy and designated by the pharmacist-in-charge as responsible for the training of pharmacy technicians.

§15-7-5. Duties and Restrictions of a Pharmacy Technician.

5.1. A pharmacy technician may not:

(a) receive verbal prescription drug orders and reduce these orders to writing either manually or electronically;

(b) interpret and evaluate prescription drug orders;

(c) select drug products;

(d) interpret patient medication records and perform drug regimen reviews;

(e) deliver the prescription to the patient before a pharmacist performs the final check of the dispensed prescription to ensure that the prescription has been dispensed accurately as prescribed;

(f) communicate to the patient or the patient's agent, information about the prescription drug or device which in the exercise of the pharmacist's professional judgment, the pharmacist considers significant;

(g) communicate to the patient or the patient's agent, information concerning any prescription drugs dispensed to the patient by the pharmacy; or

(h) receive or place a call for a transferred prescription.

5.2. The duties of a registered pharmacy technician may include, but are not limited, to the following:

(a) the placement, receipt, unpacking and storage of drug orders;

(b) maintenance of the work area and equipment in a clean and orderly condition;

(c) the ordering and stocking of all pharmacy supplies;

(d) the checking of all prescription and non-prescription stock for outdates and the processing of outdated returns;

(e) the operation of the cash register. However the pharmacy technician shall

(1) only handle the complete transaction on refill prescriptions when specifically requested to do so by the pharmacist and when the patient has no questions for the pharmacist;

(2) only handle the transactions on new prescriptions after counseling by the pharmacist has been offered; and

(3) refer all questions regarding over the counter and prescription drug product selection or advice to the pharmacist;

(f) the filing of completed hard-copies of new prescriptions, (except schedule II drugs) in numerical order. A pharmacist shall file schedule II drug prescription hard-copies;

(g) the placement of completed prescription orders on the will-call shelf;

(h) the wrapping of completed orders for mailing and the logging of mailed and delivered orders into a record;

(i) the printing of third-party billings, the processing of the billings for mailing and the transmission of electronically handled third-party billings;

(j) the reconciliation of third-party payments;

(k) the contacting of third-party billers and payers if problems arise while handling a patient's insurance transmissions;

(l) the posting of patient purchases to private charge accounts and assisting with the printing and distribution of the monthly statements;

(m) the handling of non-professional phone calls to or from:

(1) patients requesting refills of prescriptions by number and patient name;

(2) physicians' offices authorizing refills, if no changes in the prescription are involved, and where the patient's name, medication and strength, number of doses, and date of prior fill is stated. The pharmacy technician shall refer any other inquiries by the prescribing physician's office to the pharmacist;

(3) patients concerning price information that has been calculated by computer;

(4) patients concerning business hours, mailing and delivery services, and the availability of goods and services;

(5) patients asking if their prescriptions are refillable and the number of refills remaining. Any interpretation of the proper length of time between refills must be handled by the pharmacist;

(6) wholesalers and distributors dealing with the ordering of goods and supplies; and

(7) physicians' offices regarding patient profile information, where no interpretation or judgment is necessary and only after the pharmacy technician verifies to whom the information is being given.

(n) the acceptance of refill requests and the acceptance of new written prescriptions from patients or their agents after determining the following: the patient's correct name, address, phone number, birth date, drug allergies, disease state(s), and the method of payment;

(o) the entering of prescription data and patient profile data into the computer. The pharmacy technician shall refer any information needing clarification or interpretation to the pharmacist. The pharmacy technician shall:

(1) Monitor the label printing; and

(2) Alert the pharmacist to any duplication of medication, drug therapy overlap, drug interactions, drug-disease state interactions, and any questions that arise from entering the information.

(p) the performance of tasks under the pharmacist's supervision, such as obtaining stock bottles for prescription filling;

(q) the counting and pouring from stock bottles for individual prescriptions only under the direct supervision of a pharmacist. The pharmacist shall initial the hard copy of the prescription and the label to account for the accuracy of the prescription contents and the accuracy of the labeling;

(r) the reconstitution and restoration of the original form of medication previously altered for preservation and storage by the addition of a specific quantity of an appropriate diluent requiring no calculations. The pharmacy technician may assist in the preparation of sterile parenteral/enteral products under the direct supervision of a pharmacist. In all cases, the pharmacist shall check and verify the accuracy of the pharmacy technician; and

(s) the weighing or measuring of specific ingredients for the pharmacist to use in extemporaneous compounding. In all cases the accuracy of the weighing and measuring must be verified by the pharmacist.

5.3. The pharmacist-in-charge shall not allow anyone within the pharmacy area to perform pharmaceutical care other than, pharmacists, registered pharmacy technicians, pharmacy technician trainees and pharmacy interns. A ratio of no more than four pharmacy technicians and/or pharmacy technician trainees per on-duty pharmacist operating in any pharmacy shall be maintained. This ratio shall not include pharmacy interns.

5.4. A registered pharmacy technician shall not handle any telephone calls for new prescriptions from a physician's office and shall immediately transfer the calls to a pharmacist, except in the case of refill requests as set forth in subsection 5.2(m).

§15-7-6. Identification of Technicians and Technician Trainees.

6.1. Pharmacy technicians shall wear a name tag approved by the Board which contains the designation "Pharmacy Technician" while working in a pharmacy within this State. The name tags shall contain lettering of a legible size. Pharmacy technicians and pharmacy technician trainees shall wear appropriate sanitary attire, other than a white coat.

6.2. During the period of training, a pharmacy technician trainee shall wear a name tag approved by the Board which contains the designation "Pharmacy Technician Trainee". The name tags shall be a holder on a lanyard or to be pinned or clipped to the trainee’s lab coat capable of holding and displaying a board-issued wallet-sized copy of the pharmacy technician trainee’s credential, which shall identify the trainee by name and registration number.

§15-7-7. Certificate of Registration; Transfer of Registration.

7.1. The Board will provide a certificate of registration to applicants meeting the requirements for registration as a pharmacy technician.

7.2. The registration of the pharmacy technician may not be transferred to another pharmacy unless:

(a) the pharmacies are under common ownership and control and have a common training program; or

(b) the pharmacist-in-charge of the pharmacy at which the pharmacy technician intends to work certifies that the pharmacy technician is competent to perform the duties assigned in that pharmacy, and the pharmacist-in-charge submits to the Board certification in the form of an affidavit from the pharmacist-in-charge that the pharmacy technician trainee has adequately completed the pharmacy-specific 20-hour training program as outlined in subsection 3.2 of this rule.

TITLE 15
LEGISLATIVE RULE
WEST VIRGINIA BOARD OF PHARMACY

SERIES 8
CONTROLLED SUBSTANCES MONITORING PROGRAM

§15-8-1. General.

1.1. Scope. -- This rule establishes requirements for the recordation and retention in a single repository of information regarding the prescribing, dispensing and consumption of certain controlled substances.

1.2. Authority. -- W. Va. Code §§ 30-5-7 and 60A-9-6.

1.3. Filing Date. -- April 28, 2017.

1.4. Effective Date. -- April 28, 2017.

1.5. Sunset Date. -- This rule shall terminate and have no further force or effect on April 28, 2027.

§15-8-2. Definitions.

2.1. The definitions applicable to the Uniform Controlled Substances Act set forth in West Virginia Code § 60A-1-101 apply to this Series.

2.2. The following words and phrases have the following meanings:

2.2.a. "Central repository" means the repository designated by the board for the collection of the transmitted information, which may be a vendor designated by the board and under contract with the board to act as the central repository.

2.2.b. “Controlled Substances Monitoring Program” or “CSMP” means the database maintained through the central repository for the information required to be transmitted by this rule.

2.2.c. “Date sold” means, for purposes of American Society for Automation in Pharmacy (ASAP) standard prescription drug monitoring program reporting formats, the date a prescription is delivered to the patient or the patient’s caregiver or agent on behalf of the patient, Provided that, for prescriptions delivered by mail or other common carrier, it is the date placed in the mail or for delivery.

2.2.d. "Deliver" or "delivery" means the actual, constructive or attempted transfer from one person to another of: (1) A controlled substance, whether or not there is an agency relationship; (2) a counterfeit substance; or (3) an imitation controlled substance.

2.2.e. "Dispense" means to deliver a controlled substance to an ultimate user or research subject by or pursuant to the lawful order of a practitioner, including the prescribing, administering, packaging, labeling or compounding necessary to prepare the substance for that delivery. Dispensing has not occurred for purposes of this definition until the controlled substance is actually delivered to the recipient or recipient representative.

2.2.f. “Duly authorized agent” means an individual, who is an employee of any of the covered persons or entities permitted to have access to the central repository pursuant to Rule 15-8-7.3 of this

rule, who is specifically designated by the covered person or duly authorized representative of the covered entity to access the central repository on behalf of the covered person or entity.

2.2.g. “Electronic access” means the ability to connect with and view the information in the central repository maintained by the board using the Internet or some other electronic means, such as an Intranet or satellite connection which permits real-time connectivity to the central repository the same as if connected through the Internet.

2.2.h. “Government-issued photo identification card” means an identification card of an individual that provides a photograph of him or her and is issued by a State or the Federal Government of the Unites States of America, or a document that, with respect to identification, is considered acceptable for purposes of sections 274a.2(b)(1)(v)(A) and 274a.2(b)(1)(v)(B) of title 8, Code of Federal Regulations.

2.2i. “Internet” means an interconnected system of networks that connects computers around the world via the Transmission Control Protocol (TCP) and the Internet Protocol (IP) established by the Internet Society (ISOC).

2.2.j. “Intranet” means a privately maintained computer network that can be accessed only by authorized persons, especially members or employees of the organization that owns it.

2.2.k. "Medical Services Provider" means a licensed practitioner with the legal authority to dispense controlled substances.

2.2.l. “Opioid antagonist or opiate antagonist” means drugs approved by the federal Food and Drug Administration for treatment of drug overdose which have a high affinity for opiate receptors but do not activate these receptors, and which block the effects of exogenously administered opioids such as morphine, heroin, meperidine, and methadone, or of endogenously released endorphins and enkephalins.

2.2.m. “Patient”, for purposes of access to the CSMP, means an individual who:

2.2.m.1. has a valid ongoing practitioner-patient relationship; or

2.2.m.2. has not yet established an ongoing practitioner-patient relationship, but:

2.2.m.2.A. has requested to establish such a relationship with the practitioner; or

2.2.m.2.B. has been referred to that practitioner for evaluation or care by another practitioner.

2.2.n. "Recipient" means the patient, ultimate user or research subject for whom a controlled substance is dispensed or filled.

2.2.o. "Recipient representative" means an individual to whom a controlled substance is

dispensed or filled if the recipient is either less than 18 years of age or unavailable to receive the controlled substance.

2.2.p. "Reporter" means a medical services provider, health care facility, pharmacist, or pharmacy that is required to submit the information outlined in section 4 of this rule.

2.2.q. "Schedule II, III, or IV Controlled Substance" means a controlled substance classified in those categories under W. Va. Code §§60A-2-206, 208 and 210.

2.2.r. "Security prescription blank" means a prescription blank that complies with the requirements of Section 15-1-27 of the West Virginia Code of State Rules.

2.2.s. "Universal Claim Form" means a nationally recognized standard form developed by the National Council for Prescription Drug Programs used for billing drug claims to insurance plans.

§15-8-3. Prescription Monitoring Program.

3.1. Each time a Schedule II, III, or IV Controlled Substance or opioid antagonist is dispensed for out-patient use, the medical services provider, health care facility, or pharmacy that dispensed the controlled substance or opioid antagonist shall transmit to the central repository the information required by West Virginia Code § 60A-9-4. This includes the following:

3.1.a. The name, address, pharmacy prescription number and Drug Enforcement Administration controlled substance registration number of the dispensing pharmacy or the dispensing medical services provider;

3.1.b. The full legal name, address and birth date of the recipient. When reporting the full legal name, address, and date of birth of the recipient, the reporter shall include any middle name or initial and any suffix (e.g., Jr., II, III) as listed on the patient's government-issued photo identification card, Provided that, if the patient does not have such an identification card, such as a minor, then the reporter shall obtain and input the information to the best of its knowledge and ability based upon the information available to it from the prescription, the patient profile or record, and any other information known to the reporter. Examples of acceptable forms of ID include, but are not limited to: driver's licenses, non-driver identification cards, passports, and military IDs;

3.1.c. The Drug Enforcement Administration controlled substances registration number of the practitioner writing the prescription. By providing this registration number, the Controlled Substances Monitoring Program database will extract the prescriber's name and address required by statute; therefore, the reporters do not need to additionally supply the prescriber's name and address in addition to the prescriber's DEA number;

3.1.d. The national drug code number of the Schedule II, III and IV controlled substance or opioid antagonist dispensed. By providing this NDC number, the Controlled Substances Monitoring Program database will extract the name and dosage or (strength) of the controlled substance required by the statute such that the reporters do not need to additionally supply the name and dosage;

3.1.e. The quantity of the Schedule II, III and IV controlled substance or opioid antagonist dispensed;

3.1.f. The date the prescription was written and the date filled;

3.1.g. The number of refills, if any, authorized by the prescription;

3.1.h. If the prescription being dispensed is being picked up by a recipient representative on behalf of the recipient, the full legal name, address and birth date of the recipient representative as set forth on the person's government-issued photo identification card. When reporting the full legal name, address, and date of birth of the person picking up the prescription on behalf of the patient, the reporter shall include any middle name or initial and any suffix (e.g., Jr., II, III) as listed on the person's government-issued photo identification card; and

3.1.i. The source of payment for the controlled substance dispensed.

3.2 The board and the central repository shall provide for the electronic transmission of the information required to be provided by and through the use of a toll-free telephone line or other Internet connection.

§15-8-4. Information To Be Transmitted Within 24 Hours.

4.1. The information may be transmitted at any time, but shall be transmitted at least within twenty-four (24) hours of the dispensing. If the dispensing is done by mail or other postal, courier, or logistics services such as United Parcel Service or Federal Express, then the information shall be submitted at least within forty-eight (48) hours of the time the dispensing is placed in the mail for delivery. If a reporter is closed for a holiday, or week-end day, the reporter shall make the required report as soon as is practicable upon reopening, or within forty-eight (48) hours, whichever occurs first. If there are no dispensings of any Schedule II, III, or IV controlled substances or opioid antagonists, then the reporter shall submit a daily "zero" report, Provided that if there are no such dispensings within up to seven days of the last report, the reporter may submit a weekly "zero" report no later than seven days after the last date and time reported on the previous report. If a reporter is unable to make the required reporting in a timely manner due to an emergency, the reporter shall inform the board of the emergency and provide the board with information on when the reporter believes it will return to full compliance. Such notification may be taken into consideration by any agency, licensing board, or court, when determining if the reporter is in compliance with reporting requirements of West Virginia Code Section 60A-9-3 and Section 3 of this Series, and any penalties that may attach for any violation thereof.

4.2. If a reporter does not possess for the purpose of dispensing any Schedule II, III, or IV controlled substances or opioid antagonists, the dispenser may notify the board in writing by requesting a waiver from reporting on a form supplied by the board. If the waiver is granted by the board, the reporter is not required to submit a zero report unless and until the reporter possesses a Schedule II, III, or IV controlled substance or opioid antagonist for the purpose of dispensing.

§15-8-5. Accuracy of Information Transmitted.

Information shall be reported accurately. If the reporting individual or entity discovers that information contained in the central repository is not accurate, he or she shall make the necessary corrections and resubmit the correct information as soon as possible, but in no event longer than 7 days after the discovery of the inaccurate reporting.

§15-8-6. Central Repository; Designation; Powers and Duties.

6.1. The central repository shall maintain a database for the information required to be transmitted by this rule. This database shall be referred to as the "Controlled Substances Monitoring Program", or the "CSMP".

6.2. The central repository shall provide the board with continuous 24-hour a day, on-line access to the database maintained by the central repository.

6.3. The central repository shall secure the information collected by the central repository and the database maintained by the central repository against access by unauthorized persons.

6.4. If the relationship between the board and the central repository is terminated by statute, the central repository shall provide to the board within a reasonable time, all collected information and the database maintained by the central repository.

6.5. The board may accept a designated grant, public and private financial assistance, and licensure fees to provide funding for the central repository.

§15-8-7. Confidentiality.

7.1. The board shall carry out a program to protect the confidentiality of the information received by the central repository.

7.2. The board may disclose confidential information received by the central repository to any person who is engaged in receiving, processing, or storing the information.

7.3. The board may release confidential information received by the central repository to the following persons:

7.3.a. A duly authorized agent of a board in this state or another state that licenses practitioners authorized to prescribe Schedules II, III, and IV controlled substances who is engaged in an investigation, an adjudication, or a prosecution of a violation under any state or federal law that involves a controlled substance;

7.3.b. Members of the West Virginia State Police expressly authorized by the superintendent of the West Virginia State Police to have access to the information;

7.3.c. An authorized agent of a local law-enforcement agency who is acting as a member of a Federally affiliated drug task force who is engaged in an investigation, an adjudication, or a prosecution of a violation under any state or federal law that involves a controlled substance;

7.3.d. Authorized agents of the federal Drug Enforcement Administration who is engaged in an investigation, an adjudication, or a prosecution of a violation under any state or federal law that involves a controlled substance;

7.3.e. The Chief Medical Examiner for the State of West Virginia or his or her duly authorized agent for use in post-mortem examinations;

7.3.f. A person with an enforceable court order or regulatory agency administrative subpoena;

7.3.g. Inspectors and agents of the board to carry out the lawful purposes of the CSMP program, for purposes of a pharmacy inspection or drug inventory, or who are engaged in an investigation, an adjudication, or a prosecution of a violation under any state or federal law that involves a controlled substance;

7.3.h. Prescribing practitioners or their duly authorized agents;

7.3.i. Pharmacists or a registered pharmacy technician as the agent of the pharmacist; and

7.3.j. A person using the data for compilation of educational, scholarly, or statistical purposes so long as the individually identifiable data of the persons or entities stored in the central repository remains confidential.

7.4. All information released by the board shall be related to a specific patient or a specific individual or entity under investigation by any of the persons set forth in subsection 7.3 (a) through (i) of this section except that practitioners who prescribe or dispense controlled substances may also request specific data related to any and all dispensings reported to the database as prescribed and/or dispensed under their drug enforcement administration controlled substance registration number or for the purpose of providing treatment to a patient.

7.4.a. A practitioner or practitioner's delegate may, prior to affirmatively accepting a patient into the practitioner's practice, obtain confidential information from the CSMP related to that patient for the purpose of determining whether or not to accept the patient and provide treatment.

7.4.b. If the patient is a newborn child or child being fed human breast milk, a practitioner or practitioner's delegate may obtain confidential information from the CSMP related to the child's mother, wet nurse, or other direct source of human breast milk, as the practitioner believes may be relevant for the purpose of providing treatment to that child-patient.

7.5. All access to the data collected by the central repository shall be limited to regular business hours of the board's office unless an individual authorized to receive the information proves that an immediate danger to the public exists and immediate access is necessary to prevent further harm, Provided That the

board may permit access at any time to authorized users through the use of a secure connection and through the use of proper security features designed to protect the integrity and confidentiality of the information from unauthorized access or disclosure.

7.6. Any person or entity having access to the central repository and who is permitted to designate a duly authorized agent to have access to the central repository pursuant to this rule shall make the designation on a form to be supplied by the board. It is the responsibility of the designating individual to insure that the designated agent maintains the confidentiality of the information in the central repository as required. Further, should the designating individual remove the authority of the designated agent to act as the duly authorized agent, or should the designated agent leave the employment of the designating individual or entity such that he or she is no longer eligible to act as the duly authorized agent, then the designating individual shall immediately notify the board, at which time the designee's access to the central repository shall be removed.

7.7. A practitioner may file or store copies of any patient-specific report obtained from the CSMP in the patient's confidential medical file or chart maintained by the practitioner. The practitioner may share the information contained in the report with other practitioners providing treatment to the patient, the patient, or the patient's properly authorized guardian or representative for the purpose of providing treatment. However, the information held in the patient file or chart is not subject to discovery in a civil or criminal matter absent a court order. The information is obtainable from the practitioner in a proper regulatory agency administrative matter through a regulatory agency administrative subpoena.

7.8. The board shall review records in the CSMP in accordance with parameters set by the Advisory Committee to identify abnormal or unusual practices of patients who exceed those parameters and are therefore outliers in the CSMP data. The board shall issue reports of the results of these searches to the Review Committee for its regular review and action. Further, the board shall communicate with prescribers and dispensers of the patients who exceed the parameters to inform them of each practitioner's patient's activities as demonstrated in the CSMP reports. All such reports and communications produced by the board shall be kept confidential by the board and the Review Committee, and are not open to inspection except as provided for confidential records and reports of the Review Committee.

7.9. The Review Committee may query the CSMP based on parameters established by the advisory committee to identify abnormal or unusual practices of patients who are outliers in the data according to their controlled substance prescribing, dispensing, or usage patterns or other indicators available in the system. The Review Committee may also query the CSMP based on parameters established by the advisory committee to identify abnormal prescribing and/or dispensing patterns of practitioners indicated by outliers in the system. The Review Committee may also query the CSMP for any relevant prescribing or dispensing records of involved patients or practitioners as it carries out its duty to review notices provided by the chief medical examiner pursuant to West Virginia Code § 61-12-10(h) and determine on a case-by-case basis whether a practitioner who prescribed or dispensed a controlled substance may have resulted in or contributed to the drug overdose, and, if so, if the practitioner may have breached professional or occupational standards or committed a criminal act when prescribing the controlled substance at issue to the decedent. The Review Committee, in accordance with parameters established by the Advisory Committee, may provide any pertinent information in its discretion from the CSMP to the

relevant practitioner, the practitioner's licensing board, or law enforcement as permitted by West Virginia Code § 60A-9-5(b). The Review Committee, in accordance with parameters established by the Advisory Committee, may also communicate with pertinent practitioners or patients to make them aware of the practitioner's own prescribing or dispensing patterns or history, or the patient's own usage patterns or history as reflected in the CSMP in an effort to reduce inappropriate use of prescription drugs in accordance with West Virginia Code § 60A-9-5(3)(C). The information obtained and developed by or on behalf of the Review Committee may not be shared except as provided in West Virginia Code § 60A-9-5(b) and as provided specifically in subsection 7.8 and this subsection of this section.

TITLE 15
LEGISLATIVE RULE
WEST VIRGINIA BOARD OF PHARMACY

SERIES 9
COMPLAINT PROCEDURES

'15-9-1. General.

1.1. Scope. -- This rule relates to the complaint and hearing procedures for all licensees and registrants.

1.2. Authority. -- W. Va. Code ''30-5-1 et. seq. and 30-1-8(h).

1.3. Filing Date. -- December 7, 2000.

1.4. Effective Date. -- January 15, 2001.

'15-9-2. Complaint Procedures.

2.1. Any individual may make a complaint to the board concerning a licensee or registrant.

2.2. The board may accept an anonymous complaint if the information provided is adequate to begin an investigation.

2.3. The board shall accept a complaint in writing, by phone or in person. The board may provide a form for the purpose of submitting a written complaint, but shall accept a complaint if the information includes:

2.3.1. the alleged violation which prompted the complaint;

2.3.2. the name and address of the individual against whom the complaint is lodged;

2.3.3. the date or dates the incident or incidents occurred; and

2.3.4. the name or names of witnesses to the incident or incidents.

2.4. All complaints shall be referred to the Executive Director, Investigator, inspector, or counsel for the Board, who shall act as a representative for the board. A complaint committee shall be established to review such matters. This committee shall consist of two (2) board members, including at least one pharmacist.

2.5. The board shall maintain a complaint log which records the receipt of each complaint, and the nature and the disposition of the complaint. The board shall also maintain a separate file on each complaint received, and each file shall have a number assigned it.

2.6. Upon receipt of complaint or on its own initiative, the representative for the board shall initiate an investigation into the conduct which is occurring or has occurred which violates W. Va. Code '30-5-1 et seq. or rules governing the practice of pharmacy. The complaint committee may employ the services of consultants or other employees necessary to assist the representative for the board in an investigation.
2.6.1. The representative for the board shall issue subpoenas to gather necessary facts and evidence to determine validity of the allegations contained in the complaint. The representative shall have the authority to institute proceedings in the courts of this state to enforce its subpoenas for the production of documents and witnesses and its orders and to restrain and enjoin violations of W. Va. Code '30-5-1 et seq., or rules governing the practice of pharmacy.

2.6.2. The board shall provide copies of complaint forms and other available evidence to the licensee or registrant against whom a complaint is filed when the licensee is invited to appear before the complaint committee to address the complaint..

2.6.3. The representative for the board may depose witnesses, take sworn statements, and collect other evidence.

2.6.4. The representative for the board may require a criminal history records check. The licensee or registrant under investigation shall furnish to the board a full set of fingerprints for purposes of conducting a criminal history check. Records will be checked through the criminal identification bureau of the West Virginia State Police, a similar agency within the licensee=s or registrant=s state of residence, and the United States Federal Bureau of Investigation.

2.6.5. The representative for the board shall evaluate the complaint, any licensee response and other investigative information to determine if a violation of law has occurred and to determine the need for additional investigation. The representative shall have the authority to enter any pharmacy to review documents related to the complaint and to interview any individual during the course of an investigation. Subpoenas duces tecum to compel the production of documents may be issued by the representative for the board. The subpoenas shall be issued pursuant to W. Va. Code '29A-5-1(b).

2.7. Upon completion of investigation, the representative for the board shall present investigative information in a report to the complaint committee. The report shall contain a statement of allegations, a statement of facts, and an analysis of the complaint. The analysis shall consist of a description of the conduct of the licensee or registrant, the records reviewed, and a statement of findings and recommendations. If probable cause for further action is not identified, the representative may make a recommendation that a complaint be dismissed. All investigative information shall be provided to the

committee for review for any case recommended for dismissal due to lack of probable cause. The committee may approve dismissal of the case or direct the representative for the board to proceed with further investigation if the committee believes further investigation is necessary.

2.8. Upon completion of the investigation and after the investigative information has been reviewed by the complaint committee and probable cause is established, the committee may negotiate terms of a consent agreement with a licensee or recommend to the board that the case be set for hearing.

2.9. The complaint committee shall review the terms of a consent agreement and all investigative information. The committee may then approve the consent agreement, request revisions to the consent agreement or reject the consent agreement.

2.10. If the licensee or registrant contests the allegations and refuses to enter into a consent agreement, the committee may recommend to the board that the case be set for hearing. All hearings shall be in accordance with W. Va. Code '29A-1-1 et seq. and 15CSR1-7 of the board=s legislative rules. All complaint committee recommendations shall be presented to the board in an anonymous fashion so as not to identify the specific individual(s) or location(s) involved. The board members that are not on the complaint committee shall vote upon the recommendations. The recommendation shall be approved by a majority vote or the board may reject the recommendation and return the complaint to the committee for further consideration. After considering the complaint a second time, if the recommendation of the committee is not approved, then the case shall be set for hearing before the board members not on the complaint committee.

2.11. Members of the complaint committee shall be disqualified from the formal hearing process if the case has been presented to the committee prior to the formal hearing.

2.12. All powers of the board, the complaint committee, and its representatives may be exercised to investigate a matter, even if a hearing or disciplinary action does not result from the investigative findings.

TITLE 15
LEGISLATIVE RULE
BOARD OF PHARMACY

SERIES 10
BOARD OF PHARMACY RULES FOR PHARMACIST RECOVERY NETWORK

§15-10-1. General.

1.1. Scope. -- This rule establishes definitions of impairment; guidelines for program elements; procedures for receipt and use of information of suspected impairment; procedures for intervention and referral; arrangements for mandatory monitoring, treatment, rehabilitation, post-treatment support and performance; reports of individual cases to the Board; periodic reporting of statistical information; assurance of confidentiality of nonpublic information and of the peer review process; and assessment of a fee to be added to each licensure renewal for operation of pharmacist recovery networks.

1.2. Authority. -- W. Va. Code §30-5-7c(d).

1.3. Filing Date. -- June 23, 2003.

1.4. Effective Date. -- June 23, 2003.

§15-10-2. Definitions.

2.1. "Committee" means the Board of Directors established to function as a supervisory and advisory body to the Program.

2.2. "Executive Director" means the administrator or clinical director selected by the Committee to administer the program.

2.3. "Impairment" means mental illness, chemical dependency, physical illness, or any abnormal physical or mental condition of a pharmacist, intern or technician which threatens a licensee or the safety of persons to whom that licensee might sell or dispense prescription drugs or devices.

2.4. "Licensee" means a licensed pharmacist, licensed intern, or registered pharmacy technician.

2.5. "Program or West Virginia Pharmacist Recovery Network (WVPRN)" means the program established by agreements between special impaired pharmacist peer review organizations and the Board.

§15-10-3. Pharmacist Recovery Network Agreements.

3.1. Pharmacist Recovery Network Agreements with the Board require the following:

3.1.1. Upon receiving a report or request about possible impairment of a licensee from a licensee or another interested party, the Executive Director will make contact with the licensee to verify the

information.

3.1.2. If it is determined there is sufficient reason for action, such as behavioral signs, documented evidence of impairment, and/or drug diversion, the Executive Director shall encourage the licensee to present himself or herself to the WVPRN office within 48 hours of initial contact for a complete substance abuse assessment.

a. If the licensee resists coming in for an assessment, the Executive Director shall pursue one repeat contact.

b. After two unsuccessful interventions within a period not to exceed 14 days, the Executive Director shall inform the licensee of the program's intent to close the file and disclose all evidence of impairment allowed by law to the Board.

3.1.3. After the licensee arrives at the network office, the program's Executive Director shall conduct a substance abuse evaluation to include among other things, a psychoactive substance use history, administration of a Substance Abuse Subtle Screening Inventory (SASSI), urinalysis, and Breathalyzer;

3.1.4. If a diagnosis of substance abuse or dependence as per the current edition of the Diagnostic and Statistical Manual of Mental Disorders published by the American Psychiatric Association is made, the Executive Director shall arrange for further evaluation and treatment of the licensee to be conducted at a facility or by an individual approved by the program. If there is insufficient evidence to warrant a diagnosis of substance abuse or dependence, the Executive Director shall place the file in an inactive status, and destroy the file after 5 years.

3.1.5. The Executive Director shall draw up a final agreement between the licensee and the program for the licensee to enter into a treatment or other appropriate program. The Executive Director shall work with the treatment provider to determine the guidelines of treatment and aftercare, and shall consult with the primary care giver on a regular basis;

3.1.6. The Executive Director shall collect appropriate paper work, as specified in the contract, regarding treatment progress, group therapy participation, urine and blood analysis, discharge summaries, etc.;

3.1.7. Monitors shall assist the licensee in transition into the workplace by providing information if requested to the supervisors and co-workers regarding chemical dependency, relapse, and diversion; and

3.1.8. Upon the completion of treatment and rehabilitation, and the expiration of the 5 year recovery contract, the network shall conclude involvement with the licensee.

§15-10-4. Due Process.

4.1. Any action taken pursuant to a pharmacist recovery network shall afford the licensee all due process rights enumerated in W. Va. Code §§29A-1-1 et. seq.

§15-10-5. Receipt and Use of Information of Suspected Impairment

5.1. Licensees, family members, and other persons may submit reports containing information concerning suspected impairment of a licensee to the program.

5.2. Upon receipt of information of a suspected impairment, the program shall initiate an investigation.

5.3. The program may conduct routine inquiries regarding suspected impairments.

5.4. The program may require a licensee suspected of impairment to submit to personal interviews before any person authorized by the program.

§15-10-6. Intervention and Referral.

6.1. When, following an investigation, the impairment of a licensee is confirmed, the Executive Director shall cause an intervention to be conducted using specialized techniques designed to assist the licensee in acknowledging responsibility for dealing with the impairment. The Executive Director shall then refer the licensee to an appropriate treatment source acceptable to the program.

6.2. The program shall decide the methods and objectives of interventions on a case-by-case basis.

6.3. The program shall arrange and conduct interventions as soon as possible.

6.4. The program shall evaluate treatment sources before making case referrals for treatment.

6.5. The program shall record intervention outcomes including treatment contracts that are elements of an intervention.

§15-10-7. Monitoring Treatment.

7.1. The program shall monitor a treatment source receiving referrals from it as to the treatment source's ability to provide:

7.1.1. adequate medical and non-medical staffing;

7.1.2. appropriate treatment;

7.1.3. affordable treatment;

7.1.4. adequate facilities; and

7.1.5. appropriate post-treatment support.

§15-10-8. Monitoring Rehabilitation and Performance.

8.1. The program shall designate monitoring requirements for each licensee participating in the

program. Licensees may be required to be tested regularly or randomly on demand of the program.

8.2. The program may require treatment sources to submit reports regarding a licensee's rehabilitation and performance to the program.

8.3. The program may require impaired licensees to submit to periodic personal interviews before any person authorized by the program.

8.4. The program shall maintain appropriate case records regarding each licensee that is a participant.

§15-10-9. Monitoring Post-Treatment Support.

9.1. Post-treatment support may include family counseling, advocacy and other services and programs considered appropriate to the licensee's recovery.

9.2. The program shall monitor the post-treatment support of treatment sources on an ongoing basis.

9.3. The program's own post-treatment support shall be monitored by the program on an ongoing basis.

§15-10-10. Reports of Cases of Impairment to the Board.

10.1. After investigation and review of a licensee, the program shall report immediately to the Board detailed information about any licensee as required by W. Va. Code §30-5-7c(e).

10.2. The program shall submit quarterly a report to the Board on the status of all licensees involved in the program who have been previously reported to the Board. The program shall submit a monthly report to the Board on the status of any licensee previously reported to the Board who is in active treatment until a time mutually agreed to by the Board and the program.

10.3. In the event the program becomes aware that the licensee has diverted controlled substances to a person other than himself or herself, the program shall report this infraction to the Board. In this case, the licensee is not protected by the program's confidentiality provisions or from disciplinary action by the Board.

§15-10-11. Periodic Reporting of Statistical Information.

11.1. The program shall compile and annually report to the Board comprehensive statistical reports concerning suspected impairments, impairments, self-referrals, post-treatment support and other significant demographic and substantive information collected through program operations.

§15-10-12. Confidentiality.

12.1. All information, interviews, reports, statements, memoranda, or other documents furnished to or produced by the program, all communications to or from the program, and all proceedings, findings, and conclusions of the program, including those relating to intervention, treatment, or rehabilitation, that in any way pertain to or refer to a person participating in a pharmacist recovery network are privileged

and confidential.

12.2. All records and proceedings of the program that pertain or refer to a person participating in a pharmacist recovery network shall be privileged and confidential, used by the program and its members only in the exercise of the proper function of the program, not be considered public records, and not be subject to court subpoena, discovery, or introduction as evidence in any civil, criminal, or administrative proceedings, except as provided in subsection 10.1of this rule.

12.3. The program may only disclose the information relative to an impaired licensee if:

12.3.1. it is essential to disclose the information to persons or organizations needing the information in order to address the intervention, treatment, or rehabilitation needs of the impaired licensee;

12.3.2. the release is authorized in writing by the impaired licensee; or

12.3.3. the program is required to make a report to the board pursuant to subsection 10.1 of this rule.

§15-10-13. Fees.

13.1. The Board shall assess the following fees to be added to each licensure renewal application fee payable to the Board with any revenue generated by the assessment dedicated to the operation of the pharmacist recovery network:

13.1.1. Pharmacist - $20 with each biennial renewal;

13.1.2. Intern - $5 with each annual renewal; and

13.1.3. Pharmacy Technician - $10 with each biennial renewal.

TITLE 15

LEGISLATIVE RULE
WEST VIRGINIA BOARD OF PHARMACY

SERIES 11
EPHEDRINE AND PSEUDOEPHEDRINE CONTROL

§15-11-1. General.

1.1. Scope. -- To establish rules for ephedrine and pseudoephedrine control in West Virginia including pharmacy reporting requirements; notification processes; and special registration for distributors.

1.2. Authority. -- W. Va. Code §60A-10-1 et.seq .

1.3. Filing Date. -- June 10, 2013.

1.4. Effective Date. -- June 10, 2013.

§15-11-2. Definitions.

2.1. "Central repository" refers to the central repository designated by the board for the collection of controlled substance information. It may be a vendor designated by the board and under contract with the board to act as the central repository.

2.2. “Government-issued photo identification card” means an identification card of an individual that provides a photograph of him or her and is issued by a State or the Federal Government of the Unites States of America, or a document that, with respect to identification, is considered acceptable for purposes of sections 274a.2(b)(1)(v)(A) and 274a.2(b)(1)(v)(B) of title 8, Code of Federal Regulations.

2.3. “Schedule V pseudoephedrine products” means any compound, mixture or preparation containing ephedrine, pseudoephedrine or phenylpropanolamine, their salts or optical isomers, or salts of optical isomers, including any drug products added to the supplemental list pursuant to W. Va. Code §60A-10-7, except products which are for pediatric use primarily intended for administration to children under the age of twelve.

§15-11-3. Pharmacy Requirements.

3.1. Schedule V pseudoephedrine products may be sold, delivered, or provided only in licensed pharmacies, behind the pharmacy counter, by a pharmacist, registered pharmacy intern, or registered pharmacy technician. This limitation applies to consumer transactions or dispensings, and does not apply to wholesale or distribution transactions between licensed manufactures, wholesale drug distributors, pharmacies or other healthcare practitioners holding the products as stock. Schedule V pseudoephedrine products may not be sold, delivered, or provided to any person who is under the age of eighteen.

3.2. The pharmacy, pharmacist, registered pharmacy intern, and registered pharmacy technician with access to the Schedule V pseudoephedrine products have an affirmative duty to guard against the theft and diversion of the products.

3.3. A pharmacy that sells Schedule V pseudoephedrine products shall offer patient counseling for each transaction, and require the person purchasing, receiving or otherwise acquiring the drug product to:

3.3.a. Produce a valid government-issued photo identification showing his or her date of birth. Examples of acceptable forms of ID include, but are not limited to: driver's licenses, non-driver identification cards, passports, and military IDs; and

3.3.b. Sign a logbook containing the information required by subsection 4.1 of this rule and attesting to the validity of the information. The signature may be captured electronically and the information maintained as an electronic record as long as a hard copy may be produced upon request.

3.4. The pharmacy, pharmacist, registered pharmacy intern, and/or registered pharmacy technician involved in the sale of the product have the responsibility to ensure that the information required in this rule provided by the customer is recorded accurately as indicated on the required government-issued photo identification.

3.5. The bound record book kept for distribution of Schedule V exempt narcotics pursuant to West Virginia Board of Pharmacy Rule, Rules of the Board of Pharmacy for the Uniform Controlled Substances Act, 15 CSR 2.7.19.1(e), may be used for recording the information required by this rule.

§15-11-4. Pseudoephedrine Monitoring Program.

4.1. After January 1, 2006, and continuing thereafter until January 1, 2013, each time any Schedule V pseudoephedrine product is transferred, sold, or delivered, the pharmacy shall electronically transmit not less than monthly to the central repository the information required by West Virginia Code § 60A-10-8.

4.2. The information may be transmitted at any time during the month as a batch transmission and may be sent with the Schedule II, III, and IV information.

4.3. Until January 1, 2013, the board and the central repository shall receive the electronic transmission of the information required to be provided by and through the use of a secure upload from the pharmacy via the internet or other means approved by the board. Beginning on January 1, 2013, the information shall be transmitted to the Multi-State Real-Time Tracking System as required by West Virginia Code § 60A-10-8. The pharmacy shall retain the information until transmission to the central repository has been confirmed.

§15-11-5. Lawful Possession of Schedule V Pseudoephedrine Products.

5.1. The following persons are allowed to lawfully possess Schedule V pseudoephedrine products while in the course of legitimate business:

5.1.a. Any Schedule V pseudoephedrine-only limited pharmaceutical distributor, or it agents, licensed by the board;

5.1.b. Any wholesale distributor, or its agents, licensed by the board;

5.1.c. Any manufacturer of controlled substances, or its agents, licensed by the board;

5.1.d. A pharmacy, pharmacist, registered pharmacy intern, registered pharmacy technician, or other pharmacy employee under the direct supervision of a pharmacist;

5.1.e. Health care professionals appropriately licensed and engaged in legitimate patient care: and

5.1.f. Persons possessing the products pursuant to a valid prescription.

§15-11-6. Prescriptions for Schedule V Pseudoephedrine Products.

6.1. Schedule V pseudoephedrine products that are dispensed pursuant to a valid prescription are exempt from the reporting required by this Rule, and by West Virginia Code Chapter 60A, Article 10, and are subject to the requirements of non-scheduled prescription drugs. Any product that is dispensed by prescription shall be provided in a container that is supplied by the pharmacy and shall be labeled with the information required on a prescription label.

§15-11-7. Records and Invoices.

7.1. Any pharmacy, wholesaler, manufacturer, or distributor of Schedule V pseudoephedrine products shall keep readily retrievable records and invoices documenting the sale and distribution of these products. All pharmacy log records of sales of Schedule V pseudoephedrine products shall be kept for a minimum of 5 years from the date of sale or distribution.

§15-11-8. Registration to Sell, Distribute, or Transfer Schedule V Pseudoephedrine Products.

8.1. Every wholesaler, manufacturer, or distributor of Schedule V pseudoephedrine products shall obtain a registration annually from the board.

8.2. A facility that holds a license as a pharmacy, manufacturer, or wholesaler from the board does not need to obtain an additional permit to sell, distribute, or transfer Schedule V pseudoephedrine products or be required to meet any additional storage or security requirements.

8.3. A facility that does not hold a license as a pharmacy, manufacturer, or wholesaler from the board may apply for and be granted a limited Schedule V pseudoephedrine distributor license. An applicant for this registration shall meet the following conditions:

8.3.a. The applicant is actively engaged in the interstate sale of grocery or pharmaceutical items;

8.3.b. The applicant's sales are not limited to pseudoephedrine items alone, or to pseudoephedrine items in conjunction with other items associated with the illegal manufacture of methamphetamine or other controlled drugs;

8.3.c. The applicant does not have a history of diversion of pseudoephedrine; or of having failed to guard against the diversion of pseudoephedrine or other products used in manufacturing illegal drugs

8.3.d. The applicant verifies that Schedule V pseudoephedrine products shall be stored in a locked area that is monitored and the applicant has established security measures to guard against diversion; and

8.3.e. The applicant submits a fully completed application to the board with a fee of $200 for annual registration.

8.4. Licenses allowing the sale, distribution, or transfer of Schedule V pseudoephedrine products expire on June 30th of each year, and shall be renewed on an annual basis.

§15-11-9. Supplemental List.

9.1. The Superintendent of the State Police and the Executive Director of the board shall meet at least quarterly to identify drug products which are a designated precursor, in addition to those that contain ephedrine, pseudoephedrine, or phenylpropanolamine, that are commonly being used in the production and distribution of methamphetamine.

9.2. The Superintendent of the State Police shall demonstrate by empirical evidence those drug products being used in the manufacture of methamphetamine and recommend the addition of these products to the list of Schedule V pseudoephedrine products.

9.3. The board, upon receiving a recommendation from the Superintendent of the State Police, shall promulgate emergency and legislative rules to implement an updated supplemental list of Schedule V pseudoephedrine products.

9.4. The board shall provide written notification to the pharmacist-in-charge of each pharmacy physically located in West Virginia and to the West Virginia Community Pharmacy Council that Schedule V pseudoephedrine products shall be sold, transferred or dispensed only from behind a pharmacy counter and a list of brand name Schedule V pseudoephedrine products that are subject to this rule.

9.5. The board shall provide written notification to the pharmacist-in-charge of each pharmacy physically located in West Virginia and to the West Virginia Retailers Association Community Pharmacy Council, West Virginia Oil Marketers and Grocers Association, and West Virginia Wholesalers Association of each drug product added to the list of Schedule V pseudoephedrine products pursuant to the legislative rule referred to in subsection 9.3 of this rule. Any changes in pseudoephedrine products subject to this rule shall become effective 30 days after notice is provided pursuant to this section.

TITLE 15
LEGISLATIVE RULE
WEST VIRGINIA BOARD OF PHARMACY

SERIES 12
Board of Pharmacy Rules Regarding Immunizations Administered By Pharmacists and Pharmacy Interns

§15-12-1. General.

1.1. Scope. -- To ~~amend~~ provide the rules for pharmacists and pharmacy interns licensed in West Virginia to administer immunizations to patients in this State through joint rulemaking by the West Virginia Board of Pharmacy, Board of Medicine, and Board of Osteopathy.

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

1.3. Filing Date. -- ~~April 16, 2015~~_____.

1.4. Effective Date. -- ~~May 17, 2015~~_____.

1.5. Sunset Date -- This rule shall terminate and have no further force or effect upon the expiration of 10 years from its effective date..

§15-12-2. Definitions.

2.1. "Board", unless otherwise specifically indicated, means the West Virginia Board of Pharmacy.

2.2. "Immunizations" means, for the purpose of this rule, the vaccines specifically listed in this subsection which a pharmacist or licensed pharmacy intern may administer as follows:

2.2.a. to any person eighteen years of age or older, including:

~~(a)~~ 2.2.a.1. Influenza;

2.2.a.2. Pneumococcal;

~~(c)~~ 2.2.a.3. Hepatitis A;

~~(d)~~ 2.2.a.4. Hepatitis B;

~~(e)~~ 2.2.a.5. Herpes Zoster;

~~(f)~~ 2.2.a.6. Tetanus, tetanus-diphtheria (commonly referred to as "Td"), or tetanus-diphtheria-and-pertussis (commonly referred to as "Tdap"); ~~and~~

~~(g)~~ 2.2.a.7. Meningococcal~~.~~; and

2.2.a.8. Human Papilloma Virus (HPV); and

2.2.b. to any person age eleven through eighteen years of age, with written informed parental consent, when presented with a prescription from a physician and there are no contraindications to that patient receiving that vaccine, including:

2.2.b.1. Influenza; and

2.2.b.2. Human Papilloma Virus (HPV)

2.3. "Personal supervision" means the supervising immunizing pharmacist is physically present in the room during the administration of a vaccine.

§15-12-3. Qualifications.

3.1. A pharmacist licensed by the Board may administer immunizations ~~to any person eighteen years of age or older~~ as defined by Section 2.2 of this rule provided the pharmacist has met all of the following requirements:

~~(a)~~ 3.1.a. registered with the board to administer immunizations;

~~(b)~~ 3.1.b. successfully completed the American Pharmacists Association's (APhA) immunization training program, or such other immunization training course as may be approved by the Board, which courses must be based on the standards established for immunization training by the Centers for Disease Control and Prevention in the public health service of the United States Department of Health and Human Services;

~~(c)~~ 3.1.c. maintains current certification in basic life-support training, including basic cardiopulmonary resuscitation (CPR), offered by the American Heart Association, or the American Red Cross; and

~~(d)~~ 3.1.d. completed a minimum of 2 hours of continuing pharmacy education related to immunizations each licensing year for a total of 4 hours each renewal period. The continuing education must be by a provider approved by the Accreditation Council for Pharmacy Education (A.C.P.E.).

3.2. A pharmacy intern licensed by the Board may administer immunizations as permitted by this rule provided that:

~~(a)~~ 3.2.a. the licensed pharmacy intern is under the personal supervision by a pharmacist who is registered with the board to administer immunizations as required by this rule; and

~~(b)~~ 3.2.b. has completed all of the training and current certification required by subsections ~~3.1 (b)~~ 3.1.b. and ~~(c)~~3.1.c. of this section.

3.3. It is unprofessional conduct for a pharmacist or pharmacy intern to administer an immunization, who is not in compliance with this rule.

§15-12-4. Registration.

4.1. Prior to administering immunizations, a pharmacist shall submit an application supplied by the Board for review and approval of the Board, providing that all of the requirements of Section ~~3(a)~~3.1. have been met. The application must be submitted along with a required fee of $10.00. Provided all requirements of Section ~~3(a)~~3.1. have been met and the required fee is received, the Board shall issue a registration to administer immunizations. Registrations shall expire bi-annually on June 30 of year in which the pharmacist's license to practice pharmacy expires.

4.2. A pharmacist may not administer an immunization unless currently registered with the Board to do so under this rule. Further, such registration must be posted conspicuously at any location at which the registered pharmacist is doing any administration.

4.3 Prior to administering immunizations, a licensed pharmacy intern shall provide to his or her supervising pharmacist documentation that the pharmacy intern has completed all of the training and current certification required by subsections ~~3.1 (b)~~ 3.1.b. and ~~(c)~~3.1.c. of this rule. The supervising pharmacist shall maintain this documentation in the pharmacy where the pharmacist and licensed pharmacy intern who administers an immunization is employed or otherwise practicing at the time any immunization is administered by a licensed pharmacy intern.

§15-12-5. Immunizations.

5.1. Immunizations authorized by this rule shall be administered:

~~(a)~~5.1.a. in accordance with definitive treatment guidelines for immunizations promulgated by the latest notice from the U.S. Department of Health and Human Services, Centers for Disease Control and Prevention (CDC), including, but not limited to, CDC's ~~"Recommended Adult Immunization Schedule, by Vaccine and Age Group" and "Recommended Adult Immunization Schedule, by Vaccine and Medical and Other Indications"~~ recommended immunization schedule for adults and children and adolescents, including the footnotes provided for each schedule

(available at ~~www.cdc.gov/vaccines/recs/schedules/adult-schedule.htm~~ https://www.cdc.gov/vaccines/schedules/index.html); or

~~(b)~~5.1.b. in accordance with a proper order from a properly authorized practitioner, Provided that, for minors age eleven through eighteen, the order must be a prescription from a properly authorized physician.

5.2 Administration must be done in accordance with the training required by Section ~~3.1(b)~~3.1.b. of this Series, including, but not limited to indications, contraindications, route of administration, sanitary environment for administration, specifics regarding administration, and storage requirements for each specific immunization authorized by this rule, and, when done pursuant to a prescription, in accordance therewith;

5.3. Administration must include implementation of the CDC's recommended appropriate observation for an adverse reaction of an individual following an immunization.

5.4. Under no circumstances may a pharmacist delegate his or her authority to administer immunizations to any other person, including but not limited to, any pharmacy technician, except as otherwise provided herein for a properly licensed pharmacy intern who is administering under the direct supervision of the pharmacist.

5.5. A current Vaccine Information Statement, as provided by CDC, shall be provided to each person receiving an immunization for each immunization administered.

§15-12-6. Record-keeping and reporting.

6.1. An immunization questionnaire and consent form shall be completed for each person receiving an immunization. When the immunization is for influenza or HPV for a minor age eleven through eighteen years of age, the questionnaire and consent form must include written informed parental consent for the minor. A record of the immunization administration shall be forwarded to the primary care physician or other licensed health care provider as identified by the person receiving the immunization, within not more than 30 days of the date of the administration. In the event that the patient affirmatively indicates in writing that he or she does not have a primary care physician or other health care provider to whom to forward the report, the pharmacist or licensed pharmacy intern must document such in the immunization record, and provide a record of the immunization administration to the patient. Such record shall contain the name of the pharmacist, and, where applicable, the name of the licensed pharmacy intern, administering the immunization.

6.2. In addition, the pharmacist must report the administration of the patient immunization to the West Virginia Statewide Immunization Information (WVSII) database in the format and

containing such information as may be required by the WVSII within not more than 30 days of the date of the administration.

6.3. The immunization questionnaire and consent form and record of the immunization administration shall be filed in the pharmacy in a manner that will allow timely retrieval, and shall be kept on file for a time period not less than five (5) years from the date of the immunization. All such records shall be maintained in the pharmacy where the immunization is administered. In the event it is administered off-site, then the records shall be maintained in the pharmacy where the pharmacist or licensed pharmacy intern who administered the immunization is employed or otherwise practicing at the time the immunization is given.

6.4 Pharmacists shall report all adverse events to the Vaccine Adverse Events Reporting System (VAERS), and promptly provide a copy of all reports to the Board; the West Virginia Department of Health and Human Resources Bureau for Public Health, Office of Epidemiology and Prevention Services, Division of Immunization Services; and the patient's primary care physician or other licensed health care provider as identified by the person receiving the immunization in accordance with subsection 6.1. VAERS is a national vaccine safety surveillance program co-sponsored by the Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA), and is available at http://vaers.hhs.gov/index.

§15-12-7. Emergencies.

7.1. A pharmacist or licensed pharmacy intern authorized to administer immunizations under this rule may administer epinephrine and diphenhydramine in the management of an acute allergic reaction to an immunization following guidelines issued by CDC for such situations.

7.2. A pharmacist or licensed pharmacy intern shall have a readily retrievable emergency response plan as outlined ~~in~~ by the CDC, and maintain a readily retrievable emergency kit to manage an acute allergic reaction to an immunization administered.

§15-12-8. Immunization Training Programs.

8.1. The Board must approve a course or program in immunization administration for that course to be used to meet the qualification requirement of section 3.1(b). In order to be approved by the Board, the course or program, at a minimum, must include practical training and instruction on the following:

~~(a)~~ 8.1.a. basic immunology, including the human immune response;

~~(b)~~ 8.1.b. adverse reactions, contraindications, warnings and precautions;

~~(c)~~ 8.1.c .response to emergency situations, including administration of epinephrine and diphenhydramine;

~~(d)~~ 8.1.d. storage and handling requirements;

~~(e)~~ 8.1.e. recordkeeping and reporting requirements, including screening and informed consent documentation;

~~(f)~~ 8.1.f. proper environment for administration and observation;

~~(g)~~ 8.1.g. legal and regulatory issues, including, but not limited to, state law and regulations, OSHA compliance, biohazard control, and such other relevant and applicable standards; and

~~(h)~~ 8.1.h. policies and procedures for establishing and implementing appropriate immunization treatment guidelines.

8.2. Any course approved by the Board must include a minimum of 15 hours of didactic and practical based components of instruction and training, including self-study and live instruction. The live instruction must be a minimum of six (6) hours, and shall include documented and supervised instruction on physical administration of vaccinations.

TITLE 15
LEGISLATIVE RULE
WEST VIRGINIA BOARD OF PHARMACY

SERIES 13
REGULATION OF CHARITABLE CLINIC PHARMACIES

§15-13-1. General.

1.1. Scope. -- This rule establishes the requirements for charitable clinic pharmacies to operate in West Virginia to prepare and dispense prescriptions to patients of the clinics in this State.

1.2. Authority. -- W. Va. Code §§ 30-5-14 and 30-5-19.

1.3. Filing Date. -- June 9, 2009.

1.4. Effective Date. -- July 1, 2009.

§15-13-2. Definitions.

2.1. The following terms and phrases as used in this Rule shall have the following meanings:

2.1.1. "Charitable clinic pharmacy" means a clinic or facility organized as a not-for-profit corporation that offers pharmaceutical care and dispenses prescriptions free of charge to appropriately screened and qualified patients. A charitable clinic pharmacy shall meet the minimum standards for a pharmacy as set forth in W. Va. Code §30-5-1, et seq., and by this rule, but may not be charged any applicable licensing fees. A charitable clinic pharmacy may have pharmacists-in-charge, as that term is defined in this section, who volunteers his or her services. A charitable clinic may also receive donated drugs. It is not the intent of this rule to affect any organizations which are merely operating a prescribing practitioner's or clinic's free sample drug room.

2.1.2. "Charitable organization" means an organization which operates a clinic or facility organized as a not-for-profit corporation which is qualified as a charitable organization pursuant to Section 501(c)(3) of the Internal Revenue Code, or its successor.

2.1.3. "Legend drug sample" for purposes of this Series means an unopened package of a manufacturers legend drug product that has been distributed to either a practitioner or the charitable clinic pharmacy in accordance with the provisions of the Prescription Drug Marketing Act of 1987, 21 U.S.C. §301 et seq, or its successor.

2.1.4. "Qualified patient" means a patient of the charitable clinic pharmacy that has been screened and approved by the charitable organization as meeting the organization's mission of providing pharmaceutical care to those who are without sufficient funds to obtain needed legend drugs. The requirements and screening process employed by the charitable organization must be in accordance with the "Guidelines" and other program requirements developed by the West Virginia Department of Health

and Human Resources, Office of Community Health Systems, Division of Primary Care, for eligibility to receive funding as a “Free Clinic” for “Uncompensated Care and Equipment and Capital Costs Funding”.

§15-13-3. Charitable Clinic Pharmacy Permit Required.

3.1. A charitable clinic pharmacy is considered to be a pharmacy and must follow all federal and state laws, rules, and regulations that pertain to pharmacies and the practice of pharmacy, except as otherwise provided specifically herein. A charitable clinic pharmacy permit is required for a charitable organization to operate a pharmacy in this State to dispense prescription drugs to qualified patients. No fee is required to apply for or obtain the permit.

3.2. Permits obtained pursuant to this section expire on June 30 of each calendar year. Renewal will be conducted in accordance with the laws and rules for renewing pharmacy permits as outlined in this rule.

3.3. Charitable Clinic Pharmacies may petition the Board for exemptions from portions of the requirements set forth in this rule which are not addressed here on a case by case basis, including, but not limited to, such things as the requirement for weights and measures if no compounding is to be done, the requirement for separate security features and alarms if they are available on the clinic building as a whole, and other such requirements.

§15-13-4. Controlled Substances Restricted; Prescriptions to qualified patients.

4.1. A charitable clinic pharmacy shall not purchase, possess, trade, distribute, or dispense controlled substances.

4.2. Patient Dispensing. Prescriptions filled in a charitable clinic pharmacy may only be dispensed to qualified patients of that pharmacy on lawful orders or prescriptions of practitioners authorized by law to prescribe or administer said drugs.

4.2.1. All prescriptions filled by the charitable clinic pharmacy must be checked by a pharmacist or a prescribing practitioner licensed as such in the State of West Virginia prior to being dispensed; Provided That any prescribing practitioner licensed in this State may access the charitable clinic pharmacy to fill, check, or dispense prescriptions when no pharmacist is present, provided that he or she insures proper labeling and documentation of the dispensing.

4.2.2. Any other rule notwithstanding, in the absence of a pharmacist, a prescribing practitioner who is licensed in the State of West Virginia may also supervise the work of pharmacy technicians within the pharmacy, so that they may continue to work during that period of time.

4.2.3. Any other rule notwithstanding, if there is no pharmacist or prescribing practitioner who is licensed in the State of West Virginia present to supervise the pharmacy technicians, the pharmacy technicians may continue to process and fill prescriptions, and perform all other duties which may be performed by a pharmacy technician, for up to two hours during the charitable clinic pharmacy’s regular hours of operation provided that no actual dispensing may occur until the prescriptions filled are checked in accordance with subsection 4.2.1 above.

4.3. The charitable clinic pharmacy may not charge any fee for dispensing prescription drug samples or prescription legend drugs to qualified patients of the charitable clinic pharmacy. However, this rule does not prevent a charitable clinic or charitable clinic pharmacy from requesting voluntary donations from its patients who receive prescriptions, provided that a sign is posted in a conspicuous location where it can be seen by all patients stating that a donation is not required to receive prescription drugs.

4.4. Any other rule notwithstanding, a charitable clinic pharmacy may allow completed prescription orders to be dispensed to its patients by permitting a pharmacy technician or other licensed health care provider working on behalf of the charitable clinic to transport the completed prescription to another remote clinic operated by the charitable clinic, Provided That:

4.4.1. the completed prescriptions are kept in a locked tote or other such storage container and remain in the possession of the licensed health care provider until such time as they are actually dispensed directly to the patient or someone picking up on behalf of the patient;

4.4.2. the completed prescriptions are accompanied by a manifest indicating the contents of the tote at the time they leave the pharmacy;

4.4.3. the patient or person picking up the prescription on behalf of the patient signs for receipt of the prescription; and

4.4.4. any prescriptions which are not dispensed at the remote clinic site are returned in the locked tote to the charitable clinic pharmacy, along with the manifest, by a licensed health care provider working on behalf of the charitable clinic, and are reconciled by the pharmacy.

4.5. Charitable clinic pharmacies are exempt from the restrictions in Section 15-1.19.10 insofar as the charitable clinic pharmacy may provide prescription blanks imprinted with its name for prescribers working in the clinic to write prescriptions to be filled at the charitable clinic pharmacy.

§15-13-5. Prescription Drug Samples.

5.1. Except insofar as it may conflict with federal law, charitable clinic pharmacies are exempt from any State law or rule which restricts who may receive sample drugs from a manufacturer. Specifically, unless it conflicts with federal law, a charitable clinic pharmacy may accept donated prescription drugs in their unbroken original packaging from pharmacies, licensed prescribers, wholesalers, or manufacturers provided appropriate records of transfer, donation, and receipt are maintained: Provided That the samples have been stored under the proper conditions required by the manufacturer and applicable law to prevent deterioration or contamination. However, a charitable clinic pharmacy may only receive, possess, and dispense prescription drug samples if the following conditions are satisfied:

5.1.1. The samples are dispensed at no charge to qualified patients of that charitable clinic pharmacy;

5.1.2. The samples are possessed in compliance with the Federal Prescription Drug Marketing Act of 1987, 21 U.S.C. §301 et seq, or its successor;

5.1.3. The samples are in the original container in which they were placed by the manufacturer and the container is clearly marked sample;

5.1.4. Prior to being furnished or dispensed, the samples have been stored under the proper conditions to prevent deterioration or contamination;

5.1.5. The samples are clearly marked with an expiration date and lot number;

5.1.6. The samples are not expired; and

5.1.7. The samples are not a controlled substance.

5.2. If donated samples are received which do not comply with Section 15-13-5.1, then they must be refused, returned, or properly disposed of by the charitable clinic pharmacy.

5.3. A charitable clinic pharmacy may not sell, purchase, or trade prescription drug samples.

5.4. A Charitable Clinic Pharmacy dispensing a sample drug shall comply with the following:

5.4.1. A pharmacist in a charitable clinic pharmacy must have a valid prescription prior to dispensing a sample drug to a patient.

5.4.2. The charitable clinic pharmacy must determine the eligibility requirements for a patient to receive a sample drug.

5.4.3. The sample drug is dispensed:

5.4.3.a. In the original container in which it was placed by its manufacturer where the container is clearly marked as sample; or

5.4.3.b. By removing the sample drug from the original container only if the prescription label on the appropriate container clearly states that the drug dispensed is a sample drug.

5.4.4. Nothing is this rule shall restrict a prescribing practitioner from providing samples in their original container from being given to the practitioner's patients in accordance with federal law.

§15-13-6. Pharmacist-In-Charge Responsibilities.

6.1. The pharmacist-in-charge at the charitable clinic pharmacy is responsible for implementing policies and procedures and a quality assurance program for operation of the charitable clinic pharmacy.

6.2. The pharmacist-in-charge at the charitable clinic pharmacy shall ensure through implementation of policies and procedures that the following occurs at the charitable clinic pharmacy:

6.2.1. donated drugs dispensed from pharmacy are properly labeled;

6.2.2. donated drugs that are expired, adulterated, misbranded, recalled, deteriorated, not kept under proper conditions, or did not have the identifying drug information on them as required are not dispensed to patients;

6.2.3. donated drugs are inspected prior to dispensing to determine that the donated drugs meet all federal and state requirements for product integrity;

6.2.4. donated drugs that are expired, adulterated, misbranded, recalled, deteriorated, not kept under proper conditions, or did not have the identifying drug information on them as required are destroyed; and

6.2.5. manifests for donated drugs that are dispensed pursuant to prescriptions from the charitable clinic pharmacy are created and maintained at the charitable clinic pharmacy as required for all prescription records.

§15-13-7. Limitations of Charitable Clinic Pharmacies.

Charitable Clinic Pharmacies shall comply with the following:

7.1. All drug therapies and prescriptions shall be prescribed on an individual basis.

7.2. A Charitable Clinic Pharmacy may not accept lost identity or unknown drugs.

7.3. Misbranded drugs may not be accepted by the Charitable Clinic Pharmacy.

7.4. A Charitable Pharmacy may accept donated and unadulterated prescription drugs in their unbroken original manufacturer packaging from pharmacies, licensed prescribers, wholesalers or manufacturers, the State of West Virginia, the Board of Pharmacy or by other means, provided appropriate records of receipt are maintained.

§15-13-8. Continuing Education Credits for Volunteering in Charitable Clinic Pharmacy.

A pharmacists who volunteers as a pharmacist-in-charge or a staff pharmacist in a charitable clinic pharmacy may earn up to a maximum of six live continuing education credits for such activities. For every eight hours worked in a charitable clinic pharmacy as the PIC, the PIC may earn one hour of live continuing education credit. For every ten hours worked in a charitable clinic pharmacy as a staff pharmacist, the pharmacist may earn one hour of live continuing education credit.

§15-13-9. Inspection and Investigation of Charitable Clinic Pharmacies.

9.1. The Board of Pharmacy will use an Inspection Form which is consistent with the requirements under which a Charitable Clinic Pharmacy shall operate as contemplated by W. Va. Code §30-5-1b.

9.2. Upon receipt of the completed inspection form, the Board of Pharmacy and any appointed Quality Control Committee or other such body of the Charitable Clinic Pharmacy may meet and confer to address and resolve issues which may impact the health and safety of the pharmacy's patients. To the

extent necessary, corrective plans may result from such meeting(s) with timeframes established by the Board of Pharmacy for the resolution of Quality control issues.

TITLE 15
LEGISLATIVE RULE, WEST VIRGINIA BOARD OF PHARMACY
SERIES 14
CENTRALIZED PRESCRIPTION PROCESSING

§15-14-1. General.

1.1. Scope -- To establish standards for central prescription processing.

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

1.3. Filing date -- _____.

1.4. Effective date -- _____.

1.5. Sunset Date -- This rule shall terminate and have no further force or effect upon the expiration of 5 years from its effective date.

§15-14-2. Definitions.

2.1. The following words and phrases as used in this Rule have the following meanings:

2.1.a. "Central fill pharmacy" means a pharmacy or central filling operation registered as a pharmacy by the Board acting as an agent of or under contract with the originating pharmacy to fill or refill a prescription.

2.1.b. "Central prescription filling" means filling of a new or refilling of a prescription drug order by a central fill pharmacy at the request of an originating pharmacy for delivery to the patient or patient's agent pursuant to the lawful order of a practitioner.

2.1.c. "Originating pharmacy" means a pharmacy registered with the Board that uses a central fill pharmacy to fill or refill a prescription order received by or transferred to that pharmacy by the patient, the patient's agent, or the patient's prescriber.

§15-14-3. General Requirements.

3.1. Any other rule notwithstanding, a pharmacy may outsource a prescription drug order filling to another pharmacy via central prescription filling provided the pharmacies:

3.1.a. Have the same owner; or

3.1.b. Have entered into a written contract or agreement which outlines the services to be provided and responsibilities and accountabilities of each pharmacy in compliance with federal and state laws and regulations, and include confidentiality of patient information; and

3.1.c. Share a common electronic file or have appropriate technology or interface to allow secure access to sufficient information necessary or required to fill or process a prescription drug order.

3.2. The pharmacist in charge of the central fill pharmacy shall assure that:

3.2.a. The pharmacy maintains and uses adequate storage or shipment containers and shipping processes to ensure drug stability and potency. Such shipping processes shall include the use of appropriate packaging material and/or devices to ensure that the drug is maintained at an appropriate temperature range to maintain the integrity of the medication through the delivery process; and

3.2.b. The filled prescriptions are shipped in containers which are sealed in a manner as to show evidence of opening or tampering.

3.3. The filling, processing and delivery of a drug order by a central fill pharmacy for an originating pharmacy pursuant to this Series shall not be considered a drug order transfer or a wholesale distribution.

3.4. Any filled prescription which was not picked up by or actually delivered to the patient must be put into the originating pharmacy's inventory.

3.5. Prior to outsourcing the filling of a prescription to a central fill pharmacy, the originating pharmacy must notify patients that their prescription may be outsourced to a central fill pharmacy, and provide the name and address of the central fill pharmacy. Such notice may be provided through a one-time written notice to the patient or through the use of a sign in the pharmacy.

3.6. The originating pharmacy, as the delivering pharmacy, is responsible for making the offer to counsel to the patient or patient's agent picking up the prescription on behalf of the patient.

3.7. Pharmacies that perform central prescription filling shall create operating policies and procedures. The policies and procedures must include:

3.7.a. an audit trail that records and documents the central prescription filling process and the individuals accountable at each step in the process for complying with Federal and State laws and regulations including recordkeeping; and

3.7.b. provisions for dispensing prescription drug orders when the filled order is not received from the central fill pharmacy, or the patient or patient's representative comes in to the originating pharmacy before the order is received from the central fill pharmacy. The standard of care must not be altered by the pharmacies' central fill program. Ultimately the patient's therapy cannot be unreasonably delayed.

3.8. The prescription label of a centrally filled prescription shall display the name and address of the originating pharmacy and may include the name of the central fill pharmacy, as well as all other information required by Rule § 15-1-22.

3.9. Each pharmacy engaging in central prescription filling shall be jointly responsible for:

3.9.a. Maintaining manual or electronic records that identify, individually for each drug order processed, the name, initials, or other unique identifier of each pharmacist, intern or pharmacy technician who took part in the central prescription filling functions performed at that pharmacy;

3.9.b. Maintaining manual or electronic records that identify, individually for each drug order filled or dispensed, the name, initials, or other unique identifier of each pharmacist, pharmacy intern, pharmacy technician, and pharmacy technician trainee who took part in the filling and dispensing functions performed at that pharmacy;

3.9.c. Maintaining a mechanism for tracking the drug order during each step of the processing and filling procedures performed at the pharmacy. The central fill pharmacy must keep a record of the date the filled prescription was delivered to the originating pharmacy and the method of delivery (i.e., private, common or contract carrier). The originating pharmacy must keep a record of receipt of the filled prescription, including the date of receipt, the method of delivery (i.e. private, common or contract carrier) and the name of the originating pharmacy employee accepting delivery;

3.9.d. Providing for adequate security to protect the confidentiality and integrity of patient information; and

3.9.e. Providing for inspection of any required record or information within 72 hours of any request by the Board or its designee.

15-14-4. Remote Order Entry and Remote Order Review

4.1. Remote-order-entry or remote-order-review of prescription orders for prescriptions received at a pharmacy registered by this state is permitted to be performed by another pharmacy registered by the state, Provided that:
4.1.a. for purposes of data entry, the data entry must be performed by a licensed pharmacist, licensed pharmacy intern, or registered pharmacy technician or pharmacy technician trainee who is located at the other pharmacy registered by the state which shares a common automated data processing system, and such system creates an audit trail of which pharmacist, pharmacy intern, or pharmacy technician or pharmacy technician trainee entered the data; and
4.1.b. for purpose of drug regimen review, the review must be performed by a licensed pharmacist or licensed pharmacy intern who is located at the other pharmacy registered by the state 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.

TITLE 11
LEGISLATIVE RULE
WEST VIRGINIA BOARD OF MEDICINE

SERIES 8
COLLABORATIVE PHARMACY PRACTICE§11-8-1. General.

1.1. Scope. -- This rule is jointly agreed upon and proposed by the Boards of Pharmacy, Medicine, and Osteopathy for legislative approval pertaining to a pharmacist's scope of practice pursuant to collaborative pharmacy practice and collaborative pharmacy practice agreements, and the selection of up to five pilot project sites in the community based pharmacy setting for collaborative pharmacy practice.

1.2. Authority. -- W. Va. Code §30-5-28.

1.3. Filing date. -- April 4, 2008.

1.4. Effective date. -- July 1, 2008.

§11-8-2. Definitions.

2.1. For purposes of this rule, the following definitions apply:

a. "*CLIA*" means the Clinical Laboratory Improvement Amendments, a program operated through the Center for Medicare and Medicaid Services.

b. "*Collaborative pharmacy practice*" is that practice of pharmacy where one or more pharmacists have jointly agreed, on a voluntary basis, to work in conjunction with one or more physicians under written protocol where the pharmacist or pharmacists may perform certain patient care functions authorized by the physician or physicians under certain specified conditions and limitations.

c. "*Collaborative pharmacy practice agreement*" is a written and signed agreement between a pharmacist, a physician, and the individual patient or the patient's authorized representative who has granted his or her informed consent, that provides for collaborative pharmacy practice for the purpose of drug therapy management of a patient, which has been approved by the Board of Pharmacy, the Board of Medicine in the case of an allopathic physician or the West Virginia Board of Osteopathy in the case of an osteopathic physician.

d. "*Collaborative pharmacy practice protocol*" is the detailed written portion of the collaborative pharmacy practice agreement pursuant to which the authorized pharmacist will base drug therapy management decisions for patients.

e. *"Community practice protocol"* means a written, executed agreement entered into voluntarily between an authorized pharmacist and a physician establishing drug therapy management for one or more of the pharmacist's and physician's patients residing in a community setting. A community practice protocol shall comply with the requirements of paragraph 4.3 of this rule.

f. *"Community based pharmacy setting"* means a pharmacy within the state licensed by the West Virginia Board of Pharmacy, where prescription drugs are dispensed and pharmaceutical care is provided by a licensed pharmacist and located outside a hospital inpatient, acute care setting.

g. "*Drug therapy management*" means the review of drug therapy regimens of patients by a pharmacist for the purpose of evaluating and rendering advice to a physician regarding adjustment of the regimen in accordance with the collaborative pharmacy practice agreement. Decisions involving drug therapy management shall be made in the best interest of the patient. Drug therapy management shall be limited to:

A. Implementing, modifying, and managing drug therapy according to the terms of the collaborative pharmacy practice agreement;

B. Collecting and reviewing patient histories;

C. Obtaining and checking vital signs, including pulse, temperature, blood pressure and respiration;

D. Ordering screening laboratory tests that are dose related and specific to the patient's medication or are protocol driven and are specifically set out in the collaborative pharmacy practice agreement between the pharmacist and physician.

h. "*HIPAA*" means the Health Insurance Portability and Accountability Act of 1996.

i. *"Hospital practice protocol"* means a written plan, policy, procedure, or agreement that authorizes drug therapy management between pharmacists and physicians developed and determined by the hospital's P and T committee (or similar committee) and approved by the three boards. Such a protocol may apply to all pharmacists and physicians at a hospital and only to those pharmacists and physicians who are specifically recognized as engaging in collaborative drug therapy management by the hospital. A hospital practice protocol shall comply with the requirements of paragraph 4.6 of this rule.

j. "*OSHA*" means the Occupational Safety and Health Administration.

k. "*Pharmacist's scope of practice pursuant to the collaborative pharmacy practice agreement*" means those duties and limitations of duties placed upon the pharmacist by the collaborating physician, as jointly approved by the Board of Pharmacy and the Board of Medicine or the Board of Osteopathy.

l. "*P and T committee*" means the pharmacy and therapeutics committee or similar committee established within the hospital setting.

m. "*Rural health care clinic*" means a non-profit, freestanding primary care clinic in a medically underserved or health professional shortage area.

§11-8-3. General Rules for Collaborative Pharmacy Practice Authority.

3.1. No pharmacist or physician may engage in collaborative pharmacy practice except in accordance

with the provisions of this rule.

3.2. Any physician seeking the assistance of a pharmacist for the purpose of collaborative pharmacy practice must hold an unrestricted, active license to practice as a physician in West Virginia and the authority granted by the physician must be within the scope of the physician's practice.

3.3. Any pharmacist seeking to assist the physician in collaborative pharmacy practice must:

a. Have an unrestricted and current license to practice as a pharmacist in West Virginia;

b. Have at least one million dollars of professional liability insurance coverage;

c. Meet one of the following qualifications, at a minimum:

A. Earned a Certification from the Board of Pharmaceutical Specialties, is a Certified Geriatric Practitioner, or has completed an American Society of Health System Pharmacists (ASHP) accredited residency program, which includes two years of experienced approved by the appropriate boards;

B. Successfully completed the course of study and holds an academic degree of Doctor of Pharmacy and has three years of clinical experience approved by the Board and has completed an Accreditation Council for Pharmacy Education (ACPE) approved certificate program in the area of practice covered by the collaborative pharmacy practice agreement; or

C. Successfully completed the course of study and holds the academic degree Bachelor of Science in Pharmacy and has five years clinical experience approved by the appropriate boards and has completed two ACPE approved certificate programs with at least one program in the area of practice covered by the collaborative pharmacy practice agreement.

3.4. Documentation of requirements for collaborative pharmacy practice shall be submitted to and approved as satisfactory by the appropriate licensing boards with jurisdiction over the physician and pharmacist wishing to engage in collaborative pharmacy practice prior to engaging in collaborative pharmacy practice.

3.5. The approval process to engage in collaborative practice shall be:

a. The pharmacist shall submit an application for collaborative pharmacy practice to the West Virginia Board of Pharmacy with the applicable fee of $50. Upon approval of that application:

b. The pharmacist and physician shall submit the collaborative pharmacy practice protocol to the appropriate licensing board with jurisdiction over the subject physician. Upon approval of the protocol by the appropriate board, the subject pharmacist and physician may enter into collaborative pharmacy practice agreements with patients for their drug therapy management pursuant to the authorized protocol. The hospital protocol shall be submitted by the P and T committee for approval by all three boards.

§11-8-4. Collaborative Pharmacy Practice Protocols.

4.1. Collaborative pharmacy practice protocols and any changes or modifications thereto shall be submitted to and approved as satisfactory by the appropriate licensing boards with jurisdiction over the subject physician and pharmacist prior to their engaging in collaborative pharmacy practice.

4.2. A pharmacist may not practice outside the scope of the protocol approved as satisfactory by the appropriate licensing boards with jurisdiction over the subject physician and pharmacist.

4.3. Community practice protocol may authorize the following:

a. Prescription drug orders. The protocol may authorize modification of drug dosages based on symptoms or laboratory or physical findings defined in the protocol. The protocol shall include information specific to the dosage, frequency, duration, and route of administration of the drug authorized by the patient's physician. The protocol may not authorize the pharmacist to change a controlled substance or to initiate a drug not included in the established protocol.

b. Laboratory tests. The protocol may authorize the pharmacist to obtain or to conduct specific laboratory tests as long as the tests relate directly to the drug therapy management. Only the laboratory tests specified in the agreement may be ordered by the pharmacist. Laboratories utilized by the pharmacist may be in a pharmacy or pharmacy center. All laboratory results obtained are to be sent to the physician within forty-eight hours, except that any severely abnormal or critical values shall be sent by the pharmacist to the physician immediately.

c. Physical findings. The protocol may authorize the pharmacist to check only these findings: vital signs, oximetry, or peak flows, that enable the pharmacist to assess and adjust the drug therapy, detect adverse drug reactions, or determine if the patient should be referred back to the patient's physician for follow-up. Pharmacists shall not conduct any physical examination of the patient other than taking vital signs.

d. Patient activities. The protocol may authorize the pharmacist to monitor specific patient activities.

e. Procedures for securing the patient's written consent. The patient's consent must be secured by the physician.

f. Circumstances that shall cause the authorized pharmacist to initiate communication with the physician including but not limited to the need for new prescription orders and reports of the patient's therapeutic response or adverse reaction. All evaluation notes shall be in the physician's patient's chart within one week of the evaluation and drug management change.

g. A detailed statement identifying the specific drugs, laboratory tests, and physical findings upon which the authorized pharmacist shall base drug therapy management decisions. Adjustments to drug therapy management must be co-signed by the physician within one week. A pharmacist may not begin new medicines without direct consultation and with documentation by the physician nor may the medication be discontinued.

h. A provision for the collaborative drug therapy management protocol to be reviewed, updated, and re-executed or discontinued at least every two years.

i. A description of the method the pharmacist shall use to document the pharmacist's decisions or recommendations for the physician.

j. A description of the types of reports the authorized pharmacist is to provide to the physician and the schedule by which the pharmacist is to submit these reports. The schedule shall include a time frame within which a pharmacist shall report any adverse reaction to the physician.

k. A statement of the medication categories and the type of initiation and modification of drug therapy that the physician authorizes the pharmacist to perform. Flu shots and pneumonia injections may be given by the pharmacist to adults only provided that the pharmacist submits evidence of completed certification to give injections and in basic cardiac life support to the appropriate boards and is certified to give injections.

l. A description of the procedures or plan that the pharmacist shall follow if the pharmacist modifies a drug therapy.

m. Procedures for record keeping, record sharing, and long-term record storage.

n. Procedures to follow in emergency situations.

o. A statement that prohibits the authorized pharmacist from delegating drug therapy management to anyone other than another authorized pharmacist who has signed the applicable protocol.

p. A statement that prohibits a physician from delegating collaborative drug therapy management to any unlicensed or licensed person other than another physician or an authorized pharmacist.

q. A description of the mechanism for the pharmacist and the physician to communicate with each other and for documentation by the pharmacist of the implementation of collaborative drug therapy. The physician shall see the patient every three months and pharmacist visits may not be substituted for such physician visits.

4.4. A hospital's P and T committee shall determine the scope and extent of collaborative drug therapy management practices that may be conducted by the hospital's pharmacists and it then must be approved by the three boards.

4.5. Collaborative drug therapy management within a hospital setting is valid only when approved by the hospital's P and T committee and approved by the three boards.

4.6. The hospital practice protocol shall include:

a. The names or groups of pharmacists and physicians who are authorized by the P and T committee to participate in collaborative drug therapy management, and approved by the three boards.

b. A plan for development, training, administration, and quality assurance of the protocol.

c. A detailed written protocol pursuant to which the hospital pharmacist shall base drug therapy management decisions for patients. The protocol shall authorize one or more of the following:

1. Medication orders and prescription drug orders. The protocol may authorize modification of drug dosages based on symptoms or laboratory findings defined in the protocol. The protocol shall include information specific to the dosage, frequency, duration, and route of administration of the drug authorized by the physician. The protocol shall not authorize the hospital pharmacist to change a controlled substance or to initiate a drug not included in the established protocol.

2. Laboratory tests. The protocol may authorize the hospital pharmacist to obtain or to conduct specific laboratory tests as long as the tests relate directly to the drug therapy management.

3. All orders are verbal orders from the physician and must be co-signed by the physician.

4. Physical findings. The protocol may authorize the hospital pharmacist to check certain findings, vital signs, oximetry, or peak flows, that enable the pharmacist to assess and adjust the drug therapy, detect adverse drug reactions, or determine if the patient should be referred back to the physician for follow-up.

5. The physician must request the assistance of the pharmacist in the hospital setting before the pharmacist may begin assistance with the patients' drug therapy management.

d. Circumstances that shall cause the hospital pharmacist to initiate communication with the patient's physician including but not limited to the need for new medication orders and prescription drug orders and reports of a patient's therapeutic response or adverse reaction. All orders are verbal orders which must be co-signed by the physician.

e. A statement of the medication categories and the type of initiation and modification of drug therapy that the P and T committee authorizes the hospital pharmacist to perform.

f. A description of the procedures or plan that the hospital pharmacist shall follow if the hospital pharmacist modifies a drug therapy.

g. A description of the mechanism for the hospital pharmacist and the patient's physician to communicate and for the hospital pharmacist to document implementation of the collaborative drug therapy. All orders are verbal orders which must be co-signed by the physician.

§11-8-5. Termination of Protocols.

5.1. The protocol(s) may be terminated upon written notice by the subject patient, the pharmacist or the physician, which notice shall be provided to the appropriate boards with jurisdiction and to the other

parties, (subject patient) all within fifteen days of termination.

§11-8-6. Fee.

6.1. Each application for collaborative pharmacy practice is subject to a $50 fee payable to the West Virginia Board of Pharmacy.

6.2. Each protocol is subject to a $100 processing fee payable by the physician to the appropriate board. Requested modifications in between the two-year period of existence of each protocol are subject to the fee.

§11-8-7. Ethics.

7.1. There shall be no advertising of any collaborative pharmacy practice by either the physician or the pharmacist.

7.2. No physician may be employed by any pharmacist or pharmacy for the purpose of collaborative pharmacy practice.

7.3. No pharmacist or pharmacy shall make any direct or indirect referral to any physician or medical clinic for the purpose of collaborative pharmacy practice.

7.4. Nothing in this rule shall be interpreted to permit a pharmacist to
accept delegation of a physician's authority outside the limits included in the appropriate board's statute and rules.

§11-8-8. Reporting and Discipline.

8.1. Either or all of the appropriate licensing boards shall have the right to cancel any collaborative pharmacy practice agreement if there is satisfactory evidence that either the physician or pharmacist signatories to the agreement are not acting in accordance with the agreement.

8.2. Each appropriate board with jurisdiction of either of the signatories to the agreement shall report to the other appropriate board any acts which it believes are in violation of any approved agreement.

8.3. Any physician or pharmacist signatory to a collaborative pharmacy agreement shall be subject to additional monitoring and education or to disciplinary proceedings by the appropriate boards if the subject physician or pharmacist violates the terms of the collaborative pharmacy practice agreement.

§11-8-9. Pilot Project Sites.

9.1. Up to five pilot project sites in the community based pharmacy setting may be jointly selected by the Boards of Medicine, Pharmacy, and Osteopathy.

9.2. In jointly selecting the pilot project sites, the following criteria shall be met:

a. There must be a designated patient care area for private conversation;

b. There must be the ability to perform appropriate laboratory testing and to take vital signs;

c. There must be the capability of keeping comprehensive patient records in a HIPAA compliant manner;

d. Equipment must be maintained in an OSHA compliant and CLIA waived manner with appropriate records kept; and

e. A maximum of one not for profit rural health care clinic may be given preference.

9.3 Outcome Measurements

a. A report of outcomes from the up to five pilot community pharmacy sites shall be submitted for review by the appropriate legislative committee by January 31, 2010, with copies to the three boards. The measurements may include clinical, humanistic, and economic outcomes indicators.

CHAPTER 30. PROFESSIONS AND OCCUPATIONS.

ARTICLE 5. PHARMACISTS, PHARMACY TECHNICIANS, PHARMACY INTERNS AND PHARMACIES.

§30-5-1. Short title.

This article shall be known as and may be cited as the "The Larry W. Border Pharmacy Practice Act".

§30-5-1a.

Repealed.

Acts, 2013 Reg. Sess., Ch. 148.

§30-5-1b.

Repealed.

Acts, 2013 Reg. Sess., Ch. 148.

§30-5-2. Unlawful acts.

(a) It is unlawful for any person in this state to practice or offer to practice pharmacist care without a license pursuant to the provisions of this article; or to practice or offer to assist in the practice of pharmacist care without being registered pursuant to the provisions of this article. Further, it is unlawful to advertise or use any title or description tending to convey or give the impression that he or she is a pharmacist or pharmacy technician, unless the person is licensed or registered under the provisions of this article.

(b) A business entity may not render any service or engage in any activity which, if rendered or engaged in by an individual, would constitute the practice of pharmacist care, except through a licensee.

(c) It is unlawful for the proprietor of a pharmacy or a ambulatory health care facility to permit a person, who is not a licensed pharmacist, to practice pharmacist care: *Provided,* That a charitable clinic pharmacy may permit a licensed prescribing practitioner to act in place of the pharmacist when no pharmacist is present in the charitable clinic.

§30-5-2a.

Repealed.

Acts, 2013 Reg. Sess., Ch. 148.

§30-5-3. Applicable law.

The practices authorized under the provisions of this article and the Board of Pharmacy are subject to article one of this chapter, the provisions of this article, and any rules promulgated pursuant this article.

§30-5-3a.

Repealed.

Acts, 2013 Reg. Sess., Ch. 148.

§30-5-4. Definitions.

As used in this article:

(1) "Ambulatory health care facility" includes any facility defined in section one, article five-b, chapter sixteen of this code, that also has a pharmacy, offers pharmacist care, or is otherwise engaged in the practice of pharmacist care.

(2) "Active Ingredients" means chemicals, substances, or other components of articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of diseases in humans or animals or for use as nutritional supplements.

(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.

(4) "Board" means the West Virginia Board of Pharmacy.

(5) "Board authorization" means a license, registration or permit issued under this article.

(6) "Chain Pharmacy Warehouse" means a permanent physical location for drugs and/or devices that acts as a central warehouse and performs intracompany sales and transfers of prescription drugs or devices to chain pharmacies, which are members of the same affiliated group, under common ownership and control.

(7) "Charitable clinic pharmacy" means a clinic or facility organized as a not-for-profit corporation that has a pharmacy, offers pharmacist care, or is otherwise engaged in the practice of pharmacist care and dispenses its prescriptions free of charge to appropriately screened and qualified indigent patients.

(8) "Collaborative pharmacy practice" is that practice of pharmacist care where one or more pharmacists have jointly agreed, on a voluntary basis, to work in conjunction with one or more physicians under written protocol where the pharmacist or pharmacists may perform certain

patient care functions authorized by the physician or physicians under certain specified conditions and limitations.

(9) "Collaborative pharmacy practice agreement" is a written and signed agreement, which is a physician directed approach, that is entered into between an individual physician or physician group, an individual pharmacist or pharmacists and an individual patient or the patient's authorized representative who has given informed consent that provides for collaborative pharmacy practice for the purpose of drug therapy management of a patient, which has been approved by the board, the Board of Medicine in the case of an allopathic physician or the West Virginia Board of Osteopathic Medicine in the case of an osteopathic physician.

(10) "Common Carrier" means any person or entity who undertakes, whether directly or by any other arrangement, to transport property including prescription drugs for compensation.

(11) "Component" means any active ingredient or added substance intended for use in the compounding of a drug product, including those that may not appear in such product.

(12) "Compounding" means:

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

(i) 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

(ii) 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.

(13) "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.

(14) "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."

(15) "Digital Signature" means an electronic signature based upon cryptographic methods of originator authentication, and computed by using a set of rules and a set of parameters so that the identity of the signer and the integrity of the data can be verified.

(16) "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.

(17) "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.

(18) "Drop shipment" means the sale of a prescription drug to a wholesale distributor by the manufacturer of the prescription drug or by that manufacturer's colicensed product partner, that manufacturer's third party logistics provider, that manufacturer's exclusive distributor, or by an authorized distributor of record that purchased the product directly from the manufacturer or from one of these entities whereby:

(A) The wholesale distributor takes title to but not physical possession of such prescription drug;

(B) The wholesale distributor invoices the pharmacy, pharmacy warehouse, or other person authorized by law to dispense or administer such drug; and

(C) The pharmacy, pharmacy warehouse or other person authorized by law to dispense or administer such drug receives delivery of the prescription drug directly from the manufacturer or from that manufacturer's colicensed product partner, that manufacturer's third party logistics provider, that manufacturer's exclusive distributor, or from an authorized distributor of record that purchased the product directly from the manufacturer or from one of these entities.

(19) "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.

(20) "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.

(21) "Drug therapy management" means the review of drug therapy regimens of patients by a pharmacist for the purpose of evaluating and rendering advice to a physician regarding adjustment of the regimen in accordance with the collaborative pharmacy practice agreement. Decisions involving drug therapy management shall be made in the best interest of the patient. Drug therapy management is limited to:

(A) Implementing, modifying and managing drug therapy according to the terms of the collaborative pharmacy practice agreement;

(B) Collecting and reviewing patient histories;

(C) Obtaining and checking vital signs, including pulse, temperature, blood pressure and respiration;

(D) Ordering screening laboratory tests that are dose related and specific to the patient's medication or are protocol driven and are also specifically set out in the collaborative pharmacy practice agreement between the pharmacist and physician.

(22) "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 pharmacy 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.

(23) "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".

(24) "Electronic Signature" means an electronic sound, symbol, or process attached to or logically associated with a record and executed or adopted by a person with the intent to sign the record.

(25) "Electronic transmission" means transmission of information in electronic form or the transmission of the exact visual image of a document by way of electronic equipment.

(26) "Emergency medical reasons" include, but are not limited to, transfers of a prescription drug by one pharmacy to another pharmacy to alleviate a temporary shortage of a prescription drug; sales to nearby emergency medical services, i.e., ambulance companies and firefighting organizations in the same state or same marketing or service area, or nearby licensed practitioners of prescription drugs for use in the treatment of acutely ill or injured persons; and provision of minimal emergency supplies of prescription drugs to nearby nursing homes for use in emergencies or during hours of the day when necessary prescription drugs cannot be obtained.

(27) "Exclusive distributor" means an entity that:

(A) Contracts with a manufacturer to provide or coordinate warehousing, wholesale distribution, or other services on behalf of a manufacturer and who takes title to that manufacturer's prescription drug, but who does not have general responsibility to direct the sale or disposition of the manufacturer's prescription drug; and

(B) Is licensed as a wholesale distributor under this article.

(28) "FDA" means the Food and Drug Administration, a federal agency within the United States Department of Health and Human Services.

(29) "Health care entity" means a person that provides diagnostic, medical, pharmacist care, surgical, dental treatment, or rehabilitative care but does not include a wholesale distributor.

(30) "Health information" means any information, whether oral or recorded in a form or medium, that:

(A) Is created or received by a health care provider, health plan, public health authority, employer, life insurer, school or university, or health care clearinghouse, and

(B) Relates to the past, present, or future physical or mental health or condition of an individual; or the past, present, or future payment for the provision of health care to an individual.

(31) "HIPAA" is the federal Health Insurance Portability and Accountability Act of 1996 (Public Law 104-191).

(32) "Immediate container" means a container and does not include package liners.

(33) "Individually identifiable health information" is information that is a subset of health information, including demographic information collected from an individual and is created or received by a health care provider, health plan, employer, or health care clearinghouse; and relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual; and that identifies the individual; or with respect to which there is a reasonable basis to believe the information can be used to identify the individual.

(34) "Intracompany sales" means any transaction between a division, subsidiary, parent, and/or affiliated or related company under the common ownership and control of a corporate or other legal business entity.

(35) "Label" means a display of written, printed, or graphic matter upon the immediate container of any drug or device.

(36) "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.

(37) "Long-Term care facility" means a nursing home, retirement care, mental care, or other facility or institution that provides extended health care to resident patients.

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

(39) "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.

(40) "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.

(41) "Medical order" means a lawful order of a practitioner that may or may not include a prescription drug order.

(42) "Medication therapy management" is a distinct service or group of services that optimize medication therapeutic outcomes for individual patients. Medication therapy management services are independent of, but can occur in conjunction with, the provision of a medication or a medical device. Medication therapy management encompasses a broad range of professional activities and responsibilities within the licensed pharmacist's scope of practice.

These services may include the following, according to the individual needs of the patient:

(A) Performing or obtaining necessary assessments of the patient's health status pertinent to medication therapy management;

(B) Optimize medication use, performing medication therapy, and formulating recommendations for patient medication care plans;

(C) Developing therapeutic recommendations, to resolve medication related problems;

(D) Monitoring and evaluating the patient's response to medication therapy, including safety and effectiveness;

(E) Performing a comprehensive medication review to identify, resolve, and prevent medication-related problems, including adverse drug events;

(F) Documenting the care delivered and communicating essential information to the patient's primary care providers;

(G) Providing verbal education and training designed to enhance patient understanding and appropriate use of his or her medications;

(H) Providing information, support services and resources designed to enhance patient adherence with his or her medication therapeutic regimens;

(I) Coordinating and integrating medication therapy management services within the broader health care management services being provided to the patient; and

(J) Such other patient care services as may be allowed by law.

(43) "Misbranded" means a drug or device that has a label that is false or misleading in any particular; or the label does not bear the name and address of the manufacturer, packer, or distributor and does not have an accurate statement of the quantities of the active ingredients in the case of a drug; or the label does not show an accurate monograph for prescription drugs.

(44) "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.

(45) "Normal distribution channel" means a chain of custody for a prescription drug that goes directly or by drop shipment, from a manufacturer of the prescription drug, the manufacturer's third-party logistics provider, or the manufacturer's exclusive distributor to:

(A) A wholesale distributor to a pharmacy to a patient or other designated persons authorized by law to dispense or administer such prescription drug to a patient;

(B) A wholesale distributor to a chain pharmacy warehouse to that chain pharmacy warehouse's intracompany pharmacy to a patient or other designated persons authorized by law to dispense or administer such prescription drug to a patient;

(C) A chain pharmacy warehouse to that chain pharmacy warehouse's intracompany pharmacy to a patient or other designated persons authorized by law to dispense or administer such prescription drug to a patient;

(D) A pharmacy or to other designated persons authorized by law to dispense or administer such prescription drug to a patient; or

(E) As prescribed by the board's legislative rules.

(46) "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.

(47) "Pedigree" means a statement or record in a written form or electronic form, approved by the board, that records each wholesale distribution of any given prescription drug (excluding veterinary prescription drugs), which leaves the normal distribution channel.

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

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

(50) "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, elimination or reduction of a patient's symptoms, or arresting or slowing of a disease process and as provided for in section ten.

(51) "Pharmacist-in-charge" means a pharmacist currently licensed in this state who accepts responsibility for the operation of a pharmacy in conformance with all laws and legislative rules pertinent to the practice of pharmacist care and the distribution of drugs and who is personally in full charge of the pharmacy and pharmacy personnel.

(52) "Pharmacist's scope of practice pursuant to the collaborative pharmacy practice agreement" means those duties and limitations of duties placed upon the pharmacist by the collaborating physician, as jointly approved by the board and the Board of Medicine or the West Virginia Board of Osteopathic Medicine.

(53) "Pharmacy" means any place within this state where drugs are dispensed and pharmacist care is provided and any place outside of this state where drugs are dispensed and pharmacist care is provided to residents of this state.

(54) "Pharmacy Intern" or "Intern" means an individual who is currently licensed to engage in the practice of pharmacist care while under the supervision of a pharmacist.

(55) "Pharmacy related primary care" means the pharmacist's activities in patient education, health promotion, selection and use of over the counter drugs and appliances and referral or assistance with the prevention and treatment of health related issues and diseases.

(56) "Pharmacy Technician" means a person registered with the board to practice certain tasks related to the practice of pharmacist care as permitted by the board.

(57) "Physician" means an individual currently licensed, in good standing and without restrictions, as an allopathic physician by the West Virginia Board of Medicine or an osteopathic physician by the West Virginia Board of Osteopathic Medicine.

(58) "Practice of telepharmacy" means the provision of pharmacist care by properly licensed pharmacists located within United States jurisdictions through the use of telecommunications or other technologies to patients or their agents at a different location that are located within United States jurisdictions.

(59) "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.

(60) "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.

(61) "Prescription or prescription drug 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.

(62) "Product Labeling" means all labels and other written, printed, or graphic matter upon any article or any of its containers or wrappers, or accompanying such article.

(63) "Repackage" means changing the container, wrapper, quantity, or product labeling of a drug or device to further the distribution of the drug or device.

(64) "Repackager" means a person who repackages.

(65) "Therapeutic equivalence" mean drug products classified as therapeutically equivalent can be substituted with the full expectation that the substituted product will produce the same clinical effect and safety profile as the prescribed product which contain the same active ingredient(s); dosage form and route of administration; and strength.

(66) "Third-party logistics provider" means a person who contracts with a prescription drug manufacturer to provide or coordinate warehousing, distribution or other services on behalf of a manufacturer, but does not take title to the prescription drug or have general responsibility to direct the prescription drug's sale or disposition. A third-party logistics provider shall be licensed as a wholesale distributor under this article and, in order to be considered part of the normal distribution channel, shall also be an authorized distributor of record.

(67) "Valid patient-practitioner relationship" means the following have been established:

(A) A patient has a medical complaint;

(B) A medical history has been taken;

(C) A face-to-face physical examination adequate to establish the medical complaint has been performed by the prescribing practitioner or in the instances of telemedicine through telemedicine practice approved by the appropriate practitioner board; and

(D) Some logical connection exists between the medical complaint, the medical history, and the physical examination and the drug prescribed.

(68) "Wholesale distribution" and "wholesale distributions" mean distribution of prescription drugs, including directly or through the use of a third-party logistics provider or any other situation in which title, ownership or control over the prescription drug remains with one person or entity but the prescription drug is brought into this state by another person or entity on his, her or its behalf, to persons other than a consumer or patient, but does not include:

(A) Intracompany sales, as defined in subdivision thirty-four of this subsection;

(B) The purchase or other acquisition by a hospital or other health care entity that is a member of a group purchasing organization of a drug for its own use from the group purchasing organization or from other hospitals or health care entities that are members of such organizations;

(C) The sale, purchase or trade of a drug or an offer to sell, purchase or trade a drug by a charitable organization described in section 501(c)(3) of the United States Internal Revenue Code of 1986 to a nonprofit affiliate of the organization to the extent otherwise permitted by law;

(D) The sale, purchase or trade of a drug or an offer to sell, purchase or trade a drug among hospitals or other health care entities that are under common control. For purposes of this article, "common control" means the power to direct or cause the direction of the management and policies of a person or an organization, whether by ownership of stock, voting rights, by contract, or otherwise;

(E) The sale, purchase or trade of a drug or an offer to sell, purchase or trade a drug for "emergency medical reasons" for purposes of this article includes transfers of prescription drugs by a retail pharmacy to another retail pharmacy to alleviate a temporary shortage, except that the gross dollar value of such transfers shall not exceed five percent of the total prescription drug sales revenue of either the transferor or transferee pharmacy during any twelve consecutive month period;

(F) The sale, purchase or trade of a drug, an offer to sell, purchase, or trade a drug or the dispensing of a drug pursuant to a prescription;

(G) The distribution of drug samples by manufacturers' representatives or distributors' representatives, if the distribution is permitted under federal law [21 U. S. C. 353(d)];

(H) Drug returns by a pharmacy or chain drug warehouse to wholesale drug distributor or the drug's manufacturer; or

(J) The sale, purchase or trade of blood and blood components intended for transfusion.

(69) "Wholesale drug distributor" or "wholesale distributor" means any person or entity engaged in wholesale distribution of prescription drugs, including, but not limited to, manufacturers, repackers, own-label distributors, jobbers, private-label distributors, brokers, warehouses, including manufacturers' and distributors' warehouses, chain drug warehouses and wholesale drug warehouses, independent wholesale drug traders, prescription drug repackagers, physicians, dentists, veterinarians, birth control and other clinics, individuals, hospitals, nursing homes and/or their providers, health maintenance organizations and other health care providers, and retail and hospital pharmacies that conduct wholesale distributions, including, but not limited to, any pharmacy distributor as defined in this section. A wholesale drug distributor shall not include any for hire carrier or person or entity hired solely to transport prescription drugs.

§14b.

Repealed.

Acts, 2013 Reg. Sess., Ch. 30.

§30-5-5. West Virginia Board of Pharmacy.

(a) The West Virginia Board of Pharmacy is continued. The members of the board in office on July 1, 2013, shall, unless sooner removed, continue to serve until their respective terms expire and until their successors have been appointed and qualified.

(b) The Governor, by and with the advice and consent of the Senate, shall appoint:

(1) Five members who are licensed to practice pharmacist care in this state; and

(2) Two citizen members, who are not licensed under the provisions of this article, and who do not perform any services related to the practice of the pharmacist care regulated under the provisions of this article.

(c) After the initial appointment term, the appointment term is five years. A member may not serve more than two consecutive terms. A member who has served two consecutive full terms may not be reappointed for at least one year after completion of his or her second full term. A member may continue to serve until his or her successor has been appointed and qualified.

(d) Each licensed member of the board, at the time of his or her appointment, shall have held a license in this state for a period of not less than three years immediately preceding the appointment.

(e) Each member of the board shall be a resident of this state during the appointment term.

(f) A vacancy on the board shall be filled by appointment by the Governor for the unexpired term of the member whose office is vacant.

(g) The Governor may remove any member from the board for neglect of duty, incompetency or official misconduct.

(h) A licensed member of the board immediately and automatically forfeits membership to the board if his or her license to practice is suspended or revoked in any jurisdiction.

(i) A member of the board immediately and automatically forfeits membership to the board if he or she is convicted of a felony under the laws of any jurisdiction or becomes a nonresident of this state.

(j) The board shall elect annually one of its members as president, one member as vice president and one member as treasurer who shall serve at the will and pleasure of the board.

(k) Each member of the board is entitled to receive compensation and expense reimbursement in accordance with article one of this chapter.

(l) A simple majority of the membership serving on the board at a given time is a quorum for the transaction of business.

(m) The board shall hold at least two meetings annually. Other meetings shall be held at the call of the chairperson or upon the written request of three members, at the time and place as designated in the call or request.

(n) Prior to commencing his or her duties as a member of the board, each member shall take and subscribe to the oath required by section five, article four of the Constitution of this state.

(o) The members of the board when acting in good faith and without malice shall enjoy immunity from individual civil liability while acting within the scope of their duties as board members.

§30-5-5a.

Repealed.

Acts, 2013 Reg. Sess., Ch. 148.

§30-5-5b.

Repealed.

Acts, 2013 Reg. Sess., Ch. 148.

§30-5-6. Powers and duties of the board.

The board has all the powers and duties set forth in this article, by rule, in article one of this chapter and elsewhere in law, including the power to:

(a) Hold meetings;

(b) Establish additional requirements for a license, permit and registration;

(c) Establish procedures for submitting, approving and rejecting applications for a license, permit and registration;

(d) Determine the qualifications of any applicant for a license, permit and registration;

(e) Establish a fee schedule;

(f) Issue, renew, deny, suspend, revoke or reinstate a license, permit, and registration;

(g) Prepare, conduct, administer and grade written, oral or written and oral examinations for a license and registration and establish what constitutes passage of the examination;

(h) Contract with third parties to administer the examinations required under the provisions of this article;

(i) Maintain records of the examinations the board or a third party administers, including the number of persons taking the examination and the pass and fail rate;

(j) Regulate mail order pharmacies

(k) Maintain an office, and hire, discharge, establish the job requirements and fix the compensation of employees and contract with persons necessary to enforce the provisions of this article. Inspectors shall be licensed pharmacists;

(l) Investigate alleged violations of the provisions of this article, legislative rules, orders and final decisions of the board;

(m) Conduct disciplinary hearings of persons regulated by the board;

(n) Determine disciplinary action and issue orders;

(o) Institute appropriate legal action for the enforcement of the provisions of this article;

(p) Maintain an accurate registry of names and addresses of all persons regulated by the board;

(q) Keep accurate and complete records of its proceedings, and certify the same as may be necessary and appropriate;

(r) Propose rules in accordance with the provisions of article three, chapter twenty-nine-a of this code to implement the provisions of this article;

(s) Sue and be sued in its official name as an agency of this state;

(t) Confer with the Attorney General or his or her assistant in connection with legal matters and questions; and

(u) Take all other actions necessary and proper to effectuate the purposes of this article.

§30-5-6a.

Repealed.

Acts, 2013 Reg. Sess., Ch. 148.

§30-5-7. Rule-making authority.

(a) The board shall propose rules for legislative approval, in accordance with the provisions of article three, chapter twenty- nine-a of this code, to implement the provisions of this article, and articles two, three, eight, nine and ten of chapter sixty-A including:

(1) Standards and requirements for a license, permit and registration;

(2) Educational and experience requirements;

(3) Procedures for examinations and reexaminations;

(4) Requirements for third parties to prepare, administer or prepare and administer examinations and reexaminations;

(5) The passing grade on the examination;

(6) Procedures for the issuance and renewal of a license, permit and registration;

(7) A fee schedule;

(8) Continuing education requirements;

(9) Set standards for professional conduct;

(10) Establish equipment and facility standards for pharmacies;

(11) Approve courses and standards for training pharmacist technicians;

(12) Regulation of charitable clinic pharmacies;

(13) Regulation of mail order pharmacies: *Provided,* That until the board establishes requirements that provide further conditions for pharmacists whom consult with or who provide pharmacist care to patients regarding prescriptions dispensed in this state by a mail order pharmacy, the pharmacist in charge of the out-of-state mail order pharmacy shall be licensed in West Virginia and any other pharmacist providing pharmacist care from the mail order pharmacy shall be licensed in the state where the pharmacy is located.

(14) Agreements with organizations to form pharmacist recovery networks;

(15) Create an alcohol or chemical dependency treatment program;

(16) Establish a ratio of pharmacy technicians to on-duty pharmacist operating in any outpatient, mail order or institutional pharmacy;

(17) Regulation of telepharmacy;

(18) The minimum standards for a charitable clinic pharmacy and rules regarding the applicable definition of a pharmacist-in- charge, who may be a volunteer, at charitable clinic pharmacies: *Provided,* That a charitable clinic pharmacy may not be charged any applicable licensing fees and such clinics may receive donated drugs.

(19) Establish standards for substituted drug products;

(20) Establish the regulations for E-prescribing;

(21) Establish the proper use of the automated data processing system;

(22) Registration and control of the manufacture and distribution of controlled substances within this state.

(23) Regulation of pharmacies;

(24) Sanitation and equipment requirements for wholesalers, distributers and pharmacies.

(25) Procedures for denying, suspending, revoking, reinstating or limiting the practice of a licensee, permittee or registrant;

(26) Regulations on prescription paper as provided in section five, article five-w, chapter sixteen;

(27) Regulations on controlled substances as provided in article two, chapter sixty-a;

(28) Regulations on manufacturing, distributing, or dispensing any controlled substance as provided in article three, chapter sixty-a;

(29) Regulations on wholesale drug distribution as provided in article eight, chapter sixty-a;

(30) Regulations on controlled substances monitoring as provided in article nine, chapter sixty-a;

(31) Regulations on Methamphetamine Laboratory Eradication Act as provided in article ten, chapter sixty-a;

(32) Establish and maintain an official prescription paper program; and

(33) Any other rules necessary to effectuate the provisions of this article.

(b) The board may provide an exemption to the pharmacist-in- charge requirement for the opening of a new retail pharmacy or during a declared emergency;

(c) The board, the Board of Medicine and the Board of Osteopathic Medicine shall jointly agree and propose rules concerning collaborative pharmacy practice for legislative approval in accordance with the provisions of article three, chapter twenty- nine-a of the code;

(d) The board with the advice of the Board of Medicine and the Board of Osteopathic Medicine shall propose rules for legislative approval in accordance with the provisions of article three, chapter twenty-nine-a of this code to perform influenza and pneumonia immunizations, on a person of eighteen years of age or older. These rules shall provide, at a minimum, for the following:

(1) Establishment of a course, or provide a list of approved courses, in immunization administration. The courses shall be based on the standards established for such courses by the Centers for Disease Control and Prevention in the public health service of the United States Department of Health and Human Services;

(2) Definitive treatment guidelines which shall include, but not be limited to, appropriate observation for an adverse reaction of an individual following an immunization;

(3) Prior to administration of immunizations, a pharmacist shall have completed a board approved immunization administration course and completed an American Red Cross or American Heart Association basic life-support training, and maintain certification in the same.

(4) Continuing education requirements for this area of practice;

(5) Reporting requirements for pharmacists administering immunizations to report to the primary care physician or other licensed health care provider as identified by the person receiving the immunization;

(6) Reporting requirements for pharmacists administering immunizations to report to the West Virginia Statewide Immunization Information (WVSII);

(7) That a pharmacist may not delegate the authority to administer immunizations to any other person; unless administered by a licensed pharmacy intern under the direct supervision of a pharmacist of whom both pharmacist and intern have successfully completed all board required training; and

(8) Any other provisions necessary to implement the provisions of this section.

(e) The board, the Board of Medicine and the Board of Osteopathic Medicine shall propose joint rules for legislative approval in accordance with the provisions of article three, chapter twenty-nine-a of this code to permit a licensed pharmacist or pharmacy intern to administer other immunizations such as Hepatitis A, Hepatitis B, Herpes Zoster and Tetanus. These rules shall provide, at a minimum, the same provisions contained in subsection (d)(1) through (d)(8) of this section.

(f) All of the board's rules in effect and not in conflict with these provisions, shall remain in effect until they are amended or rescinded.

§30-5-7a.

Repealed.

Acts, 2013 Reg. Sess., Ch. 148.

§30-5-7b.

Repealed.

Acts, 2013 Reg. Sess., Ch. 148.

§30-5-7c.

Repealed.

Acts, 2013 Reg. Sess., Ch. 148.

§30-5-8. Fees; special revenue account; administrative fines.

(a) All fees and other moneys, except fines, received by the board shall be deposited in a separate special revenue fund in the State Treasury designated the "Board of Pharmacy Fund", which fund is continued. The fund is used by the board for the administration of this article. Except as may be provided in article one of this chapter, the board shall retain the amounts in the special revenue account from year to year. Any compensation or expense incurred under this article is not a charge against the General Revenue Fund.

(b) The board shall deposit any amounts received as administrative fines imposed pursuant to this article into the General Revenue Fund of the State Treasury.

30-5-9. Qualifications for licensure as pharmacist;

(a) To be eligible for a license to practice pharmacist care under the provisions of this article, the applicant shall:

(1) Submit a written application to the board;

(2) Be eighteen years of age or older;

(3) Pay all applicable fees;

(4) Graduate from an accredited school of pharmacy;

(5) Complete at least fifteen hundred hours of internship in a pharmacy under the instruction and supervision of a pharmacist;

(6) Pass an examination or examinations approved by the board;

(7) Not be an alcohol or drug abuser, as these terms are defined in section eleven, article one-a, chapter twenty-seven of this code: *Provided*, That an applicant in an active recovery process, which may, in the discretion of the board, be evidenced by participation in a twelve-step program or other similar group or process, may be considered;

(8) Present to the board satisfactory evidence that he or she is a person of good moral character, has not been convicted of a felony involving the sale or distribution of controlled substances;

(9) Not been convicted in any jurisdiction of any other felony or crime which bears a rational nexus to the individual's ability to practice pharmacist care, *Provided*, That an applicant with a felony conviction other than the felony conviction specified in subdivision eight of this section may apply to the board for licensure no sooner than five years after the date of the conviction. The board shall evaluate each applicant on a case by case basis; and

(10) Has fulfilled any other requirement specified by the board in rule.

(b) An applicant from another jurisdiction shall comply with all the requirements of this article.

§30-5-9a.

Repealed.

Acts, 2013 Reg. Sess., Ch. 148.

§30-5-10. Scope practice for licensed pharmacist;

(a) A licensed pharmacist may:

(1) Provide care related to the interpretation, evaluation, and implementation of medical orders;

(2) Dispense of prescription drug orders; participate in drug and device selection;

(3) Provide drug administration;

(4) Provide drug regimen review;

(5) Provide drug or drug-related research;

(6) Perform patient counseling;

(7) Provide pharmacy related primary care;

(8) Provide pharmacist care in all areas of patient care, including collaborative pharmacy practice;

(9) Compound and label drugs and drug devices;

(10) Proper and safe storage of drugs and devices;

(11) Maintain proper records;

(12) Provide patient counseling concerning the therapeutic value and proper use of drugs and devices;

(13) Order laboratory tests in accordance with drug therapy management; and

(14) Provide medication therapy management.

(b) A licensee meeting the requirements as promulgated by legislative rule may administer immunizations.

(c) The sale of any medicine, if the contents of its container, or any part thereof, taken at one time, are likely to prove poisonous, deleterious, or habit-forming is prohibited by any person other than a registered pharmacist, who shall take precautions to acquaint the purchaser of the nature of the medicine at the time of sale.

§30-5-10a.

Repealed.

Acts, 2013 Reg. Sess., Ch. 148.

§30-5-11. Registration of pharmacy technicians;

(a) To be eligible for registration as a pharmacy technician to assist in the practice of pharmacist care, the applicant shall:

(1) Submit a written application to the board;

(2) Pay the applicable fees;

(3) Have graduated from high school or obtained a Certificate of General Educational Development (GED) or equivalent;

(4) Have:

(A) Graduated from a competency-based pharmacy technician education and training program as approved by legislative rule of the board; or

(B)Completed a pharmacy provided, competency-based education and training program approved by the board;

(5) Effective July 1, 2014, have successfully passed an examination developed using nationally recognized and validated psychometric and pharmacy practice standards approved by the board;

(6) Not be an alcohol or drug abuser, as these terms are defined in section eleven, article one-a, chapter twenty-seven of this code: *Provided*, That an applicant in an active recovery process, which may, in the discretion of the board, be evidenced by participation in a twelve-step program or other similar group or process, may be considered;

(8) Not have been convicted of a felony in any jurisdiction within ten years preceding the date of application for license, which conviction remains unreversed;

(9) Not have been convicted of a misdemeanor or felony in any jurisdiction if the offense for which he or she was convicted bearing a rational nexus to the practice of pharmacist care, which conviction remains unreversed; and

(10) Have fulfilled any other requirement specified by the board in rule.

(b) A person whose license to practice pharmacist care has been denied, revoked, suspended, or restricted for disciplinary purposes in any jurisdiction is not eligible to be registered as a pharmacy technician.

(c) A person registered to assist in the practice pharmacist care issued by the board prior to June 30, 2014, shall for all purposes be considered registered under this article and may renew pursuant to the provisions of this article.

§30-5-12. Scope practice for registered pharmacy technician.

(a) A registered pharmacy technician shall, under the direct supervision of the licensed pharmacist, perform at a minimum the following:

(1) Assist in the dispensing process;

(2) Receive new written or electronic prescription drug orders;

(3) Compound; and

(4) Stock medications.

(b) A registered pharmacy technician may perform the following under indirect supervision of a licensed pharmacists:

(1) Process medical coverage claims; and

(2) Cashier.

(c) A registered pharmacy technician may not perform the following:

(1) Drug regimen review;

(2) Clinical conflict resolution;

(3) Contact a prescriber concerning prescription drug order clarification or therapy modification;

(4) Patient counseling;

(5) Dispense process validation;

(6) Prescription transfer; and

(7) Receive new oral prescription drug orders.

(d) Indirect supervision of a registered pharmacy technician is permitted to allow a pharmacist to take one break of no more than thirty minutes during any contiguous eight-hour period. The pharmacist may leave the pharmacy area but may not leave the building during the break. When a pharmacist is on break, a pharmacy technician may continue to prepare prescriptions for the pharmacist's verification. A prescription may not be delivered until the pharmacist has verified the accuracy of the prescription, and counseling, if required, has been provided to or refused by the patient.

(e) A pharmacy that permits indirect supervision of a pharmacy technician during a pharmacist's break shall have either an interactive voice response system or a voice mail system installed on the pharmacy phone line in order to receive new prescription orders and refill authorizations during the break.

(f) The pharmacy shall establish protocols that require a registered pharmacy technician to interrupt the pharmacist's break if an emergency arises.

§30-5-12a.

Repealed.

Acts, 1995 Reg. Sess., Ch. 193.

§30-5-12b. Definitions; selection of generic drug products; exceptions; records; labels; manufacturing standards; rules; notice of substitution; complaints; notice and hearing; immunity.

(a) As used in this section:

(1) "Brand name" means the proprietary or trade name selected by the manufacturer and placed upon a drug or drug product, its container, label or wrapping at the time of packaging.

(2) "Generic name" means the official title of a drug or drug combination for which a new drug application, or an abbreviated new drug application, has been approved by the United States Food and Drug Administration and is in effect.

(3) "Substitute" means to dispense without the prescriber's express authorization a therapeutically equivalent generic drug product in the place of the drug ordered or prescribed.

(4) "Equivalent" means drugs or drug products which are the same amounts of identical active ingredients and same dosage form and which will provide the same therapeutic efficacy and toxicity when administered to an individual and is approved by the United States Food and Drug Administration.

(b) A pharmacist who receives a prescription for a brand name drug or drug product shall substitute a less expensive equivalent generic name drug or drug product unless in the exercise of his or her professional judgment the pharmacist believes that the less expensive drug is not suitable for the particular patient: Provided, That no substitution may be made by the pharmacist where the prescribing practitioner indicates that, in his or her professional judgment, a specific brand name drug is medically necessary for a particular patient.

(c) A written prescription order shall permit the pharmacist to substitute an equivalent generic name drug or drug product except where the prescribing practitioner has indicated in his or her own handwriting the words "Brand Medically Necessary". The following sentence shall be printed on the prescription form. "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.": *Provided*, That "Brand Medically Necessary" may be indicated on the prescription order other than in the prescribing practitioner's own handwriting unless otherwise required by federal mandate.

(d) A verbal prescription order shall permit the pharmacist to substitute an equivalent generic name drug or drug product except where the prescribing practitioner shall indicate to the pharmacist that the prescription is "Brand Necessary" or "Brand Medically Necessary". The pharmacist shall note the instructions on the file copy of the prescription or chart order form.

(e) No person may by trade rule, work rule, contract or in any other way prohibit, restrict, limit or attempt to prohibit, restrict or limit the making of a generic name substitution under the provisions of this section. No employer or his or her agent may use coercion or other means to interfere with the professional judgment of the pharmacist in deciding which generic name drugs or drug products shall be stocked or substituted: Provided, That this section shall not be construed to permit the pharmacist to generally refuse to substitute less expensive therapeutically equivalent generic drugs for brand name drugs and that any pharmacist so refusing shall be subject to the penalties prescribed in section thirty-four of this article.

(f) A pharmacist may substitute a drug pursuant to the provisions of this section only where there will be a savings to the buyer. Where substitution is proper, pursuant to this section, or where the practitioner prescribes the drug by generic name, the pharmacist shall, consistent with his or her professional judgment, dispense the lowest retail cost, effective brand which is in stock.

(g) All savings in the retail price of the prescription shall be passed on to the purchaser; these savings shall be equal to the difference between the retail price of the brand name product and the customary and usual price of the generic product substituted therefor: *Provided*, That in no event shall such savings be less than the difference in acquisition cost of the brand name product prescribed and the acquisition cost of the substituted product.

(h) Each pharmacy shall maintain a record of any substitution of an equivalent generic name drug product for a prescribed brand name drug product on the file copy of a written, electronic or verbal prescription or chart order. Such record shall include the manufacturer and generic name of the drug product selected.

(i) All drugs shall be labeled in accordance with the instructions of the practitioner.

(j) Unless the practitioner directs otherwise, the prescription label on all drugs dispensed by the pharmacist shall indicate the generic name using abbreviations, if necessary, and either the name of the manufacturer or packager, whichever is applicable in the pharmacist's discretion. The same notation will be made on the original prescription retained by the pharmacist.

(k) A pharmacist may not dispense a product under the provisions of this section unless the manufacturer has shown that the drug has been manufactured with the following minimum good manufacturing standards and practices by:

(1) Labeling products with the name of the original manufacturer and control number;

(2) Maintaining quality control standards equal to or greater than those of the United States Food and Drug Administration;

(3) Marking products with identification code or monogram; and

(4) Labeling products with an expiration date.

(l) The West Virginia Board of Pharmacy shall promulgate rules in accordance with the provisions of chapter twenty-nine-a of this code which establish a formulary of generic type and brand name drug products which are determined by the board to demonstrate significant biological or therapeutic inequivalence and which, if substituted, would pose a threat to the health and safety of patients receiving prescription medication. The formulary shall be promulgated by the board within ninety days of the date of passage of this section and may be amended in accordance with the provisions of chapter twenty-nine-a of this code.

(m) No pharmacist shall substitute a generic-named therapeutically equivalent drug product for a prescribed brand name drug product if the brand name drug product or the generic drug type is listed on the formulary established by the West Virginia Board of Pharmacy pursuant to this article or is found to be in violation of the requirements of the United States Food and Drug Administration.

(n) Any pharmacist who substitutes any drug shall, either personally or through his or her agent, assistant or employee, notify the person presenting the prescription of such substitution. The person presenting the prescription shall have the right to refuse the substitution. Upon request the pharmacist shall relate the retail price difference between the brand name and the drug substituted for it.

(o) Every pharmacy shall post in a prominent place that is in clear and unobstructed public view, at or near the place where prescriptions are dispensed, a sign which shall read: "West Virginia law requires pharmacists to substitute a less expensive generic-named therapeutically equivalent drug for a brand name drug, if available, unless you or your physician direct otherwise." The sign shall be printed with lettering of at least one and one-half inches in height with appropriate margins and spacing as prescribed by the West Virginia Board of Pharmacy.

(p) The West Virginia Board of Pharmacy shall promulgate rules in accordance with the provisions of chapter twenty-nine-a of this code setting standards for substituted drug products, obtaining compliance with the provisions of this section and enforcing the provisions of this section.

(q) Any person shall have the right to file a complaint with the West Virginia Board of Pharmacy regarding any violation of the provisions of this article. Such complaints shall be investigated by the Board of Pharmacy.

(r) Fifteen days after the board has notified, by registered mail, a person, firm, corporation or copartnership that such person, firm, corporation or copartnership is suspected of being in violation of a provision of this section, the board shall hold a hearing on the matter. If, as a result of the hearing, the board determines that a person, firm, corporation or copartnership is violating any of the provisions of this section, it may, in addition to any penalties prescribed by section twenty-two of this article, suspend or revoke the permit of any person, firm, corporation or copartnership to operate a pharmacy.

(s) No pharmacist or pharmacy complying with the provisions of this section shall be liable in any way for the dispensing of a generic-named therapeutically equivalent drug, substituted under the provisions of this section, unless the generic-named therapeutically equivalent drug was incorrectly substituted.

(t) In no event where the pharmacist substitutes a drug under the provisions of this section shall the prescribing physician be liable in any action for loss, damage, injury or death of any person occasioned by or arising from the use of the substitute drug unless the original drug was incorrectly prescribed.

(u) Failure of a practitioner to specify that a specific brand name is necessary for a particular patient shall not constitute evidence of negligence unless the practitioner had reasonable cause to believe that the health of the patient required the use of a certain product and no other.

§30-5-12c.

Repealed.

Acts, 2013 Reg. Sess., Ch. 148.

§30-5-13. Pharmacist interns.

(a) To be eligible for a license to assist in the practice of pharmacist care as a pharmacy intern, the applicant shall be:

(1) Enrolled and progressing to obtain a degree in a professional degree program of a school or college of pharmacy that has been approved by the board, and is satisfactorily progressing toward meeting the requirements for licensure as a pharmacist; or

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

(3) A qualified applicant awaiting examination for licensure or meeting board requirements for relicensure; or

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

§30-5-14. Prohibiting the dispensing of prescription orders in absence of practitioner-patient relationship.

A pharmacist may not compound or dispense any prescription order when he or she has knowledge that the prescription was issued by a practitioner without establishing a valid practitioner-patient relationship. An online or telephonic evaluation by questionnaire, or an online or telephonic consultation, is inadequate to establish a valid practitioner-patient relationship: *Provided,* That this prohibition does not apply:

(1) In a documented emergency;

(2) In an on-call or cross-coverage situation;

(3) For the treatment of sexually transmitted diseases by expedited partner therapy as set forth in article four-f, chapter sixteen of this code; or

(4) Where patient care is rendered in consultation with another practitioner who has an ongoing relationship with the patient and who has agreed to supervise the patient's treatment, including the use of any prescribed medications.

§30-5-14a.

Repealed.

Acts, 2013 Reg. Sess., Ch. 148.

§30-5-14b.

Repealed.

Acts, 2013 Reg. Sess., Ch. 148.

§30-5-15. Reciprocal licensure of pharmacists from other states or countries.

(a) The board may by reciprocity license pharmacists in this state who have been authorized to practice pharmacist care in another state: *Provided*, That the applicant for licensure meets the requirements of the rules for reciprocity promulgated by the board in accordance with the provisions of chapter twenty-nine-a of this code: *Provided, however*, That reciprocity is not authorized for pharmacists from another state where that state does not permit reciprocity to pharmacists licensed in West Virginia.

(b) The board may refuse reciprocity to pharmacists from another country unless the applicant qualifies under the legislative rules as may be promulgated by the board for licensure of foreign applicants.

§30-5-16. Renewal requirements.

(a) All persons regulated by this article shall annually or biannually, renew his or her board authorization by completing a form prescribed by the board and submitting any other information required by the board.

(b) The board shall charge a fee for each renewal of an board authorization and shall charge a late fee for any renewal not paid by the due date.

(c) The board shall require as a condition of renewal that each licensee or registrant complete continuing education.

(d) The board may deny an application for renewal for any reason which would justify the denial of an original application.

(e) After June 30, 2014, a previously registered pharmacy technician may renew his or her current registration without having successfully completed the requirements of subdivision six, subsection (a), of section eleven. The previously registered pharmacist may continue to renew his or her registration under this provision.

§30-5-16a.

Repealed.

Acts, 2013 Reg. Sess., Ch. 148.

§30-5-16b.

Repealed.

Acts, 2013 Reg. Sess., Ch. 148.

§30-5-16c.

Repealed.

Acts, 2013 Reg. Sess., Ch. 148.

§30-5-17. Special volunteer pharmacist license; civil immunity for voluntary services rendered to indigents.

(a) There is a special volunteer pharmacist license for pharmacists retired or retiring from the active practice of pharmacist care who wish to donate their expertise for the pharmacist care and treatment of indigent and needy patients in the clinic setting of clinics organized, in whole or in part, for the delivery of health care services without charge. The special volunteer pharmacist license shall be issued by the board to pharmacists licensed or otherwise eligible for licensure under this article and the legislative rules promulgated hereunder without the payment of an application fee, license fee or renewal fee, and the initial license shall be issued for the remainder of the licensing period, and renewed consistent with the boards other licensing requirements. The board shall develop application forms for the special license provided in this subsection which shall contain the pharmacist's acknowledgment that:

(1) The pharmacist's practice under the special volunteer pharmacist license shall be exclusively devoted to providing pharmacist care to needy and indigent persons in West Virginia;

(2) The pharmacist may not receive any payment or compensation, either direct or indirect, or have the expectation of any payment or compensation, for any pharmacist care rendered under the special volunteer pharmacist license;

(3) The pharmacist will supply any supporting documentation that the board may reasonably require; and

(4) The pharmacist agrees to continue to participate in continuing professional education as required by the board for the special volunteer pharmacist license.

(b) Any pharmacist who renders any pharmacist care to indigent and needy patients of a clinic organized, in whole or in part, for the delivery of health care services without charge under a special volunteer pharmacist license authorized under subsection (a) of this section without payment or compensation or the expectation or promise of payment or compensation is immune from liability for any civil action arising out of any act or omission resulting from the rendering of the pharmacist care at the clinic unless the act or omission was the result of the pharmacist's gross negligence or willful misconduct. In order for the immunity under this subsection to apply, there shall be a written agreement between the pharmacist and the clinic pursuant to which the

pharmacist provides voluntary uncompensated pharmacist care under the control of the clinic to patients of the clinic before the rendering of any services by the pharmacist at the clinic: *Provided,* That any clinic entering into such written agreement is required to maintain liability coverage of not less than $1 million per occurrence.

(c) Notwithstanding the provisions of subsection (b) of this section, a clinic organized, in whole or in part, for the delivery of health care services without charge is not relieved from imputed liability for the negligent acts of a pharmacist rendering voluntary pharmacist care at or for the clinic under a special volunteer pharmacist license authorized under subsection (a) of this section.

(d) For purposes of this section, "otherwise eligible for licensure" means the satisfaction of all the requirements for licensure as listed in section nine of this article and in the legislative rules promulgated thereunder, except the fee requirements of that section and of the legislative rules promulgated by the board relating to fees.

(e) Nothing in this section may be construed as requiring the board to issue a special volunteer pharmacist license to any pharmacist whose license is or has been subject to any disciplinary action or to any pharmacist who has surrendered a license or caused such license to lapse, expire and become invalid in lieu of having a complaint initiated or other action taken against his or her license, or who has elected to place a pharmacist license in inactive status in lieu of having a complaint initiated or other action taken against his or her license, or who has been denied a pharmacist license.

(f) Any policy or contract of liability insurance providing coverage for liability sold, issued or delivered in this state to any pharmacist covered under the provisions of this article shall be read so as to contain a provision or endorsement whereby the company issuing such policy waives or agrees not to assert as a defense on behalf of the policyholder or any beneficiary thereof, to any claim covered by the terms of such policy within the policy limits, the immunity from liability of the insured by reason of the care and treatment of needy and indigent patients by a pharmacist who holds a special volunteer pharmacist license.

§30-5-18. Pharmacist requirements to participate in a collabora- tive pharmacy practice agreement.

For a pharmacist to participate in a collaborative pharmacy practice agreement, the pharmacist shall:

(a) Have an unrestricted and current license to practice as a pharmacist in West Virginia;

(b) Personally have or have employer coverage of at least $1 million of professional liability insurance coverage;

(c) Meet one of the following qualifications, at a minimum:

(1) Earned a Certification from the Board of Pharmaceutical Specialties, is a Certified Geriatric Practitioner, or has completed an American Society of Health System Pharmacists(ASHP) accredited residency program, which includes two years of clinical experience approved by the board; or

(2) Successfully completed the course of study and holds the academic degree of Doctor of Pharmacy and has three years of clinical experience approved by the board and has completed an Accreditation Council for Pharmacy Education (ACPE) approved practice based continuing pharmacy education activity in the area of practice covered by the collaborative pharmacy practice agreement; or

(3) Successfully completed the course of study and hold the academic degree of Bachelor of Science in Pharmacy and has five years of clinical experience approved by the board and has completed two ACPE approved practice based continuing pharmacy education activity with at least one program in the area of practice covered by a collaborative pharmacy practice agreement.

§30-5-19. Collaborative pharmacy practice agreement.

(a) A pharmacist engaging in collaborative pharmacy practice shall have on file at his or her place of practice the collaborative pharmacy practice agreement. The existence and subsequent termination of the agreement and any additional information the rules may require concerning the agreement, including the agreement itself, shall be made available to the appropriate licensing board for review upon request. The agreement may allow the pharmacist, within the pharmacist's scope of practice pursuant to the collaborative pharmacy practice agreement, to conduct drug therapy management activities approved by the collaborating physician. The collaborative pharmacy practice agreement shall be a voluntary process, which is a physician directed approach, that is entered into between an individual physician or physician group, an individual pharmacist or pharmacists and an individual patient or the patient's authorized representative who has given informed consent as per subsection (c).

(b) A collaborative pharmacy practice agreement may authorize a pharmacist to provide drug therapy management. In instances where drug therapy is discontinued, the pharmacist shall notify the treating physician of the discontinuance in the time frame and in the manner established by joint legislative rules. Each protocol developed, pursuant to the collaborative pharmacy practice agreement, shall contain detailed direction concerning the services that the pharmacists may perform for that patient. The protocol shall include, but need not be limited to:

(1) The specific drug or drugs to be managed by the pharmacist;

(2) The terms and conditions under which drug therapy may be implemented, modified or discontinued;

(3) The conditions and events upon which the pharmacist is required to notify the physician; and

(4) The laboratory tests that may be ordered in accordance with drug therapy management.

(c) All activities performed by the pharmacist in conjunction with the protocol shall be documented in the patient's medical record. The pharmacists shall report at least every thirty days to the physician regarding the patient's drug therapy management. The collaborative pharmacy practice agreement and protocols shall be available for inspection by the board, the West Virginia Board of Medicine, or the West Virginia Board of Osteopathic Medicine, depending on the licensing board of the participating physician. A copy of the protocol shall be filed in the patient's medical record.

(d) Collaborative pharmacy agreements may not include the management of controlled substances.

(e) A collaborative pharmacy practice agreement, meeting the requirements herein established and in accordance with joint rules, shall be allowed in the hospital setting, the nursing home setting, the medical school setting and the hospital, community-based pharmacy setting and ambulatory care clinics. The pharmacist shall be employed by or under contract to provide services to the hospital, pharmacy, nursing home or medical school, or hold a faculty appointment with one of the schools of pharmacy or medicine in this state.

(f) Nothing pertaining to collaborative pharmacy practice shall be interpreted to permit a pharmacist to accept delegation of a physician's authority outside the limits included in the appropriate board's statute and rules.

§30-5-20. Board authorizations shall be displayed.

(a) The board shall prescribe the form for an board authorization, and may issue a duplicate upon payment of a fee.

(b) Any person regulated by the article shall conspicuously display his or her board authorization at his or her principal business location.

§30-5-21. Responsibility for quality of drugs dispensed; exception; falsification of labels; deviation from prescription.

(a) All persons, whether licensed pharmacists or not, shall be responsible for the quality of all drugs, chemicals and medicines they may sell or dispense, with the exception of those sold in or dispensed unchanged from the original retail package of the manufacturer, in which event the manufacturer shall be responsible.

(b) Except as provided in section twelve-b of this article, the following acts shall be prohibited:

(1) The falsification of any label upon the immediate container, box and/or package containing a drug;

(2) The substitution or the dispensing of a different drug in lieu of any drug prescribed in a prescription without the approval of the practitioner authorizing the original prescription: *Provided,* That this may not be construed to interfere with the art of prescription compounding which does not alter the therapeutic properties of the prescription or appropriate generic substitute;

(3) The filling or refilling of any prescription for a greater quantity of any drug or drug product than that prescribed in the original prescription without a written or electronic order or an oral order reduced to writing, or the refilling of a prescription without the verbal, written or electronic consent of the practitioner authorizing the original prescription.

§30-5-22. Pharmacies to be registered.

(a) A pharmacy, an ambulatory health care facility, and a charitable clinic pharmacy shall register with the board.

(b) A person desiring to operate, maintain, open or establish a pharmacy shall register with the board.

(c) To be eligible for a registration to operate, maintain, open or establish a pharmacy the applicant shall:

(1) Submit a written application to the board;

(2) Pay all applicable fees;

(3) Designate a pharmacist-in-charge; and

(4) Successfully complete an inspection by the board.

(d) A separate application shall be made and separate registration issued for each location.

(e) Registration are not transferable.

(f) Registration expire and shall be renewed annually.

(g) If a registration expires, the pharmacy shall be reinspected and an inspection fee is required.

(h) A registrant shall employ a pharmacist-in-charge and operate in compliance with the legislative rules governing the practice of pharmacist care and the operation of a pharmacy.

(i) The provisions of this section do not apply to the sale of nonprescription drugs which are not required to be dispensed pursuant to a practitioner's prescription.

§30-5-22a.

Repealed.

Acts, 2013 Reg. Sess., Ch. 148.

§30-5-23. Pharmacist-in-charge.

(a) A pharmacy shall be under the direction and supervision of a licensed pharmacist who shall be designated by the owner of the pharmacy as the pharmacist-in-charge: *Provided,* That the Board may permit by rule for a charitable clinic pharmacy to be supervised by a committee of pharmacists-in-charge who accept as a group the responsibilities of the required pharmacist-in-charge. This designation shall be filed with the board within thirty days of the designation.

(b) The pharmacist-in-charge is responsible for the pharmacy's compliance with state and federal pharmacy laws and regulations and for maintaining records and inventory.

(c) A pharmacist-in-charge may not hold such designated position at more than one pharmacy, whether within or outside the State of West Virginia: *Provided,* That the Board may permit by rule that he or she may volunteer as the pharmacist-in-charge at a charitable clinic pharmacy while serving as a pharmacist-in-charge in another pharmacy.

(d) An interim pharmacist-in-charge may be designated for a period not to exceed sixty days. The request for an interim pharmacist-in-charge shall detail the circumstances which warrant the change. This change in designation shall be filed with the board within thirty days of the designation.

§30-5-24. Permits for mail-order pharmacy.

(a) A mail-order pharmacy which dispenses drugs shall register with the board.

(b) A mail-order pharmacy shall submit an application for a permit to the board. The application shall require the following information:

(1) The owner of the mail-order pharmacy, whether an individual, a partnership, or a corporation.

(2) The names and titles of all individual owners, partners or corporate officers.

(3) The pharmacy manager.

(4) The pharmacist-in-charge.

(5) The complete address, telephone number and fax number of the mail-order pharmacy.

(c) This section does not apply to any mail-order pharmacy which operates solely as a wholesale distributor.

§30-5-25. Permit for manufacture and packaging of drugs, medicines, distribution of prescription drugs.

(a) Drugs may not be manufactured, made, produced, packed, packaged or prepared within the state, except under the personal supervision of a pharmacist or other qualified person as may be approved by the board;

(b) A person may not manufacture, package or prepare a drug without obtaining a permit from the board.

(c) A person, who offers for sale, sells, offers for sale through the method of distribution any prescription drugs is subject to this article.

(d) The application for a permit shall be made on a form to be prescribed and furnished by the board and shall be accompanied by an application fee.

(e) The board shall promulgate rules on permit requirements and sanitation requirements.

(f) Separate applications shall be made and separate permits issued for each place of manufacture, distribution, making, producing, packing, packaging or preparation.

§30-5-26. Filling of prescriptions more than one year after issuance.

A prescription order may not be dispensed after twelve months from the date of issuance by the practitioner. A pharmacist may fill the prescription after twelve months if the prescriber confirms to the pharmacist that he or she still wants the prescription filled and the pharmacist documents upon the prescription that the confirmation was obtained.

§30-5-27. Partial filling of prescriptions.

(a) The partial filling of a prescription is permissible for any prescription if the pharmacist is unable to supply, or the patient requests less than the full quantity called for in a written, electronic, or oral prescription, provided the pharmacist makes a notation of the quantity supplied on either the written prescription or in the electronic record.

(b) The partial filling of a prescription for a controlled substance listed in Schedule II is permissible if the pharmacist is unable to supply or the patient requests less than the full quantity called for in the prescription. The remaining portion of the prescription may be filled within seventy-two hours of the first partial filling: *Provided*, That if the remaining portion is not or cannot be filled within the seventy-two hour period, the pharmacist shall notify the prescribing individual practitioner. Further quantity may not be supplied beyond seventy-two hours without a new prescription.

§30-5-28. Partial filling of prescriptions for long-term care facility or terminally ill patients; requirements; records; violations.

(a) As used in this section, "long-term care facility" or "LTCF" means any nursing home, personal care home, or residential board and care home as defined in section two, article five-c, chapter sixteen of this code which provides extended health care to resident patients: *Provided,* That the care or treatment in a household, whether for compensation or not, of any person related by blood or marriage, within the degree of consanguinity of second cousin to the head of the household, or his or her spouse, may not be deemed to constitute a nursing home, personal care home or residential board and care home within the meaning of this article. This section does not apply to:

(1) Hospitals, as defined under section one, article five-b, chapter sixteen of this code or to extended care facilities operated in conjunction with a hospital;

(2) State institutions as defined in section six, article one, chapter twenty-seven or in section three, article one, chapter twenty-five, all of this code;

(3) Nursing homes operated by the federal government;

(4) Facilities owned or operated by the state government;

(5) Institutions operated for the treatment and care of alcoholic patients;

(6) Offices of physicians; or

(7) Hotels, boarding homes or other similar places that furnish to their guests only a room and board.

(b) As used in this section, "terminally ill" means that an individual has a medical prognosis that his or her life expectancy is six months or less.

(c) Schedule II prescriptions for patients in a LTCF and for terminally ill patients shall be valid for a period of sixty days from the date of issue unless terminated within a shorter period by the discontinuance of the medication.

(d) A prescription for a Schedule II controlled substance written for a patient in a LTCF or for a terminally ill patient may be filled in partial quantities, including, but not limited to, individual dosage units. The total quantity of Schedule II controlled substances dispensed in all partial filling may not exceed the total quantity prescribed.

(1) If there is any question whether a patient may be classified as having a terminal illness, the pharmacist shall contact the prescribing practitioner prior to partially filling the prescription.

(2) Both the pharmacist and the prescribing practitioner have a corresponding responsibility to assure that the controlled substance is for a terminally ill patient.

(e) The pharmacist shall record on the prescription that the patient is "terminally ill" or a "LTCF patient". A prescription that is partially filled and does not contain the notation "terminally ill" or "LTCF patient" shall be deemed to have been filled in violation of section three hundred eight, article three, chapter sixty-a of this code.

(f) For each partial filling, the dispensing pharmacist shall record on the back of the prescription, or on another appropriate record which is readily retrievable, the following information:

(1) The date of the partial filling;

(2) The quantity dispensed;

(3) The remaining quantity authorized to be dispensed; and

(4) The identification of the dispensing pharmacist.

(g) Information pertaining to current Schedule II prescriptions for terminally ill and LTCF patients may be maintained in a computerized system if such a system has the capability to permit either by display or printout, for each patient and each medication, all of the information required by this section as well as the patient's name and address, the name of each medication, original prescription number, date of issue, and prescribing practitioner information. The system shall also allow immediate updating of the prescription record each time a partial filling of the prescription is performed and immediate retrieval of all information required under this section.

§30-5-29. Limitations of article.

(a) This article may not be construed to prevent, restrict or in any manner interfere with the sale of nonnarcotic nonprescription drugs which may be lawfully sold without a prescription in accordance with the United States Food, Drug and Cosmetic Act or the laws of this state, nor may any legislative rule be adopted by the board which shall require the sale of nonprescription drugs by a licensed pharmacist or in a pharmacy or which shall prevent, restrict or otherwise interfere with the sale or distribution of such drugs by any retail merchant. The sale or distribution of nonprescription drugs may not be deemed to be improperly engaging in the practice of pharmacist care.

(b) This article may not be construed to interfere with any legally qualified practitioner of medicine, dentistry or veterinary medicine, who is not the proprietor of the store for the dispensing or retailing of drugs and who is not in the employ of such proprietor, in the compounding of his or her own prescriptions or to prevent him or her from supplying to his or her patients such medicines as he or she may deem proper, if such supply is not made as a sale.

(c) The exception provided in subsection (b) of this section does not apply to an ambulatory health care facility: *Provided,* That a legally licensed and qualified practitioner of medicine or dentistry may supply medicines to patients that he or she treats in a free clinic and that he or she deems appropriate.

§30-5-30. Actions to enjoin violations.

(a) If the board obtains information that any person has engaged in, is engaging in or is about to engage in any act which constitutes or will constitute a violation of the provisions of this article, the rules promulgated pursuant to this article, or a final order or decision of the board, it may issue a notice to the person to cease and desist in engaging in the act and/or apply to the circuit court in the county of the alleged violation for an order enjoining the act.

(b) The circuit court may issue a temporary injunction pending a decision on the merits, and may issue a permanent injunction based on its findings in the case.

(c) The judgment of the circuit court on an application permitted by the provisions of this section is final unless reversed, vacated or modified on appeal to the West Virginia Supreme Court of Appeals.

§30-5-31. Complaints; investigations; due process procedure; grounds for disciplinary action.

(a) The board may initiate a complaint upon receipt of credible information, and shall upon the receipt of a written complaint of any person, cause an investigation to be made to determine whether grounds exist for disciplinary action under this article or the legislative rules promulgated pursuant to this article.

(b) After reviewing any information obtained through an investigation, the board shall determine if probable cause exists that the licensee, registrant or permittee has violated subsection (g) of this section or rules promulgated pursuant to this article.

(c) Upon a finding of probable cause to go forward with a complaint, the board shall provide a copy of the complaint to the licensee, registrant or permittee.

(d) Upon a finding that probable cause exists that the licensee, registrant or permittee has violated subsection (g) of this section or rules promulgated pursuant to this article, the board may enter into a consent decree or hold a hearing for disciplinary action against the licensee, registrant or permittee. Any hearing shall be held in accordance with the provisions of this article, and shall require a violation to be proven by a preponderance of the evidence.

(e) Any member of the board or the executive director of the board may issue subpoenas and subpoenas duces tecum to obtain testimony and documents to aid in the investigation of allegations against any person regulated by the article.

(f) Any member of the board or its executive director may sign a consent decree or other legal document on behalf of the board.

(g) The board may, after notice and opportunity for hearing, deny or refuse to renew, suspend, restrict or revoke the license, registration or permit of, or impose probationary conditions upon or take disciplinary action against, any licensee, registrant or permittee for any of the following reasons:

(1) Obtaining a board authorization by fraud, misrepresentation or concealment of material facts;

(2) Being convicted of a felony, other crime involving moral turpitude or a violation of chapter sixty-a of this code.

(3) Being guilty of unprofessional conduct which placed the public at risk, as defined by legislative rule of the board;

(4) Intentional violation of a lawful order or legislative rule of the board;

(5) Having had a board authorization revoked or suspended, other disciplinary action taken, or an application for a board authorization revoked or suspended by the proper authorities of another jurisdiction;

(6) Aiding or abetting unlicensed practice;

(7) Engaging in an act while acting in a professional capacity which has endangered or is likely to endanger the health, welfare or safety of the public;

(8) Incapacity that prevents a licensee or registrant from engaging in the practice of pharmacist care or assisting in the practice of pharmacist care, with reasonable skill, competence, and safety to the public;

(9) Violation of any laws, including rules pertaining thereto, of this or any other jurisdiction, relating to the practice of pharmacist care, drug samples, drug manufacturing, wholesale or retail drug or device distribution, or controlled substances;

(10) Committing fraud in connection with the practice of pharmacist care;

(11) Disciplinary action taken by another state or jurisdiction against a board authorization to practice pharmacist care based upon conduct by the licensee, registrant or permittee similar to conduct that would constitute grounds for actions as defined in this section;

(12) Failure to report to the board any adverse action taken by another licensing jurisdiction, government agency, law- enforcement agency, or court for conduct that would constitute grounds for action as defined in this section;

(13) Failure to report to the board one's surrender of a license or authorization to practice pharmacist care in another jurisdiction while under disciplinary investigation by any of those authorities or bodies for conduct that would constitute grounds for action as defined in this section;

(14) Failure to report to the board any adverse judgment, settlement, or award arising from a malpractice claim related to conduct that would constitute grounds for action as defined in this section;

(15) Knowing or suspecting that a licensee or registrant is incapable of engaging in the practice of pharmacist care or assisting in the practice of pharmacist care, with reasonable skill, competence, and safety to the public, and failing to report any relevant information to the board;

(16) Illegal use or disclosure of protected health information;

(17) Engaging in any conduct that subverts or attempts to subvert any licensing examination or the administration of any licensing examination;

(18) Failure to furnish to the board or its representatives any information legally requested by the board, or failure to cooperate with or knowingly engaging in any conduct which obstructs an investigation being conducted by the board;

(19) Agreeing to participate in a prescription drug product conversion program promoted or offered by a manufacturer, wholesaler or distributor of such product for which the pharmacist or pharmacy received any form of financial remuneration, or agreed to participate in a prescription drug program in which the pharmacist or pharmacy is promoted or offered as the exclusive provider of prescription drug products or whereby in any way the public is denied, limited or influenced in selecting pharmacist care or counseling;

(20) Violation of any of the terms or conditions of any order entered in any disciplinary action.

(h) For the purposes of subsection (g) of this section, effective July 1, 2013, disciplinary action may include:

(1) Reprimand;

(2) Probation;

(3) Restrictions;

(4) Suspension;

(5) Revocation;

(6) Administrative fine, not to exceed $1,000 per day per violation;

(7) Mandatory attendance at continuing education seminars or other training;

(8) Practicing under supervision or other restriction; or

(9) Requiring the licensee, registrant or permittee to report to the board for periodic interviews for a specified period of time.

(i) In addition to any other sanction imposed, the board may require a licensee, registrant or permittee to pay the costs of the proceeding.

(j) The board may defer disciplinary action with regard to an impaired licensee or registrant who voluntarily signs an agreement, in a form satisfactory to the board, agreeing not to practice pharmacist care and to enter an approved treatment and monitoring program in accordance with the board's legislative rule. This subsection, provided that this section should not apply to a licensee or registrant who has been convicted of, pleads guilty to, or enters a plea of nolo contendere or a conviction relating to a controlled substance in any jurisdiction.

(k) A person authorized to practice under this article, who reports or otherwise provides evidence of the negligence, impairment or incompetence of another member of this profession to the board or to any peer review organization, is not liable to any person for making such a report if such report is made without actual malice and in the reasonable belief that such report is warranted by the facts known to him or her at the time.

§30-5-32. Procedures for hearing; right of appeal.

(a) Hearings are governed by the provisions of section eight, article one of this chapter.

(b) The board may conduct the hearing or elect to have an administrative law judge conduct the hearing.

(c) If the hearing is conducted by an administrative law judge, at the conclusion of a hearing he or she shall prepare a proposed written order containing findings of fact and conclusions of law. The proposed order may contain proposed disciplinary actions if the board so directs. The board may accept, reject or modify the decision of the administrative law judge.

(d) Any member or the executive director of the board has the authority to administer oaths, examine any person under oath and issue subpoenas and subpoenas duces tecum.

(e) If, after a hearing, the board determines the licensee, registrant or permittee has violated provisions of this article or the board's rules, a formal written decision shall be prepared which contains findings of fact, conclusions of law and a specific description of the disciplinary actions imposed.

§30-5-33. Judicial review.

Any person adversely affected by a decision of the board entered after a hearing may obtain judicial review of the decision in accordance with section four, article five, chapter twenty-nine-a of this code, and may appeal any ruling resulting from judicial review in accordance with article six, chapter twenty-nine-a of this code.

§30-5-34. Criminal offenses.

(a) When, as a result of an investigation under this article or otherwise, the board has reason to believe that a person authorized under this article has committed a criminal offense under this article, the board may bring its information to the attention of an appropriate law-enforcement official.

(b) Any person who intentionally practices, or presents himself or herself out as qualified to practice pharmacist care or to assist in the practice of pharmacist care, or uses any title, word or abbreviation to indicate to or induce others to believe he or she is licensed to practice as a pharmacist or pharmacist technician without obtaining an active, valid West Virginia license to practice that profession; or

With a license that is:

(1) Expired, suspended or lapsed; or

(2) Inactive, revoked, suspended as a result of disciplinary action, or surrendered;

is guilty of a misdemeanor and, upon conviction thereof, shall be fined not more than ten thousand dollars.

Note: WV Code updated with legislation passed through the 2016 Regular Session

CHAPTER 60A. UNIFORM CONTROLLED SUBSTANCES ACT.
ARTICLE 1. DEFINITIONS.

§60A-1-101. Definitions.

As used in this act:

(a) "Administer" means the direct application of a controlled substance whether by injection, inhalation, ingestion or any other means to the body of a patient or research subject by:

(1) A practitioner (or, in his or her presence, by his or her authorized agent); or

(2) The patient or research subject at the direction and in the presence of the practitioner.

(b) "Agent" means an authorized person who acts on behalf of or at the direction of a manufacturer, distributor or dispenser. It does not include a common or contract carrier, public warehouseman or employee of the carrier or warehouseman.

(c) "Analogue" means a substance that, in relation to a controlled substance, has a substantially similar chemical structure.

(d) "Bureau" means the "Bureau of Narcotics and Dangerous Drugs, United States Department of Justice" or its successor agency.

(e) "Controlled substance" means a drug, substance or immediate precursor in Schedules I through V of article two of this chapter.

(f) "Counterfeit substance" means a controlled substance which, or the container or labeling of which, without authorization, bears the trademark, trade name or other identifying mark, imprint, number or device, or any likeness thereof, of a manufacturer, distributor or dispenser other than the person who in fact manufactured, distributed or dispensed the substance.

(g) "Imitation controlled substance" means: (1) A controlled substance which is falsely represented to be a different controlled substance; (2) a drug or substance which is not a controlled substance but which is falsely represented to be a controlled substance; or (3) a controlled substance or other drug or substance or a combination thereof which is shaped, sized, colored, marked, imprinted, numbered, labeled, packaged, distributed or priced so as to cause a reasonable person to believe that it is a controlled substance.

(h) "Deliver" or "delivery" means the actual, constructive or attempted transfer from one person to another of: (1) A controlled substance, whether or not there is an agency relationship; (2) a counterfeit substance; or (3) an imitation controlled substance.

(i) "Dispense" means to deliver a controlled substance to an ultimate user or research subject by or pursuant to the lawful order of a practitioner, including the prescribing, administering, packaging, labeling or compounding necessary to prepare the substance for that delivery.

(j) "Dispenser" means a practitioner who dispenses.

(k) "Distribute" means to deliver, other than by administering or dispensing, a controlled substance, a counterfeit substance or an imitation controlled substance.

(l) "Distributor" means a person who distributes.

(m) "Drug" means: (1) Substances recognized as drugs in the official "United States Pharmacopoeia, official Homeopathic Pharmacopoeia of the United States or official National Formulary", or any supplement to any of them; (2) substances intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in man or animals; (3) substances (other than food) intended to affect the structure or any function of the body of man or animals; and (4) substances intended for use as a component of any article specified in subdivision (1), (2) or (3) of this subdivision. It does not include devices or their components, parts or accessories.

(n) "Immediate derivative" means a substance which is the principal compound or any analogue of the parent compound manufactured from a known controlled substance primarily for use and which has equal or similar pharmacologic activity as the parent compound which is necessary to prevent, curtail or limit manufacture.

(o) "Immediate precursor" means a substance which is the principal compound commonly used or produced primarily for use and which is an immediate chemical intermediary used or likely to be used in the manufacture of a controlled substance, the control of which is necessary to prevent, curtail or limit manufacture.

(p) "Manufacture" means the production, preparation, propagation, compounding, conversion or processing of a controlled substance, either directly or indirectly or by extraction from substances of natural origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis, and includes any packaging or repackaging of the substance or labeling or relabeling of its container, except that this term does not include the preparation, compounding, packaging or labeling of a controlled substance:

(1) By a practitioner as an incident to his or her administering or dispensing of a controlled substance in the course of his or her professional practice; or

(2) By a practitioner, or by his or her authorized agent under his or her supervision, for the purpose of, or as an incident to, research, teaching or chemical analysis and not for sale.

(q) "Marijuana" means all parts of the plant "Cannabis sativa L.", whether growing or not; the seeds thereof; the resin extracted from any part of the plant; and every compound, manufacture, salt, immediate derivative, mixture or preparation of the plant, its seeds or resin. It does not

include the mature stalks of the plant, fiber produced from the stalks, oil or cake made from the seeds of the plant, any other compound, manufacture, salt, immediate derivative, mixture or preparation of the mature stalks (except the resin extracted therefrom), fiber, oil or cake, or the sterilized seed of the plant which is incapable of germination.

(r) "Narcotic drug" means any of the following, whether produced directly or indirectly by extraction from substances of vegetable origin or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis:

(1) Opium and opiate and any salt, compound, immediate derivative or preparation of opium or opiate.

(2) Any salt, compound, isomer, immediate derivative or preparation thereof which is chemically equivalent or identical with any of the substances referred to in paragraph (1) of this subdivision, but not including the isoquinoline alkaloids of opium.

(3) Opium poppy and poppy straw.

(4) Coca leaves and any salt, compound, immediate derivative or preparation of coca leaves and any salt, compound, isomer, immediate derivative or preparation thereof which is chemically equivalent or identical with any of these substances, but not including decocainized coca leaves or extractions of coca leaves which do not contain cocaine or ecgonine.

(s) "Opiate" means any substance having an addiction-forming or addiction-sustaining liability similar to morphine or being capable of conversion into a drug having addiction-forming or addiction-sustaining liability. It does not include, unless specifically designated as controlled under section two hundred one, article two of this chapter, the dextrorotatory isomer of 3-methoxy-n-methylmorphinan and its salts (dextromethorphan). It does not include its racemic and levorotatory forms.

(t) "Opium poppy" means the plant of the species "Papaver somniferum L.", except its seeds.

(u) "Person" means individual, corporation, government or governmental subdivision or agency, business trust, estate, trust, partnership or association, or any other legal entity.

(v) "Placebo" means an inert medicament or preparation administered or dispensed for its psychological effect, to satisfy a patient or research subject or to act as a control in experimental series.

(w) "Poppy straw" means all parts, except the seeds, of the opium poppy after mowing.

(x) "Practitioner" means:

(1) A physician, dentist, veterinarian, scientific investigator or other person licensed, registered or otherwise permitted to distribute, dispense, conduct research with respect to, or to administer a controlled substance in the course of professional practice or research in this state.

(2) A pharmacy, hospital or other institution licensed, registered or otherwise permitted to distribute, dispense, conduct research with respect to, or to administer a controlled substance in the course of professional practice or research in this state.

(y) "Production" includes the manufacture, planting, cultivation, growing or harvesting of a controlled substance.

(z) "State", when applied to a part of the United States, includes any state, district, commonwealth, territory, insular possession thereof and any area subject to the legal authority of the United States of America.

(aa) "Ultimate user" means a person who lawfully possesses a controlled substance for his or her own use or for the use of a member of his or her household or for administering to an animal owned by him or her or by a member of his or her household.

CHAPTER 60A. UNIFORM CONTROLLED SUBSTANCES ACT.
ARTICLE 5. ENFORCEMENT AND ADMINISTRATIVE PROVISIONS.

§60A-5-501. Powers of enforcement personnel.
(a) Any member of the state police, any sheriff, any deputy sheriff, any municipal police officer and any campus police officer may in the enforcement of the provisions of this act:

(1) Carry firearms;

(2) Execute and serve search warrants, arrest warrants, subpoenas, and summonses issued under the authority of this state;

(3) Make arrests without warrant for any offense under this act committed in his presence, or if he has probable cause to believe that the person to be arrested has committed or is committing a violation of this act which may constitute a felony;

(4) Make seizures of property pursuant to this act; or

(5) Perform such other law-enforcement duties as said state board of pharmacy or said appropriate department, board or agency, as specified in section 301, designates.

(b) All officers, agents, inspectors, and representatives of the said state board of pharmacy and of the said appropriate department, board, or agency, as specified in section 301, and members of the state police may execute and serve administrative warrants issued incident to the enforcement of the provisions of this act. Any such officer, agent, inspector, and representative of the said

state board of pharmacy and of the said appropriate department, board, or agency, as specified in said section 301, may:

(1) Execute and serve subpoenas and summonses issued under the authority of this state;

(2) Make arrests without warrant for any offense under this act committed in his presence, or if he has probable cause to believe that the person to be arrested has committed or is committing a violation of this act which may constitute a felony; or

(3) Make seizures of property pursuant to this act.

(c) All prosecuting attorneys and the attorney general, or any of their assistants, shall assist in the enforcement of all provisions of this act and shall cooperate with all agencies charged with the enforcement of the laws of the United States, of this state, and of all other states relating to controlled substances.

§60A-5-502. Administrative inspections and warrants.

(a) Issuance and execution of administrative inspection warrants shall be as follows:

(1) A judge of any court of record in this state having criminal jurisdiction, and upon proper oath or affirmation showing probable cause, may issue warrants for the purpose of conducting administrative inspections authorized by this act or rules hereunder, and seizures of property appropriate to the inspections. For purposes of the issuance of administrative inspection warrants, probable cause exists upon showing a valid public interest in the effective enforcement of this act or rules hereunder, sufficient to justify administrative inspection of the area, premises, building, or conveyance in the circumstances specified in the application for the warrant;

(2) A warrant shall issue only upon an affidavit of a designated officer or employee having knowledge of the facts alleged, sworn to before the judge and establishing the grounds for issuing the warrant. If the judge is satisfied that grounds for the application exist or that there is probable cause to believe they exist, he shall issue a warrant identifying the area, premises, building, or conveyance to be inspected, the purpose of the inspection, and, if appropriate, the type of property to be inspected, if any. The warrant shall:

(i) State the grounds for its issuance and the name of each person whose affidavit has been taken in support thereof;

(ii) Be directed to a person authorized by section 501 to execute it;

(iii) Command the person to whom it is directed to inspect the area, premises, building, or conveyance identified for the purpose specified and, if appropriate, direct the seizure of the property specified;

(iv) Identify the item or types of property to be seized, if any;

(v) Direct that it be served during normal business hours and designate the judge to whom it shall be returned.

(3) A warrant issued pursuant to this section must be executed and returned within ten days of its date unless, upon a showing of a need for additional time, the court orders otherwise. If property is seized pursuant to a warrant, a copy shall be given to the person from whom or from whose premises the property is taken, together with a receipt for the property taken. The return of the warrant shall be made promptly, accompanied by a written inventory of any property taken. The inventory shall be made in the presence of the person executing the warrant and of the person from whose possession or premises the property was taken, if present, or in the presence of at least one credible person other than the person executing the warrant. A copy of the inventory shall be delivered to the person from whom or from whose premises the property was taken and to the applicant for the warrant;

(4) The judge who has issued a warrant shall attach thereto a copy of the return and all papers returnable in connection therewith and file them with the clerk of the court.

(b) Administrative inspections of controlled premises shall be made in accordance with the following provisions:

(1) For purposes of this section only, "controlled premises" means:

(i) Places where persons registered or exempted from registration requirements under this act are required to keep records; and

(ii) Places including factories, warehouses, establishments, and conveyances in which persons registered or exempted from registration requirements under this act are permitted to hold, manufacture, compound, process, sell, deliver, or otherwise dispose of any controlled substance.

(2) When authorized by an administrative inspection warrant issued pursuant to subsection (a), any person authorized in subsection (b), section 501 of this article to execute and serve the same, upon presenting the warrant and appropriate credentials to the owner, operator, or agent in charge, may enter controlled premises for the purpose of conducting an administrative inspection.

(3) When authorized by an administrative inspection warrant, any such person may:

(i) Inspect and copy records required by this act to be kept;

(ii) Inspect, within reasonable limits and in a reasonable manner, controlled premises and all pertinent equipment, finished and unfinished material, containers and labeling found therein, and, except as provided in subsection (b) (5), all other things therein, including records, files, papers, processes, controls, and facilities bearing on violation of this act; and

(iii) Inventory any stock of any controlled substance therein and obtain samples thereof.

(4) This section does not prevent the inspection without a warrant of books and records pursuant to an administrative subpoena issued in accordance with any pertinent provision of this code, nor does it prevent entries and administrative inspections, including seizures of property, without a warrant:

(i) If the owner, operator, or agent in charge of the controlled premises consents;

(ii) In situations presenting imminent danger to health or safety;

(iii) In situations involving inspection of conveyances if there is reasonable cause to believe that the mobility of the conveyance makes it impracticable to obtain a warrant;

(iv) In any other exceptional or emergency circumstance where time or opportunity to apply for a warrant is lacking; or,

(v) In all other situations in which a warrant is not constitutionally required.

(5) An inspection authorized by this section shall not extend to financial data, sales data, other than shipment data, or pricing data unless the owner, operator, or agent in charge of the controlled premises consents in writing.

§60A-5-503. Injunctions.
(a) The courts of record of this state have and may exercise jurisdiction to restrain or enjoin violations of this act.

(b) The defendant may demand trial by jury for an alleged violation of an injunction or restraining order under this section.

§60A-5-504. Cooperative arrangements; confidentiality; treatment of minor without knowledge or consent of parent or guardian.
(a) The state board of pharmacy and the appropriate departments, boards, and agencies, as specified in section 301, shall cooperate with federal and other state agencies in discharging their responsibilities concerning traffic in controlled substances and in suppressing the abuse of controlled substances. To this end, they may:

(1) Arrange for the exchange of information among governmental officials concerning the use and abuse of controlled substances;

(2) Coordinate and cooperate in training programs concerning controlled substance law enforcement at local and state levels;

(3) Cooperate with the bureau by establishing a centralized unit to accept, catalogue, file, and collect statistics, including records of drug dependent persons and other controlled substance law offenders within the state, and make the information available for federal, state, and local law

enforcement purposes. They shall not furnish the name or identity of a patient or research subject whose identity could not be obtained under subsection (c); and

(4) Conduct programs of eradication aimed at destroying wild or illicit growth of plant species from which controlled substances may be extracted.

(b) Results, information, and evidence received from the bureau relating to the regulatory functions of this chapter, including results of inspections conducted by it may be relied and acted upon by the state board of pharmacy in the exercise of its regulatory functions under this chapter.

(c) A practitioner engaged in medical practice or research is not required or compelled to furnish the name or identity of a patient or research subject to the state board of pharmacy or to the appropriate department, board, or agency by which he is licensed or registered, as specified in section 301, nor may he be compelled in any state or local civil, criminal, administrative, legislative, or other proceedings to furnish the name or identity of an individual that the practitioner is obligated to keep confidential.

(d) No mental health organization or hospital shall be compelled in any state or local civil, criminal, administrative, legislative or other proceeding to furnish the name or identity of any person voluntarily requesting treatment for or rehabilitation from addiction to or dependency upon the use of a controlled substance as defined in article one of this chapter.

(e) Notwithstanding any other provision of law, any licensed physician or competent medically trained person under his direction may examine, diagnose, and treat any minor at his or her request for any addiction to or dependency upon the use of a controlled substance as defined in article one of this chapter without the knowledge or consent of the minor's parent or guardian. Such physician and such other persons shall not incur any civil or criminal liability in connection therewith except for negligence or willful injury.

CHAPTER 60A. UNIFORM CONTROLLED SUBSTANCES ACT.
ARTICLE 9. CONTROLLED SUBSTANCES MONITORING.

§60A-9-1. Short title.
This article shall be referred to as the West Virginia Controlled Substances Monitoring Act.

§60A-9-2. Establishment of program; purpose.
There is hereby established a West Virginia controlled substances monitoring act the purpose of which is to require the recordation and retention in a single repository of information regarding the prescribing, dispensing and consumption of certain controlled substances.

§60A-9-3. Reporting system requirements; implementation; central repository requirement.

(a) The Board of Pharmacy shall implement a program wherein a central repository is established and maintained which shall contain such information as is required by the provisions

of this article regarding Schedule II, III, and IV controlled substance prescriptions written or filled in this state. In implementing this program, the Board of Pharmacy shall consult with the West Virginia State Police, the licensing boards of practitioners affected by this article and affected practitioners.

(b) The program authorized by subsection (a) of this section shall be designed to minimize inconvenience to patients, prescribing practitioners and pharmacists while effectuating the collection and storage of the required information. The board shall allow reporting of the required information by electronic data transfer where feasible, and where not feasible, on reporting forms promulgated by the board. The information required to be submitted by the provisions of this article shall be required to be filed no more frequently than within twenty-four hours.

(c) (1) The board shall provide for the electronic transmission of the information required to be provided by this article by and through the use of a toll-free telephone line.

(2) A dispenser, who does not have an automated record-keeping system capable of producing an electronic report in the established format may request a waiver from electronic reporting. The request for a waiver shall be made to the board in writing and shall be granted if the dispenser agrees in writing to report the data by submitting a completed "Pharmacy Universal Claim Form" as defined by legislative rule.

§60A-9-4. Required information.

(a) Whenever a medical services provider dispenses a controlled substance listed in Schedule II, III or IV as established under the provisions of article two of this chapter or an opioid antagonist, or whenever a prescription for the controlled substance or opioid antagonist is filled by: (i) A pharmacist or pharmacy in this state; (ii) a hospital, or other health care facility, for out-patient use; or (iii) a pharmacy or pharmacist licensed by the Board of Pharmacy, but situated outside this state for delivery to a person residing in this state, the medical services provider, health care facility, pharmacist or pharmacy shall, in a manner prescribed by rules promulgated by the board under this article, report the following information, as applicable:

(1) The name, address, pharmacy prescription number and Drug Enforcement Administration controlled substance registration number of the dispensing pharmacy or the dispensing physician or dentist;

(2) The full legal name, address and birth date of the person for whom the prescription is written;

(3) The name, address and Drug Enforcement Administration controlled substances registration number of the practitioner writing the prescription;

(4) The name and national drug code number of the Schedule II, III and IV controlled substance or opioid antagonist dispensed;

(5) The quantity and dosage of the Schedule II, III and IV controlled substance or opioid antagonist dispensed;

(6) The date the prescription was written and the date filled;

(7) The number of refills, if any, authorized by the prescription;

(8) If the prescription being dispensed is being picked up by someone other than the patient on behalf of the patient, the first name, last name and middle initial, address and birth date of the person picking up the prescription as set forth on the person's government-issued photo identification card shall be retained in either print or electronic form until such time as otherwise directed by rule promulgated by the board; and

(9) The source of payment for the controlled substance dispensed.

(b) The board may prescribe by rule promulgated under this article the form to be used in prescribing a Schedule II, III, and IV substance or opioid antagonist if, in the determination of the board, the administration of the requirements of this section would be facilitated.

(c) Products regulated by the provisions of article ten of this chapter shall be subject to reporting pursuant to the provisions of this article to the extent set forth in said article.

(d) Reporting required by this section is not required for a drug administered directly to a patient by a practitioner. Reporting is, however, required by this section for a drug dispensed to a patient by a practitioner: *Provided*, That the quantity dispensed by a prescribing practitioner to his or her own patient may not exceed an amount adequate to treat the patient for a maximum of seventy-two hours with no greater than two seventy-two-hour cycles dispensed in any fifteen-day period of time.

(e) The Board of Pharmacy shall notify a physician prescribing buprenorphine or buprenorphine/naloxone within sixty days of the availability of the an abuse deterrent form of buprenorphine or buprenorphine/naloxone is approved by the Food and Drug Administration as provided in FDA Guidance to Industry. Upon receipt of the notice, a physician may switch their patients using buprenorphine or buprenorphine/naloxone to the abuse deterrent form of the drug.

§60A-9-4a. Verification of identity.

Prior to releasing a Schedule II, III, or IV controlled substance sold at retail, a pharmacist or pharmacy shall verify the full legal name, address and birth date of the person picking up the controlled substance dispensed by requiring the presentation of a valid government-issued photo identification card. This information shall be reported in accordance with the provisions of this article.

§60A-9-5. Confidentiality; limited access to records; period of retention; no civil liability for required reporting.

(a)(1) The information required by this article to be kept by the board is confidential and not subject to the provisions of chapter twenty-nine-b of this code or obtainable as discovery in civil matters absent a court order and is open to inspection only by inspectors and agents of the board, members of the West Virginia State Police expressly authorized by the Superintendent of the West Virginia State Police to have access to the information, authorized agents of local law-enforcement agencies as members of a federally affiliated drug task force, authorized agents of the federal Drug Enforcement Administration, duly authorized agents of the Bureau for Medical Services, duly authorized agents of the Office of the Chief Medical Examiner for use in post-mortem examinations, duly authorized agents of licensing boards of practitioners in this state and other states authorized to prescribe Schedules II, III and IV controlled substances, prescribing practitioners and pharmacists and persons with an enforceable court order or regulatory agency administrative subpoena: *Provided*, That all law-enforcement personnel who have access to the Controlled Substances Monitoring Program database shall be granted access in accordance with applicable state laws and the board's legislative rules, shall be certified as a West Virginia law-enforcement officer and shall have successfully completed training approved by the board. All information released by the board must be related to a specific patient or a specific individual or entity under investigation by any of the above parties except that practitioners who prescribe or dispense controlled substances may request specific data related to their Drug Enforcement Administration controlled substance registration number or for the purpose of providing treatment to a patient: *Provided, however*, That the West Virginia Controlled Substances Monitoring Program Database Review Committee established in subsection (b) of this section is authorized to query the database to comply with said subsection.

(2) Subject to the provisions of subdivision (1) of this subsection, the board shall also review the West Virginia Controlled Substance Monitoring Program database and issue reports that identify abnormal or unusual practices of patients who exceed parameters as determined by the advisory committee established in this section. The board shall communicate with practitioners and dispensers to more effectively manage the medications of their patients in the manner recommended by the advisory committee. All other reports produced by the board shall be kept confidential. The board shall maintain the information required by this article for a period of not less than five years. Notwithstanding any other provisions of this code to the contrary, data obtained under the provisions of this article may be used for compilation of educational, scholarly or statistical purposes, and may be shared with the West Virginia Department of Health and Human Resources for those purposes, as long as the identities of persons or entities and any personally identifiable information, including protected health information, contained therein shall be redacted, scrubbed or otherwise irreversibly destroyed in a manner that will preserve the confidential nature of the information. No individual or entity required to report under section four of this article may be subject to a claim for civil damages or other civil relief for the reporting of information to the board as required under and in accordance with the provisions of this article.

(3) The board shall establish an advisory committee to develop, implement and recommend parameters to be used in identifying abnormal or unusual usage patterns of patients in this state. This advisory committee shall:

(A) Consist of the following members: A physician licensed by the West Virginia Board of Medicine, a dentist licensed by the West Virginia Board of Dental Examiners, a physician licensed by the West Virginia Board of Osteopathic Medicine, a licensed physician certified by the American Board of Pain Medicine, a licensed physician board certified in medical oncology recommended by the West Virginia State Medical Association, a licensed physician board certified in palliative care recommended by the West Virginia Center on End of Life Care, a pharmacist licensed by the West Virginia Board of Pharmacy, a licensed physician member of the West Virginia Academy of Family Physicians, an expert in drug diversion and such other members as determined by the board.

(B) Recommend parameters to identify abnormal or unusual usage patterns of controlled substances for patients in order to prepare reports as requested in accordance with subsection (a), subdivision (2) of this section.

(C) Make recommendations for training, research and other areas that are determined by the committee to have the potential to reduce inappropriate use of prescription drugs in this state, including, but not limited to, studying issues related to diversion of controlled substances used for the management of opioid addiction.

(D) Monitor the ability of medical services providers, health care facilities, pharmacists and pharmacies to meet the twenty-four hour reporting requirement for the Controlled Substances Monitoring Program set forth in section three of this article, and report on the feasibility of requiring real-time reporting.

(E) Establish outreach programs with local law enforcement to provide education to local law enforcement on the requirements and use of the Controlled Substances Monitoring Program database established in this article.

(b) The board shall create a West Virginia Controlled Substances Monitoring Program Database Review Committee of individuals consisting of two prosecuting attorneys from West Virginia counties, two physicians with specialties which require extensive use of controlled substances and a pharmacist who is trained in the use and abuse of controlled substances. The review committee may determine that an additional physician who is an expert in the field under investigation be added to the team when the facts of a case indicate that the additional expertise is required. The review committee, working independently, may query the database based on parameters established by the advisory committee. The review committee may make determinations on a case-by-case basis on specific unusual prescribing or dispensing patterns indicated by outliers in the system or abnormal or unusual usage patterns of controlled substances by patients which the review committee has reasonable cause to believe necessitates further action by law enforcement or the licensing board having jurisdiction over the practitioners or dispensers under consideration. The review committee shall also review notices provided by the chief medical examiner pursuant to subsection (h), section ten, article twelve, chapter sixty-one of this code and determine on a case-by-case basis whether a practitioner who prescribed or dispensed a controlled substance resulting in or contributing to the drug overdose may have breached professional or occupational standards or committed a criminal act when

prescribing the controlled substance at issue to the decedent. Only in those cases in which there is reasonable cause to believe a breach of professional or occupational standards or a criminal act may have occurred, the review committee shall notify the appropriate professional licensing agency having jurisdiction over the applicable practitioner or dispenser and appropriate law-enforcement agencies and provide pertinent information from the database for their consideration. The number of cases identified shall be determined by the review committee based on a number that can be adequately reviewed by the review committee. The information obtained and developed may not be shared except as provided in this article and is not subject to the provisions of chapter twenty-nine-b of this code or obtainable as discovering in civil matters absent a court order.

(c) The board is responsible for establishing and providing administrative support for the advisory committee and the West Virginia Controlled Substances Monitoring Program Database Review Committee. The advisory committee and the review committee shall elect a chair by majority vote. Members of the advisory committee and the review committee may not be compensated in their capacity as members but shall be reimbursed for reasonable expenses incurred in the performance of their duties.

(d) The board shall promulgate rules with advice and consent of the advisory committee, in accordance with the provisions of article three, chapter twenty-nine-a of this code. The legislative rules must include, but shall not be limited to, the following matters:

(1) Identifying parameters used in identifying abnormal or unusual prescribing or dispensing patterns;

(2) Processing parameters and developing reports of abnormal or unusual prescribing or dispensing patterns for patients, practitioners and dispensers;

(3) Establishing the information to be contained in reports and the process by which the reports will be generated and disseminated; and

(4) Setting up processes and procedures to ensure that the privacy, confidentiality, and security of information collected, recorded, transmitted and maintained by the review committee is not disclosed except as provided in this section.

(e) Persons or entities with access to the West Virginia Controlled Substances Monitoring Program database pursuant to this section may, pursuant to rules promulgated by the board, delegate appropriate personnel to have access to said database.

(f) Good faith reliance by a practitioner on information contained in the West Virginia Controlled Substances Monitoring Program database in prescribing or dispensing or refusing or declining to prescribe or dispense a schedule II, III, or IV controlled substance shall constitute an absolute defense in any civil or criminal action brought due to prescribing or dispensing or refusing or declining to prescribe or dispense.

(g) A prescribing or dispensing practitioner may notify law enforcement of a patient who, in the prescribing or dispensing practitioner's judgment, may be in violation of section four hundred ten, article four of this chapter, based on information obtained and reviewed from the controlled substances monitoring database. A prescribing or dispensing practitioner who makes a notification pursuant to this subsection is immune from any civil, administrative or criminal liability that otherwise might be incurred or imposed because of the notification if the notification is made in good faith.

(h) Nothing in the article may be construed to require a practitioner to access the West Virginia Controlled Substances Monitoring Program database except as provided in section five-a of this article.

(i) The board shall provide an annual report on the West Virginia Controlled Substance Monitoring Program to the Legislative Oversight Commission on Health and Human Resources Accountability with recommendations for needed legislation no later than January 1 of each year.

§60A-9-5a. Practitioner requirements to access database and conduct annual search of the database; required rulemaking.

(a) All practitioners, as that term is defined in section one hundred-one, article two of this chapter who prescribe or dispense Schedule II, III or IV controlled substances shall register with the West Virginia Controlled Substances Monitoring Program and obtain and maintain online or other electronic access to the program database: *Provided,* That compliance with the provisions of this subsection must be accomplished within thirty days of the practitioner obtaining a new license: *Provided, however,* That no licensing board may renew a practitioner's license without proof that the practitioner meet the requirements of this subsection.

(b) Upon initially prescribing or dispensing any pain-relieving controlled substance for a patient and at least annually thereafter should the practitioner or dispenser continue to treat the patient with controlled substances, all persons with prescriptive or dispensing authority and in possession of a valid Drug Enforcement Administration registration identification number and, who are licensed by the Board of Medicine as set forth in article three, chapter thirty of this code, the Board of Registered Professional Nurses as set forth in article seven, chapter thirty of this code, the Board of Dental Examiners as set forth in article four, chapter thirty of this code and the Board of Osteopathic Medicine as set forth in article fourteen, chapter thirty of this code shall access the West Virginia Controlled Substances Monitoring Program database for information regarding specific patients for whom they are providing pain-relieving controlled substances as part of a course of treatment for chronic, nonmalignant pain but who are not suffering from a terminal illness. The information obtained from accessing the West Virginia Controlled Substances Monitoring Program database for the patient shall be documented in the patient's medical record. A pain-relieving controlled substance shall be defined as set forth in section one, article three-a, chapter thirty of this code.

(c) The various boards mentioned in subsection (b) of this section above shall promulgate both emergency and legislative rules pursuant to the provisions of article three, chapter twenty-nine-a of this code to effectuate the provisions of this section.

§60A-9-6. Promulgation of rules.

The state board of pharmacy shall promulgate legislative rules to effectuate the purposes of this article in accordance with the provisions of chapter twenty-nine-a of this code.

§60A-9-7. Criminal penalties; and administrative violations.

(a) Any person who is required to submit information to the state Board of Pharmacy pursuant to the provisions of this article who fails to do so as directed by the board is guilty of a misdemeanor and, upon conviction thereof, shall be fined not less than $100 nor more than $500.

(b) Any person who is required to submit information to the state Board of Pharmacy pursuant to the provisions of this article who knowingly and willfully refuses to submit the information required by this article is guilty of a misdemeanor and, upon conviction thereof, shall be confined in a county or regional jail not more than six months or fined not more than $1,000, or both confined and fined.

(c) Any person who is required by the provisions of this article to submit information to the state Board of Pharmacy who knowingly submits thereto information known to that person to be false or fraudulent is guilty of a misdemeanor and, upon conviction thereof, shall be confined in a county or regional jail not more than one year or fined not more than $5,000, or both confined and fined.

(d) Any person granted access to the information required by the provisions of this article to be maintained by the state Board of Pharmacy, who shall willfully disclose the information required to be maintained by this article in a manner inconsistent with a legitimate law-enforcement purpose, a legitimate professional regulatory purpose, the terms of a court order or as otherwise expressly authorized by the provisions of this article is guilty of a misdemeanor and, upon conviction thereof, shall be confined in a county or regional jail for not more than six months or fined not more than $1,000, or both confined and fined.

(e) Unauthorized access or use or unauthorized disclosure for reasons unrelated to the purposes of this article of the information in the database is a felony punishable by imprisonment in a state correctional facility for not less than one year nor more than five years or fined not less than $3,000 nor more than $10,000, or both imprisoned or fined.

(f) Any practitioner who fails to register with the West Virginia Controlled Substances Monitoring Program and obtain and maintain online or other electronic access to the program database as required in subsection (a), section five-a, article nine of this chapter, shall be subject to an administrative penalty of $1,000 by the licensing board of his or her licensure. All such fines collected pursuant to this subsection shall be remitted by the applicable licensing board to

the Fight Substance Abuse Fund created under section eight of this article. The provisions of this subsection shall become effective on July 1, 2016.

(g) Any practitioner or dispenser who is required to access the information contained in the West Virginia Controlled Substances Monitoring Program database as set forth in subsection (a), section five-a of this article and fails to do so as directed by the rules of his or her licensing board shall be subject to such discipline as the licensing board deems appropriate and on or after July 1, 2016, be subject to a $100 administrative penalty per violation by the applicable licensing board. All such fines collected pursuant to this subsection shall be transferred by the applicable licensing board to the Fight Substance Abuse Fund created under section eight of this article.

(h) Lack of available internet connectivity is a defense to any action brought pursuant to subsections (d) or (f) of this section.

§60A-9-8. Creation of Fight Substance Abuse Fund.

There is hereby created a special revenue account in the state treasury, designated the Fight Substance Abuse Fund, which shall be an interest-bearing account. The fund shall consist of all moneys received from whatever source to further the purpose of this article. The fund shall be administered by the West Virginia Bureau for Public Health to provide funding for substance abuse prevention, treatment, treatment coordination, recovery and education. Any moneys remaining in the fund at the close of a fiscal year shall be carried forward for use in the next fiscal year. Fund balances shall be invested with the state's consolidated investment fund and any and all interest earnings on these investments shall be used solely for the purposes that moneys deposited in the fund may be used pursuant to this article. There is created within the Office of the Secretary of the Department of Health and Human Resources the Grant Writer Pilot Project. The Secretary shall hire a person as a grant writer, who shall be placed within the Office of the Secretary. This person shall identify, application and monitoring policies and procedures to increase grant applications and improve management and oversight of grants. The grant writer shall focus his or her abilities on obtaining grants concerning the prevention and treatment of substance abuse. The grant writer is not eligible for civil service. The department shall report to the Legislative Oversight Commission on Health and Human Resources Accountability on the implementation of the new grant policy; the number of grants obtained; and an analysis examining the costs associated with obtaining a grant verses the federal money received.

CHAPTER 60A. UNIFORM CONTROLLED SUBSTANCES ACT.
ARTICLE 10. METHAMPHETAMINE LABORATORY ERADICATION ACT.

§60A-10-1. Short title.
The provisions of this article shall be known and referred to as the Methamphetamine Laboratory Eradication Act.

§60A-10-2. Purpose; findings.
The Legislature finds:

(a) That the illegal production and distribution of methamphetamine is an increasing problem nationwide and particularly prevalent in rural states such as West Virginia.

(b) That methamphetamine is a highly addictive drug that can be manufactured in small and portable laboratories. These laboratories are operated by individuals who manufacture the drug in a clandestine and unsafe manner, often resulting in explosions and fires that can injure not only the individuals involved, but their families, neighbors, law-enforcement officers and firemen.

(c) That use of methamphetamine can result in fatal kidney and lung disorders, brain damage, liver damage, blood clots, chronic depression, hallucinations, violent and aggressive behavior, malnutrition, disturbed personality development, deficient immune system and psychosis. Children born to mothers who are abusers of methamphetamine can be born addicted and suffer birth defects, low birth weight, tremors, excessive crying, attention deficit disorder and behavior disorders.

(d) That in addition to the physical consequences to an individual who uses methamphetamine, usage of the drug also produces an increase in automobile accidents, explosions and fires, increased criminal activity, increased medical costs due to emergency room visits, increases in domestic violence, increased spread of infectious diseases and a loss in worker productivity.

(e) That environmental damage is another consequence of the methamphetamine epidemic. Each pound of methamphetamine produced leaves behind five to six pounds of toxic waste. Chemicals and byproducts that result from the manufacture of methamphetamine are often poured into plumbing systems, storm drains or directly onto the ground. Clean up of methamphetamine laboratories is extremely resource-intensive, with an average remediation cost of five thousand dollars.

(f) That it is in the best interest of every West Virginian to develop a viable solution to address the growing methamphetamine problem in the State of West Virginia. The Legislature finds that restricting access to over-the-counter drugs used to facilitate production of methamphetamine is necessary to protect the public safety of all West Virginians.

(g) That it is further in the best interests of every West Virginian to create impediments to the manufacture of methamphetamine by requiring persons purchasing chemicals necessary to the process to provide identification.

§60A-10-3. Definitions.

In this article:

(a) "Board of Pharmacy" or "board" means the West Virginia Board of Pharmacy established by the provisions of article five, chapter thirty of this code.

(b) "Designated precursor" means any drug product made subject to the requirements of this article by the provisions of section ten of this article.

(c) "Distributor" means any person within this state or another state, other than a manufacturer or wholesaler, who sells, delivers, transfers or in any manner furnishes a drug product to any person who is not the ultimate user or consumer of the product.

(d) "Drug product" means a pharmaceutical product that contains ephedrine, pseudoephedrine or phenylpropanolamine or a substance identified on the supplemental list provided in section seven of this article which may be sold without a prescription and which is labeled for use by a consumer in accordance with the requirements of the laws and rules of this state and the federal government.

(e) "Ephedrine " means ephedrine, its salts or optical isomers or salts of optical isomers.

(f) "Manufacturer" means any person within this state who produces, compounds, packages or in any manner initially prepares for sale or use any drug product or any such person in another state if they cause the products to be compounded, packaged or transported into this state.

(g) "National Association of Drug Diversion Investigators" or "NADDI" means the non-profit 501(c)(3) organization established in 1989, made up of members who are responsible for investigating and prosecuting pharmaceutical drug diversion, and that facilitates cooperation between law enforcement, health care professionals, state regulatory agencies and pharmaceutical manufacturers in the investigation and prevention of prescription drug abuse and diversion.

(h) "Multi-State Real-Time Tracking System" or "MSRTTS" means the real-time electronic logging system provided by NADDI at no cost to states that have legislation requiring real-time electronic monitoring of precursor purchases, and agree to use the system. MSRTTS is used by pharmacies and law enforcement to track sales of over-the-counter (OTC) cold and allergy medications containing precursors to the illegal drug, methamphetamine.

(i) "Phenylpropanolamine" means phenylpropanolamine, its salts, optical isomers and salts of optical isomers.

(j) "Pseudoephedrine" means pseudoephedrine, its salts, optical isomers and salts of optical isomers.

(k) "Precursor" means any substance which may be used along with other substances as a component in the production and distribution of illegal methamphetamine.

(l) "Pharmacist" means an individual currently licensed by this state to engage in the practice of pharmacist care as defined in article five, chapter thirty of this code.

(m) "Pharmacy intern" has the same meaning as the term "intern" as set forth in section one-b, article five, chapter thirty of this code.

(n) "Pharmacy" means any drugstore, apothecary or place within this state where drugs are dispensed and sold at retail or display for sale at retail and pharmacist care is provided outside of this state where drugs are dispensed and pharmacist care is provided to residents of this state.

(o) "Pharmacy counter" means an area in the pharmacy restricted to the public where controlled substances are stored and housed and where controlled substances may only be sold, transferred or dispensed by a pharmacist, pharmacy intern or pharmacy technician.

(p) "Pharmacy technician" means a registered technician who meets the requirements for registration as set forth in article five, chapter thirty of this code.

(q) "Retail establishment" means any entity or person within this state who sells, transfers or distributes goods, including over-the-counter drug products, to an ultimate consumer.

(r) "Schedule V" means the schedule of controlled substances set out in section two hundred twelve, section two of this chapter.

(s) "Superintendent of the State Police" or "Superintendent" means the Superintendent of the West Virginia State Police as set forth in section five, article two, chapter fifteen of this code.

(t) "Wholesaler" means any person within this state or another state, other than a manufacturer, who sells, transfers or in any manner furnishes a drug product to any other person in this state for the purpose of being resold.

§60A-10-4. Purchase, receipt, acquisition and possession of substances to be used as precursor to manufacture of methamphetamine or another controlled substance; offenses; exceptions; penalties.

(a) A pharmacy may not sell, transfer or dispense to the same person, and a person may not purchase more than three and six- tenths grams per day, more than seven and two-tenths grams in a thirty-day period or more than forty-eight grams annually of ephedrine, pseudoephedrine or phenylpropanolamine without a prescription. The limits shall apply to the total amount of ephedrine, pseudoephedrine and phenylpropanolamine contained in the products, and not the overall weight of the products.

(1) Any person who or knowingly purchases, receives or otherwise possesses more than seven and two-tenths grams in a thirty-day period of ephedrine, pseudoephedrine or phenylpropanolamine in any form without a prescription is guilty of a misdemeanor and, upon conviction, shall be confined in a jail for not more than one year, fined not more than $1,000, or both fined and confined.

(2) Any pharmacy, wholesaler or other entity operating the retail establishment which sells, transfers or dispenses a product in violation of this section is guilty of a misdemeanor and, upon conviction, shall be fined not more than $1,000 for the first offense, or more than $10,000 for each subsequent offense.

(b) Notwithstanding the provisions of subdivision (a)(1) of this section, any person convicted of a second or subsequent violation of the provisions of said subdivision or a statute or ordinance of the United States or another state which contains the same essential elements is guilty of a felony and, upon conviction, shall be imprisoned in a state correctional facility for not less than one nor more than five years, fined not more than $25,000, or both imprisoned and fined.

(c) The provisions of subsection (a) of this section shall not apply to:

(1) Products dispensed pursuant to a valid prescription;

(2) Drug products which are for pediatric use primarily intended for administration to children under the age of twelve;

(3) Drug products containing ephedrine, pseudoephedrine or phenylpropanolamine, their salts or optical isomers or salts of optical isomers or other designated precursor which have been determined by the Board of Pharmacy to be in a form which is not feasible for being used for the manufacture of methamphetamine; or

(4) Persons lawfully possessing drug products in their capacities as distributors, wholesalers, manufacturers, pharmacists, pharmacy interns, pharmacy technicians, or health care professionals.

(d) Notwithstanding any provision of this code to the contrary, any person who knowingly possesses any amount of ephedrine, pseudoephedrine, phenylpropanolamine or other designated precursor with the intent to use it in the manufacture of methamphetamine or who knowingly possesses a substance containing ephedrine, pseudoephedrine or phenylpropanolamine or their salts, optical isomers or salts of optical isomers in a state or form which is, or has been altered or converted from the state or form in which these chemicals are, or were, commercially distributed is guilty of a felony and, upon conviction, shall be imprisoned in a state correctional facility for not less than two nor more than ten years, fined not more than $25,000, or both imprisoned and fined.

(e) (1) Any pharmacy, wholesaler, manufacturer or distributor of drug products containing ephedrine, pseudoephedrine, phenylpropanolamine, their salts or optical isomers or salts of optical isomers or other designated precursor shall obtain a registration annually from the State Board of Pharmacy as described in section six of this article. Any such pharmacy, wholesaler, manufacturer or distributor shall keep complete records of all sales and transactions as provided in section eight of this article. The records shall be gathered and maintained pursuant to legislative rule promulgated by the Board of Pharmacy.

(2) Any drug products possessed without a registration as provided in this section are subject to forfeiture upon conviction for a violation of this section.

(3) In addition to any administrative penalties provided by law, any violation of this subsection is a misdemeanor, punishable upon conviction by a fine in an amount not more than $10,000.

§60A-10-5. Restrictions on the sale, transfer or delivery of certain drug products; penalties.

(a) No pharmacy or individual may display, offer for sale or place a drug product containing ephedrine, pseudoephedrine or phenylpropanolamine or other designated precursor where the public may freely access the drug product. All such drug products or designated precursors shall be placed behind a pharmacy counter where access is restricted to a pharmacist, a pharmacy intern, a pharmacy technician or other pharmacy employee.

(b) All storage of drug products regulated by the provisions of this section shall be in a controlled and locked access location that is not accessible by the general public and shall maintain strict inventory control standards and complete records of quantity of the product maintained in bulk form.

(c) No pharmacy may sell, deliver or provide any drug product regulated by the provisions of this section to any person who is under the age of eighteen.

(d) If a drug product regulated by the provisions of this section is transferred, sold or delivered, the individual, pharmacy or retail establishment transferring, selling or delivering the drug product shall offer to have a pharmacist provide patient counseling, as defined by article five, chapter thirty of this code and the rules of the Board of Pharmacy, to the person purchasing, receiving or acquiring the drug product in order to improve the proper use of the drug product and to discuss contraindications.

(e) If a drug product regulated by the provisions of this section is transferred, sold or delivered, the individual, pharmacy or retail establishment transferring, selling or delivering the drug product shall require the person purchasing, receiving or otherwise acquiring the drug product to:

(1) Produce a valid government-issued photo identification showing his or her date of birth; and

(2) Sign a logbook, in either paper or electronic format, containing the information set forth in subsection (b), section eight of this article and attesting to the validity of the information.

(f) Any person who knowingly makes a false representation or statement pursuant to the requirements of this section is guilty of a misdemeanor and, upon conviction, be confined in a jail for not more than six months, fined not more than $5,000, or both fined and confined.

(g) (1) The pharmacist, pharmacy intern or pharmacy technician processing the transaction shall determine that the name entered in the logbook corresponds to the name provided on the identification.

(2) Beginning January 1, 2013, a pharmacy or retail establishment shall, before completing a sale under this section, electronically submit the information required by section eight of this article to the Multi-State Real-Time Tracking System (MSRTTS) administered by the National Association of Drug Diversion Investigators (NADDI): *Provided,* That the system is available to retailers in the state without a charge for accessing the system. This system shall be capable of generating a stop-sale alert, which shall be a notification that completion of the sale would result in the seller or purchaser violating the quantity limits set forth in this article. The seller may not complete the sale if the system generates a stop-sale alert. The system shall contain an override function that may be used by a dispenser of a drug product who has a reasonable fear of imminent bodily harm if he or she does not complete a sale. Each instance in which the override function is utilized shall be logged by the system. Absent negligence, wantonness, recklessness or deliberate misconduct, any retailer utilizing the Multi-State Real-Time Tracking System in accordance with this subdivision may not be civilly liable as a result of any act or omission in carrying out the duties required by this subdivision and is immune from liability to any third party unless the retailer has violated any provision of this subdivision in relation to a claim brought for the violation.

(3) If a pharmacy or retail establishment selling a nonprescription product containing ephedrine, pseudoephedrine or phenylpropanolamine experiences mechanical or electronic failure of the Multi-State Real-Time Tracking System and is unable to comply with the electronic sales tracking requirement, the pharmacy or retail establishment shall maintain a written log or an alternative electronic record keeping mechanism until such time as the pharmacy or retail establishment is able to comply with the electronic sales tracking requirement.

(h) This section does not apply to drug products that are dispensed pursuant to a prescription, are pediatric products primarily intended for administration, according to label instructions, to children under twelve years of age.

(i) Any violation of this section is a misdemeanor, punishable upon conviction by a fine in an amount not more than $10,000.

(j) The provisions of this section supersede and preempt all local laws, ordinances, rules and regulations pertaining to the sale of any compounds, mixtures or preparation containing ephedrine, pseudoephedrine or phenylpropanolamine. **§60A-10-6. Registration to sell, manufacture or distribute products; rule-making authority.**

The State Board of Pharmacy shall propose rules for legislative approval in accordance with the provisions of article three, chapter twenty-nine-a of this code to require that every wholesaler, manufacturer or distributor of any drug product containing as their single active ingredient ephedrine or pseudoephedrine or a substance identified on the supplemental list provided for in section seven of this article shall obtain a registration and permit issued by the State Board of

Pharmacy to sell, distribute or transfer the product containing as their single active ingredient ephedrine, pseudoephedrine or phenylpropanolamine.

§60A-10-7. Restricted products; rule-making authority.

(a) On or before July 1, 2005, the Board of Pharmacy shall promulgate emergency and legislative rules pursuant to the provision of article three, chapter twenty-nine-a of this code to implement a program wherein the Board of Pharmacy shall consult with the Superintendent of the State Police in identifying drug products which are a designated precursor, in addition to those that contain ephedrine, pseudoephedrine or phenylpropanolamine, that are commonly being used in the production and distribution of methamphetamine. Those drug products which the Superintendent of the State Police have demonstrated by empirical evidence are commonly used in the manufacture of methamphetamine shall be added to a supplemental list and shall be subject to all of the restrictions of this article. These rules established pursuant to this section shall include:

(1) A process whereby pharmacies are made aware of all drug products that contain ephedrine, pseudoephedrine and phenylpropanolamine that will be listed as a Schedule V substance and must be sold, transferred or dispensed from behind a pharmacy counter;

(2) A process whereby pharmacies and retail establishments are made aware of additional drug products added to Schedule V that are required to be placed behind the pharmacy counter for sale, transfer or distribution can be periodically reviewed and updated.

(b) At any time after July 1, 2005, the Board of Pharmacy, upon the recommendation of the Superintendent of the State Police, shall promulgate emergency and legislative rules pursuant to the provision of article three, chapter twenty-nine-a of this code to implement an updated supplemental list of products containing the controlled substances ephedrine, pseudoephedrine or phenylpropanolamine as an active ingredient or any other drug used as a precursor in the manufacture of methamphetamine, which the Superintendent of the State Police has demonstrated by empirical evidence is being used in the manufacture of methamphetamine. This listing process shall comport with the requirements of subsection (a) of this section. **§60A-10-8. Reporting requirements; confidentiality.**

(a) Until January 1, 2013, upon each sale, retail, transfer or distribution of any drug product referred to in section seven of this article or another designated precursor, the pharmacist, pharmacy intern, or pharmacy technician making the sale, transfer or distribution shall report the following information for inclusion in the central repository established and maintained by the Board of Pharmacy:

(1) The date of the transaction;

(2) The name, address and driver's license or state-issued identification number of the person; and

(3) The name, quantity of packages and total gram weight of the product or products purchased, received or otherwise acquired.

(b) The information required to be reported by this section shall be reported by paper log maintained at the point of sale: Provided, That, beginning on January 1, 2007, reporting shall be by electronic transmission to the Board of Pharmacy no more frequently than once a week. Beginning on January 1, 2013, the electronic transmission of the information required to be reported in subsection (a) of this section shall be reported to the MSRTTS, and shall be made in real time at the time of the transaction.

(c) The information required by this section shall be the property of the state. The information shall be disclosed as appropriate to the federal Drug Enforcement Administration and to state and local law-enforcement agencies. The information shall not be accessed, used or shared for any purpose other than to ensure compliance with this article and federal law. NADDI shall forward state transaction records in the MSRTTS to the West Virginia State Police weekly, and provide real-time access to MSRTTS information through the MSRTTS online portal to authorized agents of the federal Drug Enforcement Administration and certified law enforcement in this and other states for use in the detection of violations of this article or of federal laws designed to prevent the illegal use, production or distribution of methamphetamine. **§60A-10-9. Persons mandated to report suspected injuries related to methamphetamine production; failure to report; penalty.**

(a) When any medical, dental or mental health professional, Christian Science practitioner, religious healer or emergency medical services personnel has reason to believe that an injury is the direct result of exposure to the production of methamphetamine such person shall immediately, and not more than forty-eight hours after such suspicion arises, report the circumstances or cause a report to be made to a state, county or local law-enforcement agency.

(b) Any person required by this section to report a suspected methamphetamine-related injury who knowingly and intentionally fails to do so or knowingly and intentionally prevents another person acting reasonably from doing so shall be guilty of a misdemeanor and, upon conviction thereof, shall be fined not more than one hundred dollars or imprisoned in jail not more than ten days, or both fined and imprisoned.

§60A-10-10. Authority of the Superintendent of the State Police to leverage grant funds.

The Superintendent of the State Police is encouraged to leverage available grant funds from individuals, foundations, corporations, the federal government, governmental agencies and other organizations or institutions, make and sign any agreement to and perform any act that may be necessary to effectuate these grants. The grant funds shall be dedicated toward a drug court, to provide training programs to state and local prosecutors and law-enforcement agents for the investigation and prosecution of methamphetamine offenses and to enhance funding available to jails.

§60A-10-11. Reporting to the Legislative Oversight Commission on Health and Human Resources Accountability.

Beginning July 1, 2013, the Superintendent of the West Virginia State Police shall submit an annual report no later than July 1 of each year to the Legislative Oversight Commission on Health and Human Resources Accountability with data and statistics related to methamphetamine use, production and distribution in this state including, but not limited to, the number of clandestine methamphetamine lab incidents per year. **§60A-10-12. Exposure of children to methamphetamine manufacturing; penalties.**

(a) Any person eighteen years of age or older who knowingly causes or permits a minor to be present in a location where methamphetamine is manufactured or attempted to be manufactured is guilty of a felony and, upon conviction, shall be confined in a state correctional facility for not less than one nor more than five years, fined not more than ten thousand dollars, or both.

(b) Notwithstanding the provisions of subsection (a) of this section, the penalty for a violation of said subsection when the child suffers serious bodily injury as such is defined in the provisions of section one, chapter eight-b of this code shall be confined in a state correctional facility for not less than three nor more than fifteen years, fined not more than twenty-five thousand dollars, or both.

§60A-10-13. Exposure of first responders to manufacture methamphetamine; penalties.

Any person who, as a result of or in the course of unlawfully and intentionally manufacturing methamphetamine, causes a police officer, probation officer, humane officer, emergency medical service personnel, firefighter, state fire marshal or employee, division of forestry employee, county correctional employee or state correctional employee acting in his or her official capacity to ingest, inhale or be dermally exposed to a chemical, product, byproduct, residue or substance involved in the manufacture or attempted manufacture of such controlled substance, without prior knowledge of such, and thereby causes bodily injury to such persons, shall be guilty of a felony and, upon conviction thereof, shall be fined not less than five hundred nor more than five thousand dollars and confined in a correctional facility for not less than one year nor more than five years. A violation of this section shall constitute a separate offense from the manufacture or attempt to manufacture methamphetamine.

§60A-10-14. Illegal storage of anhydrous ammonia; exceptions.

(a) Any person who stores or conveys anhydrous ammonia in a container that:

(1) Is not approved by the United States Department of Transportation to hold anhydrous ammonia; or

(2) Was not constructed to meet state and federal industrial health and safety standards for holding anhydrous ammonia is guilty of a felony and, upon conviction, shall be confined in a state correctional facility for a determinate period not to exceed five years, fined not more than ten thousand dollars, or both.

(b) The provisions of this section shall not apply to persons authorized by federal or state law, rule or regulation to handle and dispose of hazardous waste or toxic substances while engaged in such conduct.

(c) Any damages arising out of the unlawful possession of, storage of or tampering with anhydrous ammonia equipment shall be the sole responsibility of the person or persons unlawfully possessing, storing or tampering with anhydrous ammonia. In no case shall liability for damages arising out of the unlawful possession of, storage of or tampering with anhydrous ammonia or anhydrous ammonia equipment extend to the lawful owner, installer, maintainer, designer, manufacturer, possessor or seller of the anhydrous ammonia or anhydrous ammonia equipment, unless such damages arise out of the acts or omissions of the owner, installer, maintainer, designer, manufacturer, possessor or seller that constitute negligent misconduct to abide by the laws regarding anhydrous ammonia possession and storage.

§60A-10-15. Iodine solution greater than two percent; prescription or permit required; offenses; penalties.

(a) A person may offer to sell, sell or distribute an iodine matrix only:

(1) As a prescription drug, pursuant to a prescription issued by a veterinarian or physician licensed within the state; or

(2) To a person who is actively engaged in the legal practice of animal husbandry of livestock.

(b) Prescriptions issued under this section:

(1) Shall provide for a specified number of refills;

(2) May be issued by any means authorized by the Board of Pharmacy; and

(3) May be filled by a person other than the veterinarian or physician issuing the prescription.

(c) A person offering iodine matrix for sale:

(1) Shall store the iodine matrix so that the public does not have access to the iodine matrix without the direct assistance or intervention of a retail employee;

(2) Shall keep a record, which may consist of sales receipts of each person purchasing iodine matrix; and

(3) Shall, if necessary to ascertain the identity of the purchaser, ask for proof of identification from the purchaser.

(d) A person engaging in a regulated transaction pursuant to the provisions of subsection (a) of this section shall not possess with intent to distribute or distribute an iodine matrix to a person who:

(1) Does not present a prescription or is not engaged in animal husbandry, as required under subsection (a) of this section; or

(2) Is not excepted under subsection (h) of this section.

(e) Any person who violates subsection (d) of this section is guilty of a misdemeanor and, upon conviction, shall be fined not more than ten thousand dollars.

(f) A person shall not:

(1) Possess iodine crystals and/or an iodine matrix without proof of obtaining the crystals and/or solution in compliance with subsection (a) of this section; or

(2) Possess with intent to distribute or distribute iodine crystals and/or an iodine matrix in violation of subsection (a) of this section.

(g) Any person who violates subsection (f) of this section is guilty of a misdemeanor and, upon conviction, shall be fined not more than ten thousand dollars.

(h) The provisions of subdivision (1), subsection (f) of this section do not apply to:

(1) A public or private regularly established primary or secondary school or a public or private institution of higher education that is accredited by a regional or national accrediting agency recognized by the United States Department of Education;

(2) A veterinarian licensed to practice pursuant to the provisions of article ten, chapter thirty of this code;

(3) A health care facility; or

(4) A veterinarian, physician, pharmacist, retail distributor, wholesaler, manufacturer, warehouseman or common carrier, or an agent of any of these persons, who possesses an iodine matrix in the regular course of lawful business activities.

(5) The transfer or receipt of any betadine or povidone solution with an iodine content not exceeding ten percent in containers of eight ounces or less, or any tincture of iodine not exceeding two percent in containers of one ounce or less that is sold over the counter and is employed solely for its intended common household use.

(i) As used in this section, "iodine matrix" means iodine at a concentration greater than two percent, by weight, in a matrix or solution.

§60A-10-16. Expiration of enactments made during 2017 regular session.

The provisions of this article enacted during the 2017 regular legislative session establishing the Multi-State Real-Time Tracking System shall expire on June 30, 2023.

The most current edition of **The Code of Federal Rules** may be found at:
https://www.gpo.gov/fdsys/browse/collectionCfr.action?selectedYearFrom=2016&go=Go

The **DEA Pharmacists Manual** can be found at:
http://www.deadiversion.usdoj.gov/pubs/manuals/pharm2/index.html
at the bottom of the page is a link to download a complete PDF copy for your use.

The DEA table of Providers vs Controlled Substance category authorized by state may be found at:
http://www.deadiversion.usdoj.gov/drugreg/practioners/mlp_by_state.pdf

NIOSH Hazardous Drugs 2014
http://www.cdc.gov/niosh/docs/2014-138/pdfs/2014-138_v3.pdf

USP Chapter 800 Guidelines
http://www.usp.org/sites/default/files/usp_pdf/EN/m7808.pdf

USP Chapter 795 Guidelines
http://www.usp.org/sites/default/files/usp_pdf/EN/gc795.pdf

USP Chapter 797 Guidelines
http://www.usp.org/sites/default/files/usp_pdf/EN/USPNF/usp-gc-797-proposed-revisions-sep-2015.pdf

CHAPTER 30. PROFESSIONS AND OCCUPATIONS.

ARTICLE 3. WEST VIRGINIA MEDICAL PRACTICE ACT.

§30-3-1. Legislative findings.

The Legislature hereby finds and declares that the practice of medicine and surgery and the practice of podiatry is a privilege and not a natural right of individuals. As a matter of public policy, it is necessary to protect the public interest through enactment of this article and to regulate the granting of such privileges and their use.

§30-3-2. Purpose.

The purpose of this article is to provide for the licensure and professional discipline of physicians and podiatrists and for the licensure and professional discipline of physician assistants and to provide a professional environment that encourages the delivery of quality medical services within this state.

§30-3-3. Short title.

This article shall be known and may be cited as the "West Virginia Medical Practice Act."

§30-3-4. Definitions.

As used in this article:

(1) "Board" means the West Virginia Board of Medicine established in section five of this article.

(2) "Medical peer review committee" means a committee of, or appointed by, a state or local professional medical society, or a committee of, or appointed by, a medical staff of a licensed hospital, long-term care facility or other health care facility, or any health care peer review organization as defined in section one, article three-c of this chapter, or any other organization of professionals in this state formed pursuant to state or federal law and authorized to evaluate medical and health care services.

(3) "Practice of medicine and surgery" means the diagnosis or treatment of, or operation or prescription for, any human disease, pain, injury, deformity or other physical or mental condition. "Surgery" includes the use on humans of lasers, ionizing radiation, pulsed light and radiofrequency devices. The provisions of this section do not apply to any person who is a duly licensed health care provider under other pertinent provisions of this code and who is acting within the scope of his or her license.

(4) "Practice of podiatry" means the examination, diagnosis, treatment, prevention and care of conditions and functions of the human foot and ankle by medical, surgical and other scientific

knowledge and methods; with surgical treatment of the ankle authorized only when a podiatrist has been granted privileges to perform ankle surgery by a hospital's medical staff credentialing committee based on the training and experience of the podiatrist; and medical and surgical treatment of warts and other dermatological lesions of the hand which similarly occur in the foot. When a podiatrist uses other than local anesthesia, in surgical treatment of the foot, the anesthesia must be administered by, or under the direction of, an anesthesiologist or certified registered nurse anesthetist authorized under the State of West Virginia to administer anesthesia. A medical evaluation shall be made by a physician of every patient prior to the administration of other than local anesthesia.

(5) "State health officer" means the commissioner for the Bureau for Public Health or his or her designee, which officer or designee shall be a physician and shall act as secretary of the board and shall carry out any and all responsibilities assigned in this article to the secretary of the board.

§30-3-5. West Virginia Board of Medicine powers and duties continued; appointment and terms of members; vacancies; removal.

The West Virginia Board of Medicine has assumed, carried on and succeeded to all the duties, rights, powers, obligations and liabilities heretofore belonging to or exercised by the Medical Licensing Board of West Virginia. All the rules, orders, rulings, licenses, certificates, permits and other acts and undertakings of the medical licensing board of West Virginia as heretofore constituted have continued as those of the West Virginia Board of Medicine until they expired or were amended, altered or revoked. The board remains the sole authority for the issuance of licenses to practice medicine and surgery and to practice podiatry and to practice as physician assistants in this state under the supervision of physicians licensed under this article. The board shall continue to be a regulatory and disciplinary body for the practice of medicine and surgery and the practice of podiatry and for physician assistants in this state.

The board shall consist of fifteen members. One member shall be the state health officer ex officio, with the right to vote as a member of the board. The other fourteen members shall be appointed by the Governor, with the advice and consent of the Senate. Eight of the members shall be appointed from among individuals holding the degree of doctor of medicine and two shall hold the degree of doctor of podiatric medicine. One member shall be an individual licensed by the board as a physician assistant. Each of these members must be duly licensed to practice his or her profession in this state on the date of appointment and must have been licensed and actively practicing that profession for at least five years immediately preceding the date of appointment. Three lay members shall be appointed to represent health care consumers. Neither the lay members nor any person of the lay members' immediate families shall be a provider of or be employed by a provider of health care services. The state health officer's term shall continue for the period that he or she holds office as state health officer. Each other member of the board shall be appointed to serve a term of five years: *Provided,* That the members of the Board of Medicine holding appointments on the effective date of this section shall continue to serve as members of the Board of Medicine until the expiration of their term unless sooner

removed. Each term shall begin on October 1 of the applicable year, and a member may not be appointed to more than two consecutive full terms on the board.

A person is not eligible for membership on the board who is a member of any political party executive committee or, with the exception of the state health officer, who holds any public office or public employment under the federal government or under the government of this state or any political subdivision thereof.

In making appointments to the board, the Governor shall, so far as practicable, select the members from different geographical sections of the state. When a vacancy on the board occurs and less than one year remains in the unexpired term, the appointee shall be eligible to serve the remainder of the unexpired term and two consecutive full terms on the board.

No member may be removed from office by the Governor except for official misconduct, incompetence, neglect of duty or gross immorality: *Provided*, That the expiration, surrender or revocation of the professional license by the board of a member of the board shall cause the membership to immediately and automatically terminate.

§30-3-6. Conduct of business of West Virginia Board of Medicine; meetings; officers; compensation; expenses; quorum.

Every two years the board shall elect from among its members a president and vice president. Regular meetings shall be held as scheduled by the rules of the board. Special meetings of the board may be called by the joint action of the president and vice president or by any three members of the board on seven days' prior written notice by mail postage prepaid or electronic means or, in case of emergency, on two days' notice by telephone and electronic means. With the exception of the state health officer, members of the board shall receive compensation and expense reimbursement in accordance with section eleven, article one of this chapter.

A majority of the membership of the board constitutes a quorum for the transaction of business, and business is transacted by a majority vote of a quorum, except for disciplinary actions which shall require the affirmative vote of not less than five members or a majority vote of those present, whichever is greater.

Meetings of the board shall be held in public session. Disciplinary proceedings, prior to a finding of probable cause as provided in subsection (p), section fourteen of this article, shall be held in closed sessions, unless the party subject to discipline requests that the proceedings be held in public session.

§30-3-7. Powers and duties of West Virginia Board of Medicine.

(a) The board is autonomous and, in accordance with this article, shall determine qualifications of applicants for licenses to practice medicine and surgery, to practice podiatry, and to practice as a physician assistant for a physician licensed under this article, and shall issue licenses to

qualified applicants and shall regulate the professional conduct and discipline of such individuals. In carrying out its functions, the board may:

(1) Adopt such rules as are necessary to carry out the purposes of this article;

(2) Hold hearings and conduct investigations, subpoena witnesses and documents and administer oaths;

(3) Institute proceedings in the courts of this state to enforce its subpoenas for the production of witnesses and documents and its orders and to restrain and enjoin violations of this article and of any rules promulgated under it;

(4) Employ investigators, attorneys, hearing examiners, consultants and such other employees as may be necessary, who shall be exempt from the classified service of the Division of Personnel and who shall serve at the will and pleasure of the board. In addition, all personnel employed through the Department of Health and Human Resources on June 30, 2009, to provide services for the board are hereby transferred to the board effective July 1, 2009. However, the employment, salary, benefits or position classification of any person transferred under this section may not be reduced or diminished by reason of this section. All persons transferred shall retain their coverage under the classified service of the Division of Personnel and all matters relating to job classification, job tenure and conditions of employment shall remain in force and effect from and after the date of this section, to the same extent as if this section had not been reenacted. Also, nothing herein shall prohibit the disciplining or dismissal of any employee for cause.

(5) Enter into contracts and receive and disburse funds according to law;

(6) Establish and certify standards for the supervision and certification of physician assistants;

(7) Authorize medical and podiatry corporations in accordance with the limitations of section fifteen of this article to practice medicine and surgery or podiatry through duly licensed physicians or podiatrists; and

(8) Perform such other duties as are set forth in this article or otherwise provided for in this code.

(b) The board shall submit an annual report of its activities to the Legislature. The report shall include a statistical analysis of complaints received, charges investigated, charges dismissed after investigation, the grounds for each such dismissal and disciplinary proceedings and disposition.

§30-3-7a. Findings and Rule-making authority.

(a) The Legislature finds that it is appropriate and in the public interest to require the Board of Medicine to regulate the practice of Radiologist Assistants.

(b) The West Virginia Board of Medicine, with the advice of the West Virginia Medical Imaging and Radiation Therapy Technology Board of Examiners, shall propose rules for legislative approval, in accordance with the provisions of article three, chapter twenty-nine-a of this code, to:

(1) Establish the scope of practice of a Radiologist Assistant;

(2) Develop the education and training requirements for a Radiologist Assistant; and

(3) Regulate Radiologist Assistants.

§30-3-8. State health officer to act as secretary of the board.

The state health officer, in addition to being a member of the board, shall act as its secretary. He or she shall, together with the president of the board, sign all licenses, reports, orders and other documents that may be required by the board in the performance of its duties.

§30-3-9. Records of board; expungement; examination; notice; public information; voluntary agreements relating to alcohol or chemical dependency; confidentiality of same; physician-patient privileges.

(a) The board shall maintain a permanent record of the names of all physicians, podiatrists, and physician assistants, licensed, certified or otherwise lawfully practicing in this state and of all persons applying to be so licensed to practice, along with an individual historical record for each such individual containing reports and all other information furnished the board under this article or otherwise. Such record may include, in accordance with rules established by the board, additional items relating to the individual's record of professional practice that will facilitate proper review of such individual's professional competence.

(b) Upon a determination by the board that any report submitted to it is without merit, the report shall be expunged from the individual's historical record.

(c) A physician, podiatrist, physician assistant or applicant, or authorized representative thereof, has the right, upon request, to examine his or her own individual historical record maintained by the board pursuant to this article and to place into such record a statement of reasonable length of his or her own view of the correctness or relevance of any information existing in such record. Such statement shall at all times accompany that part of the record in contention.

(d) A physician, podiatrist, physician assistant or applicant has the right to seek through court action the amendment or expungement of any part of his or her historical record.

(e) A physician, podiatrist, physician assistant or applicant shall be provided written notice within thirty days of the placement and substance of any information in his or her individual historical record that pertains to him or her and that was not submitted to the board by him or her.

(f) Except for information relating to biographical background, education, professional training and practice, a voluntary agreement entered into pursuant to subsection (h) of this section and which has been disclosed to the board, prior disciplinary action by any entity, or information contained on the licensure application, the board shall expunge information in an individual's historical record unless it has initiated a proceeding for a hearing upon such information within two years of the placing of the information into the historical record.

(g) Orders of the board relating to disciplinary action against a physician, podiatrist or physician assistant are public information.

(h)(1) In order to encourage voluntary participation in monitored alcohol chemical dependency or major mental illness programs and in recognition of the fact that major mental illness, alcoholism and chemical dependency are illnesses, a physician, podiatrist or physician assistant licensed, certified or otherwise lawfully practicing in this state or applying for a license to practice in this state may enter into a voluntary agreement with the physician health program as defined in section two, article three-d of this chapter. The agreement between the physician, podiatrist or physician assistant and the physician health program shall include a jointly agreed upon treatment program and mandatory conditions and procedures to monitor compliance with the program of recovery.

(2) Any voluntary agreement entered into pursuant to this subsection shall not be considered a disciplinary action or order by the board, shall not be disclosed to the board and shall not be public information if:

(A) Such voluntary agreement is the result of the physician, podiatrist or physician assistant self-enrolling or voluntarily participating in the board-designated physician health program;

(B) The board has not received nor filed any written complaints regarding said physician, podiatrist or physician assistant relating to an alcohol, chemical dependency or major mental illness affecting the care and treatment of patients, nor received any reports pursuant to subsection (b), section fourteen of this article relating to an alcohol or chemical dependency impairment; and

(C) The physician, podiatrist or physician assistant is in compliance with the voluntary treatment program and the conditions and procedures to monitor compliance.

(3) If any physician, podiatrist or physician assistant enters into a voluntary agreement with the board-approved physician health program, pursuant to this subsection and then fails to comply with or fulfill the terms of said agreement, the physician health program shall report the noncompliance to the board within twenty-four hours. The board may initiate disciplinary proceedings pursuant to subsection (a), section fourteen of this article or may permit continued participation in the physician health program or both.

(4) If the board has not instituted any disciplinary proceeding as provided for in this article, any information received, maintained or developed by the board relating to the alcohol or chemical

dependency impairment of any physician, podiatrist or physician assistant and any voluntary agreement made pursuant to this subsection shall be confidential and not available for public information, discovery or court subpoena, nor for introduction into evidence in any medical professional liability action or other action for damages arising out of the provision of or failure to provide health care services.

In the board's annual report of its activities to the Legislature required under section seven of this article, the board shall include information regarding the success of the voluntary agreement mechanism established therein: *Provided,* That in making such report, the board shall not disclose any personally identifiable information relating to any physician, podiatrist or physician assistant participating in a voluntary agreement as provided herein.

Notwithstanding any of the foregoing provisions, the board may cooperate with and provide documentation of any voluntary agreement entered into pursuant to this subsection to licensing boards in other jurisdictions of which the board has become aware and may be appropriate.

(i) Any physician-patient privilege does not apply in any investigation or proceeding by the board or by a medical peer review committee or by a hospital governing board with respect to relevant hospital medical records, while any of the aforesaid are acting within the scope of their authority: *Provided,* That the disclosure of any information pursuant to this provision shall not be considered a waiver of any such privilege in any other proceeding.

§30-3-10. Licenses to practice medicine and surgery or podiatry.

(a) The board shall issue a license to practice medicine and surgery or to practice podiatry to any individual who is qualified to do so in accordance with the provisions of this article.

(b) For an individual to be licensed to practice medicine and surgery in this state, he or she must meet the following requirements:

(1) He or she shall submit an application to the board on a form provided by the board and remit to the board a reasonable fee, the amount of the reasonable fee to be set by the board. The application must, as a minimum, require a sworn and notarized statement that the applicant is of good moral character and that he or she is physically and mentally capable of engaging in the practice of medicine and surgery;

(2) He or she must provide evidence of graduation and receipt of the degree of doctor of medicine or its equivalent from a school of medicine, which is approved by the liaison committee on medical education or by the board;

(3) He or she must submit evidence to the board of having successfully completed a minimum of one year of graduate clinical training in a program approved by the Accreditation Council for Graduate Medical Education; and

(4) He or she must pass an examination approved by the board, which examination can be related to a national standard. The examination shall be in the English language and be designed to ascertain an applicant's fitness to practice medicine and surgery. The board shall before the date of examination determine what will constitute a passing score: *Provided,* That the board, or a majority of it, may accept in lieu of an examination of applicants the certificate of the National Board of Medical Examiners: *Provided, however,* That an applicant is required to attain a passing score on all components or steps of the examination within a period of ten consecutive years. The board need not reject a candidate for a nonmaterial technical or administrative error or omission in the application process that is unrelated to the candidate's professional qualifications as long as there is sufficient information available to the board to determine the eligibility of the candidate for licensure.

(c) In addition to the requirements of subsection (b) of this section, any individual who has received the degree of doctor of medicine or its equivalent from a school of medicine located outside of the United States, the Commonwealth of Puerto Rico and Canada to be licensed to practice medicine in this state must also meet the following additional requirements and limitations:

(1) He or she must be able to demonstrate to the satisfaction of the board his or her ability to communicate in the English language;

(2) Before taking a licensure examination, he or she must have fulfilled the requirements of the Educational Commission for Foreign Medical Graduates for certification or he or she must provide evidence of receipt of a passing score on the examination of the Educational Commission for Foreign Medical Graduates: *Provided,* That an applicant who: (i) Is currently fully licensed, excluding any temporary, conditional or restricted license or permit, under the laws of another state, the District of Columbia, Canada or the Commonwealth of Puerto Rico; (ii) has been engaged on a full-time professional basis in the practice of medicine within the state or jurisdiction where the applicant is fully licensed for a period of at least five years; and (iii) is not the subject of any pending disciplinary action by a medical licensing board and has not been the subject of professional discipline by a medical licensing board in any jurisdiction is not required to have a certificate from the Educational Commission for Foreign Medical Graduates;

(3) He or she must submit evidence to the board of either: (i) Having successfully completed a minimum of two years of graduate clinical training in a program approved by the Accreditation Council for Graduate Medical Education; or (ii) current certification by a member board of the American Board of Medical Specialties.

(d) For an individual to be licensed to practice podiatry in this state, he or she must meet the following requirements:

(1) He or she shall submit an application to the board on a form provided by the board and remit to the board a reasonable fee, the amount of the reasonable fee to be set by the board. The application must, as a minimum, require a sworn and notarized statement that the applicant is of

good moral character and that he or she is physically and mentally capable of engaging in the practice of podiatric medicine;

(2) He or she must provide evidence of graduation and receipt of the degree of doctor of podiatric medicine or its equivalent from a school of podiatric medicine which is approved by the Council of Podiatry Education or by the board;

(3) He or she must pass an examination approved by the board, which examination can be related to a national standard. The examination shall be in the English language and be designed to ascertain an applicant's fitness to practice podiatric medicine. The board shall before the date of examination determine what will constitute a passing score: *Provided,* That an applicant is required to attain a passing score on all components or steps of the examination within a period of ten consecutive years; and

(4) He or she must submit evidence to the board of having successfully completed a minimum of one year of graduate clinical training in a program approved by the Council on Podiatric Medical Education or the Colleges of Podiatric Medicine. The board may consider a minimum of two years of graduate podiatric clinical training in the U. S. armed forces or three years' private podiatric clinical experience in lieu of this requirement.

(e) Notwithstanding any of the provisions of this article, the board may issue a restricted license to an applicant in extraordinary circumstances under the following conditions:

(1) Upon a finding by the board that based on the applicant's exceptional education, training and practice credentials, the applicant's practice in the state would be beneficial to the public welfare;

(2) Upon a finding by the board that the applicant's education, training and practice credentials are substantially equivalent to the requirements of licensure established in this article;

(3) Upon a finding by the board that the applicant received his or her post-graduate medical training outside of the United States and its territories;

(4) That the restricted license issued under extraordinary circumstances is approved by a vote of three fourths of the members of the board;

(5) That orders denying applications for a restricted license under this subsection are not appealable; and

(6) That the board report to the President of the Senate and the Speaker of the House of Delegates all decisions made pursuant to this subsection and the reasons for those decisions.

(f) The board shall propose rules for legislative approval in accordance with the provisions of article three, chapter twenty-nine-a of this code, that establish and regulate the restricted license issued to an applicant in extraordinary circumstances pursuant to the provisions of this section.

(g) Personal interviews by board members of all applicants are not required. An applicant for a license may be required by the board, in its discretion, to appear for a personal interview and may be required to produce original documents for review by the board.

(h) All licenses to practice medicine and surgery granted prior to July 1, 2008, and valid on that date shall continue in full effect for the term and under the conditions provided by law at the time of the granting of the license: *Provided,* That the provisions of subsection (d) of this section do not apply to any person legally entitled to practice chiropody or podiatry in this state prior to June 11, 1965: *Provided, however,* That all persons licensed to practice chiropody prior to June 11, 1965, shall be permitted to use the term "chiropody-podiatry" and shall have the rights, privileges and responsibilities of a podiatrist set out in this article.

(i) The board may not issue a license to a person not previously licensed in West Virginia whose license has been revoked or suspended in another state until reinstatement of his or her license in that state.

§30-3-10a. Special volunteer medical license; civil immunity for voluntary services rendered to indigents.

(a) There is hereby established a special volunteer medical license for physicians retired or retiring from the active practice of medicine who wish to donate their expertise for the medical care and treatment of indigent and needy patients in the clinic setting of clinics organized, in whole or in part, for the delivery of health care services without charge. The special volunteer medical license shall be issued by the West Virginia Board of Medicine to physicians licensed or otherwise eligible for licensure under this article and the rules promulgated hereunder without the payment of any application fee, license fee or renewal fee, shall be issued for a fiscal year or part thereof, and shall be renewable annually. The board shall develop application forms for the special license provided for in this subsection which shall contain the physician's acknowledgment that: (1) The physician's practice under the special volunteer medical license will be exclusively and totally devoted to providing medical care to needy and indigent persons in West Virginia; (2) the physician will not receive any payment or compensation, either direct or indirect, or have the expectation of any payment or compensation, for any medical services rendered under the special volunteer medical license; (3) the physician will supply any supporting documentation that the board may reasonably require; and (4) the physician agrees to continue to participate in continuing medical education as required of physicians in active practice.

(b) Any physician who renders any medical service to indigent and needy patients of a clinic organized, in whole or in part, for the delivery of health care services without charge under a special volunteer medical license authorized under subsection (a) of this section without payment or compensation or the expectation or promise of payment or compensation is immune from liability for any civil action arising out of any act or omission resulting from the rendering of the medical service at the clinic unless the act or omission was the result of the physician's gross negligence or willful misconduct. In order for the immunity under this subsection to apply, there must be a written agreement between the physician and the clinic pursuant to which the

physician will provide voluntary non-compensated medical services under the control of the clinic to patients of the clinic before the rendering of any services by the physician at the clinic: *Provided,* That any clinic entering into such written agreement shall be required to maintain liability coverage of not less than one million dollars per occurrence.

(c) Notwithstanding the provisions of subsection (a) of this section, a clinic organized, in whole or in part, for the delivery of health care services without charge shall not be relieved from imputed liability for the negligent acts of a physician rendering voluntary medical services at or for the clinic under a special volunteer medical license authorized under subsection (a) of this section.

(d) For purposes of this section, "otherwise eligible for licensure" means the satisfaction of all the requirements for licensure as listed in section ten of this article and in the legislative rules promulgated hereunder, except the fee requirements of subsections (b) and (d) of said section and of the legislative rule promulgated by the board relating to fees.

(e) Nothing in this section may be construed as requiring the board to issue a special volunteer medical license to any physician whose medical license is or has been subject to any disciplinary action or to any physician who has surrendered a medical license or caused such license to lapse, expire and become invalid in lieu of having a complaint initiated or other action taken against his or her medical license, or who has elected to place a medical license in inactive status in lieu of having a complaint initiated or other action taken against his or her medical license, or who have been denied a medical license.

(f) Any policy or contract of liability insurance providing coverage for liability sold, issued or delivered in this state to any physician covered under the provisions of this article shall be read so as to contain a provision or endorsement whereby the company issuing such policy waives or agrees not to assert as a defense on behalf of the policyholder or any beneficiary thereof, to any claim covered by the terms of such policy within the policy limits, the immunity from liability of the insured by reason of the care and treatment of needy and indigent patients by a physician who holds a special volunteer medical license: *Provided,* That this subsection shall not apply to a terminated policy, terminated contract of liability insurance or extended reporting endorsement attached thereto that provides "tail insurance" as defined by section two, article twenty-d, chapter thirty-three of this code: *Provided further,* That nothing within this subsection shall be construed to extend coverage under a terminated policy or terminated contract of liability insurance or any extended reporting endorsement attached thereto to: (1) Alter or amend the effective policy period of any policy, contract of liability insurance or extended reporting endorsement; or (2) cover the treatment of indigent and needy patients by a physician who holds a special volunteer medical license.

§30-3-11. Endorsement of licenses to practice medicine and surgery and podiatry; fees; temporary license; summer camp doctors.

(a) Any person seeking to be licensed to practice medicine and surgery in this state who holds a valid license to practice medicine and surgery attained under requirements substantially similar

to the requirement of section ten of this article from another state, the District of Columbia, the Commonwealth of Puerto Rico or Canada, and any person seeking to be licensed to practice podiatry in this state who holds a valid license to practice podiatry attained under requirements substantially similar to the requirements in section ten of this article from another state, territory or foreign country or the District of Columbia shall be issued a license to practice medicine and surgery or podiatry, as appropriate, in this state if he or she meets the following requirements:

(1) He or she must submit an application to the board on forms provided by the board and remit a reasonable licensure fee, the amount of such reasonable fee to be set by the board. The application must, as a minimum, require a statement that the applicant is a licensed physician or podiatrist in good standing and indicate whether any medical disciplinary action has been taken against him or her in the past; and

(2) He or she must demonstrate to the satisfaction of the board that he or she has the requisite qualifications to provide the same standard of care as a physician or podiatrist initially licensed in this state.

(b) The board may investigate the applicant and may request a personal interview to review the applicant's qualifications and professional credentials.

(c) The board may, at its discretion, grant a temporary license to an individual applying for licensure under this section if the individual meets the requirements of subdivision (1), subsection (a) of this section. Such temporary license shall only be valid until the board is able to meet and consider the endorsement request. The board may fix and collect a reasonable fee for a temporary license, the amount of such reasonable fee to be set by the board.

(d) The application fee shall be waived, and to the extent consistent with the integrity of the licensure process and the requirements for licensure as set forth in this section and in the relevant legislative rules, the board shall expedite its processing of an individual's application to practice medicine and surgery, or practice podiatry: *Provided*, That the sole purpose for licensure is to provide services at a children's summer camp for not more than one specifically designated three week period annually. The license shall be issued for a period of the specifically designated three weeks only, on an annual basis.

§30-3-11a. Endorsement of licenses to practice medicine and surgery as medical school faculty.

(a) The board shall issue a limited license to practice medicine and surgery without examination to an individual appointed to a West Virginia medical school faculty who holds a valid license to practice medicine and surgery from another state, the District of Columbia, the Commonwealth of Puerto Rico, Canada or other country the board determines has substantially equivalent requirements for licensure as those jurisdictions, and who has completed the application form prescribed by the board, remitted a nonrefundable application fee in the amount of one hundred fifty dollars and who presents satisfactory proof to the board that:

(1) He or she is of good moral and professional character;

(2) He or she is physically and mentally capable of engaging in the practice of medicine and surgery;

(3) He or she is able to communicate in English;

(4) He or she is a graduate of a school of medicine which is approved by the liaison committee on medical education or by the World Health Organization or by the board with the degree of doctor of medicine or its equivalent;

(5) He or she has successfully completed one year of approved graduate clinical training or a fellowship of at least one year, or has received training which the board determines to be equivalent to or exceeds the one year graduate clinical training or fellowship requirement;

(6) He or she has not committed any act in this or any other jurisdiction which would constitute the basis for disciplining a physician under section fourteen of this article; and

(7) He or she has been offered and has accepted a faculty appointment to teach in a medical school in this state.

(b) The board shall investigate the applicant and may request a personal interview to review the applicant's qualifications and professional credentials.

(c) The medical practice of a physician licensed under this section is limited to the medical center of the medical school to which the physician has been appointed to the faculty.

(d) A limited license issued under this section is valid for a term of one year. No limited license issued pursuant to this section may be renewed.

(e) Before the limited license has expired, a physician licensed under this section may apply for a license to practice medicine and surgery in West Virginia pursuant to the provisions of section twelve of this article: *Provided,* That any license granted by the board pursuant to this subsection, retains the practice limitations set out in subsection (c) of this section.

(f) Any license issued under this section will automatically expire and be void, without notice to the physician, when the physician's faculty appointment is terminated. The dean of the medical school shall notify the board within five days of the termination of a faculty appointment of a physician licensed pursuant to this section.

(g) A physician licensed under this section must keep all medical licenses issued by other jurisdictions in good standing and must notify the board, within fifteen days of its occurrence, of any denial, suspension or revocation of or any limitation placed on a medical license issued by another jurisdiction.

§30-3-11b. License to practice medicine and surgery at certain state veterans nursing home facilities.

(a) The board is authorized and encouraged to the best of its ability to issue a license to practice medicine and surgery in this state without examination to a physician that currently holds a license to practice medicine and surgery at a Federal Veterans Administration Hospital upon completion of an application form prescribed by the board and who presents satisfactory proof to the board that he or she is currently employed and practicing in a Federal Veterans Administration Hospital that is located in a county in which a nursing home operated by the West Virginia Department of Veteran's Assistance is located: *Provided,* That the physician shall maintain an valid, unrestricted license to practice medicine in another state.

(b) The medical practice for which a physician is licensed under this section is limited to practice in a nursing home operated by the West Virginia Department of Veteran's Assistance that is located in the same county in which the Federal Veterans Administration Hospital where the individual is employed.

(c) No fee may be assessed to an individual licensed or seeking licensure pursuant to this section.

(d) The board shall propose emergency rules pursuant to the provisions of section fifteen, article three, chapter twenty-nine-a of this code to implement the provisions of this section.

(e) The board shall report to the Legislative Oversight Commission on Health and Human Resources Accountability and the Legislative Oversight Commission on Education Accountability by July 1, 2016 on the implementation of this section including the number of licenses issued, number of complaints, and any other pertinent legislation.

§30-3-12. Biennial renewal of license to practice medicine and surgery or podiatry; continuing education; rules; fee; inactive license.

(a) A license to practice medicine and surgery or podiatry in this state is valid for a term of two years.

(b) The license shall be renewed:

(1) Upon receipt of a reasonable fee, as set by the board;

(2) Submission of an application on forms provided by the board; and

(3) A certification of participation in and successful completion of a minimum of fifty hours of continuing medical or podiatric education satisfactory to the board, as appropriate to the particular license, during the preceding two-year period.

(c) The application may not require disclosure of a voluntary agreement entered into pursuant to subsection (h), section nine of this article.

(d) Continuing medical education satisfactory to the board is continuing medical education designated as Category I by the American Medical Association or the Academy of Family Physicians and alternate categories approved by the board.

(e) Continuing podiatric education satisfactory to the board is continuing podiatric education approved by the Council on Podiatric Education and alternate categories approved by the board.

(f) Notwithstanding any provision of this chapter to the contrary, beginning the first day of July, two thousand seven, failure to timely submit to the board a certification of successful completion of a minimum of fifty hours of continuing medical or podiatric education satisfactory to the board, as appropriate to the particular license, shall result in the automatic expiration of any license to practice medicine and surgery or podiatry until such time as the certification, with all supporting written documentation, is submitted to and approved by the board.

(g) If a license is automatically expired and reinstatement is sought within one year of the automatic expiration, the former licensee shall:

(1) Provide certification with supporting written documentation of the successful completion of the required continuing education;

(2) Pay a renewal fee; and

(3) Pay a reinstatement fee equal to fifty percent of the renewal fee.

(h) If a license is automatically expired and more than one year has passed since the automatic expiration, the former licensee shall:

(1) Apply for a new license;

(2) Provide certification with supporting written documentation of the successful completion of the required continuing education; and

(3) Pay such fees as determined by the board.

(i) Any individual who accepts the privilege of practicing medicine and surgery or podiatry in this state is required to provide supporting written documentation of the continuing education represented as received within thirty days of receipt of a written request to do so by the board. If a licensee fails or refuses to provide supporting written documentation of the continuing education represented as received as required in this section, such failure or refusal to provide supporting written documentation is prima facie evidence of renewing a license to practice medicine and surgery or podiatry by fraudulent misrepresentation.

(j) The board may renew, on an inactive basis, the license of a physician or podiatrist who is currently licensed to practice medicine and surgery or podiatry in, but is not actually practicing, medicine and surgery or podiatry in this state. A physician or podiatrist holding an inactive license shall not practice medicine and surgery or podiatry in this state.

(k) An inactive license may be converted by the board to an active license upon a written request by the licensee to the board that:

(1) Accounts for his or her period of inactivity to the satisfaction of the board; and

(2) Submits written documentation of participation in and successful completion of a minimum of fifty hours of continuing medical or podiatric education satisfactory to the board, as appropriate to the particular license, during each preceding two-year period.

(l) An inactive license may be obtained upon receipt of a reasonable fee, as set by the board, and submission of an application on forms provided by the board on a biennial basis.

(m) The board may not require any physician or podiatrist who is retired or retiring from the active practice of medicine and surgery or the practice of podiatry and who is voluntarily surrendering their license to return to the board the license certificate issued to them by the board.

§30-3-13. Licensing requirements for the practice of medicine and surgery or podiatry; exceptions; unauthorized practice; notice; criminal penalties.

(a) It is unlawful for any person who does not hold an active, unexpired license issued pursuant to this article, or who is not practicing pursuant to the licensure exceptions set forth in this section, to:

(1) Engage in the practice of medicine and surgery or podiatry in this state;

(2) Represent that he or she is a physician, surgeon or podiatrist authorized to practice medicine and surgery or podiatry in this state; or

(3) Use any title, word or abbreviation to indicate or induce others to believe that he or she is licensed to practice medicine and surgery or podiatry in this state.

(b) It is unlawful for any person who does not hold an active, unexpired license issued pursuant to this article to engage in the practice of telemedicine within this state. As used in this section, the "practice of telemedicine" means the practice of medicine using communication tools such as electronic communication, information technology or other means of interaction between a licensed health care professional in one location and a patient in another location, with or without an intervening health care provider, and typically involves secure real time audio/video conferencing or similar secure audio/video services, remote monitoring, interactive video and store and forward digital image or health data technology to provide or support health care

delivery by replicating the interaction of a traditional in person encounter between a provider and a patient. The practice of telemedicine occurs in this state when the patient receiving health care services through a telemedicine encounter is physically located in this state.

(c) It is not unlawful for a person:

(1) Who is a licensed health care provider under this code to act within his or her scope of practice;

(2) Who is not a licensed health care professional in this state to provide first aid care in an emergency situation; or

(3) To engage in the bona fide religious tenets of any recognized church in the administration of assistance to the sick or suffering by mental or spiritual means.

(d) The following persons are exempt from the licensure requirements under this article:

(1) A person enrolled in a school of medicine approved by the Liaison Committee on Medical Education or by the board;

(2) A person enrolled in a school of podiatric medicine approved by the Council of Podiatry Education or by the board;

(3) A person engaged in graduate medical training in a program approved by the Accreditation Council for Graduate Medical Education or the board;

(4) A person engaged in graduate podiatric training in a program approved by the Council on Podiatric Education or by the board;

(5) A physician or podiatrist engaged in the performance of his or her official duties holding one or more licenses from another state or foreign country and who is a commissioned medical officer of, a member of or employed by:

(A) The United States Military;

(B) The Department of Defense;

(C) The United States Public Health Service; or

(D) Any other federal agency;

(6) A physician or podiatrist holding one or more unrestricted licenses granted by another state or foreign country serving as visiting medical faculty engaged in education, training or research duties at a medical school or institution recognized by the board for up to six months if:

(A) The physician does not engage in the practice of medicine and surgery or podiatry outside of the auspices of the sponsoring school or institution; and

(B) The sponsoring medical school or institution provides prior written notification to the board including the physician's name, all jurisdictions of licensure and the beginning and end date of the physician's visiting medical faculty status;

(7) A physician or podiatrist holding one or more unrestricted licenses granted by another state present in the state as a member of an air ambulance treatment team or organ harvesting team;

(8) A physician or podiatrist holding one or more unrestricted licenses granted by another state or foreign country providing a consultation on a singular occasion to a licensed physician or podiatrist in this state, whether the consulting physician or podiatrist is physically present in the state for the consultation or not;

(9) A physician or podiatrist holding one or more unrestricted licenses granted by another state or foreign country providing teaching assistance, in a medical capacity, for a period not to exceed seven days;

(10) A physician or podiatrist holding one or more unrestricted licenses granted by another state or foreign country serving as a volunteer in a non-compensated role for a charitable function for a period not to exceed seven days; and

(11) A physician or podiatrist holding one or more unrestricted licenses granted by another state or foreign country providing medical services to a college or university affiliated and/or sponsored sports team or an incorporated sports team if:

(A) He or she has a written agreement with that sports team to provide

care to team members, band member, cheerleader, mascot, coaching staff and families traveling with the team for a specific sporting event, team appearance or training camp occurring in this state;

(B) He or she may only provide care or consultation to team members, coaching staff and families traveling with the team no longer than seven consecutive days per sporting event;

(C) He or she is not authorized to practice at a health care facility or clinic, acute care facility or urgent care center located in this state, but the physician may accompany the patient to the facility and consult; and

(D) The physician or podiatrist may be permitted, by written permission from the executive director, to extend his or her authorization to practice medicine for a maximum of seven additional consecutive days if the requestor shows good cause for the extension.

(e) A physician or podiatrist who does not hold a license issued by the board and who is practicing medicine in this state pursuant to the exceptions to licensure set forth in this section may practice in West Virginia under one or more of the licensure exceptions for no greater than a cumulative total of thirty days in any one calendar year.

(f) The executive director shall send by certified mail to a physician not licensed in this state a written order that revokes the privilege to practice medicine under this section if the executive director finds good cause to do so. If no current address can be determined, the order may be sent by regular mail to the physician's last known address.

(g) A person who engages in the unlawful practice of medicine and surgery or podiatry while holding a license issued pursuant to this article which has been classified by the board as expired for ninety days or fewer is guilty of a misdemeanor and, upon conviction, shall be fined not more than $5,000 or confined in jail not more than twelve months, or both fined and confined.

(h) A person who is found to be engaging in the practice of medicine and: (1) Has never been licensed by the board under this article; (2) holds a license which has been classified by the board as expired for greater than ninety days; or (3) holds a license which has been placed in inactive status, revoked, suspended or surrendered to the board is guilty of a felony and, upon conviction, shall be fined not more than $10,000 or imprisoned in a correctional facility for not less than one year nor more than five years or both fined and imprisoned.

(i) Upon a determination by the board that any report or complaint submitted to it concerns allegations of the unlawful practice of medicine and surgery by an individual who is licensed under another article of this chapter, the board shall refer the complaint to the appropriate licensing authority. Additionally, whenever the board receives credible information that an individual is engaging in the unlawful practice of medicine and surgery or podiatry in violation of this section, the board may report such information to the appropriate state and/or federal law enforcement authority and/or prosecuting attorney.

§30-3-13a. Telemedicine practice; requirements; exceptions; definitions; rule-making

(a) *Definitions* -- For the purposes of this section:

(1) "Chronic nonmalignant pain" means pain that has persisted after reasonable medical efforts have been made to relieve the pain or cure its cause and that has continued, either continuously or episodically, for longer than three continuous months. "Chronic non-malignant pain" does not include pain associated with a terminal condition or illness or with a progressive disease that, in the normal course of progression, may reasonably be expected to result in a terminal condition or illness.

(2) "Physician" means a person licensed by the West Virginia Board of Medicine to practice allopathic medicine in West Virginia.

(3) "Store and forward telemedicine" means the asynchronous computer-based communication of medical data or images from an originating location to a physician or podiatrist at another site for the purpose of diagnostic or therapeutic assistance.

(4) "Telemedicine" means the practice of medicine using tools such as electronic communication, information technology, store and forward telecommunication, or other means of interaction between a physician or podiatrist in one location and a patient in another location, with or without an intervening healthcare provider.

(5) "Telemedicine technologies" means technologies and devices which enable secure electronic communications and information exchange in the practice of telemedicine, and typically involve the application of secure real-time audio/video conferencing or similar secure video services, remote monitoring, or store and forward digital image technology to provide or support healthcare delivery by replicating the interaction of a traditional in-person encounter between a physician or podiatrist and a patient.

(b) *Licensure.*

(1) The practice of medicine occurs where the patient is located at the time the telemedicine technologies are used.

(2) A physician or podiatrist who practices telemedicine must be licensed as provided in this article.

(3) This section does not apply to:

(A) An informal consultation or second opinion, at the request of a physician or podiatrist who is licensed to practice medicine or podiatry in this state, provided that the physician or podiatrist requesting the opinion retains authority and responsibility for the patient’s care; and

(B) Furnishing of medical assistance by a physician or podiatrist in case of an emergency or disaster, if no charge is made for the medical assistance.

(c) *Physician-Patient or Podiatrist-Patient Relationship Through Telemedicine Encounter*.

(1) A physician-patient or podiatrist-patient relationship may not be established through:

(A) Audio-only communication;

(B) Text-based communications such as e-mail, internet questionnaires, text-based messaging or other written forms of communication; or

(C) Any combination thereof.

(2) If an existing physician-patient or podiatrist-patient relationship does not exist prior to the utilization to telemedicine technologies, or if services are rendered solely through telemedicine technologies, a physician-patient or podiatrist-patient relationship may only be established:

(A) Through the use of telemedicine technologies which incorporate interactive audio using store and forward technology, real-time videoconferencing or similar secure video services during the initial physician-patient or podiatrist-patient encounter; or

(B) For the practice of pathology and radiology, a physician-patient relationship may be established through store and forward telemedicine or other similar technologies.

(3) Once a physician-patient or podiatrist-patient relationship has been established, either through an in-person encounter or in accordance with subsection (c)(2) of this section, the physician or podiatrist may utilize any telemedicine technology that meets the standard of care and is appropriate for the particular patient presentation.

(d) *Telemedicine Practice.* A physician or podiatrist using telemedicine technologies to practice medicine or podiatry shall:

(1) Verify the identity and location of the patient;

(2) Provide the patient with confirmation of the identity and qualifications of the physician or podiatrist;

(3) Provide the patient with the physical location and contact information of the physician;

(4) Establish or maintain a physician-patient or podiatrist-patient relationship that conforms to the standard of care;

(5) Determine whether telemedicine technologies are appropriate for the particular patient presentation for which the practice of medicine or podiatry is to be rendered;

(6) Obtain from the patient appropriate consent for the use of telemedicine technologies;

(7) Conduct all appropriate evaluations and history of the patient consistent with traditional standards of care for the particular patient presentation; and

(8) Create and maintain healthcare records for the patient which justify the course of treatment and which verify compliance with the requirements of this section,

(9) The requirements of subdivisions (1) through (8) of subsection (d) in this section do not apply to the practice of pathology or radiology medicine through store and forward telemedicine.

(e) *Standard of Care.*

The practice of medicine or podiatry provided via telemedicine technologies, including the establishment of a physician-patient or podiatrist-patient relationship and issuing a prescription via electronic means as part of a telemedicine encounter, are subject to the same standard of care, professional practice requirements and scope of practice limitations as traditional in-person physician-patient or podiatrist-patient encounters. Treatment, including issuing a prescription, based solely on an online questionnaire, does not constitute an acceptable standard of care.

(f) *Patient Records.*

The patient record established during the use of telemedicine technologies shall be accessible and documented for both the physician or podiatrist and the patient, consistent with the laws and legislative rules governing patient healthcare records. All laws governing the confidentiality of healthcare information and governing patient access to medical records shall apply to records of practice of medicine or podiatry provided through telemedicine technologies. A physician or podiatrist solely providing services using telemedicine technologies shall make documentation of the encounter easily available to the patient, and subject to the patient's consent, to any identified care provider of the patient.

(g) *Prescribing Limitations*.

(1) A physician or podiatrist who practices medicine to a patient solely through the utilization of telemedicine technologies may not prescribe to that patient any controlled substances listed in Schedule II of the Uniform Controlled Substances Act.

(2) A physician or podiatrist may not prescribe any pain-relieving controlled substance listed in Schedules II through V of the Uniform Controlled Substance Act as part of a course of treatment for chronic non-malignant pain solely based upon a telemedicine encounter.

(h) *Exceptions*.

This article does not prohibit the use of audio-only or text-based communications by a physician or podiatrist who is:

(1) Responding to call for patients with whom a physician-patient or podiatrist-patient relationship has been established through an in-person encounter by the physician or podiatrist;

(2) Providing cross coverage for a physician or podiatrist who has established a physician-patient or podiatrist-patient relationship with the patient through an in-person encounter; or

(3) Providing medical assistance in the event of an emergency situation.

(i) *Rulemaking.*

The West Virginia Board of Medicine and West Virginia Board of Osteopathic Medicine may propose joint rules for legislative approval in accordance with article three, chapter twenty-nine-

a of this code to implement standards for and limitations upon the utilization of telemedicine technologies in the practice of medicine and podiatry in this state.

(j) *Preserving Traditional Physician-Patient or Podiatrist-Patient Relationship*.

Nothing in this section changes the rights, duties, privileges, responsibilities and liabilities incident to the physician-patient or podiatrist-patient relationship, nor is it meant or intended to change in any way the personal character of the physician-patient or podiatrist-patient relationship. This section does not alter the scope of practice of any healthcare provider or authorize the delivery of healthcare services in a setting, or in a manner, not otherwise authorized by law.

§30-3-14. Professional discipline of physicians and podiatrists; reporting of information to board pertaining to medical professional liability and professional incompetence required; penalties; grounds for license denial and discipline of physicians and podiatrists; investigations; physical and mental examinations; hearings; sanctions; summary sanctions; reporting by the board; reapplication; civil and criminal immunity; voluntary limitation of license; probable cause determinations.

(a) The board may independently initiate disciplinary proceedings as well as initiate disciplinary proceedings based on information received from medical peer review committees, physicians, podiatrists, hospital administrators, professional societies and others.

The board may initiate investigations as to professional incompetence or other reasons for which a licensed physician or podiatrist may be adjudged unqualified based upon criminal convictions; complaints by citizens, pharmacists, physicians, podiatrists, peer review committees, hospital administrators, professional societies or others; or unfavorable outcomes arising out of medical professional liability. The board shall initiate an investigation if it receives notice that three or more judgments, or any combination of judgments and settlements resulting in five or more unfavorable outcomes arising from medical professional liability have been rendered or made against the physician or podiatrist within a five-year period. The board may not consider any judgments or settlements as conclusive evidence of professional incompetence or conclusive lack of qualification to practice.

(b) Upon request of the board, any medical peer review committee in this state shall report any information that may relate to the practice or performance of any physician or podiatrist known to that medical peer review committee. Copies of the requests for information from a medical peer review committee may be provided to the subject physician or podiatrist if, in the discretion of the board, the provision of such copies will not jeopardize the board's investigation. In the event that copies are provided, the subject physician or podiatrist is allowed fifteen days to comment on the requested information and such comments must be considered by the board.

The chief executive officer of every hospital shall, within sixty days after the completion of the hospital’s formal disciplinary procedure and also within sixty days after the commencement of and again after the conclusion of any resulting legal action, report in writing to the board the

name of any member of the medical staff or any other physician or podiatrist practicing in the hospital whose hospital privileges have been revoked, restricted, reduced or terminated for any cause, including resignation, together with all pertinent information relating to such action. The chief executive officer shall also report any other formal disciplinary action taken against any physician or podiatrist by the hospital upon the recommendation of its medical staff relating to professional ethics, medical incompetence, medical professional liability, moral turpitude or drug or alcohol abuse. Temporary suspension for failure to maintain records on a timely basis or failure to attend staff or section meetings need not be reported. Voluntary cessation of hospital privileges for reasons unrelated to professional competence or ethics need not be reported.

Any managed care organization operating in this state which provides a formal peer review process shall report in writing to the board, within sixty days after the completion of any formal peer review process and also within sixty days after the commencement of and again after the conclusion of any resulting legal action, the name of any physician or podiatrist whose credentialing has been revoked or not renewed by the managed care organization. The managed care organization shall also report in writing to the board any other disciplinary action taken against a physician or podiatrist relating to professional ethics, professional liability, moral turpitude or drug or alcohol abuse within sixty days after completion of a formal peer review process which results in the action taken by the managed care organization. For purposes of this subsection, "managed care organization" means a plan that establishes, operates or maintains a network of health care providers who have entered into agreements with and been credentialed by the plan to provide health care services to enrollees or insureds to whom the plan has the ultimate obligation to arrange for the provision of or payment for health care services through organizational arrangements for ongoing quality assurance, utilization review programs or dispute resolutions.

Any professional society in this state comprised primarily of physicians or podiatrists which takes formal disciplinary action against a member relating to professional ethics, professional incompetence, medical professional liability, moral turpitude or drug or alcohol abuse shall report in writing to the board within sixty days of a final decision the name of the member, together with all pertinent information relating to the action.

Every person, partnership, corporation, association, insurance company, professional society or other organization providing professional liability insurance to a physician or podiatrist in this state, including the State Board of Risk and Insurance Management, shall submit to the board the following information within thirty days from any judgment or settlement of a civil or medical professional liability action excepting product liability actions: The name of the insured; the date of any judgment or settlement; whether any appeal has been taken on the judgment and, if so, by which party; the amount of any settlement or judgment against the insured; and other information required by the board.

Within thirty days from the entry of an order by a court in a medical professional liability action or other civil action in which a physician or podiatrist licensed by the board is determined to have rendered health care services below the applicable standard of care, the clerk of the court in which the order was entered shall forward a certified copy of the order to the board.

Within thirty days after a person known to be a physician or podiatrist licensed or otherwise lawfully practicing medicine and surgery or podiatry in this state or applying to be licensed is convicted of a felony under the laws of this state or of any crime under the laws of this state involving alcohol or drugs in any way, including any controlled substance under state or federal law, the clerk of the court of record in which the conviction was entered shall forward to the board a certified true and correct abstract of record of the convicting court. The abstract shall include the name and address of the physician or podiatrist or applicant, the nature of the offense committed and the final judgment and sentence of the court.

Upon a determination of the board that there is probable cause to believe that any person, partnership, corporation, association, insurance company, professional society or other organization has failed or refused to make a report required by this subsection, the board shall provide written notice to the alleged violator stating the nature of the alleged violation and the time and place at which the alleged violator shall appear to show good cause why a civil penalty should not be imposed. The hearing shall be conducted in accordance with article five, chapter twenty-nine-a of this code. After reviewing the record of the hearing, if the board determines that a violation of this subsection has occurred, the board shall assess a civil penalty of not less than $1,000 nor more than $10,000 against the violator. The board shall notify any person so assessed of the assessment in writing and the notice shall specify the reasons for the assessment. If the violator fails to pay the amount of the assessment to the board within thirty days, the Attorney General may institute a civil action in the circuit court of Kanawha County to recover the amount of the assessment. In any civil action, the court's review of the board's action shall be conducted in accordance with section four, article five, chapter twenty-nine-a of this code. Notwithstanding any other provision of this article to the contrary, when there are conflicting views by recognized experts as to whether any alleged conduct breaches an applicable standard of care, the evidence must be clear and convincing before the board may find that the physician or podiatrist has demonstrated a lack of professional competence to practice with a reasonable degree of skill and safety for patients.

Any person may report to the board relevant facts about the conduct of any physician or podiatrist in this state which in the opinion of that person amounts to medical professional liability or professional incompetence.

The board shall provide forms for filing reports pursuant to this section. Reports submitted in other forms shall be accepted by the board.

The filing of a report with the board pursuant to any provision of this article, any investigation by the board or any disposition of a case by the board does not preclude any action by a hospital, other health care facility or professional society comprised primarily of physicians or podiatrists to suspend, restrict or revoke the privileges or membership of the physician or podiatrist.

(c) The board may deny an application for license or other authorization to practice medicine and surgery or podiatry in this state and may discipline a physician or podiatrist licensed or otherwise lawfully practicing in this state who, after a hearing, has been adjudged by the board as unqualified due to any of the following reasons:

(1) Attempting to obtain, obtaining, renewing or attempting to renew a license to practice medicine and surgery or podiatry by bribery, fraudulent misrepresentation or through known error of the board;

(2) Being found guilty of a crime in any jurisdiction, which offense is a felony, involves moral turpitude or directly relates to the practice of medicine. Any plea of nolo contendere is a conviction for the purposes of this subdivision;

(3) False or deceptive advertising;

(4) Aiding, assisting, procuring or advising any unauthorized person to practice medicine and surgery or podiatry contrary to law;

(5) Making or filing a report that the person knows to be false; intentionally or negligently failing to file a report or record required by state or federal law; willfully impeding or obstructing the filing of a report or record required by state or federal law; or inducing another person to do any of the foregoing. The reports and records covered in this subdivision mean only those that are signed in the capacity as a licensed physician or podiatrist;

(6) Requesting, receiving or paying directly or indirectly a payment, rebate, refund, commission, credit or other form of profit or valuable consideration for the referral of patients to any person or entity in connection with providing medical or other health care services or clinical laboratory services, supplies of any kind, drugs, medication or any other medical goods, services or devices used in connection with medical or other health care services;

(7) Unprofessional conduct by any physician or podiatrist in referring a patient to any clinical laboratory or pharmacy in which the physician or podiatrist has a proprietary interest unless the physician or podiatrist discloses in writing such interest to the patient. The written disclosure shall indicate that the patient may choose any clinical laboratory for purposes of having any laboratory work or assignment performed or any pharmacy for purposes of purchasing any prescribed drug or any other medical goods or devices used in connection with medical or other health care services;

As used in this subdivision, "proprietary interest" does not include an ownership interest in a building in which space is leased to a clinical laboratory or pharmacy at the prevailing rate under a lease arrangement that is not conditional upon the income or gross receipts of the clinical laboratory or pharmacy;

(8) Exercising influence within a patient-physician relationship for the purpose of engaging a patient in sexual activity;

(9) Making a deceptive, untrue or fraudulent representation in the practice of medicine and surgery or podiatry;

(10) Soliciting patients, either personally or by an agent, through the use of fraud, intimidation or undue influence;

(11) Failing to keep written records justifying the course of treatment of a patient, including, but not limited to, patient histories, examination and test results and treatment rendered, if any;

(12) Exercising influence on a patient in such a way as to exploit the patient for financial gain of the physician or podiatrist or of a third party. Any influence includes, but is not limited to, the promotion or sale of services, goods, appliances or drugs;

(13) Prescribing, dispensing, administering, mixing or otherwise preparing a prescription drug, including any controlled substance under state or federal law, other than in good faith and in a therapeutic manner in accordance with accepted medical standards and in the course of the physician's or podiatrist's professional practice. A physician who discharges his or her professional obligation to relieve the pain and suffering and promote the dignity and autonomy of dying patients in his or her care and, in so doing, exceeds the average dosage of a pain relieving controlled substance, as defined in Schedules II and III of the Uniform Controlled Substance Act, does not violate this article;

(14) Performing any procedure or prescribing any therapy that, by the accepted standards of medical practice in the community, would constitute experimentation on human subjects without first obtaining full, informed and written consent;

(15) Practicing or offering to practice beyond the scope permitted by law or accepting and performing professional responsibilities that the person knows or has reason to know he or she is not competent to perform;

(16) Delegating professional responsibilities to a person when the physician or podiatrist delegating the responsibilities knows or has reason to know that the person is not qualified by training, experience or licensure to perform them;

(17) Violating any provision of this article or a rule or order of the board or failing to comply with a subpoena or subpoena duces tecum issued by the board;

(18) Conspiring with any other person to commit an act or committing an act that would tend to coerce, intimidate or preclude another physician or podiatrist from lawfully advertising his or her services;

(19) Gross negligence in the use and control of prescription forms;

(20) Professional incompetence; or

(21) The inability to practice medicine and surgery or podiatry with reasonable skill and safety due to physical or mental impairment, including deterioration through the aging process, loss of motor skill or abuse of drugs or alcohol. A physician or podiatrist adversely affected under this

subdivision shall be afforded an opportunity at reasonable intervals to demonstrate that he or she may resume the competent practice of medicine and surgery or podiatry with reasonable skill and safety to patients. In any proceeding under this subdivision, neither the record of proceedings nor any orders entered by the board shall be used against the physician or podiatrist in any other proceeding.

(d) The board shall deny any application for a license or other authorization to practice medicine and surgery or podiatry in this state to any applicant who, and shall revoke the license of any physician or podiatrist licensed or otherwise lawfully practicing within this state who, is found guilty by any court of competent jurisdiction of any felony involving prescribing, selling, administering, dispensing, mixing or otherwise preparing any prescription drug, including any controlled substance under state or federal law, for other than generally accepted therapeutic purposes. Presentation to the board of a certified copy of the guilty verdict or plea rendered in the court is sufficient proof thereof for the purposes of this article. A plea of nolo contendere has the same effect as a verdict or plea of guilt. Upon application of a physician that has had his or her license revoked because of a drug related felony conviction, upon completion of any sentence of confinement, parole, probation or other court-ordered supervision and full satisfaction of any fines, judgments or other fees imposed by the sentencing court, the board may issue the applicant a new license upon a finding that the physician is, except for the underlying conviction, otherwise qualified to practice medicine: *Provided,* That the board may place whatever terms, conditions or limitations it deems appropriate upon a physician licensed pursuant to this subsection.

(e) The board may refer any cases coming to its attention to an appropriate committee of an appropriate professional organization for investigation and report. Except for complaints related to obtaining initial licensure to practice medicine and surgery or podiatry in this state by bribery or fraudulent misrepresentation, any complaint filed more than two years after the complainant knew, or in the exercise of reasonable diligence should have known, of the existence of grounds for the complaint shall be dismissed: *Provided,* That in cases of conduct alleged to be part of a pattern of similar misconduct or professional incapacity that, if continued, would pose risks of a serious or substantial nature to the physician's or podiatrist's current patients, the investigating body may conduct a limited investigation related to the physician's or podiatrist's current capacity and qualification to practice and may recommend conditions, restrictions or limitations on the physician's or podiatrist's license to practice that it considers necessary for the protection of the public. Any report shall contain recommendations for any necessary disciplinary measures and shall be filed with the board within ninety days of any referral. The recommendations shall be considered by the board and the case may be further investigated by the board. The board after full investigation shall take whatever action it considers appropriate, as provided in this section.

(f) The investigating body, as provided in subsection (e) of this section, may request and the board under any circumstances may require a physician or podiatrist or person applying for licensure or other authorization to practice medicine and surgery or podiatry in this state to submit to a physical or mental examination by a physician or physicians approved by the board. A physician or podiatrist submitting to an examination has the right, at his or her expense, to

designate another physician to be present at the examination and make an independent report to the investigating body or the board. The expense of the examination shall be paid by the board. Any individual who applies for or accepts the privilege of practicing medicine and surgery or podiatry in this state is considered to have given his or her consent to submit to all examinations when requested to do so in writing by the board and to have waived all objections to the admissibility of the testimony or examination report of any examining physician on the ground that the testimony or report is privileged communication. If a person fails or refuses to submit to an examination under circumstances which the board finds are not beyond his or her control, failure or refusal is prima facie evidence of his or her inability to practice medicine and surgery or podiatry competently and in compliance with the standards of acceptable and prevailing medical practice.

(g) In addition to any other investigators it employs, the board may appoint one or more licensed physicians to act for it in investigating the conduct or competence of a physician.

(h) In every disciplinary or licensure denial action, the board shall furnish the physician or podiatrist or applicant with written notice setting out with particularity the reasons for its action. Disciplinary and licensure denial hearings shall be conducted in accordance with article five, chapter twenty-nine-a of this code. However, hearings shall be heard upon sworn testimony and the rules of evidence for trial courts of record in this state shall apply to all hearings. A transcript of all hearings under this section shall be made, and the respondent may obtain a copy of the transcript at his or her expense. The physician or podiatrist has the right to defend against any charge by the introduction of evidence, the right to be represented by counsel, the right to present and cross-examine witnesses and the right to have subpoenas and subpoenas duces tecum issued on his or her behalf for the attendance of witnesses and the production of documents. The board shall make all its final actions public. The order shall contain the terms of all action taken by the board.

(i) In disciplinary actions in which probable cause has been found by the board, the board shall, within twenty days of the date of service of the written notice of charges or sixty days prior to the date of the scheduled hearing, whichever is sooner, provide the respondent with the complete identity, address and telephone number of any person known to the board with knowledge about the facts of any of the charges; provide a copy of any statements in the possession of or under the control of the board; provide a list of proposed witnesses with addresses and telephone numbers, with a brief summary of his or her anticipated testimony; provide disclosure of any trial expert pursuant to the requirements of Rule 26(b)(4) of the West Virginia Rules of Civil Procedure; provide inspection and copying of the results of any reports of physical and mental examinations or scientific tests or experiments; and provide a list and copy of any proposed exhibit to be used at the hearing: *Provided,* That the board shall not be required to furnish or produce any materials which contain opinion work product information or would be a violation of the attorney-client privilege. Within twenty days of the date of service of the written notice of charges, the board shall disclose any exculpatory evidence with a continuing duty to do so throughout the disciplinary process. Within thirty days of receipt of the board's mandatory discovery, the respondent shall provide the board with the complete identity, address and telephone number of any person known to the respondent with knowledge about the facts of any of the charges;

provide a list of proposed witnesses with addresses and telephone numbers, to be called at hearing, with a brief summary of his or her anticipated testimony; provide disclosure of any trial expert pursuant to the requirements of Rule 26(b)(4) of the West Virginia Rules of Civil Procedure; provide inspection and copying of the results of any reports of physical and mental examinations or scientific tests or experiments; and provide a list and copy of any proposed exhibit to be used at the hearing.

(j) Whenever it finds any person unqualified because of any of the grounds set forth in subsection (c) of this section, the board may enter an order imposing one or more of the following:

(1) Deny his or her application for a license or other authorization to practice medicine and surgery or podiatry;

(2) Administer a public reprimand;

(3) Suspend, limit or restrict his or her license or other authorization to practice medicine and surgery or podiatry for not more than five years, including limiting the practice of that person to, or by the exclusion of, one or more areas of practice, including limitations on practice privileges;

(4) Revoke his or her license or other authorization to practice medicine and surgery or podiatry or to prescribe or dispense controlled substances for a period not to exceed ten years;

(5) Require him or her to submit to care, counseling or treatment designated by the board as a condition for initial or continued licensure or renewal of licensure or other authorization to practice medicine and surgery or podiatry;

(6) Require him or her to participate in a program of education prescribed by the board;

(7) Require him or her to practice under the direction of a physician or podiatrist designated by the board for a specified period of time; and

(8) Assess a civil fine of not less than $1,000 nor more than $10,000.

(k) Notwithstanding the provisions of section eight, article one of this chapter, if the board determines the evidence in its possession indicates that a physician's or podiatrist's continuation in practice or unrestricted practice constitutes an immediate danger to the public, the board may take any of the actions provided in subsection (j) of this section on a temporary basis and without a hearing if institution of proceedings for a hearing before the board are initiated simultaneously with the temporary action and begin within fifteen days of the action. The board shall render its decision within five days of the conclusion of a hearing under this subsection.

(l) Any person against whom disciplinary action is taken pursuant to this article has the right to judicial review as provided in articles five and six, chapter twenty-nine-a of this code: *Provided*, That a circuit judge may also remand the matter to the board if it appears from competent

evidence presented to it in support of a motion for remand that there is newly discovered evidence of such a character as ought to produce an opposite result at a second hearing on the merits before the board and:

(1) The evidence appears to have been discovered since the board hearing; and

(2) The physician or podiatrist exercised due diligence in asserting his or her evidence and that due diligence would not have secured the newly discovered evidence prior to the appeal.

A person may not practice medicine and surgery or podiatry or deliver health care services in violation of any disciplinary order revoking, suspending or limiting his or her license while any appeal is pending. Within sixty days, the board shall report its final action regarding restriction, limitation, suspension or revocation of the license of a physician or podiatrist, limitation on practice privileges or other disciplinary action against any physician or podiatrist to all appropriate state agencies, appropriate licensed health facilities and hospitals, insurance companies or associations writing medical malpractice insurance in this state, the American Medical Association, the American Podiatry Association, professional societies of physicians or podiatrists in the state and any entity responsible for the fiscal administration of Medicare and Medicaid.

(m) Any person against whom disciplinary action has been taken under this article shall, at reasonable intervals, be afforded an opportunity to demonstrate that he or she can resume the practice of medicine and surgery or podiatry on a general or limited basis. At the conclusion of a suspension, limitation or restriction period the physician or podiatrist may resume practice if the board has so ordered.

(n) Any entity, organization or person, including the board, any member of the board, its agents or employees and any entity or organization or its members referred to in this article, any insurer, its agents or employees, a medical peer review committee and a hospital governing board, its members or any committee appointed by it acting without malice and without gross negligence in making any report or other information available to the board or a medical peer review committee pursuant to law and any person acting without malice and without gross negligence who assists in the organization, investigation or preparation of any such report or information or assists the board or a hospital governing body or any committee in carrying out any of its duties or functions provided by law is immune from civil or criminal liability, except that the unlawful disclosure of confidential information possessed by the board is a misdemeanor as provided in this article.

(o) A physician or podiatrist may request in writing to the board a limitation on or the surrendering of his or her license to practice medicine and surgery or podiatry or other appropriate sanction as provided in this section. The board may grant the request and, if it considers it appropriate, may waive the commencement or continuation of other proceedings under this section. A physician or podiatrist whose license is limited or surrendered or against whom other action is taken under this subsection may, at reasonable intervals, petition for

removal of any restriction or limitation on or for reinstatement of his or her license to practice medicine and surgery or podiatry.

(p) In every case considered by the board under this article regarding discipline or licensure, whether initiated by the board or upon complaint or information from any person or organization, the board shall make a preliminary determination as to whether probable cause exists to substantiate charges of disqualification due to any reason set forth in subsection (c) of this section. If probable cause is found to exist, all proceedings on the charges shall be open to the public who are entitled to all reports, records and nondeliberative materials introduced at the hearing, including the record of the final action taken: *Provided,* That any medical records, which were introduced at the hearing and which pertain to a person who has not expressly waived his or her right to the confidentiality of the records, may not be open to the public nor is the public entitled to the records.

(q) If the board receives notice that a physician or podiatrist has been subjected to disciplinary action or has had his or her credentials suspended or revoked by the board, a hospital or a professional society, as defined in subsection (b) of this section, for three or more incidents during a five-year period, the board shall require the physician or podiatrist to practice under the direction of a physician or podiatrist designated by the board for a specified period of time to be established by the board.

(r) Notwithstanding any other provisions of this article, the board may, at any time, on its own motion, or upon motion by the complainant, or upon motion by the physician or podiatrist, or by stipulation of the parties, refer the matter to mediation. The board shall obtain a list from the West Virginia State Bar's mediator referral service of certified mediators with expertise in professional disciplinary matters. The board and the physician or podiatrist may choose a mediator from that list. If the board and the physician or podiatrist are unable to agree on a mediator, the board shall designate a mediator from the list by neutral rotation. The mediation shall not be considered a proceeding open to the public and any reports and records introduced at the mediation shall not become part of the public record. The mediator and all participants in the mediation shall maintain and preserve the confidentiality of all mediation proceedings and records. The mediator may not be subpoenaed or called to testify or otherwise be subject to process requiring disclosure of confidential information in any proceeding relating to or arising out of the disciplinary or licensure matter mediated: *Provided,* That any confidentiality agreement and any written agreement made and signed by the parties as a result of mediation may be used in any proceedings subsequently instituted to enforce the written agreement. The agreements may be used in other proceedings if the parties agree in writing.

(s) A physician licensed under this article may not be disciplined for providing expedited partner therapy in accordance with article four-f, chapter sixteen of this code.

§30-3-15. Certificate of authorization requirements for medical and podiatry corporations.

(a) *Unlawful acts*. - It is unlawful for any corporation to practice or offer to practice medicine and surgery or podiatry in this state without a certificate of authorization issued by the board designating the corporation as an authorized medical or podiatry corporation.

(b) *Certificate of authorization for in-state medical or podiatry corporation.* - One or more physicians licensed to practice medicine and surgery in this state under this article, or one or more physicians licensed under this article and one or more physicians licensed under article fourteen of this chapter, or one or more podiatrists licensed to practice podiatry in this state may receive a certificate of authorization from the board to be designated a medical or podiatry corporation by:

(1) Filing a written application with the board on a form prescribed by the board;

(2) Furnishing satisfactory proof to the board that each shareholder of the proposed medical or podiatry corporation is a licensed physician or podiatrist pursuant to this article or article fourteen of this chapter; and

(3) Submitting applicable fees which are not refundable.

(c) *Certificate of authorization for out-of-state medical or podiatry corporation.* - A medical or podiatry corporation formed outside of this state for the purpose of engaging in the practice of medicine and surgery or the practice of podiatry may receive a certificate of authorization from the board to be designated a foreign medical or podiatry corporation by:

(1) Filing a written application with the board on a form prescribed by the board;

(2) Furnishing satisfactory proof to the board that the medical or podiatry corporation has received a certificate of authorization or similar authorization from the appropriate authorities as a medical or podiatry corporation, or professional corporation in its state of incorporation and is currently in good standing with that authority;

(3) Furnishing satisfactory proof to the board that at least one shareholder of the proposed medical or podiatry corporation is a licensed physician or podiatrist pursuant to this article and is designated as the corporate representative for all communications with the board regarding the designation and continuing authorization of the corporation as a foreign medical or podiatry corporation;

(4) Furnishing satisfactory proof to the board that all of the medical or podiatry corporation's shareholders are licensed physicians or podiatrists in one or more states and submitting a complete list of the shareholders, including each shareholder's name, their state or states of licensure and their license number(s); and

(5) Submitting applicable fees which are not refundable.

(d) *Notice of certificate of authorization to Secretary of State.* - When the board issues a certificate of authorization to a medical or podiatry corporation, then the board shall notify the Secretary of State that a certificate of authorization has been issued. When the Secretary of State receives a notification from the board, he or she shall attach that certificate of authorization to the corporation application and, upon compliance by the corporation with the pertinent provisions of this code, shall notify the incorporators that the medical or podiatry corporation, through licensed physicians or licensed podiatrists, may engage in the practice of medicine and surgery or the practice of podiatry in West Virginia.

(e) *Authorized practice of medical or podiatry corporation.* - An authorized medical corporation may only practice medicine and surgery through individual physicians licensed to practice medicine and surgery in this state. An authorized podiatry corporation may only practice podiatry through individual podiatrists licensed to practice podiatry in this state. Physicians or podiatrists may be employees rather than shareholders of a medical or podiatry corporation, and nothing herein requires a license for or other legal authorization of, any individual employed by a medical or podiatry corporation to perform services for which no license or other legal authorization is otherwise required.

(f) *Renewal of certificate of authorization.* - A medical or podiatry corporation holding a certificate of authorization shall register biennially, on or before the expiration date on its certificate of authorization, on a form prescribed by the board, and pay a biennial fee. If a medical or podiatry corporation does not timely renew its certificate of authorization, then its certificate of authorization automatically expires.

(g) *Renewal for expired certificate of authorization.* - A medical or podiatry corporation whose certificate of authorization has expired may reapply for a certificate of authorization by submitting a new application and application fee in conformity with subsection (b) or (c) of this section.

(h) *Ceasing operation -- In-state medical or podiatry corporation.* - A medical or podiatry corporation formed in this state and holding a certificate of authorization shall cease to engage in the practice of medicine, surgery or podiatry when notified by the board that:

(1) One of its shareholders is no longer a duly licensed physician or podiatrist in this state; or

(2) The shares of the medical or podiatry corporation have been sold or transferred to a person who is not a licensed physician or podiatrist in this state. The personal representative of a deceased shareholder shall have a period, not to exceed twelve months from the date of the shareholder's death, to transfer the shares. Nothing herein affects the existence of the medical or podiatry corporation or its right to continue to operate for all lawful purposes other than the practice of medicine and surgery or the practice of podiatry.

(i) *Ceasing operation -- Out-of-state medical or podiatry corporation.* - A medical or podiatry corporation formed outside of this state and holding a certificate of authorization shall immediately cease to engage in the practice of medicine, surgery or podiatry in this state if:

(1) The corporate shareholders no longer include at least one shareholder who is licensed to practice as a physician or podiatrist in this state;

(2) The corporation is notified that one of its shareholders is no longer a licensed physician or podiatrist; or

(3) The shares of the medical or podiatry corporation have been sold or transferred to a person who is not a licensed physician or podiatrist. The personal representative of a deceased shareholder shall have a period, not to exceed twelve months from the date of the shareholder's death, to transfer the shares. In order to maintain its certificate of authorization to practice medicine, surgery or podiatry during the twelve month period, the medical or podiatry corporation shall, at all times, have at least one shareholder who is a licensed physician or podiatrist in this state. Nothing herein affects the existence of the medical or podiatry corporation or its right to continue to operate for all lawful purposes other than the practice of medicine, surgery or podiatry.

(j) *Notice to Secretary of State.* - Within thirty days of the expiration, revocation or suspension of a certificate of authorization by the board, the board shall submit written notice to the Secretary of State.

(k) *Unlawful acts*. - It is unlawful for any corporation to practice or offer to practice medicine and surgery or podiatry after its certificate of authorization has expired or been revoked, or if suspended, during the term of the suspension.

(l) *Application of section.* - Nothing in this section is meant or intended to change in any way the rights, duties, privileges, responsibilities and liabilities incident to the physician-patient or podiatrist-patient relationship, nor is it meant or intended to change in any way the personal character of the physician-patient or podiatrist-patient relationship.

(m) *Court evidence.* - A certificate of authorization issued by the board to a corporation to practice medicine and surgery or podiatry in this state that has not expired, been revoked or suspended is admissible in evidence in all courts of this state and is prima facie evidence of the facts stated therein.

(n) *Penalties.* - Any officer, shareholder or employee of a medical or podiatry corporation who violates this section is guilty of a misdemeanor and, upon conviction thereof, shall be fined not more than $1,000 per violation.

The practice of medicine and surgery by persons possessing the degree of doctor of osteopathy and authorized by the laws of this state to practice medicine and surgery shall in no way be affected by the provisions of this article.

TITLE 19
LEGISLATIVE RULE
REGISTERED PROFESSIONAL NURSES

SERIES 8
LIMITED PRESCRIPTIVE AUTHORITY FOR NURSES IN ADVANCED PRACTICE

'19-8-1. General.

1.1. Scope. -- This rule establishes the requirements whereby the board authorizes qualified advanced practice registered nurses to prescribe prescription drugs in accordance with the provisions of W. Va. Code ''30-7-15a, 15b, and 15c.

1.2. Authority. -- W. Va. Code '30-7-15a.

1.3. Filing Date. -- May 15, 2017.

1.4. Effective Date. -- May 15, 2017.

1.5. Sunset Date. – This rule will Sunset effective May 15, 2022.

'19-8-2. Definitions.

2.1. "Actively prescribe prescription medication" means the Advanced Practice Registered Nurse currently holds active prescriptive authority.

2.2. Advanced Practice Registered Nurse means a registered nurse who has acquired advanced clinical knowledge and skills preparing him or her to provide direct and indirect care to patients, as a certified nurse practitioner, certified nurse-midwife, certified registered nurse anesthetist, or clinical nurse specialist, who has completed a board-approved graduate-level education program and who has passed a board approved national certification examination.

2.3. AAntineoplastics@ means chemotherapeutic agents in the active treatment of current cancer.

2.4. AChronic Condition@ means a condition which lasts three months or more, generally cannot be prevented by vaccines, can be controlled but not cured by medication, and does not generally disappear. These conditions with the exception of chronic pain, include but are not limited to anemia, anxiety, arthritis, asthma, bladder outlet obstruction, cardiovascular and pulmonary disease, cancer, diabetes, epilepsy and seizures, thyroid disease, and obesity, and do not include any condition which requires Antineoplastics, all subject to the scope of practice of the advanced practice registered nurse with limited prescriptive authority privilege W.Va. Code '30-7-15(a)(b)(c) and this rule.

'19-8-3. Application and Eligibility for Limited Prescriptive Authority.

3.1. The board shall grant prescriptive authority to an advanced practice registered nurse applicant who meets all eligibility requirements specified in W. Va. Code ' 30-7-15b and the following:

3.1.a. Successfully complete an advanced pharmacotherapy graduate level course approved by the board of not less than 45 pharmacology contact hours;

3.1.b. Provide documentation of the use of pharmacotherapy in clinical practice in the education program;

3.1.c. Provide evidence of 15 graduate level pharmacology contact hours in advanced pharmacotherapy completed within 2 years prior to application for prescriptive authority;

3.1.d. Submit official graduate level transcripts or certificates documenting completion of pharmacology and pharmacotherapy course work.

3.1.e. The board may request course outlines and/or descriptions of courses if necessary to evaluate the pharmacology course content and objectives.

3.1.f. The advanced practice registered nurse shall submit a notarized application for prescriptive authority on forms provided by the Board with the following:

3.1.f.1. A fee set forth in the board=s Fees rule, 19CSR12.

3.1.f.2. When required, written verification of an agreement to a collaborative relationship with a licensed physician holding an unencumbered West Virginia license or with a licensed physician holding an unencumbered license from a contiguous state or the Veterans Administration for prescriptive practice on forms provided by the board containing the following:

3.1.f.2.A. Mutually agreed upon written guidelines or protocols for prescriptive authority as it applies to the advanced practice registered nurse=s clinical practice;

3.1.f.2.B. Statements describing the individual and shared responsibilities of the advanced practice registered nurse and the physician pursuant to the collaborative agreement between them;

3.1.f.2.C. A provision for the periodic and joint evaluation of the prescriptive practice; and,

3.1.f.2.D. A provision for the periodic and joint review and updating of the written guidelines or protocols.

3.1.f.2.E. Additional documentation at the request of the board.

3.1.f.3. The Advanced Practice Registered Nurse may have limited prescriptive authority without a collaborative agreement after meeting the following outlined requirements:

3.1.f.3.A. Have practiced at least three years in a documented collaborative relationship with prescriptive authority;

3.1.f.3.B. Be licensed in good standing with the board;

3.1.f.3.C. Submit a completed application on forms developed by the board and pay an application fee.

3.1.f.4. The Board will identify and maintain data designating those Advanced Practice Registered Nurses approved to prescribe without a collaborative agreement.

3.2. If the board obtains information that an applicant for prescriptive authority was previously addicted to or dependent upon alcohol or the use of controlled substances, the board may grant prescriptive authority with limitation. The limitations may include, but are not limited to, restricting the types of schedule drugs a nurse may prescribe.

3.3. The board shall forward a copy of the verified collaborative agreement specified in Subdivision 3.1.f.2. of this rule to the Board of Medicine or to the Board of Osteopathy, whichever is indicated.

3.4. Upon satisfactory evidence that the advanced practice registered nurse applicant has met all above requirements for prescriptive authority, the Board shall assign an identification number to that nurse.

3.5. The board shall notify the Board of Pharmacy of those advanced practice registered nurses who have been granted prescriptive authority, and shall also provide the prescriber's identification number and effective date of prescriptive authority.

3.6. The advanced practice registered nurse shall file with the board any restrictions on prescriptive authority that are not imposed by W. Va. Code '60A-3-301 *et seq.*, or this rule, but which are within the written collaborative agreement and the name of the collaborating physician for each advanced practice registered nurse on the approved list.

3.7. The advanced practice registered nurse with prescriptive authority who wishes to prescribe Schedules III through V drugs shall comply with federal Drug Enforcement Agency requirements prior to prescribing controlled substances.

3.8. The advanced practice registered nurse shall immediately file any and all of his or her Drug Enforcement Agency registrations and numbers with the board.

3.9. The board shall maintain a current record of all advanced practice registered nurses with Drug Enforcement Agency registrations and numbers.

3.10. Any information filed with the board under the provisions of this rule shall be available, upon request, to any pharmacist, regulatory agency or board or shall be made available pursuant to other state or federal law.

3.11. The APRN shall maintain with the board a current mailing and, if available, a current e-mail address.

'19-8-4. Renewal of Prescriptive Privileges.

4.1. An applicant for renewal of prescriptive authority shall be licensed as an advanced practice registered nurse and shall:

4..1.a. Maintain an active, uninterrupted national certification as an advanced practice registered nurse and maintain this information on file in the Board Office.

4.1.b. Submit to the board all documentation evidencing national certification as an advanced practice registered nurse and subsequent, uninterrupted renewal of national certification thereof.

4.2. The board shall consider the national certification as an advanced practice registered nurse of a licensee to be lapsed where such licensee fails to renew his or her national certification prior to its expiration dates, or fails to provide to the board, at the office of the board, all proper documentation and evidence of an uninterrupted renewal of such national certification prior to its expiration date.

4.3. The applicant shall complete during the 2 years prior to renewal a minimum of 8 contact hours of pharmacology education that has been approved by the board which may be part of the same 12 contact hours of advanced pharmacotherapeutics submitted for the advanced practice registered nurse license renewal requirement.

4.4. The board shall renew prescriptive authority for advanced practice registered nurses biennially on a date determined by the Board.

4.5. The application must be notarized, and the fee set forth in the board=s rule, Fees For Services Rendered by the board, 19CSR12 must accompany the application.

'19-8-5. Drugs Excluded from Prescriptive Authority; Prescriptive Authority Requirements.

5.1. The advanced practice registered nurse shall not prescribe from the following categories of drugs:

5.1.a. Schedules I and II of the Uniform Controlled Substances Act;

5.1.b. Antineoplastics;

5.1.c. Radio-pharmaceuticals; or

5.1.d. General anesthetics.

5.1.e. Drugs listed under Schedule III are limited to a 30 day supply without refill.

5.2. Each prescription and subsequent refills given by the advanced practice registered nurse shall be entered on the patient's chart.

5.3. An advanced practice registered nurse may administer local anesthetics.

5.4. An advanced practice registered nurse who has been approved for ~~limited~~ prescriptive authority by the board may sign for, accept, and provide to patients samples of drugs received from a drug company representative.

5.5. The prescription authorized by an advanced practice registered nurse shall comply with the requirements of the West Virginia Board of Pharmacy, other applicable state and federal laws, rules and regulations all applicable standards of care; must be signed by the prescriber with the legal designation or the designated certification title of the prescriber and must include the prescriber=s identification number assigned by the board.

5.5.a. All prescriptions shall:

5.5.a.1. 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;

5.5.a.2. 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;

5.5.a.3. Contain space for the prescriber to indicate the date of the prescription, the full name of the drug, the dosage, the route of administration and directions, for its use and number of refills, if any, or to indicate no refills;

5.5.a.4. Provide space for the patient's name and address, and the prescribing practitioner's signature;

5.5.a.5. 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";

5.5.a.6. 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."

5.5.b. An advanced practice registered nurse shall at the time of the initial prescription record in the patient record the plan for continued evaluation of the effectiveness of the controlled substances prescribed.

' 19-8-6. Termination of Limited Prescriptive Privileges.

6.1. The board may deny or revoke privileges for prescriptive authority if the applicant or licensee has not met conditions set forth in the law or this rule, or if the applicant has violated any part of W. Va. Code ' 30-7-1 et seq.

6.2. The board shall notify the Board of Pharmacy within 24 hours after the termination of, or a change in, an advanced practice registered nurse=s prescriptive authority.6.3. If the board finds that the public health, safety and welfare requires emergency action and incorporates a finding to that effect into its order, the board shall order summary suspension of the prescriptive authority privilege pending proceedings for other action. The board shall promptly institute and determine further disciplinary action.

6.4. The board shall immediately terminate prescriptive authority of advanced practice registered nurse if disciplinary action has been taken against his or her license to practice registered professional nursing in accordance with W. Va. Code ' 30-7-11.

6.5. Prescriptive authority for the advanced practice registered nurse terminates immediately if either the license to practice registered professional nursing or the Advanced Practice Registered Nurse license in the State of West Virginia lapses.

6.6. Prescriptive authority is immediately and automatically terminated if national certification as an advanced practice registered nurse lapses or if the advanced practice registered nurse fails to provide the board evidence of current certification or re-certification of national certification before the expiration of the last certification on record with the board.

6.7. If authorization for prescriptive authority is not renewed by the expiration date which appears on the document issued by the board reflecting approval of prescriptive authority, the authority terminates immediately on the expiration date.

6.8. An advanced practice registered nurse shall not prescribe controlled substances for his or her personal use or for the use of members of his or her immediate family.

6.9. An advanced practice registered nurse shall not provide controlled substances or prescription drugs for other than therapeutic purposes.

6.10. An advanced practice registered nurse with prescriptive authority may not delegate the prescribing of drugs to any other person.

6.11. When applicable, prescriptive authorization shall be terminated if the advanced practice registered nurse has not filed a current verified collaborative agreement with the board. Upon dissolvement of a collaborative agreement, if there is no other current collaborative agreement the advanced practice registered nurse shall cease prescribing immediately, prescribing privileges will be terminated, and the advanced practice registered nurse shall have 60 days to provide the board a verified current collaborative agreement to reinstate the prescribing privilege, after 60 days a reinstatement application must be completed and submitted for reinstatement of the prescribing privilege.

' 19-8-7. Reinstatement of Lapsed or Terminated Limited Prescriptive Privileges.

7.1. An advanced practice registered nurse whose prescriptive authority has lapsed or been terminated for failing to maintain an active West Virginia license as a registered nurse or for failing to maintain or provide the Board proof of active national certification or recertification as an advanced practice registered nurse or failing to maintain prescriptive authority granted by the Board may have the prescriptive authority reinstated upon submission of the application for prescriptive authority with the required fee and a satisfactory explanation for the lapse or termination.

Physician Assistant Prescriptive Authority

§11-1B-12. Delegation of Prescriptive Authority.

12.1. A supervising physician may delegate limited prescriptive authority to a physician assistant in a practice agreement if:

12.1.a. The physician assistant has obtained a baccalaureate or master's degree from an approved program of instruction for physician assistants or has successfully completed an accredited course of instruction in clinical pharmacology approved by the Board of not less than four semester hours. The Board may grant up to one credit hour equivalent for two or more years of prescribing experience in other jurisdictions;

12.1.b. The physician assistant provides evidence of successful completion of a minimum of three hours of drug diversion training and best practice prescribing of controlled substances training through a Board approved course within two years prior to his or her application submission to the Board for limited prescriptive privileges; and

12.1.c. The supervising physician and physician assistant attest that:

12.1.c.1. The physician assistant has successfully completed the necessary requirements to be eligible to prescribe pursuant to a practice agreement;

12.1.c.2. All prescribing activities of the physician assistant shall comply with applicable federal and state law governing the practice of physician assistants the Board approved limitations on physician assistant prescribing;

12.1.c.3. All medical charts or records shall contain a notation of any prescriptions written by a physician assistant; and

12.1.c.4. All prescriptions, including electronic prescriptions, written by the physician assistant will include the physician assistant's name and the supervising physician's name, business address and business telephone number.

12.2. To delegate prescriptive authority, the supervising physician shall ensure that the practice agreement includes a clear delineation of the delegated authority and whether it includes the prescribing, administering, dispensing and/or ordering of drugs and/or medical devices.

12.3. On an annual basis, the Board shall approve and publish on its website a list classifying pharmacologic categories of all drugs which physician assistants are prohibited from prescribing. This list shall, at a minimum, prohibit physician assistants from prescribing:

12.3.a. Schedules I and II of the Uniform Controlled Substances Act;

12.3.b. Greater than a non-refillable seventy-two hour supply of a drug listed under Schedule III of the Uniform Controlled Substances Act;

12.3.c. Antineoplastics and chemotherapeutic agents used in the active treatment of current cancer; and

12.3.d. Radio-pharmaceuticals, general anesthetics and radiographic contrast materials.

12.4. A practice agreement may not delegate the prescribing of a drug that the Board has prohibited physician assistants from prescribing.

12.5. A supervising physician who seeks to delegate prescribing authority to a physician assistant shall provide the physician assistant with treatment protocols which identify maximum prescribing dosages. Prescriptions written by a physician assistant shall be issued consistent with the supervising physician's directions and treatment protocol, and in no case may the dosage exceed the manufacturer's recommended average therapeutic dose for the prescribed drug.

12.6. Each prescription and subsequent refills given by the physician assistant shall be entered on the patient's chart.

12.7. Physician assistants authorized to issue prescriptions for Schedules III through V controlled substances shall include the Federal Drug Enforcement Administration number issued to that physician assistant. The maximum amount of Schedule IV or Schedule V drugs shall be no more than ninety dosage units or a thirty day supply, whichever is less, and may not authorize a refill.

12.8. Prescriptions for other legend drugs shall not be prescribed or refillable for a period exceeding six months, except that an annual supply of any drug, other than a controlled substance, may be prescribed for the treatment of a chronic condition other than chronic pain management. An annual supply may be prescribed or dispensed in smaller increments in order to assess the drug’s therapeutic efficacy. The chronic disease being treated shall be noted on each such prescription by the physician assistant.

12.9. Within five business days following a Board meeting, the Board of Medicine shall provide the Board of Pharmacy with a list of physician assistants with limited prescriptive privileges along with the categories of drugs or drugs within a category that the physician assistant has been authorized to prescribe.

12.10. Nothing in this rule shall be construed to permit any physician assistant to independently prescribe or dispense drugs.

12.11. Physician assistants granted limited prescriptive privileges pursuant to an authorized practice agreement may accept professional samples as defined in 11 CSR 5.

TITLE 14 LEGISLATIVE RULE
WEST VIRGINIA BOARD OF OPTOMETRY

SERIES 2
ORAL PHARMACEUTICAL CERTIFICATE

§14-2-1. General.

1.1. Scope. -- This legislative rule establishes the requirements, procedures and standards for the certification and re-certification of licensees to obtain an oral pharmaceutical certificate.

1.2. Authority. -- W. Va. §30-8-6, §30-8-9, and §30-8-14 .

1.3. Filing Date. -- August 12, 2011.

1.4. Effective Date. – August 19, 2011.

§14-2-2. Requirements For Oral Pharmaceutical Certificate.

2.1. To be permitted to prescribe oral drugs under the provisions of W. Va. Code §§30-8-9 and 30-8-14, a licensee shall apply to the Board for certification. To qualify for certification, a licensee:

2.1.a. Shall satisfactorily complete a course in clinical pharmacology as applied to optometry. This course shall have particular emphasis on the administration of oral pharmaceutical agents for the diagnosis and treatment of visual defects or abnormal conditions of the human eye and its appendages. In addition, the course shall include instruction on the clinical use of Schedule III, IV, and V agents. This course shall consist of a minimum of thirty (30) hours in clinical systemic pharmacology. The course shall be taught by:

2.1.a.1. a school or college of optometry or a medical school, accredited by a regional or professional accreditation organization which is recognized or approved by the council on postsecondary accreditation or by the United States Department of Education, federally sponsored health education center; or

2.1.a.2. other non-profit continuing education agencies in cooperation with appropriate optometry or medical school faculty. All courses of instruction shall be approved by the Board; and

2.1.b. Shall pass an examination relating to the treatment and management of ocular disease, which is prepared, administered, and graded by the National Board of Examiners in Optometry or other nationally recognized optometric organization as approved by the Board.

§14-2-3. Certificate Application.

3.1. The licensee shall complete the prescribed oral pharmaceutical certificate application form.

3.2. The licensee shall submit a certificate of successful completion by the licensee for the course listed in section 2 of this rule. The Board or its designee shall verify successful completion of the course directly with the provider.

3.3. The licensee shall submit the passing score report for the examination listed in 2.1.b. of this rule. The Board or its designee shall verify passage of the examination directly with the provider.

3.4. The licensee shall submit a copy of a liability insurance certificate in an amount of not less than One Million Dollars ($1,000,000) per occurrence and Three Million ($3,000,000) aggregate coverage.

3.5. The licensee shall submit the fee listed in the Board's rule, Schedule of Fees,

W. Va. Code of Rules, §14-5.

§14-2-4. Certification.

4.1. Upon the licensee's successful completion of the requirements and application listed in sections 2 and 3

and approval by the Board or its designee a certificate may be issued.

4.2. Upon issuance of the certificate, the licensee's license number shall be changed. The license number will be followed by a dash and "OD" for oral prescriptive authority.

§14-2-5. Re-certification.

5.1. The certificate holder applying for re- certification shall have available for the Board, satisfactory evidence that he or she has acquired the continuing education hours required under the W. Va. Code of Rules, §14-10 and this rule, to renew his or her annual license. Of those required hours, an optometrist certified under the provisions of this rule shall furnish to the Board satisfactory evidence that at least six (6) hours of the required hours were acquired in educational optometric programs in ocular pathology or therapeutic pharmacological agents.

5.2. The certificate holder shall submit a copy of a liability insurance certificate in an amount of not less than One Million Dollars ($1,000,000) per occurrence and Three Million ($3,000,000) aggregate coverage.

5.3. The certificate holder shall submit the fee listed in the W. Va. State Code of Rules, §14-5, Schedule of Fees.

licensee shall practice under the provisions of this rule unless and until he or she has submitted to the board evidence of the liability insurance coverage in an amount not less than One Million Dollars ($1,000,000) per occurrence and Three Million Dollars ($3,000,000) aggregate coverage.

§14-2-7. Drug Formulary.

7.1. Licensees certified under the provisions of this rule may prescribe the drugs set forth in W. Va. Code §§30-8-9, 30-8-14 and this section.

7.2. W. Va. Code §30-8-6 authorizes the Board to develop a formulary of categories of oral drugs to be considered rational to the diagnosis and treatment of visual defects or abnormal conditions of the human eye and its appendages from Schedules III, IV and V, excluding Schedule I and Schedule II of the Uniform Controlled Substances Act. The categories include:

7.2.a. Oral Antibiotics;

7.2.b. Oral Nonsteroidal Anti- Inflammatory Drugs;

7.2.c. Oral Carbonic Anhydrase Inhibitors;

7.2.d. Antihistamines;

7.2.e. Oral Corticosteroids, may be prescribed for a duration of no more than six days;

5.4. It is the responsibility of each licensee to furnish proof of current liability insurance coverage to the Board upon application for certification and re-certification.

§14-2-6. Insurance.

6.1. All licensees certified under this rule shall carry liability insurance coverage in an amount of not less than One Million Dollars ($1,000,000) per occurrence and Three Million Dollars ($3,000,000) aggregate coverage. No Analgesics, provided that no oral narcotic analgesic may be prescribed for a duration of more than three days; and

7.2.f. Nutritional Supplements.

7.2. h. New drugs or new drug indications from Schedules III, IV and V, excluding Schedule I and Schedule II of the Uniform Controlled Substances Act which, regardless of their listed classification, have been shown to be effective in the examination, diagnosis or treatment of diseases and conditions of the human eye and its appendages may be

approved by the Board according to the provisions of W. Va. Code §§30-8-9 and 30-8- 14.

7.2.i. A list of approved new drugs and new drug indications proven to be effective in the examination, diagnosis or treatment of diseases and conditions of the human eye and its appendages will be maintained by the Board for public inspection.

7.2.j. The approval of Schedule I and Schedule II drugs is prohibited.

§14-2-8. New Drug Approval.

8.1. The addition of new drugs or drug indications by the Board as cited in subsection 7.2 of this rule may be based on any of the following criteria:

8.1.a. A new or existing drug has been approved by the Food and Drug Administration for the treatment of the eye or its appendages.

8.1.b. A new drug or new drug indication has gained accepted use in the eye care field. Such acceptance may be indicated by its inclusion in the curriculum of an optometry school accredited by the Accreditation Council on Optometric Education or its successor approved by the U.S. Department of Education or approved post-graduate continuing education, through peer-reviewed, evidence-based research and professional journal articles, or by inclusion in established standards of practice and care published by professional organizations.

§14-2-9. Education and Training on the Use of New Drugs and New Drug Indications.

9.1. Additional education and training may be required by the Board as it deems appropriate when it adds new drugs or new drug indications.

9.2. This training may be provided through an optometry school accredited by the Accreditation

Council on Optometric Education or its successor recognized by the U.S. Department of Education or approved post- graduate training.

9.3. A list of Board required training for new drugs or new drug indications will be maintained by the Board for public inspection.

§14-2-10. Restrictions.

10.1. A certificate holder may not establish a pharmacy in an optometric office or sell oral pharmaceutical agents prescribed in treatment unless there is a licensed pharmacist on staff and present when the prescriptions are filled.

10.1.a. The certificate holder may also pass on to the patient a charge for any medications provided to initiate treatment which reflects only the actual amount paid by the optometrist for the agents. In no event shall an optometrist increase the cost of the pharmaceutical agent beyond the wholesale cost of that medication.

10.2. The certificate holder practicing under the authority of this rule shall be held to the same standards of care as that of other health care practitioners providing similar services.