# PHARMACY LAWS AND LEGISLATIVE RULES OF WEST VIRGINIA

GOVERNING

THE PRACTICE OF PHARMACY

CONTROLLED SUBSTANCES ACT

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**2015 EDITION**

WEST VIRGINIA

BOARD OF PHARMACY

Reprinted from the West Virginia Code and Rules

# INFORMATION REGARDING PRESCRIPTIVE AUTHORITY OF PHYSICIAN ASSISTANTS AND ADVANCED PRACTICE REGISTERED NURSES

## PHYSICIAN ASSISTANTS

**§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 (4) semester hours. The Board may, at its discretion, grant up to one credit hour equivalent for two (2) 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 (3) hours of drug diversion training and best practice prescribing of controlled substances training through a Board approved course within two (2) 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 seventy-two (72) hour supply of any 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 any 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. Prescriptions written for Schedule III drugs shall be limited to a seventy-two (72) hour supply and may not authorize a refill. The maximum amount of Schedule IV or Schedule V drugs shall be no more than ninety (90) dosage units or a thirty (30) 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 (6) months, except that an annual supply of any drug, other than a controlled substance, may be prescribed for the treatment of a chronic condition as defined in subdivision 2.1.g., other than chronic pain management: Provided, an annual supply may be prescribed or dispensed in smaller increments, at the discretion of the practitioner, in order to assess the drug's therapeutic efficacy: Provided further, 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 the Board's Rules for Dispensing of Legend Drugs by Physicians and Podiatrists, 11 CSR 5, on behalf of the supervising physician.

## 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 nurses in advanced practice to prescribe prescription drugs in accordance with the provisions of W. Va. Code §§30-7-15a, 15b, 15c, and 30-15-1 through 7c. An authorized advanced practice registered nurse practitioner may write or sign prescriptions or transmit prescriptions verbally or by other means of communication.

**§19-8-5. Drugs Excluded from Prescriptive Authority.**

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. MAO Inhibitors, except when in a collaborative agreement with a psychiatrist.

5.2. Drugs listed under Schedule III and benzodiazepines are limited to a 72 hour supply without refill.

5.3. The advanced practice registered nurse may prescribe drugs from Schedules IV through V in a quantity necessary for up to a 90 day supply, with only 1 refill, and shall provide that the prescription expires in 6 months, with the following exceptions:

5.3.a. Prescriptions for phenothiazines shall be limited to up to a 30 day supply and shall be non-refillable;

5.3.b. Prescriptions for non-controlled substances of antipsychotics, and sedatives prescribed by the advanced practice registered nurse shall not exceed the quantity necessary for a 90 day supply, shall provide for no more than 1 prescription refill and shall expire in 6 months.

5.4. Pursuant to a collaborative agreement as set forth in the law governing prescriptive authority the advanced practice registered nurse may prescribe an annual supply of any drug, with the exception of controlled substances, which is prescribed for the treatment of a chronic condition, other than chronic pain management.

5.5. The maximum dosage of any drug, including antidepressants, prescribed by the advanced practice registered nurse shall be consistent with the advanced practice registered nurse's area of practice.

5.6. Each prescription and subsequent refills given by the advanced practice registered nurse shall be entered on the patient's chart.

5.7. Advanced practice registered nurse shall not prescribe other prescription drugs or refill for a period exceeding 6 months; provided, that this limitation shall not include contraceptives or those treating a chronic condition as defined in WV Code §30-7-15a and section 19-8-5.4 of this rule.

5.8. An advanced practice registered nurse may administer local anesthetics.

5.9. The 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.

5.10. The prescription authorized by an advanced practice registered nurse shall comply with all applicable state and federal laws and regulations; 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 or the prescriber's national provider identifier assigned by the National Provider System pursuant to 45 CFR §162.408.

5.10.a. All prescriptions shall include the following information:

5.10.a.1. The name, title, address and phone number of the prescribing advanced practice registered nurse;

5.10.a.2. The name and date of birth of the patient;

5.10.a.3. The date of the prescription;

5.10.a.4. The full name of the drug, the dosage, the route of administration and directions, for its use;

5.10.a.5. The number of refills;

5.10.a.6. The Drug Enforcement Agency number of the prescriber, when required by federal laws; and

5.10.a.7. The prescriptive authority identification number issued by the board.

5.10.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.

5.10.c. An advanced practice registered nurse shall prescribe refills of controlled substances according to current laws and standards.

5.10.d. Drugs considered to be proved human teratogens shall not be prescribed during a known pregnancy by the advanced practice registered nurse. This prohibition includes all Category D and X drugs from the Federal Drug Administration Categories of teratogen risks (21 CFR 201.57). Category C drugs should be given only if the patient benefit justifies the potential risks to the fetus and only after consultation with the collaborating physician.

5.11. The board may approve a formulary classifying pharmacologic categories of all drugs which may be prescribed by an advanced practice registered nurse with prescriptive authority.

**WEST VIRGINIA CODE**

**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; and

(32) 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.

(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 licensed pharmacists 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 controlled substances or violent crime;

(9) Not been convicted in any jurisdiction of a felony or any crime which bears a rational nexus to the individual's ability to practice pharmacist care; 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 twenty-two 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 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; or

(3) 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 collaborative 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.**

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 the board may bring its information to the attention of an appropriate law-enforcement official.

**WEST VIRGINIA CODE**
**CHAPTER 33. INSURANCE.**
**ARTICLE 15E. DISCOUNT MEDICAL PLAN ORGANIZATIONS AND DISCOUNT PRESCRIPTION DRUG PLAN ORGANIZATIONS ACT.**

**§33-15E-1. Short title.**
This article shall be cited as the "Discount Medical Plan Organizations and Discount Prescription Drug Plan Organizations Act."

**§33-15E-2. Purpose.**
The purpose of this article is to establish standards for discount medical plan organizations and discount prescription drug plan organizations in order to better protect consumers from unfair or deceptive marketing, sales and enrollment practices and to facilitate consumer understanding of the role and function of the organizations in providing access to medical or ancillary services.

**§33-15E-3. Definitions.**
For purposes of this article:

(1) "Affiliate" means a person that directly, or indirectly through one or more intermediaries, controls, is controlled by, or is under common control with, the specified person.

(2) "Ancillary services" includes audiology, dental, vision, mental health, substance abuse, chiropractic and podiatry services.

(3) "Control" or "controlled by" or "under common control with" has the same meaning ascribed to them in subsection (d), section two, article forty-six of this chapter.

(4) "Discount medical plan" means a business arrangement or contract in which a person, in exchange for fees, dues, charges or other consideration, offers access for its plan members to providers of medical or ancillary services and the right to receive discounts on medical or ancillary services provided under the discount medical plan from those providers. "Discount medical plan" does not include any plan that does not charge a membership or other fee to use the plan's discount medical card.

(5) "Discount prescription drug plan" means a business arrangement or contract in which a person, in exchange for fees, dues, charges or other consideration, provides access for its plan members to providers of pharmacy services and the right to receive discounts on pharmacy services provided under the discount prescription drug plan from those providers. "Discount prescription drug plan" does not include:

(A) Any plan that does not charge a membership or other fee to use the plan's discount prescription drug card;

(B) A patient access program; or

(C) A Medicare prescription drug plan.

(6) "Discount medical plan organization" means an entity that contracts with providers, provider networks or other discount medical plan organizations to offer access to medical or ancillary services at a discount to plan members, provides access for discount medical plan members to the services in exchange for fees, dues, charges or other consideration, and determines the charges to plan members.

(7) "Discount prescription drug plan organization" means an entity that contracts with providers, pharmacy networks or other discount prescription drug plan organizations to offer access to pharmacy services to plan members at a discount, provides access for discount prescription drug plan members to the services in exchange for fees, dues, charges or other consideration, and determines the charges to plan members.

(8) "Facility" means an institution providing medical or ancillary services or a health care setting, including, hospitals or other licensed inpatient centers, ambulatory surgical or treatment centers, skilled nursing centers, residential treatment centers, rehabilitation centers or diagnostic laboratories or imaging centers.

(9) "Health care professional" means a physician, pharmacist or other health care practitioner who is licensed to perform specified medical or ancillary services within the scope of his or her license.

(10) "Marketer" means a person that markets, promotes, sells or distributes a discount medical plan, including any entity that places its name on and markets or distributes a discount medical plan pursuant to a marketing agreement with a discount medical plan organization.

(11) "Medical services" means any maintenance, care of or preventive care for the human body or care, service or treatment of an illness or dysfunction of or injury to the human body, and includes, physician care, inpatient care, hospital surgical services, emergency services, ambulance services, laboratory services and medical equipment and supplies. "Medical services" does not include pharmacy or ancillary services.

(12) "Medicare prescription drug plan" means a plan that provides a Medicare Part D prescription drug benefit in accordance with the requirements of the federal Medicare Prescription Drug, Improvement and Modernization Act of 2003, Pub. L. 108-173 §101 *et seq.*

(13) "Member" means any person who pays fees, dues, charges or other consideration for the right to receive the benefits of a discount medical plan or discount prescription drug plan.

(14) "Patient access program" means a voluntary program sponsored by one or more pharmaceutical manufacturers that provides free or discounted health care products directly to low income or uninsured individuals either through a discount card or direct shipment.

(15) "Person" means an individual, a corporation, a partnership, a joint venture, a joint stock company, a trust, an unincorporated organization, any similar entity or any combination of the foregoing.

(16) "Pharmacy services" includes pharmaceutical supplies and prescription drugs.

(17) "Provider" means any health care professional or facility that has contracted, directly or indirectly, with a discount medical plan organization to provide medical or ancillary services to members.

(18) "Provider network" means an entity that negotiates directly or indirectly with a discount medical plan organization on behalf of more than one provider to provide medical or ancillary services to members.

**§33-15E-4. Licensing requirements.**

(a) A person is required to obtain a license prior to doing business in this state as a discount medical plan organization.

(b) The commissioner shall propose rules for legislative approval in accordance with the provisions of article three, chapter twenty-nine-a of this code, as well as emergency rules in accordance with section fifteen of said article, setting forth the licensing requirements. These rules shall include, at a minimum:

(1) All necessary forms and other information considered necessary and required by the commissioner for processing the license application;

(2) Applicable fees;

(3) Reciprocity requirements;

(4) Time frames for the application and approval process;

(5) Conditions of approval of the license application or denial of the license;

(6) Renewal process;

(7) Notice requirements; and

(8) Any other provisions considered necessary by the commissioner to effectuate the provisions of this article.

**§33-15E-5. Minimum capital requirements.**

(a) Before the commissioner issues a license to any person required to obtain a license under section four of this article, the person seeking to operate a discount medical plan organization shall demonstrate that it has a positive net worth of at least one hundred fifty thousand dollars.

(b) Each discount medical plan organization shall at all times maintain a positive net worth of at least one hundred fifty thousand dollars.

**§33-15E-6. Surety bond requirements.**

Each licensed discount medical plan organization shall maintain in force a surety bond in its own name, in an amount not less than thirty-five thousand dollars, in favor of the commissioner for the benefit of any person who is damaged by any violation of this article. The bond shall cover any

violation occurring during the time period during which the bond is in effect and shall be issued by an insurance company licensed to do business in this state. A copy of the bond or a statement identifying the depository, trustee, and account number of the surety account, and thereafter proof of annual renewal of the bond or maintenance of the surety account, shall be filed with the commissioner.

**§33-15E-7. Examinations.**

The commissioner may examine the business and affairs of any discount medical plan organization to protect the interests of the residents of this state based on the following reasons, including complaint indices, recent complaints or information from other states, or as he or she deems necessary. An examination shall be performed in accordance with the provisions of section nine, article two of this chapter, except that a discount medical plan organization that is the subject of the examination shall pay the expenses incurred in conducting the examination. Failure by the discount medical plan organization to pay the expenses is grounds for the refusal to renew, revoke or suspend a license to operate as a discount medical plan organization.

**§33-15E-8. Charges and fees; refund requirements; bundling of services.**

(a) A discount medical plan organization may charge a periodic charge as well as a reasonable one-time processing fee for a discount medical plan.

(b)(1) All discount medical plan certificates or other document demonstrating membership in the plan issued to persons in this state shall have a notice, prominently printed on the first page of the document or in a similarly conspicuous manner, stating that the member has the right to cancel his or her membership for any reason within thirty days of its receipt. If a member cancels his or her membership in the discount medical plan organization within the first thirty days after the date of receipt of the written document demonstrating membership, the member shall, upon return of the discount medical plan card to the discount medical plan organization, receive a reimbursement of all periodic charges and the amount of any one-time processing fee that exceeds thirty dollars. Notice of cancellation is deemed given when delivered by hand or deposited in a mailbox, properly addressed and postage prepaid to the mailing address of the discount medical plan organization or e-mailed to the e-mail address of the discount medical plan organization.

(2) If the discount medical plan organization cancels a membership for any reason other than nonpayment of charges by the member, the discount medical plan organization shall make a pro rata reimbursement of all periodic charges to the member.

(c) When a marketer or discount medical plan organization sells a discount medical plan in conjunction with any other products, the marketer or discount medical plan organization shall:

(1) Provide the charges for each discount medical plan in writing to the member; or

(2) Reimburse the member for all periodic charges for the discount medical plan and all periodic charges for any other product if the member cancels his or her membership in accordance with subdivision (1), subsection (b) of this section.

(d) A health carrier that provides a discount medical plan product that is incidental to the insured product is not subject to this section.

**§33-15E-9. Record filing and retention requirements.**

(a) (1) Upon demand by the commissioner, a discount medical plan organization shall file with the commissioner a list of prospective member fees and charges associated with the discount medical plan.

(b) A copy of every form to be used by a discount medical plan organization, including the form for the written document demonstrating membership in the plan and all advertising, marketing materials and brochures, shall be retained by such organization and available for inspection by the commissioner for at least two years from the date on which such form was last used.

**§33-15E-10. Provider agreements; provider listing requirements.**

(a) (1) A discount medical plan organization shall have a written provider agreement with all providers offering medical or ancillary services to its members. The written provider agreement may be entered into directly with the provider or indirectly with a provider network to which the provider belongs.

(2) A provider agreement between a discount medical plan organization and a provider shall provide the following:

(A) A list of the medical or ancillary services and products to be provided at a discount;

(B) The amount or amounts of the discounts or, alternatively, a fee schedule that reflects the provider's discounted rates; and

(C) A written document demonstrating that the provider has agreed that it will not charge members more than the discounted rates.

(3) A provider agreement between a discount medical plan organization and a provider network shall require that the provider network have written agreements with its providers that:

(A) Contain the provisions described in subdivision (2) of this subsection;

(B) Authorize the provider network to contract with the discount medical plan organization on behalf of the provider; and

(C) Require the provider network to maintain an up-to-date list of its contracted providers and to provide the list on a monthly basis to the discount medical plan organization.

(4) A provider agreement between a discount medical plan organization and an entity that contracts with a provider network shall require that the entity, in its contract with the provider network, require the provider network to have written agreements with its providers that comply with subdivision (3) of this subsection.

(5) The discount medical plan organization shall maintain a copy of each of its active provider agreements; each such organization shall also retain a copy of every inactive provider agreement for at least two years after the expiration date of each such agreement.

(b) Each discount medical plan organization shall maintain on its Internet website page a current list of the names and addresses of the providers with which it has contracted directly or through a provider network; the address of the website shall be prominently displayed on all of the discount medical plan organization's advertisements, marketing materials, brochures and discount medical plan cards.

**§33-15E-11. Marketing requirements.**

(a) A discount medical plan organization may market directly or contract with other marketers for the distribution of its product.

(b) (1) A discount medical plan organization shall have a written agreement with a marketer prior to the marketer's marketing, promoting, selling or distributing the discount medical plan.

(2) The agreement between the discount medical plan organization and the marketer shall prohibit the marketer from using advertising, marketing materials, brochures and discount medical plan cards without the discount medical plan organization's approval in writing.

(3) The discount medical plan organization shall be bound by and responsible for the activities of a marketer that are within the scope of the marketer's agency relationship with the organization.

(c) A discount medical plan organization shall approve in writing all advertisements, marketing materials, brochures and discount cards used by marketers to market, promote, sell or distribute the discount medical plan prior to their use.

**§33-15E-12. Annual reports.**

(a) If the information required in subsection (b) of this section is not provided at the time of renewal of a license under section four of this article, a discount medical plan organization shall file an annual report with the commissioner in the form prescribed by the commissioner, within three months after the end of each fiscal year.

(b) The report shall include:

(1) Audited financial statements prepared in accordance with generally accepted accounting principals certified by an independent certified public accountant, including the organization's balance sheet, income statement and statement of changes in cash flow for the preceding year, except that, subject to the approval of the commissioner, an organization that is an affiliate of a parent entity that is publicly traded and that prepares audited financial statements reflecting the consolidated operations of the parent entity may instead submit the audited financial statements of the parent entity and a written guaranty that the minimum capital requirements required under section five of this article will be met by the parent entity;

(2) Any changes in the list of names and residence addresses of all persons responsible for the conduct of the organization's affairs, together with a disclosure of the extent and nature of any contracts or arrangements with these persons and the discount medical plan organization, including any possible conflicts of interest;

(3) The number of discount medical plan members in the state; and

(4) Any other information relating to the performance of the discount medical plan organization that may be required by the commissioner.

(c) Any discount medical plan organization that fails to file an annual report in the form and within the time required by this section may be fined up to five hundred dollars per day for the first ten days during which the violation continues and up to one thousand dollars per day after the first ten days during which the violation continues. The commissioner may also suspend the organization's authority to enroll new members or to do business in this state while the violation continues.

**§33-15E-13. Discount prescription drug plan organizations.**

(a) A discount prescription drug plan organization shall comply with sections eight, nine, ten and eleven of this article and shall report any of the information described in section twelve of this article in the form and manner as the commissioner may require. A discount prescription drug plan organization is also subject to sections fourteen, fifteen and sixteen of this article.

(b) Each discount prescription drug plan organization shall designate and provide the commissioner with the name, address and telephone number of a discount prescription drug plan compliance officer responsible for ensuring compliance with the provisions of this article that are applicable to discount prescription drug plans and discount prescription drug plan organizations.

**§33-15E-14. Administrative enforcement actions; injunctions.**

(a) The commissioner may investigate the business affairs and conduct of every person applying for or holding a discount medical plan organization license and the operational affairs of a discount prescription drug plan organization to determine whether a violation of this article or any rule promulgated hereunder has occurred or is occurring.

(b) If the commissioner has cause to believe that a violation of this article or any rule promulgated hereunder has occurred or is occurring and that an enforcement action may be warranted, he or she shall notify the discount medical plan organization or discount prescription drug plan organization in writing, specifically stating the grounds for enforcement action and informing the organization that it may pursue a hearing on the matter in accordance with the provisions of section thirteen, article two of this chapter.

(c) If, after notice and hearing, a violation of this article or any legislative rule promulgated under this article is found, the Insurance Commissioner may take one or more of the following enforcement actions:

(1) Place a discount medical plan organization on probation or suspend, revoke or refuse to issue or renew the organization's license;

(2) Levy a civil penalty on the organization in an amount not exceeding ten thousand dollars for each violation;

(3) Issue an administrative order requiring the discount medical plan organization or discount prescription drug plan organization to cease and desist from engaging in the act or practice that constitutes the violation; or

(4) Suspend the authority of the discount medical plan organization or discount prescription drug plan organization to enroll new members.

(d) In addition to the penalties and other provisions of this article, the commissioner may seek both temporary and permanent injunctive relief in the circuit court of Kanawha County when a discount medical plan is being operated by a person or entity that is not licensed pursuant to this article or any person has engaged or is engaging in any activity prohibited by this article or any rule adopted pursuant to this article.

**§33-15E-15. Criminal penalties.**

(a) A person that willfully operates as or aids and abets another operating as a discount medical plan organization in violation of subsection (a), section four of this article is guilty of a felony and, upon conviction thereof, shall be fined not more than $20,000 for each unauthorized act or imprisoned in the state correctional facility not less than one nor more than five years, or both fined and imprisoned.

(b) No person shall collect a fee for purported membership in a discount medical plan or discount prescription drug plan and knowingly and willfully fail to provide the promised benefits of the plan.

(1) Any person who violates this subsection and in doing so collects fees totaling $1,000 or more is guilty of a felony and, upon conviction thereof, shall be fined not more than $2,500 or imprisoned in a state correctional facility not less than one nor more than ten years or, in the discretion of the court, be confined in jail for not more than one year, or both fined and imprisoned or confined.

(2) Any person who violates this subsection and in doing so collects fees totaling less than $1,000 is guilty of a misdemeanor and, upon conviction thereof, shall be fined not more than $2,500 or confined in jail not more than one year, or both fined and confined.

**§33-15E-16. Insurance fraud unit.**

The insurance fraud unit created pursuant to the provisions of section eight, article forty-one of this chapter may investigate suspected violations of this article.

**§33-15E-17. Rules.**

The commissioner may propose rules for legislative approval in accordance with the provisions of article three, chapter twenty-nine-a of this code to carry out the provisions of this article. The commissioner may also promulgate emergency legislative rules to carry out the provisions of this article, including rules setting forth the requirements and prohibited practices with regard to the marketing of discount medical plans and discount prescription drug plans and for disclosures to members and prospective members of the plans.

**WEST VIRGINIA CODE**

**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.

**WEST VIRGINIA CODE**

**CHAPTER 60A. UNIFORM CONTROLLED SUBSTANCES ACT.**
**ARTICLE 2. STANDARDS AND SCHEDULES.**

**§60A-2-201. Authority of state board of pharmacy; recommendations to Legislature.**
(a) The state board of pharmacy shall administer the provisions of this chapter. It shall also, on the first day of each regular legislative session, recommend to the Legislature which substances should be added to or deleted from the schedules of controlled substances contained in this article or reschedule therein. The state board of pharmacy shall also have the authority between regular legislative sessions, on an emergency basis, to add to or delete from the schedules of controlled substances contained in this article or reschedule such substances based upon the recommendations and approval of the federal food, drug and cosmetic agency, and shall report such actions on the first day of the regular legislative session immediately following said actions.

In making any such recommendation regarding a substance, the state board of pharmacy shall consider the following factors:

(1) The actual or relative potential for abuse;

(2) The scientific evidence of its pharmacological effect, if known;

(3) The state of current scientific knowledge regarding the substance;

(4) The history and current pattern of abuse;

(5) The scope, duration and significance of abuse;

(6) The potential of the substance to produce psychic or physiological dependence liability; and

(7) Whether the substance is an immediate precursor of a substance already controlled under this article.

(b) After considering the factors enumerated in subsection (a), the state board of pharmacy shall make findings with respect to the substance under consideration. If it finds that any substance not already controlled under any schedule has a potential for abuse, it shall recommend to the Legislature that the substance be added to the appropriate schedule. If it finds that any substance already controlled under any schedule should be rescheduled or deleted, it shall so recommend to the Legislature.

(c) If the state board of pharmacy designates a substance as an immediate precursor, substances which are precursors of the controlled precursor shall not be subject to control solely because they are precursors of the controlled precursor.

(d) If any substance is designated, rescheduled or deleted as a controlled substance under federal laws and notice thereof is given to the state board of pharmacy, the board shall recommend similar control of such substance to the Legislature, specifically stating that such recommendation is based on federal action and the reasons why the federal government deemed such action necessary and proper.

(e) The authority vested in the board by subsection (a) of this section shall not extend to distilled spirits, wine, malt beverages or tobacco as those terms are defined or used in other chapters of this code nor to any nonnarcotic substance if such substance may under the "Federal Food, Drug and Cosmetic Act" and the law of this state lawfully be sold over the counter without a prescription.

**§60A-2-202. Nomenclature.**

The controlled substances listed in the schedules in this article are included by whatever official, common, usual, chemical or trade name designated.

**§60A-2-203. Schedule I criteria.**

The state board of pharmacy shall recommend to the Legislature that a substance be included in Schedule I if it finds that the substance:

(1) Has high potential for abuse; and

(2) Has no accepted medical use in treatment in the United States or lacks accepted safety for use in treatment under medical supervision.

**§60A-2-204. Schedule I.**

(a) Schedule I shall consist of the drugs and other substances, by whatever official name, common or usual name, chemical name, or brand name designated, listed in this section.

(b) Opiates. Unless specifically excepted or unless listed in another schedule, any of the following opiates, including their isomers, esters, ethers, salts and salts of isomers, esters and ethers, whenever the existence of such isomers, esters, ethers and salts is possible within the specific chemical designation (for

purposes of subdivision (34) of this subsection only, the term isomer includes the optical and geometric isomers):

(1) Acetyl-alpha-methylfentanyl (N-[1-(1-methyl-2-phenethyl) -4-piperidinyl]-N-phenylacetamide);

(2) Acetylmethadol;

(3) Allylprodine;

(4) Alphacetylmethadol (except levoalphacetylmethadol also known as levo-alpha-acetylmethadol, levomethadyl acetate, or LAAM);

(5) Alphameprodine;

(6) Alphamethadol;

(7)Alpha-methylfentanyl (N-[1-(alpha-methyl-beta-phenyl) ethyl-4-piperidyl] propionanilide; 1-(1-methyl-2-phenylethyl)-4-(- propanilido) piperidine);

(8) Alpha-methylthiofentanyl (N-[1-methyl-2-(2-thienyl) ethyl- 4-piperidinyl]-N-phenylpropanamide);

(9) Benzethidine;

(10) Betacetylmethadol;

(11) Beta-hydroxyfentanyl (N-[1-(2-hydroxy-2-phenethyl) -4- piperidinyl]-N-phenylpropanamide);

(12) Beta-hydroxy-3-methylfentanyl (other name: N-[1-(2- hydroxy-2-phenethyl)-3-methyl-4-piperidinyl]-N-phenylpropanamide);

(13) Betameprodine;

(14) Betamethadol;

(15) Betaprodine;

(16) Clonitazene;

(17) Dextromoramide;

(18) Diampromide;

(19) Diethylthiambutene;

(20) Difenoxin;

(21) Dimenoxadol;

(22) Dimepheptanol;

(23) Dimethylthiambutene;

(24) Dioxaphetyl butyrate;

(25) Dipipanone;

(26) Ethylmethylthiambutene;

(27) Etonitazene;

(28) Etoxeridine;

(29) Furethidine;

(30) Hydroxypethidine;

(31) Ketobemidone;

(32) Levomoramide;

(33) Levophenacylmorphan;

(34) 3-Methylfentanyl (N-[3-methyl-1-(2-phenylethyl)-4- piperidyl]-N-phenylpropanamide);

(35) 3-methylthiofentanyl (N-[3-methyl-1-(2-thienyl) ethyl-4- piperidinyl]-N-phenylpropanamide);

(36) Morpheridine;

(37) MPPP (1-methyl-4-phenyl-4-propionoxypiperidine);

(38) Noracymethadol;

(39) Norlevorphanol;

(40) Normethadone;

(41) Norpipanone;

(42) Para-fluorofentanyl (N-(4-fluorophenyl)-N-[1-(2- phenethyl)-4-piperidinyl] propanamide);

(43) PEPAP(1-(-2-phenethyl)-4-phenyl-4-acetoxypiperidine);

(44) Phenadoxone;

(45) Phenampromide;

(46) Phenomorphan;

(47) Phenoperidine;

(48) Piritramide;

(49) Proheptazine;

(50) Properidine;

(51) Propiram;

(52) Racemoramide;

(53) Thiofentanyl (N-phenyl-N-[1-(2-thienyl)ethyl-4- piperidinyl]-propanamide);

(54) Tilidine;

(55) Trimeperidine.

(c) *Opium derivatives.* -- Unless specifically excepted or unless listed in another schedule, any of the following opium immediate derivatives, its salts, isomers and salts of isomers whenever the existence of such salts, isomers and salts of isomers is possible within the specific chemical designation:

(1) Acetorphine;

(2) Acetyldihydrocodeine;

(3) Benzylmorphine;

(4) Codeine methylbromide;

(5) Codeine-N-Oxide;

(6) Cyprenorphine;

(7) Desomorphine;

(8) Dihydromorphine;

(9) Drotebanol;

(10) Etorphine (except HCl Salt);

(11) Heroin;

(12) Hydromorphinol;

(13) Methyldesorphine;

(14) Methyldihydromorphine;

(15) Morphine methylbromide;

(16) Morphine methylsulfonate;

(17) Morphine-N-Oxide;

(18) Myrophine;

(19) Nicocodeine;

(20) Nicomorphine;

(21) Normorphine;

(22) Pholcodine;

(23) Thebacon.

(d) *Hallucinogenic substances.* -- Unless specifically excepted or unless listed in another schedule, any material, compound, mixture or preparation, which contains any quantity of the following hallucinogenic substances, or which contains any of its salts, isomers and salts of isomers, whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation (for purposes of this subsection only, the term "isomer" includes the optical, position and geometric isomers):

(1) Alpha-ethyltryptamine; some trade or other names: etryptamine; Monase; alpha-ethyl-1H-indole-3-ethanamine; 3-(2- aminobutyl) indole; alpha-ET; and AET;

(2) 4-bromo-2, 5-dimethoxy-amphetamine; some trade or other names: 4-bromo-2,5-dimethoxy-alpha-methylphenethylamine; 4-bromo- 2,5-DMA;

(3) 4-Bromo-2,5-dimethoxyphenethylamine; some trade or other names: 2-(4-bromo-2,5-dimethoxyphenyl)-1-aminoethane; alpha- desmethyl DOB; 2C-B, Nexus;

(4) 2,5-dimethoxyamphetamine; some trade or other names: 2,5-dimethoxy-alpha-methylphenethylamine; 2,5-DMA;

(5) 2,5-dimethoxy-4-ethylamphet-amine; some trade or other names: DOET;

(6) 2,5-dimethoxy-4-(n)-propylthiophenethylamine (other name: 2C-T-7);

(7) 4-methoxyamphetamine; some trade or other names: 4-methoxy-alpha-methylphenethylamine; paramethoxyamphetamine; PMA;

(8) 5-methoxy-3, 4-methylenedioxy-amphetamine;

(9) 4-methyl-2,5-dimethoxy-amphetamine; some trade and other names: 4-methyl-2,5-dimethoxy-alpha-methylphenethylamine; "DOM"; and "STP";

(10) 3,4-methylenedioxy amphetamine;

(11) 3,4-methylenedioxymethamphetamine (MDMA);

(12) 3,4-methylenedioxy-N-ethylamphetamine (also known as - ethyl-alpha-methyl-3,4 (methylenedioxy) phenethylamine, N-ethyl MDA, MDE, MDEA);

(13) N-hydroxy-3,4-methylenedioxyamphetamine (also known as - hydroxy-alpha-methyl-3,4 (methylenedioxy) phenethylamine, and - hydroxy MDA);

(14) 3,4,5-trimethoxy amphetamine;

(15) 5-methoxy-N,N-dimethyltryptamine (5-MeO-DMT);

(16) Alpha-methyltryptamine (other name: AMT);

(17) Bufotenine; some trade and other names: 3-(beta-Dimethylaminoethyl)-5-hydroxyindole;3-(2-dimethylaminoeth yl) -5-indolol; N, N-dimethylserotonin; 5-hydroxy-N,N- dimethyltryptamine; mappine;

(18) Diethyltryptamine; sometrade and other names: N, N-Diethyltryptamine; DET;

(19) Dimethyltryptamine; some trade or other names: DMT;

(20) 5-Methoxy-N,N-diisopropyltryptamine (5-MeO-DIPT);

(21) Ibogaine; some trade and other names: 7-Ethyl-6, 6 Beta, 7, 8, 9, 10, 12, 13-octahydro-2-methoxy-6, 9-methano-5H- pyrido [1', 2': 1, 2] azepino [5,4-b] indole; Tabernanthe iboga;

(22) Lysergic acid diethylamide;

(23) Marihuana;

(24) Mescaline;

(25) Parahexyl-7374; some trade or other names: 3-Hexyl -1-hydroxy-7, 8, 9, 10-tetrahydro-6, 6, 9-trimethyl-6H-dibenzo [b,d] pyran; Synhexyl;

(26) Peyote; meaning all parts of the plant presently classified botanically as Lophophora williamsii Lemaire, whether growing or not, the seeds thereof, any extract from any part of such plant, and every

compound, manufacture, salts, immediate derivative, mixture or preparation of such plant, its seeds or extracts;

(27) N-ethyl-3-piperidyl benzilate;

(28) N-methyl-3-piperidyl benzilate;

(29) Psilocybin;

(30) Psilocyn;

(31) Tetrahydrocannabinols; synthetic equivalents of the substances contained in the plant, or in the resinous extractives of Cannabis, sp. and/or synthetic substances, immediate derivatives and their isomers with similar chemical structure and pharmacological activity such as the following:

delta-1 Cis or trans tetrahydrocannabinol, and their optical isomers;

delta-6 Cis or trans tetrahydrocannabinol, and their optical isomers;

delta-3,4 Cis or trans tetrahydrocannabinol, and its optical isomers;

(Since nomenclature of these substances is not internationally standardized, compounds of these structures, regardless of numerical designation of atomic positions covered.)

(32) Ethylamine analog of phencyclidine; some trade or other names: N-ethyl-1-phenylcyclohexylamine, (1-phenylcyclohexyl) ethylamine, N-(1-phenylcyclohexyl) ethylamine, cyclohexamine, PCE;

(33) Pyrrolidine analog of phencyclidine; some trade or other names: 1-(1-phenylcyclohexyl)-pyrrolidine, PCPy, PHP;

(34) Thiophene analog of phencyclidine; some trade or other names: 1-[1-(2-thienyl)-cyclohexyl]-piperidine, 2-thienylanalog of phencyclidine; TPCP, TCP;

(35) 1[1-(2-thienyl)cyclohexyl]pyrroldine; some other names: TCPy.

(36) 4-methylmethcathinone (Mephedrone);

(37) 3,4-methylenedioxypyrovalerone (MDPV);

(38) 2-(2,5-Dimethoxy-4-ethylphenyl)ethanamine (2C-E);

(39) 2-(2,5-Dimethoxy-4-methylphenyl)ethanamine (2C-D)

(40) 2-(4-Chloro-2,5-dimethoxyphenyl)ethanamine (2C-C)

(41) 2-(4-Iodo-2,5-dimethoxyphenyl)ethanamine (2C-I)

(42) 2-[4-(Ethylthio)-2,5-dimethoxyphenyl]ethanamine (2C-T-2) (43)2-[4-(Isopropylthio)-2,5-dimethoxyphenyl]ethanamine (2C-T-4)

(44) 2-(2,5-Dimethoxyphenyl)ethanamine (2C-H)

(45) 2-(2,5-Dimethoxy-4-nitro-phenyl)ethanamine (2C-N) (46) 2-(2,5-Dimethoxy-4-(n)-propylphenyl)ethanamine (2C-P)

(47) 3,4-Methylenedioxy-N-methylcathinone (Methylone)

(48) (2,5-dimethoxy-4-(n)-propyltghiophenethylamine (2C-T-7, itsoptical isomers, salts and salts of isomers

(49) 5-methoxy-N,N-dimethyltryptamine some trade or other names: 5-methoxy-3-[2-(dimethylamino)ethyl]indole; 5-MeO-DMT(5-MeO-DMT)

(50) Alpha-methyltryptamine (other name: AMT)

(51) 5-methoxy-N,N-diisopropyltryptamine (other name: 5-MeO-DIPT)

(52) Synthetic Cannabinoids as follows:

(A) 2-[(1R,3S)-3-hydroxycyclohexyl]-5- (2-methyloctan-2-yl)phenol) {also known as CP 47,497 and homologues};

(B) rel-2-[(1S,3R)-3-hydroxycyclohexyl] -5-(2-methylnonan-2-yl)phenol {also known as CP 47,497-C8 homolog};

(C) [(6a*R*)-9-(hydroxymethyl)-6, 6-dimethyl-3-(2-methyloctan-2-yl)-6a, 7,10,10a-tetrahydrobenzo[c]chromen-1-ol)] {also known as HU-210};

(D) (dexanabinol, (6a*S*,10a*S*)-9-(hydroxymethyl)-6,6-dimethyl-3-(2-methyloctan-2-yl)- 6a,7,10,10a-tetrahydrobenzol[c]chromen-1-ol) {also known as HU-211};

(E) 1-Pentyl-3-(1-naphthoyl)indole {also known as JWH-018};

(F) 1-Butyl-3-(1-naphthoyl)indole {also known as JWH-073};

(G) (2-methyl-1-propyl-1H-indol-3-yl)-1-napthalenyl-methanone {also known as JWH-015};

(H) (1-hexyl-1H-indol-3-yl)-1-naphthalenyl-methanone {also known as JWH-019};

(I) [1-[2-(4-morpholinyl) ethyl] -1H-indol-3-yl]-1-naphthalenyl-methanone {also known as JWH-200};

(J) 1-(1-pentyl-1H-indol-3-yl)-2-(3-hydroxyphenyl)-ethanone {also known as JWH-250};

(K) 2-((1S,2S,5S)-5-hydroxy-2- (3-hydroxtpropyl)cyclohexyl) -5-(2-methyloctan-2-yl)phenol {also known as CP 55,940};

(L) (4-methyl-1-naphthalenyl) (1-pentyl-1H-indol-3-yl) -methanone {also known as JWH-122};

(M) (4-methyl-1-naphthalenyl) (1-pentyl-1H-indol-3-yl) -methanone {also known as JWH-398;

(N) (4-methoxyphenyl)(1-pentyl-1H-indol-3-yl)methanone {also known as RCS-4};

(O) 1-(1-(2-cyclohexylethyl) -1H-indol-3-yl) -2-(2-methoxyphenyl) ethanone {also known as RCS-8}; (P) 1-pentyl-3-[1-(4-methoxynaphthoyl)]indole (JWH-081);

(Q) 1-(5-fluoropentyl)-3-(1-naphthoyl)indole (AM2201); and

(R) 1-(5-fluoropentyl)-3-(2-iodobenzoyl)indole (AM694).

(53)Synthetic cannabinoids or any material, compound, mixture or preparation which contains any quantity of the following substances, including their analogues, congeners, homologues, isomers, salts and salts of analogues, congeners, homologues and isomers, as follows:

(A) CP 47,497 AND homologues, 2-[(1R,3S)-3- Hydroxycyclohexyl]-5-(2-methyloctan-2-YL)phenol);

(B) HU-210, [(6AR,10AR)-9-(hydroxymethyl)-6,6-dimethyl-3-(2-Methyloctan-2-YL) -6A,7,10, 10A-tetrahydrobenzo[C] chromen-1-OL)];

(C) HU-211, (dexanabinol, (6AS,10AS)-9-(hydroxymethyl)-6,6-Dimethyl-3-(2-methyloctan-2-YL)-6A,7,10,10atetrahydrobenzo[ C]chromen-1-OL);

(D) JWH-018, 1-pentyl-3-(1-naphthoyl)indole;

(E) JWH-019, 1-hexyl-3-(1-naphthoyl)indole;

(F) JWH-073, 1-butyl-3-(1-naphthoyl)indole;

(G) JWH-200, (1-(2-morpholin-4-ylethyl)indol-3-yl)- Naphthalen-1-ylmethanone;

(H) JWH-250, 1-pentyl-3-(2-methoxyphenylacetyl)indole.]

(54) Synthetic cannabinoids including any material, compound, mixture or preparation that is not listed as a controlled substance in Schedule I through V, is not a federal Food and Drug Administration approved drug or used within legitimate and approved medical research and which contains any quantity of the following substances, their salts, isomers, whether optical positional or geometric, analogues, homologues and salts of isomers, analogues and homologues, unless specifically exempted, whenever the existence of these salts, isomers, analogues, homologues and salts of isomers, analogues and homologues if possible within the specific chemical designation:

(A) Tetrahydrocannabinols meaning tetrahydrocannabinols which are naturally contained in a plant of the genus cannabis as well as synthetic equivalents of the substances contained in the plant or in the resinous extractives of cannabis or synthetic substances, derivatives and their isomers with analogous chemical structure and or pharmacological activity such as the following:

(i) DELTA-1 CIS OR trans tetrahydrocannabinol and their Optical isomers.

(ii) DELTA-6 CIS OR trans tetrahydrocannabinol and their optical isomers.

(iii) DELTA-3,4 CIS or their trans tetrahydrocannabinol and their optical isomers.

(B) Naphthoylindoles or any compound containing a 3-(-1- Napthoyl) indole structure with substitution at the nitrogen atom of the indole ring whether or not further substituted in the indole ring to any extent and whether or not substituted in the naphthyl ring to any extent. This shall include the following:

(i) JWH 015;

(ii) JWH 018;

(iii) JWH 019;

(iv) JWH 073;

(v) JWH 081;

(vi) JWH 122;

(vii) JWH 200;

(viii) JWH 210;

(ix) JWH 398;

(x) AM 2201;

(xi) WIN 55,212.

(55) Naphylmethylindoles or any compound containing a 1hindol-3-yl-(1-naphthyl) methane structure with a substition at the nitrogen atom of the indole ring whether or not further substituted in the indole ring to any extent and whether or not substituted in the naphthyl ring to any extent. This shall include, but not be limited to, JWH 175 and JWH 184.

(56) Naphthoylpyrroles or any compound containing a 3-(1- Naphthoyl) pyrrole structure with substitution at the nitrogen atom of the pyrrole ring whether or not further substituted in the pyrrole ring to any extent and whether or not substituted in the naphthyl ring to any extent. This shall include, but not be limited to, JWH 147 and JWH 307.

(57) Naphthylmethylindenes or any compound containing a Naphthylideneindene structure with substitution at the 3- Position of the indene ring whether or not further substituted in the indene ring to any extent and whether or not substituted in the naphthyl ring to any extent. This shall include, but not be limited to, JWH 176.

(58) Phenylacetylindoles or any compound containing a 3- Phenylacetylindole structure with substitution at the nitrogen atom of the indole ring whether or not further substituted in the indole ring to any extent and whether or not substituted in the phenyl ring to any extent. This shall include the following:

(A) RCS-8, SR-18 OR BTM-8;

(B) JWH 250;

(C) JWH 203;

(D) JWH 251;

(E) JWH 302.

(59) Cyclohexylphenols or any compound containing a 2-(3- hydroxycyclohexyl) phenol structure with a substitution at the 5-position of the phenolic ring whether or not substituted in the cyclohexyl ring to any extent. This shall include the following:

(A) CP 47,497 and its homologues and analogs;

(B) Cannabicyclohexanol;

(C) CP 55,940.

(60) Benzoylindoles or any compound containing a 3-(benzoyl) indole structure with substitution at the nitrogren atom of the indole ring whether or not further substituted in the indole ring to any extent and whether or not substituted in the phenyl ring to any extent. This shall include the following:

(A) AM 694;

(B) Pravadoline WIN 48,098;

(C) RCS 4;

(D) AM 679.

(61) [2,3-dihydro-5 methyl-3-(4-morpholinylmethyl)pyrrolo [1,2,3-DE]-1, 4-benzoxazin-6-YL]-1-napthalenymethanone. This shall include WIN 55,212-2.

(62) Dibenzopyrans or any compound containing a 11-hydroxydelta 8-tetrahydrocannabinol structure with substitution on the 3-pentyl group. This shall include HU-210, HU-211, JWH 051 and JWH 133.

(63) Adamantoylindoles or any compound containing a 3-(-1- Adamantoyl) indole structure with substitution at the nitrogen atom of the indole ring whether or not further substituted in the adamantoyl ring system to any extent. This shall include AM1248.

(64) Tetramethylcyclopropylindoles or any compound containing A 3-tetramethylcyclopropylindole structure with substitution at the nitrogen atom of the indole ring whether or not further substituted in the indole ring to any extent and whether or not substituted in the tetramethylcyclopropyl ring to any extent. This shall include UR-144 and XLR-11.

(65) N-(1-Adamantyl)-1-pentyl-1h-indazole-3-carboxamide. This shall include AKB48.

(66) Any other synthetic chemical compound that is a Cannabinoid receptor type 1 agonist as demonstrated by binding studies and functional assays that is not listed in Schedules II, III, IV and V, not federal Food and Drug Administration approved drug or used within legitimate, approved medical research. Since nomenclature of these substances is not internationally standardized, any immediate precursor or immediate derivative of these substances shall be covered.

(e) *Depressants*. -- Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a depressant effect on the central nervous system, including its salts, isomers and salts of isomers whenever the existence of such salts, isomers and salts of isomers is possible within the specific chemical designation:

(1) Mecloqualone;

(2) Methaqualone.

(f) *Stimulants.* -- Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system, including its salts, isomers and salts of isomers:

(1) Aminorex; some other names: aminoxaphen; 2-amino-5- phenyl-2-oxazoline; or 4,5-dihydro-5-phenyl-2-oxazolamine;

(2) Cathinone; some trade or other names: 2-amino-1-phenyl-1- propanone, alpha-aminopropiophenone, 2-aminopropiophenone and norephedrone;

(3) Fenethylline;

(4) Methcathinone, its immediate precursors and immediate derivatives, its salts, optical isomers and salts of optical isomers; some other names: (2-(methylamino)-propiophenone; alpha-(methylamino)propiophenone; 2-(methylamino)-1-phenylpropan-1- one; alpha-N-methylaminopropiophenone; monomethylpropion; 3,4-methylenedioxypyrovalerone and/or mephedrone;3,4-methylenedioxypyrovalerone (MPVD); ephedrone; N-methylcathinone; methylcathinone; AL-464; AL-422; AL- 463 and UR1432;

(5) (+-) cis-4-methylaminorex; ((+-)cis-4,5-dihydro-4-methyl- 5-phenyl-2-oxazolamine);

(6) N-ethylamphetamine;

(7) N,N-dimethylamphetemine; also known as N,N-alpha- trimethyl-benzeneethanamine; N,N-alpha-trimethylphenethylamine.

(8) Alpha-pyrrolidinopentiophenone, also known as alpha-PVP, optical isomers, salts and salts of isomers.

(g) Temporary listing of substances subject to emergency scheduling. Any material, compound, mixture or preparation which contains any quantity of the following substances:

(1) N-[1-benzyl-4-piperidyl]-N-phenylpropanamide (benzylfentanyl), its optical isomers, salts, and salts of isomers.

(2)N-[1-(2-thienyl)methyl-4-piperidyl]-N-phenylpropanamide (thenylfentanyl), its optical isomers, salts and salts of isomers.

(3) N-benzylpiperazine, also known as BZP.

(h) The following controlled substances are included in Schedule I:

(1) Synthetic Cathinones or any compound, except bupropion or compounds listed under a different schedule, or compounds used within legitimate and approved medical research, structurally derived from 2-Aminopropan-1-one by substitution at the 1-position with Monocyclic or fused polycyclic ring systems, whether or not the compound is further modified in any of the following ways:

(A) By substitution in the ring system to any extent with Alkyl, alkylenedioxy, alkoxy, haloalkyl, hydroxyl or halide Substituents whether or not further substituted in the ring system by one or more other univalent substituents.

(B) By substitution at the 3-position with an acyclic alkyl substituent.

(C) By substitution at the 2-amino nitrogen atom with alkyl, dialkyl, benzyl or methoxybenzyl groups.

(D) By inclusion of the 2-amino nitrogen atom in a cyclic structure.

(2) Any other synthetic chemical compound that is a Cannabinoid receptor type 1 agonist as demonstrated by binding studies and functional assays that is not listed in Schedules II, III, IV and V, not federal Food and Drug Administration approved drug or used within legitimate, approved medical research. **§60A-2-205.**

**Schedule II criteria.**

The state board of pharmacy shall recommend to the Legislature that a substance be placed in Schedule II if it finds that:

(1) The substance has high potential for abuse;

(2) The substance has currently accepted medical use in treatment in the United States or currently accepted medical use with severe restrictions;

(3) Abuse of the substance may lead to severe psychic or physical dependence.

**§60A-2-206. Schedule II.**

(a) Schedule II consists of the drugs and other substances, by whatever official name, common or usual name, chemical name or brand name designated, listed in this section.

(b) *Substances, vegetable origin or chemical synthesis.* -- Unless specifically excepted or unless listed in another schedule, any of the following substances 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, derivative or preparation of opium or opiate excluding apomorphine, thebaine-derived butorphanol, dextrorphan, nalbuphine, nalmefene, naloxone and naltrexone, and their respective salts, but including the following:

(A) Raw opium;

(B) Opium extracts;

(C) Opium fluid;

(D) Powdered opium;

(E) Granulated opium;

(F) Tincture of opium;

(G) Codeine;

((H) Dihydroetorphine;

(I) Ethylmorphine;

(J) Etorphine hydrochloride;

(K) Hydrocodone;

(L) Hydromorphone;

(M) Metopon;

(N) Morphine;

(O) Oripavine;

(P) Oxycodone;

(Q) Oxymorphone; and

(R) Thebaine;

(2) Any salt, compound, derivative or preparation thereof which is chemically equivalent or identical with any of the substances referred to in subdivision (1) of this subsection, except that these substances shall not include the isoquinoline alkaloids of opium;

(3) Opium poppy and poppy straw;

(4) Coca leaves and any salt, compound, derivative or preparation of coca leaves (including cocaine and ecgonine and their salts, isomers, derivatives and salts of isomers and derivatives), and any salt, compound, derivative or preparation thereof which is chemically equivalent or identical with any of these substances, except that the substances shall not include decocainized coca leaves or extractions of coca leaves, which extractions do not contain cocaine or ecgonine;

(5) Concentrate of poppy straw (the crude extract of poppy straw in either liquid, solid or powder form which contains the phenanthrene alkaloids of the opium poppy).

(c) *Opiates*. -- Unless specifically excepted or unless in another schedule, any of the following opiates, including its isomers, esters, ethers, salts and salts of isomers, esters and ethers whenever the existence of such isomers, esters, ethers and salts is possible within the specific chemical designation, dextrorphan and levopropoxyphene excepted:

(1) Alfentanil;

(2) Alphaprodine;

(3) Anileridine;

(4) Bezitramide;

(5) Bulk dextropropoxyphene (nondosage forms);

(6) Carfentanil;

(7) Dihydrocodeine;

(8) Diphenoxylate;

(9) Fentanyl;

(10) Isomethadone;

(11) Levo-alphacetylmethadol; some other names: levo-alpha-acetylmethadol, levomethadyl acetate, LAAM;

(12) Levomethorphan;

(13) Levorphanol;

(14) Metazocine;

(15) Methadone;

(16) Methadone-Intermediate, 4-cyano-2-dimethylamino-4, 4-diphenyl butane;

(17) Moramide-Intermediate, 2-methyl-3-morpholino-1,

1-diphenylpropane-carboxylic acid;

(18) Pethidine; (meperidine);

(19) Pethidine-Intermediate-A, 4-cyano-1-methyl-4- phenylpiperidine;

(20) Pethidine-Intermediate-B, ethyl-4-phenylpiperidine-4-carboxylate;

(21) Pethidine-Intermediate-C, 1-methyl-4-phenylpiperidine-4-carboxylic acid;

(22) Phenazocine;

(23) Piminodine;

(24) Racemethorphan;

(25) Racemorphan;

(26) Remifentanil;

(27) Sufentanil; and

(28) Tapentadol.

(d) *Stimulants.* -- Unless specifically excepted or unless listed in another schedule, any material, compound, mixture or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system:

(1) Amphetamine, its salts, optical isomers and salts of its optical isomers;

(2) Methamphetamine, its salts, isomers and salts of its isomers;

(3) Methylphenidate;

(4) Phenmetrazine and its salts; and

(5) Lisdexamfetamine.

(e) *Depressants*. -- Unless specifically excepted or unless listed in another schedule, any material, compound, mixture or preparation which contains any quantity of the following substances having a depressant effect on the central nervous system, including its salts, isomers and salts of isomers whenever the existence of such salts, isomers and salts of isomers is possible within the specific chemical designation:

(1) Amobarbital;

(2) Glutethimide;

(3) Pentobarbital;

(4) Phencyclidine;

(5) Secobarbital.

(f) *Hallucinogenic substances*:

Nabilone: [Another name for nabilone: (+-)-trans-3-(1, 1-dimethylheptyl)-6, 6a, 7, 8, 10, 10a-hexahydro-1-hydroxy-6, 6-dimethyl-9H-dibenzo [b,d] pyran-9-one].

(g) *Immediate precursors.* -- Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances:

(1) Immediate precursor to amphetamine and methamphetamine:

(A) Phenylacetone;

(B) Some trade or other names: phenyl-2-propanone; P2P; benzyl methyl ketone; methyl benzyl ketone;

(2) Immediate precursors to phencyclidine (PCP):

(A) 1-phenylcyclohexylamine; and

(B) 1-piperidinocyclohexanecarbonitrile (PCC).

(3) Immediate precursor to fentanyl:

4-anilino-N-phenethyl-4-piperidine (ANPP).

**§60A-2-207. Schedule III criteria.**

The state board of pharmacy shall recommend to the Legislature that a substance be placed in Schedule III if it finds that:

(1) The substance has a potential for abuse less than the substances listed in Schedules I and II;

(2) The substance has currently accepted medical use in treatment in the United States; and

(3) Abuse of the substance may lead to moderate or low physical dependence or high psychological dependence.

**§60A-2-208. Schedule III.**

(a) Schedule III consists of the drugs and other substances, by whatever official name, common or usual name, chemical name or brand name designated, listed in this section.

(b) *Stimulants.* -- Unless specifically excepted or unless listed in another schedule, any material, compound, mixture or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system, including its salts, isomers (whether optical, position or geometric) and salts of such isomers whenever the existence of the salts, isomers and salts of isomers is possible within the specific chemical designation:

(1) Those compounds, mixtures or preparations in dosage unit form containing any stimulant substances listed in Schedule II which compounds, mixtures or preparations were listed on August 25, 1971, as excepted compounds under 21 C.F.R. §1308.32, and any other drug of the quantitative composition shown in that list for those drugs or which is the same except that it contains a lesser quantity of controlled substances;

(2) Benzphetamine;

(3) Chlorphentermine;

(4) Clortermine;

(5) Phendimetrazine.

(c) *Depressants*. -- Unless specifically excepted or unless listed in another schedule, any material, compound, mixture or preparation which contains any quantity of the following substances having a depressant effect on the central nervous system:

(1) Any compound, mixture or preparation containing:

(A) Amobarbital;

(B) Secobarbital;

(C) Pentobarbital; or any salt of pentobarbital and one or more other active medicinal ingredients which are not listed in any schedule;

(2) Any suppository dosage form containing:

(A) Amobarbital;

(B) Secobarbital;

(C) Pentobarbital; or any salt of any of these drugs and approved by the food and drug administration for marketing only as a suppository;

(3) Any substance which contains any quantity of a derivative of barbituric acid or any salt of barbituric acid;

(4) Aprobarbital;

(5) Butabarbital (secbutabarbital);

(6) Butalbital (including, but not limited to, Fioricet);

(7) Butobarbital (butethal);

(8) Chlorhexadol;

(9) Embutramide;

(10) Gamma Hydroxybutryic Acid preparations;

(11) Ketamine, its salts, isomers and salts of isomers [Some other names for ketamine: (+-)-2-(2-chlorophenyl)-2-(methylamino)-cyclohexanone];

(12) Lysergic acid;

(13) Lysergic acid amide;

(14) Methyprylon;

(15) Sulfondiethylmethane;

(16) Sulfonethylmethane;

(17) Sulfonmethane;

(18) Thiamylal;

(19) Thiopental;

(20) Tiletamine and zolazepam or any salt of tiletamine and zolazepam; some trade or other names for a tiletamine-zolazepam combination product: Telazol; some trade or other names for tiletamine: 2-(ethylamino)-2-(2-thienyl)-cyclohexanone; some trade or other names for zolazepam: 4-(2-flurophenyl)-6, 8-dihydro-1, 3, 8-trimethylpyrazolo-[3,4-e] [1,4]-diazepin-7(1H)-one, flupyrazapon; and

(21) Vinbarbital.

(d) Nalorphine.

(e) *Narcotic drugs*. -- Unless specifically excepted or unless listed in another schedule:

(1) Any material, compound, mixture or preparation containing any of the following narcotic drugs, or their salts calculated as the free anhydrous base or alkaloid, in limited quantities as set forth below:

(A) Not more than 1.8 grams of codeine per 100 milliliters and not more than 90 milligrams per dosage unit, with an equal or greater quantity of an isoquinoline alkaloid of opium;

(B) Not more than 1.8 grams of codeine per 100 milliliters or not more than 90 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts;

(3) Not more than 300 milligrams of dihydrocodeinone (hydrocodone) per 100 milliliters or not more than 15 milligrams per dosage unit, with a fourfold or greater quantity of an isoquinoline alkaloid of opium: *Provided, That* a prescription for this may not be filled for more than a one month supply or filled or refilled more than three moths after the date of the original prescription. Such prescription may not be refilled more than twice;

(4) Not more than 300 milligrams of dihydrocodeinone (hydrocodone) per 100 milliliters or not more than 15 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts: *Provided, That* a prescription for this product may not be filled for more than a one month supply or filled or refilled more than three moths after the date of the original prescription. Such prescription may not be refilled more than twice;

(C) Not more than 1.8 grams of dihydrocodeine per 100 milliliters and not more than 90 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts;

(D) Not more than 300 milligrams of ethylmorphine per 100 milliliters or not more than 15 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts;

(E) Not more than 500 milligrams of opium per 100 milliliters or per 100 grams or not more than 25 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts;

(F) Not more than 50 milligrams of morphine per 100 milliliters or per 100 grams, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.

(2) Any material, compound, mixture or preparation containing buprenorphine or its salts (including, but not limited to, Suboxone).

(f) *Anabolic steroids*. -- Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation containing any quantity of anabolic steroids, including its salts, isomers and salts of isomers whenever the existence of the salts of isomers is possible within the specific chemical designation.

(g) Human growth hormones.

(h) Dronabinol (synthetic) in sesame oil and encapsulated in a soft gelatin capsule in a United States food and drug administration approved drug product. (Some other names for dronabinol: (6aR-trans)-6a, 7, 8, 10a- tetrahydro-6, 6, 9-trimethyl-3-pentyl-6H-dibenzo [b,d] pyran-1- ol or (-)-delta-9-(trans)-tetrahydrocannabinol).

**§60A-2-209. Schedule IV criteria.**

The state board of pharmacy shall recommend to the Legislature that a substance be placed in Schedule IV if it finds that:

(1) The substance has a low potential for abuse relative to substances in Schedule III;

(2) The substance has currently accepted medical use in treatment in the United States; and

(3) Abuse of the substance may lead to limited physical dependence or psychological dependence relative to the substances in Schedule III.

**§60A-2-210. Schedule IV.**

(a) Schedule IV shall consist of the drugs and other substances, by whatever official name, common or usual name, chemical name, or brand name designated, listed in this section.

(b) *Narcotic drugs.* -- Unless specifically excepted or unless listed in another schedule, any material, compound, mixture or preparation containing any of the following narcotic drugs, or their salts calculated as the free anhydrous base or alkaloid, in limited quantities as set forth below:

(1) Not more than 1 milligram of difenoxin and not less than 25 micrograms of atropine sulfate per dosage unit;

(2) Dextropropoxyphene (alpha-(+)-4-dimethylamino-1,2-diphenyl-3-methyl-2-propionoxybuta ne).

(c) *Depressants.* -- Unless specifically excepted or unless listed in another schedule, any material, compound, mixture or preparation which contains any quantity of the following substances, including its salts, isomers and salts of isomers whenever the existence of such salts, isomers and salts of isomers is possible within the specific chemical designation:

(1) Alprazolam;

(2) Barbital;

(3) Bromazepam;

(4) Camazepam;

(5) Carisoprodol;

(6) Chloral betaine;

(7) Chloral hydrate;

(8) Chlordiazepoxide;

(9) Clobazam;

(10) Clonazepam;

(11) Clorazepate;

(12) Clotiazepam;

(13) Cloxazolam;

(14) Delorazepam;

(15) Diazepam;

(16) Dichloralphenazone;

(17) Estazolam;

(18) Ethchlorvynol;

(19) Ethinamate;

(20) Ethyl loflazepate;

(21) Fludiazepam;

(22) Flunitrazepam;

(23) Flurazepam;

(24) Fospropofol;

(25) Halazepam;

(26) Haloxazolam;

(27) Ketazolam;

(28) Loprazolam;

(29) Lorazepam;

(30) Lormetazepam;

(31) Mebutamate;

(32) Medazepam;

(33) Meprobamate;

(34) Methohexital;

(35) Methylphenobarbital (mephobarbital);

(36) Midazolam;

(37) Nimetazepam;

(38) Nitrazepam;

(39) Nordiazepam;

(40) Oxazepam;

(41) Oxazolam;

(42) Paraldehyde;

(43) Petrichloral;

(44) Phenobarbital;

(45) Pinazepam;

(46) Prazepam;

(47) Quazepam;

(48) Temazepam;

(49) Tetrazepam;

(50) Triazolam;

(51) Zaleplon;

(52) Zolpidem;

(53) Zopiclone.

(d) Any material, compound, mixture or preparation which contains any quantity of the following substance, including its salts, isomers (whether optical, position or geometric) and salts of such isomers whenever the existence of such salts, isomers and salts of isomers is possible: Fenfluramine and Dexfenfluramine.

(e) *Stimulants.* -- Unless specifically excepted or unless listed in another schedule, any material, compound, mixture or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system, including its salts, isomers and salts of isomers:

(1) Cathine ((+)-norpseudoephedrine);

(2) Diethylpropion;

(3) Fencamfamin;

(4) Fenproporex;

(5) Mazindol;

(6) Mefenorex;

(7) Modafinil;

(8) Pemoline (including organometallic complexes and chelates thereof);

(9) Phentermine;

(10) Pipradrol;

(11) Sibutramine;

(12) SPA ((-)-1-dimethylamino-1,2-diphenylethane).

(f) *Other substances.* -- Unless specifically excepted or unless listed in another schedule, any material, compound, mixture or preparation which contains any quantity of the following substances, including its salts:

(1) Pentazocine;

(2) Butorphanol;

(3) tramadol hydrochloride.

Amyl nitrite, butyl nitrite, isobutyl nitrite and the other organic nitrites are controlled substances and no product containing these compounds as a significant component shall be possessed, bought or sold other than pursuant to a bona fide prescription or for industrial or manufacturing purposes.

**§60A-2-211. Schedule V criteria.**

The state board of pharmacy shall recommend to the Legislature that a substance be placed in Schedule V if it finds that:
(1) The substance has a low potential for abuse relative to the controlled substances listed in Schedule IV;

(2) The substance has currently accepted medical use in treatment in the United States; and

(3) The substance has limited physical dependence or psychological dependence liability relative to the controlled substances listed in Schedule IV.

**§60A-2-212. Schedule V.**

(a) Schedule V shall consist of the drugs and other substances, by whatever official name, common or usual name, chemical name, or brand name designated, listed in this section.

(b) Narcotic drugs containing nonnarcotic active medicinal ingredients. Any compound, mixture or preparation containing any of the following narcotic drugs or their salts calculated as the free anhydrous base or alkaloid in limited quantities as set forth below, which shall include one or more nonnarcotic active medicinal ingredients in sufficient proportion to confer upon the compound, mixture or preparation valuable medicinal qualities other than those possessed by the narcotic drug alone:

(1) Not more than 200 milligrams of codeine per 100 milliliters or per 100 grams;

(2) Not more than 100 milligrams of dihydrocodeine per 100 milliliters or per 100 grams;

(3) Not more than 100 milligrams of ethylmorphine per 100 milliliters or per 100 grams;

(4) Not more than 2.5 milligrams of diphenoxylate and not less than 25 micrograms of atropine sulfate per dosage unit;

(5) Not more than 100 milligrams of opium per 100 milliliters or per 100 grams;

(6) Not more than 0.5 milligrams of difenoxin and not less than 25 micrograms of atropine sulfate per dosage unit.

*(c) Stimulants*. -- Unless specifically exempted or excluded or unless listed in another schedule, any material, compound, mixture or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system, including its salts, isomers and salts of isomers:

(1) Pyrovalerone.

(d) Any compound, mixture or preparation containing as its single active ingredient ephedrine, pseudoephedrine or phenylpropanolamine, their salts or optical isomers, or salts of optical isomers except products which are for pediatric use primarily intended for administration to children under the age of twelve: *Provided*, That neither the offenses set forth in section four hundred one, article four of this chapter, nor the penalties therein, shall be applicable to ephedrine, pseudoephedrine or phenylpropanolamine which shall be subject to the provisions of article ten of this chapter.

(e) *Depressants.* -- Unless specifically exempted or excluded or unless listed in another schedule, any material, compound, mixture or preparation which contains any quantity of the following substances having a depressant effect on the central nervous system, including its salts:

(1) Ezogabine [N-[2-amino-4-94-fluorobenzylamino)-phenyl]-carbamic acid ethyl ester];

(2)Lacosamide [(R)-2-acetoamido- *N* -benzyl-3-methoxy-propionamide];

(3) Pregabalin [(S)-3-(aminomethyl)-5-methylhexanoic acid]."

**§60A-2-213. Review and printing of schedules by board; public information.**

The state board of pharmacy shall annually review and cause to be printed the schedules contained in this article, which printed schedules shall be made available to the public.

**WEST VIRGINIA CODE**

**CHAPTER 60A. UNIFORM CONTROLLED SUBSTANCES ACT.**
**ARTICLE 3. REGULATION OF MANUFACTURE, DISTRIBUTION AND DISPENSING OF CONTROLLED SUBSTANCES.**

**§60A-3-301. Rules; fees.**
The state board of pharmacy shall promulgate rules and charge fees relating to the registration and control of the manufacture and distribution of controlled substances within this state, and each department, board, or agency of this state which licenses or registers practitioners authorized to dispense any controlled substance shall promulgate rules and charge fees relating to the registration and control of the dispensing of controlled substances within this state by those practitioners licensed or registered by such department, board, or agency.

The state board of pharmacy or the department, board or agency shall collect the following annual registration fees from persons who manufacture, distribute, dispense or conduct research with controlled substances: For registration of a manufacturer, fifty dollars; for registration of a wholesaler, fifty dollars; for registration of a retailer, fifteen dollars; for registration of a hospital or clinic, fifteen dollars; and for registration of a research institution, five dollars.

**§60A-3-302. Registration required; effect of registration; exemptions; waiver; inspections.**
(a) Every person who manufactures, distributes, or dispenses any controlled substance within this state or who proposes to engage in the manufacture, distribution, or dispensing of any controlled substance within this state, must obtain annually a registration issued by the state board of pharmacy or the appropriate department, board, or agency, as the case may be, as specified in section three hundred one, in accordance with its rules.

(b) Persons registered by said state board of pharmacy or said appropriate department, board, or agency, as the case may be, under this act to manufacture, distribute, dispense, or conduct research with controlled substances may possess, manufacture, distribute, dispense, or conduct research with those substances to the extent authorized by their registration and in conformity with the other provisions of this article.

(c) (1) The following persons need not register and may lawfully possess, deliver, or transport into this state controlled substances under this act:

(A) An agent or employee of any registered manufacturer, distributor, or dispenser of any controlled substance if he is acting in the usual course of his business or employment;

(B) A common or contract carrier or warehouseman, or an employee thereof, whose possession, delivery, or transportation into this state of any controlled substance is in the usual course of a lawful business or employment;

(2) The following persons need not register and may lawfully possess or transport into this state controlled substances under this act: An ultimate user or a person in possession of any controlled substance pursuant to a lawful order of a practitioner or in lawful possession of a Schedule V substance.

(d) The said state board of pharmacy or said appropriate department, board, or agency, as the case may be, may waive by rule the requirement for registration of certain manufacturers, distributors, or dispensers if it finds it consistent with the public health and safety.

(e) A separate registration is required at each principal place of business or professional practice where the applicant manufactures, distributes, or dispenses controlled substances.

(f) The said state board of pharmacy or said appropriate department, board, or agency, as the case may be, may inspect the establishment of a registrant or applicant for registration in accordance with the rule of said state board of pharmacy or said appropriate department, board, or agency, as the case may be.

**§60A-3-303. What applicants to be registered; determination of public interest; rights of registrants.**
(a) The state board of pharmacy shall register an applicant to manufacture or distribute controlled substances included in Schedules I, II, III, IV and V unless it determines that the issuance of that registration would be inconsistent with the public interest. In determining the public interest, the state board of pharmacy shall consider the following factors:

(1) Maintenance of effective controls against diversion of controlled substances into other than legitimate medical, scientific, or industrial channels;

(2) Compliance with applicable state and local law;

(3) Any convictions of the applicant under any federal or state laws relating to any controlled substance;

(4) Past experience in the manufacture or distribution of controlled substances, and the existence in the applicant's establishment of effective controls against diversion;

(5) Furnishing by the applicant of false or fraudulent material in any application filed under this act;

(6) Suspension or revocation of the applicant's federal registration to manufacture, distribute, or dispense controlled substances as authorized by federal law; and

(7) Any other factors relevant to and consistent with the public health and safety.

(b) Registration under subsection (a) does not entitle a registrant to manufacture and distribute controlled substances in Schedule I or II other than those specified in the registration.

(c) Practitioners must be registered to dispense any controlled substances or to conduct research with controlled substances in Schedules II through V if they are authorized to dispense or conduct research under the law of this state. The appropriate department, board, or agency, as specified in section 301, need not require separate registration under this article for practitioners engaging in research with nonnarcotic controlled substances in Schedules II through V where the registrant is already registered under this article in another capacity. Practitioners registered under federal law to conduct research with Schedule I substances may conduct research with Schedule I substances within this state upon furnishing the appropriate department, board, or agency evidence of that federal registration.

(d) Compliance by manufacturers and distributors with the provisions of the federal law respecting registration (excluding fees) entitles them to be registered under this act.

**§60A-3-304. Suspension or revocation of registration generally.**
(a) A registration under section 303 to manufacture, distribute, or dispense a controlled substance may be suspended or revoked by the said state board of pharmacy or said appropriate department, board, or agency, as the case may be, upon a finding that the registrant:

(1) Has furnished false or fraudulent material information in any application filed under this act;

(2) Has been convicted of a felony under any state or federal law relating to any controlled substance; or

(3) Has had his federal registration suspended or revoked to manufacture, distribute, or dispense controlled substances.

(b) The said state board of pharmacy or said appropriate department, board, or agency, as the case may be, may limit suspension or revocation of a registration to the particular controlled substance with respect to which grounds for suspension or revocation exist.

(c) If the said state board of pharmacy or said appropriate department, board, or agency, as the case may be, suspends or revokes a registration, all controlled substances owned or possessed by the registrant at the time of suspension or the effective date of the revocation order may be placed under seal. No disposition may be made of substances under seal until the time for taking an appeal has elapsed or until all appeals have been concluded unless a court, upon application therefor, orders the sale of perishable substances and the deposit of the proceeds of the sale with the court. Upon a revocation order becoming final, all controlled substances may be forfeited to the state.

(d) The said state board of pharmacy or said appropriate department, board, or agency, as the case may be, shall promptly notify the bureau of all orders suspending or revoking registration and all forfeitures of controlled substances.

**§60A-3-305. Order to show cause before denying, suspending, etc., registration; proceedings thereon; when order not required.**

(a) Before denying, suspending, or revoking a registration, or refusing a renewal of registration, the said state board of pharmacy or said appropriate department, board, or agency, as the case may be, shall serve upon the applicant or registrant an order to show cause why registration should not be denied, suspended, or revoked, or why the renewal should not be refused. The order to show cause shall contain a statement of the basis therefor and shall call upon the applicant or registrant to appear before the said state board of pharmacy or said appropriate department, board, or agency, as the case may be, at a time and place not less than thirty days after the date of service of the order, but in the case of a denial or renewal of registration the show cause order shall be served not later than thirty days before the expiration of the registration. These proceedings shall be conducted in accordance with article five, chapter twenty-nine-a of this code without regard to any criminal prosecution or other proceeding. Proceedings to refuse renewal of registration shall not abate the existing registration which shall remain in effect pending the outcome of the administrative hearing.

(b) The said state board of pharmacy or said appropriate department, board, or agency, as the case may be, may suspend, without an order to show cause, any registration simultaneously with the institution of proceedings under section 304, or where renewal of registration is refused, if it finds that there is an imminent danger to the public health or safety which warrants this action. The suspension shall continue in effect until the conclusion of the proceedings, including judicial review thereof, unless sooner withdrawn by the said state board of pharmacy or said appropriate department, board, or agency, as the case may be, or dissolved by a court of competent jurisdiction.

**§60A-3-306. Records of registrants.**

Persons registered to manufacture, distribute, or dispense controlled substances under this act shall keep records and maintain inventories in conformance with the record-keeping and inventory requirements of federal law and with any additional rules the said state board of pharmacy or said appropriate department, board, or agency, as the case may be, issues.

**§60A-3-307. Order forms.**
Controlled substances in Schedules I and II shall be distributed by a registrant to another registrant only pursuant to an order form. Compliance with the provisions of federal law respecting order forms shall be deemed compliance with this section.

**§60A-3-308. Prescriptions.**

(a) Except when dispensed directly by a practitioner, other than a pharmacy, to an ultimate user, no controlled substance in Schedule II may be dispensed without the lawful prescription of a practitioner.

(b) In emergency situations, as defined by rule of the said appropriate department, board or agency, Schedule II drugs may be dispensed upon oral prescription of a practitioner, reduced promptly to writing and filed by the pharmacy. Prescription shall be retained in conformity with the requirements of section three hundred six of this article. No prescription for a Schedule II substance may be refilled.

(c) Except when dispensed directly by a practitioner, other than a pharmacy, to an ultimate user, a controlled substance included in Schedule III or IV, which is a prescription drug as determined under appropriate state or federal statute, shall not be dispensed without a lawful prescription of a practitioner. The prescription shall not be filled or refilled more than six months after the date thereof or be refilled more than five times unless renewed by the practitioner.

(d) (1) A controlled substance included in Schedule V shall not be distributed or dispensed other than for a medicinal purpose*: Provided,* That buprenorphine shall be dispensed only by prescription pursuant to subsections (a), (b) and (c) of this section: *Provided, however,* That the controlled substances included in subsection (e), section two hundred twelve, article two of this chapter shall be dispensed, sold or distributed only by a physician, in a pharmacy by a pharmacist or pharmacy technician, or health care professional.

(2) If the substance described in subsection (e), section two hundred twelve, article two of this chapter is dispensed, sold or distributed in a pharmacy:

(A) The substance shall be dispensed, sold or distributed only by a pharmacist or a pharmacy technician; and

(B) Any person purchasing, receiving or otherwise acquiring any such substance shall produce a photographic identification issued by a state or federal governmental entity reflecting his or her date of birth.

**§60A-4-401. Prohibited acts A; penalties.**

(a) Except as authorized by this act, it is unlawful for any person to manufacture, deliver, or possess with intent to manufacture or deliver, a controlled substance.

Any person who violates this subsection with respect to:

(i) A controlled substance classified in Schedule I or II, which is a narcotic drug, is guilty of a felony and, upon conviction, may be imprisoned in the state correctional facility for not less than one year nor more than fifteen years, or fined not more than twenty-five thousand dollars, or both;

(ii) Any other controlled substance classified in Schedule I, II or III is guilty of a felony and, upon conviction, may be imprisoned in the state correctional facility for not less than one year nor more than five years, or fined not more than fifteen thousand dollars, or both;

(iii) A substance classified in Schedule IV is guilty of a felony and, upon conviction, may be imprisoned in the state correctional facility for not less than one year nor more than three years, or fined not more than ten thousand dollars, or both;

(iv) A substance classified in Schedule V is guilty of a misdemeanor and, upon conviction, may be confined in jail for not less than six months nor more than one year, or fined not more than five thousand dollars, or both: *Provided*, That for offenses relating to any substance classified as Schedule V in article ten of this chapter, the penalties established in said article apply.

(b) Except as authorized by this act, it is unlawful for any person to create, deliver, or possess with intent to deliver, a counterfeit substance.

Any person who violates this subsection with respect to:

(i) A counterfeit substance classified in Schedule I or II, which is a narcotic drug, is guilty of a felony and, upon conviction, may be imprisoned in the state correctional facility for not less than one year nor more than fifteen years, or fined not more than twenty-five thousand dollars, or both;

(ii) Any other counterfeit substance classified in Schedule I, II or III is guilty of a felony and, upon conviction, may be imprisoned in the state correctional facility for not less than one year nor more than five years, or fined not more than fifteen thousand dollars, or both;

(iii) A counterfeit substance classified in Schedule IV is guilty of a felony and, upon conviction, may be imprisoned in the state correctional facility for not less than one year nor more than three years, or fined not more than ten thousand dollars, or both;

(iv) A counterfeit substance classified in Schedule V is guilty of a misdemeanor and, upon conviction, may be confined in jail for not less than six months nor more than one year, or fined not more than five thousand dollars, or both: *Provided*, That for offenses relating to any substance classified as Schedule V in article ten of this chapter, the penalties established in said article apply.

(c) It is unlawful for any person knowingly or intentionally to possess a controlled substance unless the substance was obtained directly from, or pursuant to, a valid prescription or order of a practitioner while acting in the course of his professional practice, or except as otherwise authorized by this act. Any person who violates this subsection is guilty of a misdemeanor and, disposition may be made under section four hundred seven of this article, subject to the limitations specified in said section, or upon conviction, such person may be confined in jail not less than ninety days nor more than six months, or fined not more than one thousand dollars, or both*: Provided*, That notwithstanding any other provision of this act to the contrary, any first offense for possession of Synthetic Cannabinoids as defined by subdivision (32) subsection, (d),

section 101, article 1 of this chapter; 3,4- methylenedioxypyrovalerone (MPVD)and 3,4-methylenedioxypyrovalerone and/or mephedrone as defined in subsection (f), section 101, article 1 of this chapter; or less than 15 grams of marijuana, shall be disposed of under said section.

(d) It is unlawful for any person knowingly or intentionally:

(1) To create, distribute or deliver, or possess with intent to distribute or deliver, an imitation controlled substance; or

(2) To create, possess or sell or otherwise transfer any equipment with the intent that such equipment shall be used to apply a trademark, trade name, or other identifying mark, imprint, number or device, or any likeness thereof, upon a counterfeit substance, an imitation controlled substance, or the container or label of a counterfeit substance or an imitation controlled substance.

(3) Any person who violates this subsection is guilty of a misdemeanor and, upon conviction, may be imprisoned in jail for not less than six months nor more than one year, or fined not more than five thousand dollars, or both. Any person being eighteen years old or more who violates subdivision (1) of this subsection and, in so doing, distributes or delivers an imitation controlled substance to a minor child who is at least three years younger than such person is guilty of a felony and, upon conviction, may be imprisoned in the state correctional facility for not less than one year nor more than three years, or fined not more than ten thousand dollars, or both.

(4) The provisions of subdivision (1) of this subsection shall not apply to a practitioner who administers or dispenses a placebo.

**§60A-4-402. Prohibited acts B; penalties.**

(a) It is unlawful for any person:

(1) Who is subject to article 3 to distribute or dispense a controlled substance in violation of section 308;

(2) Who is a registrant, to manufacture a controlled substance not authorized by his registration, or to distribute or dispense a controlled substance not authorized by his registration to another registrant or other authorized person;

(3) To refuse or fail to make, keep, or furnish any record, notification, order form, statement, invoice, or information required under this act;

(4) To refuse any entry into any premises for any inspection authorized by this act; or

(5) Knowingly to keep or maintain any store, shop, warehouse, dwelling, building, vehicle, boat, aircraft, or other structure or place, which is resorted to by persons using controlled substances in violation of this act for the purpose of using these substances, or which is used for keeping or selling them in violation of this act.

(b) Any person who violates this section is guilty of a misdemeanor, and, upon conviction, may be confined in the county jail for not less than six months nor more than one year, or fined not more than twenty-five thousand dollars, or both.

(c) Notwithstanding any other provision of this act to the contrary, any first offense for distributing less than 15 grams of marihuana without any remuneration shall be disposed of under section 407.

**§60A-4-403. Prohibited acts C; penalties.**

(a) It is unlawful for any person knowingly or intentionally:

(1) To distribute as a registrant a controlled substance classified in Schedule I or II, except pursuant to an order form as required by section 307 of this act;

(2) To use in the course of the manufacture or distribution of a controlled substance a registration number which is fictitious, suspended, revoked, or issued to another person;

(3) To acquire or obtain possession of a controlled substance by misrepresentation, fraud, forgery, deception, or subterfuge;

(4) To furnish false or fraudulent material information in, or omit any material information from, any application, report, or other document required to be kept or filed under this act, or any record required to be kept by this act; or

(5) To make, distribute, or possess any punch, die, plate, stone, or other thing designed to print, imprint, or reproduce the trademark, trade name, or other identifying mark, imprint, or device of another or any likeness of any of the foregoing upon any drug or container or labeling thereof so as to render the drug a counterfeit substance.

(b) Any person who violates this section is guilty of a felony, and, upon conviction, may be imprisoned in the penitentiary for not less than one year nor more than four years, or fined not more than thirty thousand dollars, or both.

**§60A-4-403a. Prohibition of illegal drug paraphernalia businesses; definitions; places deemed common and public nuisances; abatement; suit to abate nuisances; injunction; search warrants; forfeiture of property; penalties.**

(a) Any person who conducts, finances, manages, supervises, directs or owns all or part of an illegal drug paraphernalia business is guilty of a misdemeanor, and, upon conviction thereof, shall be fined not more than five thousand dollars, or confined in jail not less than six months nor more than one year, or both.

(b) A person violates subsection (a) of this section when:

(1) The person conducts, finances, manages, supervises, directs, or owns all or part of a business which for profit, in the regular course of business or as a continuing course of conduct, manufactures, sells, stores, possesses, gives away or furnishes objects designed to be primarily useful as drug devices.

(2) The person knows or has reason to know that the design of such objects renders them primarily useful as drug devices.

(c) As used in this section, "drug device" means an object usable for smoking marijuana, for smoking controlled substances defined as tetrahydrocannabinols, or for ingesting or inhaling cocaine, and includes, but is not limited to:

(i) Metal, wooden, acrylic, glass, stone, plastic or ceramic pipes with or without screens, permanent screens, hashish heads, or punctured metal bowls;

(ii) Water pipes;

(iii) Carburetion tubes and devices;

(iv) Smoking and carburetion masks;

(v) Roach clips; meaning objects used to hold burning material, such as a marijuana cigarette, that has become too small or too short to be held in the hand;

(vi) Chamber pipes;

(vii) Carburetor pipes;

(viii) Electric pipes;

(ix) Air-driven pipes;

(x) Chillums;

(xi) Bongs;

(xii) Ice pipes or chillers; and

(xiii) Miniature cocaine spoons, and cocaine vials.

In any prosecution under this section, the question whether an object is a drug device shall be a question of fact.

(d) A place where drug devices are manufactured, sold, stored, possessed, given away or furnished in violation of this section shall be deemed a common or public nuisance. Conveyances or vehicles of any kind shall be deemed places within the meaning of this section and may be proceeded against under the provisions of subsection (e) of this section. A person who shall maintain, or shall aid or abet or knowingly be associated with others in maintaining such common or public nuisance shall be guilty of a misdemeanor, and, upon conviction thereof, shall be punished by a fine of not more than one thousand dollars, or by confinement in jail not more than six months for each offense, and judgment shall be given that such nuisance be abated or closed as a place for the manufacture, sale, storage, possession, giving away or furnishing of drug devices.

(e) The prosecuting attorney or a citizen of the county or municipality where a nuisance as defined in subsection (d) is located, may maintain a suit in the name of the state to abate and perpetually enjoin the same. Circuit courts shall have jurisdiction thereof. The injunction may be granted at the commencement of the suit and no bond shall be required if such action for injunction be brought by the prosecuting attorney. If such suit for injunction be brought or maintained by a citizen of the county or municipality where such nuisance is alleged to be located, then the court may require a bond as in other cases of injunction. On the finding that the material allegations of the complaint are true, the court or judge thereof in vacation shall order the injunction for such period of time as it or he may think proper, with the right to dissolve the injunction upon the application of the owner of the place, if a proper case is shown for such dissolution.

The continuance of the injunction as provided in this section may be ordered, although the place complained of may not at the time of hearing be unlawfully used.

(f) If there be complaint on oath or affirmation supported by affidavit or affidavits setting forth the facts for such belief that drug devices are being manufactured, sold, kept, stored or in any manner held, used or concealed in a particular house or other place with intent to engage in illegal drug paraphernalia business in violation of law, a magistrate or a circuit court, or the judge thereof in vacation to whom such complaint is made, if satisfied that there is probable cause for such belief, shall issue a warrant to search such house or other place for such devices. Such warrants, except as herein otherwise provided, shall be issued, directed and executed in accordance with the laws of West Virginia pertaining to search warrants. Warrants issued under this section for the search of any automobile, boat, conveyance or vehicle, or for the search of any trunk, grip or other article of baggage, for such devices, may be executed in any part of the state where the same are overtaken, and shall be made returnable before any magistrate or circuit court, or the judge thereof in vacation, within whose jurisdiction such automobile, boat, conveyance, vehicle, trunk, grip or other article of baggage, or any of them, were transported or attempted to be transported.

An officer charged with the execution of a warrant issued under this section, may, whenever it is necessary, break open and enter a house, or other place herein described.

(g) Any property, including money, used in violation of the provisions of this section may be seized and forfeited to the state.

**§60A-4-404. Penalties under other laws.**
Any penalty imposed for violation of this act is in addition to, and not in lieu of, any civil or administrative penalty or sanction otherwise authorized by law.

**§60A-4-405. Bar to prosecution.**
If a violation of this act is a violation of a federal law or the law of another state, a conviction or acquittal under federal law or the law of another state for the same act is a bar to prosecution in this state.

**§60A-4-406. Distribution to persons under the age of eighteen by persons over the age of twenty-one; distribution by persons eighteen or over in or on, or within one thousand feet of, school or college; increasing mandatory period of incarceration prior to parole eligibility.**
(a) Notwithstanding any other provision of law to the contrary, a person is ineligible for parole for a period of three years if he or she is sentenced to the custody of the commissioner of corrections for service of a sentence of incarceration and is convicted of a felony violation under the provisions of subdivision (i), subsection (a), section four hundred one of this article for distribution of a controlled substance and:

(1) Is twenty-one years of age or older at the time of the distribution upon which the conviction is based, and the person to whom the controlled substance was distributed was under the age of eighteen years at the time of the distribution; or

(2) Is eighteen years of age or older and the distribution upon which the conviction is based occurred in or on, or within one thousand feet of, the real property comprising a public or private elementary, vocational or secondary school or a public or private college, junior college or university in this state.

(b) Notwithstanding any other provision of law to the contrary, a person is ineligible for parole for a period of two years if he or she is sentenced to the custody of the commissioner of corrections for service of a sentence of incarceration and is convicted of a felony violation under the provisions of subdivision (ii), subsection (a), section four hundred one of this article for distribution of a controlled substance and:

(1) Is twenty-one years of age or older at the time of the distribution upon which the conviction is based, and the person to whom the controlled substance was distributed was under the age of eighteen years at the time of the distribution; or

(2) Is eighteen years of age or older and the distribution upon which the conviction is based occurred in or on, or within one thousand feet of, the real property comprising a public or private elementary, vocational or secondary school or a public or private college, junior college or university in this state.

(c) The existence of any fact which would make any person subject to the provisions of this section may not be considered unless the fact is clearly stated and included in the indictment or presentment by which the person is charged and is either:

(1) Found by the court upon a plea of guilty or nolo contendere;

(2) Found by the jury, if the matter be tried before a jury, upon submission to the jury of a special interrogatory for such purpose; or

(3) Found by the court, if the matter be tried by the court without a jury.

(d) Nothing in this section shall be construed to limit the sentencing alternatives made available to circuit court judges under other provisions of this code.

**§60A-4-407. Conditional discharge for first offense of possession.**

(a) Whenever any person who has not previously been convicted of any offense under this chapter or under any statute of the United States or of any state relating to narcotic drugs, marihuana, or stimulant, depressant, or hallucinogenic drugs, pleads guilty to or is found guilty of possession of a controlled substance under section 401(c), the court, without entering a judgment of guilt and with the consent of the accused, may defer further proceedings and place him or her on probation upon terms and conditions. Upon violation of a term or condition, the court may enter an adjudication of guilt and proceed as otherwise provided. Upon fulfillment of the terms and conditions, the court shall discharge the person and dismiss the proceedings against him or her. Discharge and dismissal under this section shall be without adjudication of guilt and is not a conviction for purposes of this section or for purposes of disqualifications or disabilities imposed by law upon conviction of a crime, including the additional penalties imposed for second or subsequent convictions under section 408. The effect of the dismissal and discharge shall be to restore the person in contemplation of law to the status he or she occupied prior to arrest and trial. No person as to whom a dismissal and discharge have been effected shall be thereafter held to be guilty of perjury, false swearing, or otherwise giving a false statement by reason of his or her failure to disclose or acknowledge his or her arrest or trial in response to any inquiry made of him or her for any purpose. There may be only one discharge and dismissal under this section with respect to any person.

(b) After a period of not less than six months which shall begin to run immediately upon the expiration of a term of probation imposed upon any person under this chapter, the person may apply to the court for an order to expunge from all official records all recordations of his or her arrest, trial, and conviction, pursuant to this section. If the court determines after a hearing that the person during the period of his or her probation and during the period of time prior to his or her application to the court under this section has not been guilty of any serious or repeated violation of the conditions of his or her probation, it shall order the expungement.

(c) Notwithstanding any provision of this code to the contrary, any person prosecuted pursuant to the provisions of this article whose case is disposed of pursuant to the provisions of this section shall be liable for any court costs assessable against a person convicted of a violation of section 401(c) of this article. Payment of such costs may be made a condition of probation.

The costs assessed pursuant to this section, whether as a term of probation or not, shall be distributed as other court costs in accordance with section two, article three, chapter fifty, section four, article two-a, chapter fourteen, section four, article twenty-nine, chapter thirty and sections two, seven and ten, article five, chapter sixty-two of this code.

**§60A-4-408. Second or subsequent offenses.**

(a) Any person convicted of a second or subsequent offense under this act may be imprisoned for a term up to twice the term otherwise authorized, fined an amount up to twice that otherwise authorized, or both. When a term of imprisonment is doubled under section 406, such term of imprisonment shall not be further increased for such offense under this subsection (a), even though such term of imprisonment is for a second or subsequent offense.

(b) For purposes of this section, an offense is considered a second or subsequent offense, if, prior to his conviction of the offense, the offender has at any time been convicted under this act or under any statute of the United States or of any state relating to narcotic drugs, marihuana, depressant, stimulant, or hallucinogenic drugs.

(c) This section does not apply to offenses under section 401(c).

**§60A-4-409. Prohibited acts -- Transportation of controlled substances into state; penalties.**

(a) Except as otherwise authorized by the provisions of this code, it shall be unlawful for any person to transport into this state a controlled substance with the intent to deliver the same or with the intent to manufacture a controlled substance.

(b) Any person who violates this section with respect to:

(1) A controlled substance classified in Schedule I or II, which is a narcotic drug, shall be guilty of a felony and, upon conviction, may be imprisoned in the state correctional facility for not less than one year nor more than fifteen years, or fined not more than twenty-five thousand dollars, or both;

(2) Any other controlled substance classified in Schedule I, II or III shall be guilty of a felony and, upon conviction, may be imprisoned in the state correctional facility for not less than one year nor more than five years, or fined not more than fifteen thousand dollars, or both;

(3) A substance classified in Schedule IV shall be guilty of a felony and, upon conviction, may be imprisoned in the state correctional facility for not less than one year nor more than three years, or fined not more than ten thousand dollars, or both;

(4) A substance classified in Schedule V shall be guilty of a misdemeanor and, upon conviction, may be confined in jail for not less than six months nor more than one year, or fined not more than five thousand dollars, or both: *Provided*, That for offenses relating to any substance classified as Schedule V in article ten of this chapter, the penalties established in said article apply.

(c) The offense established by this section shall be in addition to and a separate and distinct offense from any other offense set forth in this code.

**§60A-4-410. Prohibited acts -- Withholding information from practitioner; additional controlled substances; penalties.**

(a) It is unlawful for a patient, in an attempt to obtain a prescription for a controlled substance, to knowingly withhold from a practitioner, that the patient has obtained a prescription for a controlled substance of the same or similar therapeutic use in a concurrent time period from another practitioner.

(b) Any person who violates this section is guilty of a misdemeanor and, upon conviction thereof, may be confined in jail for not more than nine months, or fined not more than $2,500, or both fined and confined.

(c) The offense established by this section is in addition to and a separate and distinct offense from any other offense set forth in this code.

**§60A-4-411. Operating or attempting to operate clandestine drug laboratories; offenses; penalties.**

(a) Any person who operates or attempts to operate a clandestine drug laboratory is guilty of a felony and, upon conviction, shall be confined in a state correctional facility for not less than two years nor more than ten years or fined not less than five thousand dollars nor more than twenty-five thousand dollars, or both.

(b) For purposes of this section, a "clandestine drug laboratory" means any property, real or personal, on or in which a person assembles any chemicals or equipment or combination thereof for the purpose of manufacturing methamphetamine, methylenedioxymethamphetamine or lysergic acid diethylamide in violation of the provisions of section four hundred one of this article.

(c) Any person convicted of a violation of subsection (a) of this section shall be responsible for all reasonable costs, if any, associated with remediation of the site of the clandestine drug laboratory.

**§60A-4-412. Defeating drug and alcohol screening tests; penalties.**

(a) Any person who:

(1) Knowingly sells, gives away, distributes or markets any substance or product in this state or transports such a substance or product into this state with the intent that the substance or product will be used to defeat a drug or alcohol screening test;

(2) Attempts to defeat a drug or alcohol screening test by the substitution of a false sample;

(3) Knowingly advertises for sale or distribution any substance or product the advertised purpose of which is to defeat a bodily fluid screening test for drugs or alcohol;

(4) Adulterates a bodily fluid sample with the intent to defeat a drug or alcohol screening test;

(5) Knowingly possesses adulterants for the purpose of defeating a drug or alcohol screening test; or

(6) Knowingly sells adulterants which are intended to be used to adulterate a urine or other bodily fluid sample for the purpose of defeating a drug or alcohol screening test.

(b) A person who violates a provision of subsection (a) of this section:

(1) For a first offense is guilty of a misdemeanor and, upon conviction, shall be fined not more than one thousand dollars;

(2) For a second offense is guilty of a misdemeanor and, upon conviction, be fined not more than five thousand dollars; and

(3) For a third or subsequent offense is guilty of a misdemeanor and, upon conviction, be fined not more than ten thousand dollars or confined in the regional jail for not more than one year, or both.

(c) As used in this section, "adulterate" means a substance that is not expected to be in human fluids but that is a concentration so high that it is not consistent with human bodily fluids, including, but not limited to:

(1) Bleach;

(2) Chromium;

(3) Creatinine;

(4) Detergent;

(5) Glutaraldehyde;

(6) Glutaraldehyde/squalene;

(7) Hydrochloric acid;

(8) Hydroiodic acid;

(9) Iodine;

(10) Nitrite;

(11) Peroxidase;

(12) Potassium dichromate;

(13) Potassium nitrate;

(14) Pyridinium chlorochromate; and

(15) Sodium nitrite.

**§60A-4-413. Unlawful production, manufacture or possession of Salvia divinorum.**
(a) For purposes of this section, "Salvia divinorum" means an herb belonging to the Lamiaceae family, genus of Salvia, species of divinorum, with common names including, but not limited to, "Salvia," "Ska Pastora," "Shepherdess's Herb," "Maria Pastora," "yerba de Maria," "Purple Sticky" and "Sally-D."

(b) It is unlawful for any person to knowingly or intentionally manufacture or possess an extract, compound, concentrate, or other processed substance intended for human consumption which contains Salvia divinorum, unless the substance was obtained directly from, or pursuant to, a valid prescription or order of a licensed physician or dispensed by a pharmacist for a recommended or medically necessary therapeutic use. Any person who violates this subsection is guilty of a misdemeanor, and disposition may be made under section four hundred seven of this article, subject to the limitations specified in said section, or upon conviction, such person may be confined in jail not more than six months, or fined not more than $1,000, or both. Notwithstanding any other provision of this code to the contrary, any first offense for possession of Salvia divinorum shall be disposed of under section four hundred seven of this article.

(c) The provisions of this section shall not apply to licensed physicians, pharmacists, and accredited hospitals and teaching facilities engaged in the research or study of Salvia divinorum, and shall not include any person participating in clinical trials involving the use of Salvia divinorum.

**WEST VIRGINIA CODE**
**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.

**§60A-5-505.**
Repealed

Acts, 1988 Reg. Sess., Ch. 23.

**§60A-5-506. Burden of proof; liability of officers.**
(a) It is not necessary for the state to negate any exemption or exception in this act in any complaint, information, indictment, or other pleading or in any trial, hearing, or other proceeding under this act. The burden of proof of any exemption or exception is upon the person claiming it.

(b) In the absence of proof that a person is the duly authorized holder of an appropriate registration or order form issued under this act, he is presumed not to be the holder of the registration or form. The burden of proof is upon him to rebut the presumption.

(c) No liability is imposed by this act upon any authorized state, county, or municipal officer, engaged in the lawful performance of his duties.

**§60A-5-507. Judicial review.**
All final determinations, findings, and conclusions of the said state board of pharmacy or the appropriate department, board, or agency, as specified in section 301, made under this act after hearing are final and conclusive decisions of the matters involved. Any person aggrieved by the

decision may obtain review of the decision pursuant to the provisions of articles five and six, chapter twenty-nine-a of this code.

**§60A-5-508. Education and research.**

(a) The said state board of pharmacy and the appropriate departments, boards, and agencies, as specified in section 301, and the division on alcoholism and drug abuse in the department of mental health (all hereinafter in this section referred to as "such agencies"), shall carry out educational programs designed to prevent and deter misuse and abuse of controlled substances. In connection with these programs they may:

(1) Promote better recognition of the problems of misuse and abuse of controlled substances within the regulated industry and among interested groups and organizations;

(2) Assist the regulated industry and interested groups and organizations in contributing to the reduction of misuse and abuse of controlled substances;

(3) Consult with interested groups and organizations to aid them in solving administrative and organizational problems;

(4) Evaluate procedures, projects, techniques, and controls conducted or proposed as part of educational programs on misuse and abuse of controlled substances;

(5) Disseminate the results of research on misuse and abuse of controlled substances to promote a better public understanding of what problems exist and what can be done to combat them; and

(6) Assist in the education and training of state and local law-enforcement officials in their efforts to control misuse and abuse of controlled substances.

(b) Such agencies shall encourage research on misuse and abuse of controlled substances. In connection with the research, and in furtherance of the enforcement of this act, such agencies may:

(1) Establish methods to assess accurately the effects of controlled substances and identify and characterize those with potential for abuse;

(2) Makes studies and undertake programs of research to:

(i) Develop new or improved approaches, techniques, systems, equipment, and devices to strengthen the enforcement of this act;

(ii) Determine patterns of misuse and abuse of controlled substances and the social effects thereof; and,

(iii) Improve methods for preventing, predicting, understanding, and dealing with the misuse and abuse of controlled substances; and,

(3) Enter into contracts with public agencies, institutions of higher education, and private organizations or individuals for the purpose of conducting research, demonstrations, or special projects which bear directly on misuse and abuse of controlled substances.

(c) Such agencies may enter into contracts for educational and research activities without performance bonds.

(d) Such agencies may authorize persons engaged in research on the use and effects of controlled substances to withhold the names and other identifying characteristics of individuals who are the subjects of the research. Persons who obtain this authorization are not compelled in any civil, criminal, administrative, legislative, or other proceeding to identify the individuals who are the subjects of research for which the authorization was obtained.

(e) Such agencies may authorize the possession and distribution of controlled substances by persons engaged in research. Persons who obtain this authorization are exempt from state prosecution for possession and distribution of controlled substances to the extent of the authorization.

**WEST VIRGINIA CODE**
**CHAPTER 60A. UNIFORM CONTROLLED SUBSTANCES ACT.**
**ARTICLE 6. MISCELLANEOUS PROVISIONS.**

**§60A-6-601. Pending proceedings.**
(a) The provisions of this act shall govern and control as to any offenses committed in violation thereof on and after the effective date of this act, and the provisions of articles eight, eight-a and eight-b, chapter sixteen of this code shall govern and control as to any offenses committed in violation of said articles, or any of them, prior to the effective date of this act, with like effect as to such prior offenses as if said articles had not been repealed and this act had not been enacted: *Provided*, That if the offense being prosecuted is similar to one set out in article four of this act, then the penalties under article four apply if they are less than those under prior law.

(b) Civil seizures of forfeitures and injunctive proceedings commenced prior to the effective date of this act are not affected by this act.

(c) All administrative proceedings pending under prior laws which are superseded by this act shall be continued and brought to a final determination in accord with the laws and rules in effect prior to the effective date of the act. Any substance controlled under prior law which is not listed within Schedules I through V, is automatically controlled without further proceedings and shall be listed in the appropriate schedule.

(d) The state board of pharmacy or the appropriate departments, boards, and agencies, as specified in section 301, shall initially permit persons to register who own or operate any establishment engaged in the manufacture, distribution, or dispensing of any controlled substance prior to the effective date of this act and who are registered or licensed by the state.

(e) This act applies to violations of law, seizures, and forfeiture, injunctive proceedings, administrative proceedings, and investigations which occur following its effective date.

**§60A-6-602. Continuation of orders and rules.**
Any orders and rules promulgated under any law affected by this act and in effect on the effective date of this act and not in conflict with it continue in effect until modified, superseded or repealed.

**§60A-6-603. Uniformity of interpretation.**
This act shall be so applied and construed as to effectuate its general purpose to make uniform the law with respect to the subject of this act among those states which enact it.

**§60A-6-604. Short title.**
This act may be cited as the Uniform Controlled Substances Act.

**§60A-6-605. Severability.**
If any provision of this act or the application thereof to any person or circumstance is held invalid, such invalidity shall not affect other provisions or applications of the act, and to this end the provisions of this act are hereby declared to be severable.

**WEST VIRGINIA CODE**

**CHAPTER 60A. UNIFORM CONTROLLED SUBSTANCES ACT.**
**ARTICLE 7. WEST VIRGINIA CONTRABAND FORFEITURE ACT.**

**§60A-7-701. Short title.**
This article shall be known and cited as the "West Virginia Contraband Forfeiture Act."

**§60A-7-702. Legislative findings.**
The Legislature hereby finds and declares that the seizure and sale of items under the provisions of this article is not contemplated to be a forfeiture as the same is used in article twelve, section five of the West Virginia constitution and to the extent that such seizure and sale may be found to be such a forfeiture, the Legislature hereby finds and declares that the proceeds from a seizure and sale under this article is not part of net proceeds as the same is contemplated by such article twelve, section five of the West Virginia constitution.

**§60A-7-703. Items subject to forfeiture; persons authorized to seize property subject to forfeiture.**
(a) The following are subject to forfeiture:

(1) All controlled substances which have been manufactured, distributed, dispensed or possessed in violation of this chapter;

(2) All raw materials, products and equipment of any kind which are used, or intended for use, in manufacturing, compounding, processing, delivering, importing or exporting any controlled substance in violation of this chapter;

(3) All tax-not-paid tobacco products, as that term is defined in section two, article seventeen, chapter eleven of this code, declared to be contraband under said article;

(4) All property which is used, or has been used, or is intended for use, as a container for property described in subdivision (1), (2) or (3) of this subsection;

(5) All conveyances, including aircraft, vehicles or vessels, which are used, have been used, or are intended for use, to transport, or in any manner to facilitate the transportation, sale, receipt, possession or concealment of property described in subdivision (1), (2) or (3) of this subsection, except that:

(i) A conveyance used by any person as a common carrier in the transaction of business as a common carrier shall not be forfeited under this section unless it appears that the person owning the conveyance is a consenting party or privy to a violation of this chapter;

(ii) A conveyance shall not be forfeited under the provisions of this article if the person owning the conveyance establishes that he or she neither knew, nor had reason to know, that the conveyance was being employed or was likely to be employed in a violation of this chapter; and

(iii) A bona fide security interest or other valid lien in any conveyance shall not be forfeited under the provisions of this article, unless the state proves by a preponderance of the evidence that the holder of the security interest or lien either knew, or had reason to know, that the conveyance was being used or was likely to be used in a violation of this chapter;

(6) All books, records, research products and materials, including formulas, microfilm, tapes and data which are used, or have been used, or are intended for use, in violation of this chapter;

(7) All moneys, negotiable instruments, securities or other things of value furnished or intended to be furnished in violation of this chapter by any person in exchange for a controlled substance, all proceeds traceable to the exchange and all moneys, negotiable instruments and securities used, or which have been used, or which are intended to be used to facilitate any violation of this chapter: *Provided*, That no property may be forfeited under this subdivision, to the extent of the interest of an owner, by reason of any act or omission established by that owner to have been committed or omitted without his or her knowledge or consent; and

(8) All real property, including any right, title and interest in any lot or tract of land, and any appurtenances or improvements, which are used, or have been used, or are intended to be used, in any manner or part, to commit or to facilitate the commission of a violation of this chapter punishable by more than one year imprisonment: *Provided*, That no property may be forfeited under this subdivision, to the extent of an interest of an owner, by reason of any act or omission established by that owner to have been committed or omitted without his or her knowledge or consent.

The requirements of this subsection pertaining to the removal of seized property are not mandatory in the case of real property and the appurtenances to the real property.

(b) Property subject to forfeiture under this article may be seized by any person granted enforcement powers in section five hundred one, article five of this chapter (hereinafter referred to as the "appropriate person" in this article).

(c) Controlled substances listed in article two of this chapter which are manufactured, possessed, transferred, sold or offered for sale in violation of this chapter are contraband and shall be seized and summarily forfeited to the state. Controlled substances which are seized or come into the possession of the state, the owners of which are unknown, are contraband and shall be summarily forfeited to the state upon the seizure of the controlled substances.

(d) Species of plant from which controlled substances may be derived which have been planted or cultivated in violation of the provisions of this chapter, or of which the owners or cultivators are unknown, or which are wild growths may be seized and summarily forfeited to the state upon the seizure of the plants.

(e) The failure, upon demand by the appropriate person, or his or her authorized agent, of the person in occupancy or in control of land or premises upon which the species of plants are growing or being stored, to produce an appropriate registration, or proof that he or she is the holder of an appropriate registration, constitutes authority for the seizure and forfeiture of the plants.

(f) Notwithstanding any provision of this article to the contrary, controlled substances listed in article two of this chapter and species of plants from which controlled substances may be derived shall either be destroyed or used only for investigative or prosecutorial purposes.

(g) Notwithstanding any other provisions of this article to the contrary, any items of real property or any items of tangible personal property sold to a bona fide purchaser are not subject to forfeiture unless the state establishes by clear and convincing proof that the bona fide purchaser knew or should have known that the property had in the previous three years next preceding the sale been used in violation of this chapter or that the property is a controlled substance.

**§60A-7-704. Procedures for seizure of forfeitable property.**

(a) Seizure of property made subject to forfeiture by the provisions of this article may be made upon process issued by any court of record having jurisdiction over the property.

(b) Notwithstanding the provisions of subsection (a) of this section, seizure of property subject to forfeiture by the provisions of this article may be made without process if:

(1) The seizure is incident to a lawful arrest or pursuant to a search under a search warrant or an inspection warrant;

(2) The property subject to seizure has been the subject of a prior judgment in favor of the state in a forfeiture proceeding based upon this article;

(3) The appropriate person has probable cause to believe that the property is directly or indirectly dangerous to health or safety; or

(4) The appropriate person has probable cause to believe that the property was used or intended for use in violation of this chapter.

(c) In the event of seizure pursuant to subsection (b) of this section, forfeiture proceedings shall be instituted within ninety days of the seizure thereof.

(d) Property taken or detained under this section shall not be subject to replevin, but is deemed to be in the custody of the appropriate person, subject only to the orders and decrees of the court having jurisdiction over the forfeiture proceedings. When property is seized under this article, the appropriate person may:

(1) Place the property under seal;

(2) Remove the property to a place designated by him;

(3) Require the appropriate law-enforcement agency to take custody of the property and remove it to an appropriate location for disposition in accordance with law; or

(4) In the case of seized moneys, securities or other negotiable instruments, place the assets in any interest-bearing depository insured by an agency of the federal government.

The requirements of this subsection pertaining to the removal of seized property are not mandatory in the case of real property and appurtenances thereto.

**§60A-7-705. Procedures for forfeiture.**

(a) (1) Any proceeding wherein the state seeks forfeiture of property subject to forfeiture under this article shall be a civil proceeding. A petition for forfeiture may be filed on behalf of the state and any law-enforcement agency making a seizure under this article by the prosecuting attorney of a county, or duly appointed special prosecutor.

(2) A petition for forfeiture may be filed and proceedings held thereon in the circuit court of the county wherein the seizure was made, the real property subject to forfeiture is situate, or the circuit court of the county wherein any owner of the property subject to forfeiture may reside.

(3) Any civil trial stemming from a petition for forfeiture brought under this chapter at the demand of either party shall be by jury.

(4) A petition for forfeiture of the seized property shall be filed within ninety days after the seizure of the property in question. The petition shall be verified by oath or affirmation of a law-enforcement officer representing the law-enforcement agency responsible for the seizure or the prosecuting attorney and shall contain the following:

(i) A description of the property seized;

(ii) A statement as to who is responsible for the seizure;

(iii) A statement of the time and place of seizure;

(iv) The identity of the owner or owners of the property, if known;

(v) The identity of the person or persons in possession of the property at the time seized, if known;

(vi) A statement of facts upon which probable cause for belief that the seized property is subject to forfeiture pursuant to the provisions of this article is based;

(vii) The identity of all persons or corporations having a perfected security interest or lien in the subject property, as well as the identity of all persons or corporations known to the affiant who may be holding a possessory or statutory lien against such property;

(viii) A prayer for an order directing forfeiture of the seized property to the state, and vesting ownership of such property in the state.

(b) At the time of filing or as soon as practicable thereafter, a copy of the petition for forfeiture shall be served upon the owner or owners of the seized property, as well as all holders of a perfected security interest or lien or of a possessory or statutory lien in the same class, if known. Should diligent efforts fail to disclose the lawful owner or owners of the seized property, a copy of the petition for forfeiture shall be served upon any person who was in possession or alleged to be in possession of the property at the time of seizure, where such person's identity is known. The above service shall be made pursuant to the provisions of the West Virginia Rules of Civil Procedure. Any copy of the petition for forfeiture so served shall include a notice substantially as follows:

"To any claimant to the within described property: You have the right to file an answer to this petition setting forth your title in, and right to possession of, the property within thirty days from the service hereof. If you fail to file an answer, a final order forfeiting the property to the state will be entered, and such order is not subject to appeal."

If no owner or possessors, lienholders or holders of a security interest be found, then such service may be by Class II legal publication in accordance with the provisions of article three, chapter fifty-nine of this code, and the publication area shall be the county wherein such property was located at the time of seizure and the county wherein the petition for forfeiture is filed.

(c) In addition to the requirements of subsection (b) above, the prosecuting attorney or law-enforcement officer upon whose oath or affirmation the petition for forfeiture is based, shall be responsible for the publication of a further notice. Such further notice that a petition for forfeiture has been filed shall be published by Class II legal advertisement in accordance with article three, chapter fifty-nine of this code. The publication area shall be the county wherein the property was seized and the county wherein the petition for forfeiture is filed. The notice shall advise any claimant to the property of their right to file a claim on or before the date set forth in the notice, which date shall not be less than thirty days from the date of the first publication. The notice shall specify that any claim must clearly state the identity of the claimant and an address where legal

process can be served upon that person. In addition such notice shall contain the following information:

(1) A description of the property seized;

(2) A statement as to who is responsible for the seizure;

(3) A statement of the time and place of seizure;

(4) The identity of the owner or owners of the property, if known;

(5) The identity of the person or persons in possession of the property at the time of seizure, if known;

(6) A statement that prayer for an order directing forfeiture of the seized property to the state, and vesting ownership of such property in the state shall be requested of the court.

(d) If no answer or claim is filed within thirty days of the date of service of the petition pursuant to subsection (b) of this section, or within thirty days of the first publication pursuant to subsection (b) of this section, the court shall enter an order forfeiting the seized property to the state. If any claim to the seized property is timely filed, a time and place shall be set for a hearing upon such claim. The claimant or claimants shall be given notice of such hearing not less than ten days prior to the date set for the hearing.

(e) At the hearing upon the claim or claims, the state shall have the burden of proving by a preponderance of the evidence that the seized property is subject to forfeiture pursuant to the provisions of this chapter.

(f) Any order forfeiting property to the state and entered pursuant to this section perfects the state's right, title and interest in the forfeited property and relates back to the date of seizure: *Provided,* That in any proceeding under this article the circuit court shall in its final order make specific findings with respect to whether or not probable cause to seize such property existed at the time of such seizure.

(g) During the pendency of a forfeiture proceeding, it is unlawful for any property owner or holder of a bona fide security interest or other valid lienholder to transfer or attempt to transfer any ownership interest or security interest in seized property with the intent to defeat the purpose of this article, and the court wherein the petition for forfeiture is filed may enjoin a property owner or holder of a security interest or other lienholder from making such a transfer should one come to its attention. Any such transfer which is made in violation of the provisions of this subsection shall have no effect upon an order of the court forfeiting seized property to the state if a notice of lis pendens is filed prior to the recording of the instrument of transfer.

(h) The court may void any transfer of property made before or after a forfeiture proceeding has been commenced, which is subject to forfeiture, if the transfer was not to a bona fide purchaser without notice for value.

(i) An appeal of a decision of the circuit court concerning a forfeiture proceeding brought pursuant to this chapter must be filed within one hundred twenty days of the date of entry of the final appealable order. The appellant shall be required to give notice of intent to appeal within thirty days of the entry of such appealable order.

**§60A-7-705a. Additional procedures for forfeiture.**

(a) Notwithstanding the provisions of section seven hundred five of this article, forfeitable moneys are subject to administrative forfeiture by the prosecuting attorney of a county or duly appointed special prosecutor.

(b) An administrative forfeiture notice shall be provided by the prosecuting attorney after the seizure of the money in question. The notice shall contain the following:

(1) A description of the money seized;

(2) A statement as to who is responsible for the seizure;

(3) A statement of the time and place of seizure;

(4) The identity of the owner or owners of the money, if known; and

(5) The identity of the person or persons in possession of the money at the time seized.

(c) At the time of filing or as soon as practicable thereafter, a copy of the petition for forfeiture shall be served upon the owner or owners of the seized money. Should diligent efforts fail to disclose the lawful owner or owners of the seized money, a copy of the petition for forfeiture shall be served upon any person who was in possession or alleged to be in possession of the money at the time of seizure, where such person's identity is known. The above service shall be made pursuant to the provisions of the West Virginia Rules of Civil Procedure.

(d) The administrative forfeiture notice shall include a statement substantially as follows: To any claimant: "The confiscated money is subject to administrative forfeiture unless you provide a written notice, within thirty days of receipt of this notice, that you wish to contest this forfeiture. If you fail to provide a notice to the prosecuting attorney, you will immediately and forever lose all right, claim, title and interest to the confiscated money, and it will be disposed of according to law."

(e) If, after thirty days of the delivery of notice from the prosecuting attorney as provided in subsections (c) and (d) of this section, no notice is received from any person indicating a desire to contest the administrative forfeiture, all right, title and interest to the confiscated money shall immediately vest in the state, and shall be disposed of in the same manner as in a civil forfeiture.

(f) If notice is received from any person, within the required period of time, indicating a desire to contest the administrative forfeiture, then no forfeiture may be obtained except through a civil forfeiture proceeding under section seven hundred five of this article.

**§60A-7-706. Disposition of forfeited moneys, securities or other negotiable instruments; distribution of proceeds.**

(a) Whenever moneys, securities or other negotiable instruments are forfeited under the provisions of this article, such proceeds shall be distributed as follows:

(1) Ten percent of the proceeds shall be tendered to the office of the prosecuting attorney which initiated the forfeiture proceeding;

(2) The balance shall be deposited in a special law- enforcement investigation fund. The fund may be placed in any interest-bearing depository insured by an agency of the federal government. The fund shall be administered by the chief of the law-enforcement agency that seized the forfeited property.

(b) No funds shall be expended from the special law- enforcement investigation fund except as follows:

(1) In the case of the funds belonging to the State Police, the funds shall only be expended at the direction of the Superintendent of the State Police and in accordance with the provisions of article two, chapter eleven-b of this code and the provisions of subdivision (10), subsection (b), section two, article two, chapter twelve of this code;

(2) In the case of funds belonging to the office of either the sheriff or prosecuting attorney of any county in which the special fund has been created, the funds therein may only be expended in the manner provided in sections four and five, article five, chapter seven of this code; and

(3) In the case of funds belonging to the police department of any municipality in which the special fund has been created, the funds therein may only be expended in the manner provided in section twenty-two, article thirteen, chapter eight of this code.

**§60A-7-707. Disposition of other forfeited property; distribution of proceeds.**

(a) When property other than that referred to in section seven hundred six of this article is forfeited under this article, the circuit court ordering the forfeiture, upon application by the prosecuting attorney or the chief of the law-enforcement agency that seized said forfeited property, may direct that:

(1) Title to the forfeited property be vested in the law-enforcement agency so petitioning; or

(2) The law-enforcement agency responsible for the seizure retain the property for official use; or

(3) The forfeited property shall be offered at public auction to the highest bidder for cash. Notice of such public auction shall be published as a Class III legal advertisement in accordance with article three, chapter fifty-nine of this code. The publication area shall be the county where the public auction will be held.

(b) When a law-enforcement agency receives property pursuant to this section, the court may, upon request of the prosecuting attorney initiating the forfeiture proceeding, require the law-enforcement

agency to pay unto the office of said prosecuting attorney a sum not to exceed ten percent of the value of the property received to compensate said office for actual costs and expenses incurred.

(c) The proceeds of every public sale conducted pursuant to this section shall be paid and applied as follows: First, to the balance due on any security interest preserved by the court; second, to the costs incurred in the storage, maintenance and security of the property; third, to the costs incurred in selling the property.

(d) Any proceeds of a public sale remaining after distribution pursuant to subsection (c) of this section shall be distributed as follows:

(1) Ten percent of such proceeds shall be tendered to the office of the prosecuting attorney who initiated the forfeiture proceeding.

(2) The balance shall be deposited in a special law-enforcement investigation fund. Such fund shall be administered by the chief of the law-enforcement agency that seized the forfeited property sold and shall take the form of an interest-bearing account with any interest earned to be compounded to the fund. Any funds deposited in the special law-enforcement investigative fund pursuant to this article shall be expended only to defray the costs of protracted or complex investigations, to provide additional technical equipment or expertise, to provide matching funds to obtain federal grants or for such other law-enforcement purposes as the chief of the law-enforcement agency may deem appropriate; however, these funds may not be utilized for regular operating needs.

(e) If more than one law-enforcement agency was substantially involved in effecting the seizure and forfeiture of property, the court wherein the petition for forfeiture was filed shall equitably distribute the forfeited property among the law-enforcement agencies. In the event of a public sale of such property pursuant to subsection (a) of this section, the court shall equitably distribute any proceeds remaining after distribution pursuant to subsection (c) and subdivision (1), subsection (d) of this section among such law-enforcement agencies for deposit into their individual special law-enforcement investigative fund. Equitable distribution shall be based upon the overall contribution of the individual law-enforcement agency to the investigation which led to the seizure.

(f) Upon the sale of any forfeited property for which title or registration is required by law, the state shall issue a title or registration certificate to any bona fide purchaser at a public sale of the property conducted pursuant to subsection (a) of this section. Upon the request of the law-enforcement agency receiving, pursuant to the order of the court, or electing to retain, pursuant to subsection (a) of this section, any forfeited property for which title or registration is required by law, the state shall issue a title or registration certificate to the appropriate governmental body.

(g) Any funds expended pursuant to the provisions of this section, shall only be expended in the manner provided in subsection (b), section seven hundred five of this article.

(h) Every prosecuting attorney or law-enforcement agency receiving forfeited property or proceeds from the sale of forfeited property pursuant to this article shall submit an annual report to the body which has budgetary authority over such agency. Such report shall specify the type and approximate value of all forfeited property and the amount of proceeds from the sale of forfeited

property received in the preceding year. No county or municipality may use anticipated receipts of forfeited property in their budgetary process.

(i) In lieu of the sale of any forfeited property subject to a bona fide security interest preserved by an order of the court, the law-enforcement agency receiving the forfeited property may pay the balance due on any security interest preserved by the court from funds budgeted to the office or department or from the special fund and retain possession of the forfeited property for official use pursuant to subsection (a) of this section.

(j) In every case where property is forfeited, disposition of the forfeited property, in accordance with this article, shall be made within six months of the date upon which the court of jurisdiction orders forfeiture. Should the office or agency receiving the property fail either to place the property in official use or dispose of the property in accordance with law, the court of jurisdiction shall cause disposition of the property to be made with any proceeds therefrom to be awarded to the state.

(k) No disposition shall occur until all applicable periods for filing a notice of intent to appeal has expired and no party in interest shall have filed such notice. The filing of the notice of intent to appeal shall stay any such disposition until the appeal has been finally adjudicated or until the appeal period of one hundred eighty days has expired without an appeal having actually been taken or filed, unless a valid extension of the appeal has been granted by the circuit court under the provisions of section seven, article four, chapter fifty-eight of this code.

(l) The special law-enforcement investigative funds of each law-enforcement agency may be placed in an interest-bearing depository insured by the federal government.

**WEST VIRGINIA CODE**
**CHAPTER 60A. UNIFORM CONTROLLED SUBSTANCES ACT.**
**ARTICLE 8. WHOLESALE DRUG DISTRIBUTION LICENSING ACT OF 1991.**

**§60A-8-1. Short title.**
This article may be cited as the "Wholesale Drug Distribution

Licensing Act of 1991".

**§60A-8-2. Scope.**
This article applies to any person, partnership, corporation or business firm engaging in the wholesale distribution of human prescription drugs within this state.

**§60A-8-3. Purpose**.

The purpose of this article is to protect the health, safety and general welfare of residents of this state and to implement the federal Prescription Drug Marketing Act of 1987 ("PDMA"), U. S. Public Law 100-293, 102 Stat. 95, codified at 21 U. S. Code §321; and particularly PDMA requirements that no person or entity may engage in the wholesale distribution of human

prescription drugs in any state unless such person or entity is licensed by such state in accordance with federally-prescribed minimum standards, terms and conditions as set forth in guidelines issued by United States food and drug administration (FDA) regulations pursuant to 21 U. S. Code §353(e)(2)(A) and (B); and such regulations as are set forth in 21 C. F. R. Part 205.

**§60A-8-4.**

Repealed.

Acts, 2012 Reg. Sess., Ch. 203.

**§60A-8-5. Definitions**.

As used in this article:

(a) "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:

(1) Intracompany sales, being defined as any transaction, transfer or delivery into or within this state between any division, subsidiary, parent and/or affiliated or related company under the common ownership and control of a corporate entity;

(2) 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;

(3) 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;

(4) 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;

(5) 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;

(6) 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;

(7) 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)];

(8) Drug returns by a pharmacy or chain drug warehouse to wholesale drug distributor or the drug's manufacturer; or

(9) The sale, purchase or trade of blood and blood components intended for transfusion.

(b) "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.

(c) "Pharmacy distributor" means any pharmacy licensed in this state or hospital pharmacy which is engaged in the delivery or distribution of prescription drugs either to any other pharmacy licensed in this state or to any other person or entity, including, but not limited to, a wholesale drug distributor as defined in subdivision (b) of this section engaged in the delivery or distribution of prescription drugs and who is involved in the actual, constructive or attempted transfer of a drug in this state to other than the ultimate consumer except as otherwise provided for by law.

(d) "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.

(e) "West Virginia Board of Pharmacy", "Board of Pharmacy" or "board" means the agency of this state authorized to license wholesale drug distribution except where otherwise provided.

(f) "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.

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

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

(i) "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.

(j) "Person" means any individual, partnership, association, limited liability company, corporation or other entity.

(k) "Key person" means the person designated by the applicant or license holder from any of the following:

(1) An officer, director, trustee, partner, principal or proprietor of a person that has applied for or holds a license issued under this article or an affiliate or holding company that has control of a person that has applied for or holds a license under this article.

(2) A person that holds a combined direct, indirect or attributed debt or equity interest of more than five percent in a person that has applied for or holds a license under this article;

(3) A person that holds a combined direct, indirect or attributed equity interest of more than five percent in a person that has a controlling interest in a person that has applied for or holds license under this article;

(4) A managerial employee of a person that has applied for or holds a license under this article or a managerial employee of an affiliate or holding company that has control of a person that has applied for or holds a license under this article, who performs the function of principal executive officer, principal operating officer, principal accounting officer or an equivalent officer;

(5) A managerial employee of a person that has applied for or holds a license under this article or a managerial employee of an affiliate or holding company that has control of a person that has applied for or holds a license under this article who will perform or performs the function of an operations manager or will exercise or exercises management, supervisory or policy-making authority over the distribution of prescription drugs.

(l) "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 must be licensed as a wholesale distributor under this article and, in order to be considered part of the normal distribution channel, must also be an authorized distributor of record.

**§60A-8-6. Prohibited drug purchases or receipt; penalties.**

It is unlawful for any person or entity to knowingly purchase or receive any prescription drug from any source other than a person or entity licensed pursuant to the laws of this state except where otherwise provided, such person or entity to include, but not be limited to, a wholesale distributor, manufacturer, pharmacy distributor or pharmacy. Any person violating the provisions of this section is guilty of a misdemeanor, and, upon conviction thereof, shall be fined not more than one thousand dollars. Any person who violates this section shall for a second offense be guilty of a misdemeanor, and, upon conviction thereof, shall be fined not less than one thousand dollars nor more than five thousand dollars.

**§60A-8-7. Wholesale drug distributor licensing requirements**.

(a) Every applicant for a license under this article shall provide the board with the following as part of the application for a license and as part of any renewal of such license:

(1) The name, full business address and telephone number of the licensee;

(2) All trade or business names used by the licensee;

(3) Addresses, telephone numbers and the names of contact persons for all facilities used by the licensee for the storage, handling and distribution of prescription drugs;

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

(5) The name(s) of the owner and operator, or both, of the licensee, including:

(A) If a person, the name of the person;

(B) If a partnership, the name of each partner and the name of the partnership;

(C) 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

(D) If a sole proprietorship, the full name of the sole proprietor and the name of the business entity; and

(6) Any other information or documentation that the board may require.

(b) All wholesale distributors and pharmacy distributors shall be subject to the following requirements:

(1) No person or distribution outlet may act as a wholesale drug distributor without first obtaining a license to do so from the Board of Pharmacy and paying any reasonable fee required by the Board of Pharmacy, such fee not to exceed four hundred dollars per year: *Provided*, That for licenses that are effective on and after July 1, 2012, the annual fee shall be $750 per license until modified by legislative rule. All fees collected pursuant to this section shall be used for the operation and implementation of the West Virginia Controlled Substances Monitoring Program database or in the same manner as those fees governed by article five, chapter thirty of this code.

(2) The Board of Pharmacy may grant a temporary license when a wholesale drug distributor first applies to the board for a wholesale drug distributor's license and the temporary license shall remain valid until the Board of Pharmacy finds that the applicant meets or fails to meet the requirements for regular licensure, except that no temporary license shall be valid for more than ninety days from the date of issuance. Any temporary license issued pursuant to this subdivision shall be renewable for a similar period of time not to exceed ninety days pursuant to policies and procedures to be prescribed by the Board of Pharmacy.

(3) No license may be issued or renewed for a wholesale drug distributor to operate unless the distributor operates in a manner prescribed by law and according to the rules promulgated by the Board of Pharmacy with respect thereto.

(4) The Board of Pharmacy may require a separate license for each facility directly or indirectly owned or operated by the same business entity within this state, or for a parent entity with divisions, subsidiaries, or affiliate companies within this state when operations are conducted at more than one location and there exists joint ownership and control among all the entities.

(c) The minimum qualifications for licensure are set forth in this section as follows:

(1) As a condition for receiving and retaining any wholesale drug distributor license issued pursuant to this article, each applicant shall satisfy the Board of Pharmacy that it has and will continuously maintain:

(A) Acceptable storage and handling conditions plus facilities standards;

(B) Minimum liability and other insurance as may be required under any applicable federal or state law;

(C) A security system which includes after hours central alarm or comparable entry detection capability, restricted premises access, adequate outside perimeter lighting, comprehensive employment applicant screening and safeguards against employee theft;

(D) An electronic, manual or any other reasonable system of records describing all wholesale distributor activities governed by this article for the two-year period following disposition of each product and being reasonably accessible as defined by Board of Pharmacy regulations during any inspection authorized by the Board of Pharmacy;

(E) Officers, directors, managers and other persons in charge of wholesale drug distribution, storage and handling, who must at all times demonstrate and maintain their capability of conducting business according to sound financial practices as well as state and federal law;

(F) Complete, updated information to be provided to the Board of Pharmacy as a condition for obtaining and retaining a license about each wholesale distributor to be licensed under this article including all pertinent licensee ownership and other key personnel and facilities information determined necessary for enforcement of this article;

(G) Written policies and procedures which assure reasonable wholesale distributor preparation for protection against and handling of any facility security or operation problems, including, but not limited to, those caused by natural disaster or government emergency, inventory inaccuracies or product shipping and receiving, outdated product or other unauthorized product control, appropriate disposition of returned goods and product recalls;

(H) Sufficient inspection procedures for all incoming and outgoing product shipments; and

(I) Operations in compliance with all federal legal requirements applicable to wholesale drug distribution.

(2) The board of pharmacy shall consider, at a minimum, the following factors in reviewing the qualifications of persons who apply for a wholesale distributor license under this section or for renewal of that license:

(A) Any conviction of the applicant under any federal, state or local laws relating to drug samples, wholesale or retail drug distribution or distribution of controlled substances;

(B) Any felony convictions of the applicant or any key person under federal, state or local laws;

(C) The applicant's past experience in the manufacture or distribution of prescription drugs, including, but not limited to, controlled substances;

(D) The furnishing by the applicant of false or fraudulent material in any application made in connection with drug manufacturing or distribution;

(E) Suspension or revocation by federal, state or local government of any license currently or previously held by the applicant for the manufacture or distribution of any drug, including, but not limited to, controlled substances;

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

(G) Whether personnel employed by the applicant in wholesale drug distribution have appropriate education or experience, or both education and experience, to assume responsibility for positions related to compliance with the requirements of this article;

(H) Compliance with requirements to maintain and make available to the Board of Pharmacy or to federal, state or local law-enforcement officials those records required by this article; and

(I) Any other factors or qualifications the Board of Pharmacy considers relevant to and consistent with the public health and safety, including whether the granting of the license would not be in the public interest.

(3) All requirements set forth in this subsection shall conform to wholesale drug distributor licensing guidelines formally adopted by the United States Food and Drug Administration (FDA); and in case of conflict between any wholesale drug distributor licensing requirement imposed by the Board of Pharmacy pursuant to this subsection and any food and drug administration wholesale drug distributor licensing guideline, the latter shall control.

(d) An employee of any licensed wholesale drug distributor need not seek licensure under this section and may lawfully possess pharmaceutical drugs when the employee is acting in the usual course of business or employment.

(e) The issuance of a license pursuant to this article does not change or affect tax liability imposed by this state's Department of Tax and Revenue on any wholesale drug distributor.

(f) An applicant who is awarded a license or renewal of a license shall give the board written notification of any material change in the information previously submitted in, or with the application for the license or for renewal thereof, whichever is the most recent document filed with the board, within thirty days after the material change occurs or the licensee becomes aware of the material change, whichever event occurs last. Material changes include, but are not limited to:

(1) A change of the physical address or mailing address;

(2) A change of the responsible individual, compliance officer or other executive officers or board members;

(3) A change of the licensee's name or trade name;

(4) A change in the location where the records of the licensee are retained;

(5) The felony conviction of a key person of the licensee; and

(6) Any other material change that the board may specify by rule.

(g) Before denial of a license or application for renewal of a license, the applicant shall be entitled to a hearing in accordance with subsection (h), section eight, article one, chapter thirty of this code.

(h) The licensing of any person as a wholesale drug distributor subjects the person and the person's agents and employees to the jurisdiction of the board and to the laws of this state for the purpose of the enforcement of this article, article five, chapter thirty of this code and the rules of the board. However, the filing of an application for a license as a wholesale drug distributor by, or on behalf of, any person or the licensing of any person as a wholesale drug distributor may not, of itself, constitute evidence that the person is doing business within this state.

(i) The Board of Pharmacy may adopt rules pursuant to section nine of this article which permit out-of-state wholesale drug distributors to obtain any license required by this article on the basis of reciprocity to the extent that: (1) An out-of-state wholesale drug distributor possesses a valid license granted by another state pursuant to legal standards comparable to those which must be met by a wholesale drug distributor of this state as prerequisites for obtaining a license under the laws of this state; and (2) such other state would extend reciprocal treatment under its own laws to a wholesale drug distributor of this state.

(ii)

**§60A-8-8. License renewal application procedures.**

Application blanks for renewal of any license required by this article shall be mailed to each licensee at least thirty days before the first day of July of each calendar year by the board. All licenses issued under this section are not transferable and expire on the thirtieth day of June of each calendar year. If application for renewal of such license with required fee is not made before the expiration date of the license, the existing license, or renewal thereof, shall lapse and become null and void upon the last day of June of each calendar year.

**§60A-8-9. West Virginia board of pharmacy powers to promulgate rules.**
The board of pharmacy shall promulgate rules not inconsistent with law, as may be necessary to carry out the purposes and enforce the provisions of this article pursuant to chapter twenty-nine-a of this code. Rules which incorporate and set detailed standards for meeting each of the license prerequisites set forth in section seven of this article shall be promulgated in final form by no later than the fourteenth day of September, one thousand nine hundred ninety-two. All rules promulgated pursuant to this section shall conform to wholesale drug distributor licensing guidelines formally adopted by the food and drug administration at 21 C.F.R. Part 205; and in case of conflict between any rule adopted by the board of pharmacy and any food and drug administration wholesale drug distributor guideline, the latter shall control.

**§60A-8-10. West Virginia board of pharmacy complaint provisions.**
Complaints arising under any provision of this article shall be handled as follows:

(a) The board of pharmacy is hereby authorized and empowered, when complaints or examinations or inspections of a wholesale drug distributor disclose that a wholesale drug distributor is not operating or conducting business according to the state and federal laws, to file a written complaint with the board charging the holder of a license to operate a wholesale drug distributorship operation with violations of this article which are grounds for restriction, suspension or revocation of the wholesale drug distributor's license.

(b) If the board of pharmacy concludes that a wholesale drug distributor has committed an act or is engaging in a course of conduct which constitutes a clear and present danger to the public health and safety in this state, the board of pharmacy may hold an expedited hearing. Within fifteen days after service of the complaint on a wholesale drug distributor, the West Virginia board of pharmacy shall conduct a preliminary hearing to determine whether the alleged activities of the wholesale drug distributor appear to constitute a clear and present danger to the public health and safety which justify that the wholesale drug distributor's license be immediately restricted or suspended. The burden of proving that a wholesale drug distributor is a clear and present danger to the public health and safety shall be upon the board. The board shall issue its decision immediately after the hearing and shall dismiss the action or suspend, restrict or revoke the license. The board shall require any wholesale drug distributor found in violation of this article to take all necessary measures for compliance.

(c) If the board restricts, revokes or suspends the wholesale drug distributor's license, such temporary restriction, revocation or suspension shall become a final restriction or suspension if there is no request by the wholesale drug distributor for a final hearing within thirty days of the preliminary hearing. The board shall, if requested by the wholesale drug distributor named in the complaint, set a date to hold a final hearing which shall be held pursuant to the provisions of chapter twenty-nine-a of this code.

**§60A-8-11. The West Virginia board of pharmacy inspection powers and access to wholesale drug distributor records.**
(a) A person authorized by the board may inspect during normal business hours any premises being used by a wholesale drug distributor in this state in the course of its business. Any wholesale drug distributor providing adequate documentation of the most recent satisfactory inspection less than three years old of such distributor's wholesale drug distribution activities and facilities by either the

food and drug administration or a state agency, or any person or entity lawfully designated by a state agency to perform such inspection, determined to be comparable by the board shall be exempt from further inspection for a period of time to be determined by the board of pharmacy. Such exemption shall not bar the board from initiating an investigation pursuant to a public or governmental complaint received by the board regarding a wholesale drug distributor.

(b) Wholesale drug distributors may keep records regarding purchase and sales transactions at a central location apart from the principal office of the wholesale drug distributor or the location at which the drugs were stored 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.

**§60A-8-12. Judicial enforcement of the article.**

(a) Upon proper application by the board, a court of competent jurisdiction may grant an injunction, restraining order or other order as may be appropriate to enjoin a person from offering to engage or engaging in the performance of any acts or practices for which a certificate of registration or authority, permit or license is required by any applicable federal or state law, including, but not limited to, this act upon a showing that such acts or practices were or are likely to be performed or offered to be performed without a certificate of registration or authority, permit or license.

(b) Any such judicial actions shall be commenced either in the county in which such conduct occurred or in the county in which defendant resides.

(c) Any action brought under this section shall be in addition to and not in lieu of any other penalty provided by law and may be brought concurrently with other actions to enforce this article.

**§60A-8-13. Criminal penalties.**

Every person who violates any provision of section seven of this article shall be guilty of a misdemeanor, and, upon conviction thereof, shall be fined not less than two hundred dollars nor more than one thousand dollars.

**§60A-8-14. Disciplinary actions - wholesale drug distributor.**

(a) In accordance with article five, chapter thirty of this code, the Board of Pharmacy may suspend, revoke or refuse to renew any license issued to a wholesale distributor of prescription drugs pursuant to this article or may impose a civil money penalty not to exceed $1,000, in the discretion of the board for any of the following causes:

(1) Making any false material statements in an application for a license or for renewal of a license as a wholesale distributor or pharmacy distributor of prescription drugs;

(2) Violating any federal, state or local drug law, any provision of this article or any rule of the board;

(3) Conviction of a felony. For purposes of this subdivision "felony" means a felony or crime punishable as a felony under the laws of this state, any other state or the United States;

(4) Ceasing to satisfy the qualifications for licensure under section seven of this article or the rules of the board;

(5) The license or registration of a wholesale drug distributor licensed under this article has been revoked by the licensing authority of another state, jurisdiction of foreign nation; or

(6) Any reason for which the board may impose disciplinary sanctions under the provisions of chapter thirty of this code.

(b) Upon the suspension or revocation of the license of any wholesale distributor of prescription drugs, the distributor shall immediately surrender the license to the board.

(c) If the board suspends, revokes or refuses to renew any license issued to a wholesale distributor of prescription drugs and determines that there is clear and convincing evidence of a danger of immediate and serious harm to any person, the board may place under seal all drugs owned by or in the possession, custody or control of the affected wholesale distributor. Except as provided in this article, the board may not dispose of the drugs sealed under this subsection until the distributor exhausts all of his or her appeal rights under this article or article five, chapter thirty of this code. The court involved in the appeal may order the board, during the pendency of the appeal, to sell sealed dangerous drugs that are perishable. The board shall deposit the proceeds of the sale with the court.

**§60A-8-15. Maintenance of register and roster of wholesale and pharmacy distributors.**

(a) The Executive Director of the Board of Pharmacy shall maintain a register of the names, addresses and the date the current license was issued or renewed pursuant to this article for license years beginning on and after July 1, 2013. The register shall be the property of the board and shall be open for public examination and inspection at all reasonable times, as the board may direct.

(b) The register shall set forth the names and addresses of:

(1) Those persons who are or have been licensed under this article for the current license year;

(2) Those persons whose licenses have been suspended, revoked or surrendered during the current license year or during the two preceding license years; and

(3) Those persons whose licenses have not been renewed for the current license year.

(c) In lieu of annually publishing a typed or printed register providing the information required by this subsection, the board may make the information required to be published available at its website.

(d) A written statement signed and verified by the executive director of the board, in which it is stated that after diligent search of the register no record or entry of the issuance of a license or registration certificate to a person is found, is admissible in evidence and constitutes presumptive evidence of the fact that the person is not a licensed as a wholesale drug distributor under this article.

**§60A-8-16. Disposition of fees.**

The board shall pay all fees it collects under this article into the separate fund created in the State Treasury for the board pursuant to section ten, article one, chapter thirty of this code. The money in this fund shall be used exclusively by the board for the purposes of administering and enforcement of its duties pursuant to this article, articles one and five, chapter thirty of this code, or any other duty of the board prescribed by any other provision of this code.

**WEST VIRGINIA CODE**
**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) On or before September 1, 2002, 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 State Board of Pharmacy shall allow reporting of the required information by electronic data transfer where feasible, and where not feasible, on reporting forms promulgated by the Board of Pharmacy. 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 State Board of Pharmacy 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 State Board of Pharmacy 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 whenever a prescription for the controlled substance 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 of Pharmacy 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 dispensed;

(5) The quantity and dosage of the Schedule II, III and IV controlled substance 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 full legal name, 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 of pharmacy; and

(9) The source of payment for the controlled substance dispensed.

(b) The Board of Pharmacy may prescribe by rule promulgated under this article the form to be used in prescribing a Schedule II, III and IV substance 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 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.

**§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 receiving or otherwise acquiring the controlled substance 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 information shall be retained in either print or electronic form until such time as otherwise directed by rule promulgated by the board of pharmacy.

**§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 State Board of Pharmacy 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 State Board of Pharmacy, 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 Board of Pharmacy legislative rules, shall be certified as a West Virginia law-enforcement officer and shall have successfully completed United States Drug Enforcement Administration Diversion Training and National Association of Drug Diversion Investigation Training. All information released by the State Board of Pharmacy 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 prescribers 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 of Pharmacy 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 Osteopathy, 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 of Pharmacy 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 prescribers 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 prescriber 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 of Pharmacy 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 on or before June 1, 2013. 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) 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, on or before

July 1, 2011, have online or other form of electronic access to the West Virginia Controlled Substances Monitoring Program database;

(f) 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 of Pharmacy, delegate appropriate personnel to have access to said database;

(g) 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; and

(h) 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.

(i) 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.

(j) The Board of Pharmacy 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 conduct annual search of the database; required rulemaking.**

(a) Upon initially prescribing or dispensing any pain-relieving controlled substance for a patient and at least annually thereafter should the prescriber 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 Osteopathy 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.

(b) The various boards mentioned in subsection (a) 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.**

(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 or 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 or fined.

(d) Any prescriber 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) of section five-a of this article and fails to do so as directed by the rules of their licensing board shall be subject to such discipline as the licensing board deems appropriate.

(e) 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 or fined.

(f) 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.

**§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 and may be invested in

accordance with the provisions of article six, chapter twelve of this code, with interest income a proper credit to the fund. The fund shall consist of appropriations by the Legislature, gifts, donations or any other source. Expenditures from the fund shall be for the following purposes: to provide funding for substance abuse prevention, treatment, treatment coordination, recovery and education. *Note: WV*

**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 two thousand twelve regular session.**

The provisions of this article enacted during the 2012 regular legislative session establishing the Multi-State Real-Time Tracking System shall expire on June 30, 2015.

**CHAPTER 60A. UNIFORM CONTROLLED SUBSTANCES ACT.**
**ARTICLE 11. CLANDESTINE DRUG LABORATORY REMEDIATION ACT.**

**§60A-11-1. Legislative findings and purpose.**

(a) *Findings.* -- The Legislature finds that some residential and business properties are being used for the consumption, production and manufacture of illegal drugs resulting in contamination with hazardous chemical residues. These illegal laboratories present an immediate and ongoing danger to public health and safety. Innocent members of the public may be harmed when they are exposed to the chemical residues if the property is not decontaminated prior to subsequent rental, sale or use of the property.

(b) *Purpose.* -- The purpose of this article is to protect the public health, safety and welfare by designating the Department of Health and Human Resources as the state agency to set forth standards for the remediation of clandestine drug laboratories.

**§60A-11-2. Definitions.**

In this article:

(a) "Clandestine drug laboratory" means the area or areas where controlled substances, or their immediate precursors, have been, or were attempted to be, manufactured, processed, cooked,

disposed of or stored and all proximate areas that are likely to be contaminated as a result of such manufacturing, processing, cooking, disposing or storing.

(b) "Department" means the West Virginia Department of Health and Human Resources.

(c) "Controlled substance" means the same as that term is defined in section one hundred one, article one of this chapter and article ten, section three of this chapter a drug, substance or immediate precursor in Schedules I through V of article two of this chapter.

(d) "Immediate precursor" means a substance which the "West Virginia Board of Pharmacy" (hereinafter in this act referred to as the State Board of Pharmacy) has found to be and by rule designates as being 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.

(e) "Law-enforcement agency" means the West Virginia State Police or any other policing agency of the state or of any political subdivision of the state.

(f) "Remediation" means the act of rendering safe and usable for the purposes for which it is intended residential property, as defined in subsection (g) of this section, or any structure appurtenant to the residential property, or other structure on the residential property that has been used for the manufacture or consumption of methamphetamines or other illicit drug products.

(g) "Residential property" means any building or structure to be primarily occupied by people, either as a dwelling or as a business, including, but not limited to, a storage facility, a mobile home, manufactured home or recreational vehicle, hotel or motel that may be sold, leased or rented for any length of time.

(h) "Residential property owner" means the person holding record title to residential property as that term is defined in subsection (f) of this section.

**§60A-11-3. Remediation of clandestine drug laboratories; promulgation of legislative rules.**
(a) The Department of Health and Human Resources shall propose rules for legislative approval in accordance with the provisions of article three, chapter twenty-nine-a of this code to address, at a minimum, the following issues:

(1) Establishment of scientific guidelines and numeric decontamination levels for the remediation of clandestine drug laboratories;

(2) Establishment of a certification program for persons or contractors who engage in the business of clandestine drug lab remediation;

(3) Establishment of a licensure procedure whereby individuals and businesses certified to do remediation of clandestine drug laboratories obtain a license from the Department of Health and Human Resources to do such work;

(4) Requiring licensed contractors to notify the Department of Health and Human Resources prior to beginning any remediation project;

(5) Setting forth certification procedures for the department to certify that the completed remediation of the residential property fully meets the scientific guidelines and numeric decontamination levels set forth in the legislative rule; and

(6) Establishing requirements for property owners, sellers and landlords to disclose the existence of any former clandestine laboratory site or activity to any potential occupant of the residential property.

(b) Fees may be set by the legislative rule to be charged to persons or contractors engaged in the business of clandestine drug laboratory remediation for certification, licensing and notification as required in this article.

**§60A-11-4. Law-enforcement responsibility.**

Any law-enforcement agency, upon locating chemicals, equipment, supplies or precursors indicative of a clandestine drug laboratory on residential property, shall notify the residential property owner and the department in a manner prescribed by the legislative rule authorized by this article.

**§60A-11-5. Residential property owner responsibility; owner immunity; voluntary compliance.**

(a) Upon notification to the residential property owner by a law-enforcement agency that chemicals, equipment, supplies or precursors indicative of a clandestine drug laboratory have been located on the residential property owner's property, the residential property owner shall be responsible for actions necessary to meet the remediation standards established by the legislative rule authorized by this article. The residential property owner is responsible for actions to ensure the residential property shall remain unoccupied from the time the residential property owner is notified of the clandestine drug laboratory until such time as the department certifies that the completed remediation meets the numeric decontamination levels set forth in the legislative rule authorized in this article. The department shall have forty-five days from receipt of all necessary paperwork and documentation to complete remediation certification: *Provided,* That a residential property owner may demolish the residential property as an alternative to meeting the remediation standards established by the department.

(b) Once the remediation has been certified complete by the department, the residential property owner and any representative or agent of a residential property owner who neither knew or should have known of the property's illegal use shall be immune from civil liability for action brought for injuries or loss based upon the prior use of the residential property as a clandestine drug laboratory by future owners, renters, lessees or any other person who occupies the residential property.

(c) Any residential property owner who neither knew or should have known of the property's illegal use who chooses to voluntarily and successfully complete the remediation prior to notification by a law-enforcement agency shall have the same immunity from liability as set forth in subsection (b) of this section if the remediation meets the certification standards set forth in legislative rules authorized by this article.

**§60A-11-6. Liability for costs of remediation.**

Any person convicted pursuant to section four, subsection (d), article ten of this chapter and whose actions also resulted in the necessity of remediation of a clandestine drug laboratory, shall be liable to the person or entity for all costs associated with the remediation of the clandestine drug laboratory. These costs may include attorney's fees and court costs reasonably necessary to bring an action to collect the amount paid for the remediation.

## 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; orC. 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.

**TITLE 15**
**LEGISLATIVE RULE**
**WEST VIRGINIA BOARD OF PHARMACY**

**SERIES 1**
**LICENSURE AND PRACTICE OF PHARMACY**

**§15-1-1. General.**

1.1. Scope. -- This rule provides definitions of many terms and establishes general provisions for Board operation; establishes internship requirements; provides the requirements for application as a pharmacist, including examination requirements, renewals, and reinstatement of lapsed licenses; establishes the qualifications for obtaining a license by reciprocity, including requirements for a foreign pharmacy graduates; establishes proceedings for disciplinary action; establishes how drugs may be transferred and the restrictions on refilling and transferring of prescription orders, including establishing communications requirements for the manual and electronic prescribing and dispensing of prescription drugs, specifically providing for E-prescribing and Electronic Data Intermediaries; establishes how drugs and devices may be returned; states the requirements for drug product selection and substitution; establishes the requirements for pharmacy permits, including the minimum requirements, security, and professional work environment; states the required equipment, facilities, and record systems required by a pharmacy; establishes the requirements for a permit to conduct sterile pharmaceutical compounding; establishes licensure and control of nuclear pharmacies; establishes the sanitary requirements in a pharmacy; establishes rules of professional conduct for pharmacists; establishes the duties and responsibilities of a pharmacist-in-charge; establishes the manner of issuance of a prescription; states different labeling requirements; establishes the requirements and responsibilities of a consultant pharmacist; establishes different types of specialized dispensing systems, including the use of emergency kits; states the requirement for places that need to obtain a controlled substance permit, including the fees for such permit.

1.2 Authority -- W. Va. Code §§30-5-12C(d), 30-5-14, and 30-5-19.

1.3 Filing date -- April 16, 2015.

1.4 Effective date -- May 17, 2015.

**§15-1-2. Definitions.**

2.1. The following words and phrases as used in this Rule have the following meanings:

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

2.1.2. "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.

2.1.3 “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.

2.1.4. “Board of Pharmacy" or "Board" means the West Virginia State Board of Pharmacy.

2.1.5. "Compounding" means:

2.1.5.a. The preparation, mixing, assembling, packaging, or labeling of a drug or device:

2.1.5.a.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

2.1.5.a.2. for the purpose of, or as an incident to, research, teaching or chemical analysis and not for sale or dispensing, or

2.1.5.a.3. in anticipation of prescription drug orders based on routine, regularly observed prescribing patterns.

2.1.6. "Confidential information" means patient-identifiable information maintained by the pharmacist in the patient record or which is communicated to the patient as part of patient counseling, or which is communicated by the patient to the pharmacist.

This information is privileged and may be released only to the patient or to other members of the health care team and other pharmacists where, in the pharmacist's professional 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.

2.1.7. "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.

2.1.8. The term "Cosmetic" means:

2.1.8.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;

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

2.1.8.c. shall be held to include "dentifrice" and “toilet articles”

2.1.9. "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.

2.1.10. "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.

2.1.11. “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.

2.1.12. "Dispense" or "dispensing" is that aspect of the practice of pharmacy concerned with the preparation, verification of contents, and delivery of a drug or device in an appropriately labeled and suitable container to a patient or a patient's representative or surrogate pursuant to a lawful order of a practitioner for subsequent administration to, or use by, a patient. Dispensing has not occurred until the drug is actually delivered to the patient or patient’s representative.

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

2.1.14. “Distributor" means a person licensed as a wholesaler.

2.1.15. "Drug" means:

2.1.15.a. articles recognized as drugs by the U. S. Food and Drug Administration (FDA) or published in such references as the USP-NF, Facts and Comparisons, Physicians Desk Reference or supplements thereto, for use in the diagnosis, cure, mitigation, treatment or prevention of disease in human or other animals;

2.1.15.b. articles, other than food, intended to affect the structure or any function of the body of human or other animals; and

2.1.15.c. articles intended for use as a component of any articles specified in subsection (b) or (c) of this section.

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

2.1.16.a. Evaluation of prescription orders and patient records readily available to the pharmacist for:

2.1.16.a.1. Known significant allergies;

2.1.16.a.2. Rational drug therapy and contraindications;

2.1.16.a.3. Reasonable dose and route of administration; and

2.1.16.a.4. Reasonable directions for use.

2.1.16.b. Evaluation of readily available prescription drug orders and patient records for duplication of therapy;

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

2.1.16.c.1. Drug-drug;

2.1.16.c.2. Drug-food;

2.1.16.c.3. Drug-disease; and

2.1.16.c.4. Adverse drug reactions.

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

2.1.17. "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:

2.1.17.a. An electronic prescription order;

2.1.17.b. A refill authorization request;

2.1.17.c. A communication; or

2.1.17.d. Other patient care information.

2.1.18. "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".

2.1.19. “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.

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

2.1.21. “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.

2.1.22. “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.

2.1.23. "Intern" means an individual who is:

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

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

2.1.23.c. A qualified applicant who is licensed by the Board and is awaiting examination for licensure; or

2.1.23.d. An individual participating in a residency or fellowship program.

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

2.1.25. “Mail order pharmacy" means a pharmacy, regardless of its location, which dispenses greater than ten percent (10%) prescription drugs in the United States Mail or other mail or package delivery service.

2.1.26. "Manufacturer" means a person engaged in the manufacturing of drugs or devices.

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

2.1.28. "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.

2.1.29. “Nuclear pharmacist” means a pharmacist who has been certified in the specialty of nuclear pharmacy.

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

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

2.1.31.a. the applicant is a new business;

2.1.31.b. the applicant is an established business that is transferred to a successor;

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

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

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

2.1.32. "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 anyplace outside of this state where drugs are dispensed and the practice of pharmacy and pharmacist care is provided to residents of this state.

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

2.1.34. "Patient counseling" means the oral communication by the pharmacist of information, which may include supplemental media according to the pharmacist's professional judgment, to the patient or care giver, to ensure the proper use of drugs and devices.

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

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

2.1.37. "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.

2.1.38. "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.

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

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

2.1.40.a. Accepts responsibility for the operation of a pharmacy in conformance with all state and federal laws and rules pertinent to the practice of pharmacy and the distribution of drugs;

2.1.40.b. has the responsibility for the practice of pharmacy, 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;

2.1.40.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

2.1.40.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 |

2.1.41. "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.

2.1.42. “Pharmacy technician trainee” means an individual 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.

2.1.43. "The practice of pharmacy" is the personal health 3service concerned with the preparing, compounding and dispensing of drugs and medical devices used in the diagnosis, treatment or prevention of disease, dispensed on the prescription of a practitioner, or otherwise legally dispensed or sold and shall include the proper and safe storage of drugs, the maintenance of proper records and the dissemination of information to other health care professionals and proper counseling to the patient concerning the therapeutic value and proper use of drugs and devices.

2.1.44. "Practitioner" or “prescribing practitioner” means an individual currently licensed, registered or otherwise authorized by any state, territory or district of the United States to prescribe and administer drugs in the course of professional practices, including allopathic and osteopathic physicians, dentists, physician assistants, optometrists, veterinarians, podiatrists and nurse practitioners 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" or "legend drug" means a drug which, under federal law, is required, prior to being dispensed or delivered, to be labeled with any of the following statements or the language or symbol as determined by the U. S. Food and Drug Administration.

2.1.46.a. "Caution: Federal law prohibits dispensing without prescription".

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

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

2.1.47.a. Written order;

2.1.47.b. An oral order to a pharmacist who shall immediately:

2.1.47.b.1. Reduce it to writing which becomes the original order;

2.1.47.b.2. Hand initial it to identify the receiver; and

2.1.47.b.3. Show the date, time and name of person transmitting the order;

2.1.47.c. An electronic transmission which has the capability to produce a printed copy, and shows the date, time and name of person transmitting the order; or

2.1.47.d. other methods of transmission approved by the Board.

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

2.1.49. ‘sample" means a package of a legend 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.

2.1.50. An approved or recognized ‘school of Pharmacy" means a school of pharmacy accredited by the American Council on Pharmaceutical Education.

2.1.51. ‘secretary" means the Secretary of the West Virginia Board of Pharmacy.

2.1.52. "Vice-President" means the Vice-President of the West Virginia Board of Pharmacy.

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

**§15-1-3. General Provisions.**

3.1. The Board in general. – The Board of Pharmacy shall consist of five (5) practicing pharmacists and two (2) public members who shall be appointed by the governor, by and with the advice and consent of the Senate. Each member of the Board, at the time of his appointment, shall be a citizen and a licensed pharmacist of the State of West Virginia and actively engaged in the practice of pharmacy. The public members shall be residents of this state who have attained the age of majority and may not be a past or present member of the profession of pharmacy, the spouse of a member of the profession of pharmacy, a person who has ever had any material financial interest in providing of pharmacy service or who is engaged in any activity directly related to the practice of pharmacy.

3.2. Officers of the Board. – The members of the board shall annually elect as officers of the Board one (1) member to serve as President of the Board, one (1) to serve as Vice-president and one (1) to serve as Secretary, all to serve a one (1) year term or until their successors are elected. The election is to be held in June each year.

3.3. Official Seal – The Board hereby reaffirms and readopts, as the official seal of the Board the following: The outer circle of the seal has inscribed 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.

3.4. Meetings of the Board – The Board shall hold at least two (2) meetings a year for the purpose of examining applicants for licensure to practice pharmacy in West Virginia and for the transaction of any other business that may legally come before it. It may hold additional meetings for any legitimate purpose it may consider appropriate, which shall be called by the Secretary at the direction of the President or upon the written request of any three (3) members. 'Roberts Rules of Order' shall control conduct of all meetings.

3.5. Quorums – Four (4) members must be present at the time and place set for the meeting before any action can be taken by the Board. A majority vote of the members in attendance is required before any motion may be passed.

3.6. Location of Office – The Board shall determine the location of its office.

3.7. Disposition of moneys; report to auditor. – The Secretary 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.

3.8. Every member of the board shall be paid a per diem for each day actually spent in attending sessions of the Board or of its committees and the necessary travel, and shall be reimbursed for all actual and necessary expenses incurred in carrying out the provisions of chapter thirty of the West Virginia Code applicable to the Board.

3.9. Record of proceedings; registration of applicant; certified copies of records prima facie evidence, report to governor. – The Secretary of the Board shall keep a record of its proceedings and a register of all applicants for license or registration, showing for each, the date of his 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.

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

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

3.12. During the course of any inspection or investigation by an agent of the Board the agent may temporarily close any permittee upon the discovery of any of the following:

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

3.12.2. the absence of valid permit issued by the Board or by the absence of an available pharmacist to be on duty.

3.13. When a permittee is closed under subsection 3.12.a of this section they shall remain closed until an unimpaired pharmacist arrives on the premises or when a permittee is closed under subsection 3.12.b of this section, the permittee shall remain closed until a valid permit is obtained and on display as required by law.

3.14. Agents of the Board when acting in good faith and without malice 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. The principal purpose of serving an internship is for the intern to acquire practical experience under the direct supervision and instruction of a licensed pharmacist preceptor in the providing of pharmacist care, including, but not limited to, the compounding and dispensing of prescriptions.

4.1.1. No person may practice as a pharmacist intern without being licensed to do so by the board.

4.1.2. To be eligible to practice as a pharmacist intern, an applicant must:

4.1.2.a. make application to the board on a form provided by the Board;

4.1.2.b. pay the required application fee; and

4.1.2.c. meet all other requirements for licensure.

4.1.4. All intern licenses expire on the 30th day of June of each year, and, upon proper application, may be renewed annually up to four (4) years from the date of issue.

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

4.1.6. The 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 intern has been issued an intern certificate;

4.2.2b. When the intern has notified the Board within ten (10) days of the employment as an intern;

4.2.3. When the intern notifies the Board within ten (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 intern shall be certified by the Board unless the intern is enrolled in or is a graduate of a recognized school of pharmacy, or has met the requirements for educational equivalency by obtaining a Foreign Pharmacy Graduate Examination Committee Certification.

4.4. An intern may receive experience credit for any period of time during which he or she is enrolled in a recognized school of pharmacy and the Board may accept and certify up to one thousand five hundred (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. An 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 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 a recognized 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 – All applicants for examination shall apply in writing to the Board at least fifteen (15) days before the date of examination is to be conducted and shall transmit with the application the prescribed fee. The application shall be made on a form provided by the Board.

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

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

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

5.2.3. The applicant for licensure as a pharmacist shall present to the Board satisfactory evidence that he or she is a graduate of an approved school of pharmacy, 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. The applicant shall have acquired one thousand five hundred (1500) hours of internship in a licensed pharmacy.

5.2.5. The applicant shall provide a signed waiver allowing the Board to obtain a certified criminal records check on the applicant.

5.3. Examinations.

5.3.1. State and national examinations required for licensure shall be held at a time and place designated by the Board. The Board shall give at least thirty (30) days notice prior to the holding of any examination.

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 and approved by the Board.

5.3.3. An applicant for licensure as a pharmacist shall pass the North American Pharmacist Licensure Examination (NAPLEX), and the Multistate Pharmacy Jurisprudence Examination for West Virginia (MPJE), administered by NABP in subjects determined by the Board as being reasonable, in testing his or her knowledge.

5.3.4. For the purpose of grading or rating, answers to the questions shall be valued by scores based upon their importance as determined by the NABP and approved by the Board. An applicant shall attain an individual test grade of seventy-five percent (75%) on each examination in order to qualify for licensure.

5.3.5. An applicant failing to achieve the required grades may repeat the failed examination or examinations one time without re-applying to the board within six (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.

5.3.6. 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.

5.3.7. 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 or registration – 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 shall be attested by the President and Secretary. For any duplicate of this certificate the Board shall charge twenty five dollars ($25.00). A certificate is not assignable.

5.5. License and registration renewal.

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

5.5.1.a. Biennial renewal of license of pharmacist: $100.00;

5.5.1.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;

5.5.1.c. Registration of a consultant pharmacist: $20.00 for each application; and

5.5.1.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 interns shall continue to be renewed annually. Every licensed pharmacist, 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, 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 and the license or registration shall be considered lapsed.

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 two hundred fifty dollars for a pharmacist plus the renewal fee of one hundred dollars, or upon payment of a reinstatement fee of fifty dollars for a pharmacy technician plus the renewal fee of twenty dollars. 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 two hundred fifty dollars for a pharmacist plus the renewal fee of one hundred dollars, or upon payment of a reinstatement fee of fifty dollars for a pharmacy technician plus the renewal fee of twenty dollars. 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. Qualifications – 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 eighteen (18) years of age;

6.1.2. The originating state in which the applicant is licensed or registered accords similar recognition to licensed pharmacists of West Virginia;

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

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

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

6.1.6. 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;

6.1.7. 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

6.1.8. The applicant is familiar with West Virginia Laws and Rules and Regulations governing the practice of pharmacy and passes the MPJE.

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 state of West Virginia.

6.4. Foreign pharmacy graduate – Foreign pharmacy graduate – A foreign pharmacy graduate whose undergraduate pharmacy degree was conferred by a recognized school of pharmacy outside of the fifty (50) United States, the District of Columbia, and Puerto Rico, may establish educational equivalency by obtaining a Foreign Pharmacy Graduate Examination Committee Certificate (FPGEC) from the National Association of Boards of Pharmacy (NABP). An applicant for licensure who receives FPGEC certification meets the educational requirement for licensure and may sit for the NAPLEX and 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.

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 two hundred and fifty dollars ($250.00).

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

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

6.5.2.b. A recent head shot photograph with a statement signed by the applicant that it is a photograph of the applicant and has been made within the previous twelve (12) months; and

6.5.2.c. A signed waiver from the applicant allowing the Board to obtain a certified criminal records check on the applicant.

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

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

7.1. Hearing Procedures.

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

7.1.2. Any person who desires a hearing under the provisions of this section shall for the present a written demand for the hearing to the Board.

7.1.3. When the president of the Board or his or her authorized designee is presented with a demand for a hearing, he or she shall schedule a hearing within thirty (30)days of receipt of the written demand, unless postponed to a later date by mutual agreement.

7.1.4. The Board may institute charges against any person who has a permit issued by the Board when reasonable cause exists for believing that the person may have engaged in conduct or be in such condition that the permit should be suspended, revoked, or otherwise disciplined for one or more of the grounds set forth in W. Va. Code §30-5-1, et. seq. or the rules of the Board. Charges may be based upon information received by way of a verified written complaint filed with the Board and further information gathered by the Board in the process on investigating the complaint. Charges may also be based upon information received solely through inspection or investigative activities undertaken by the Board.

7.1.5. The Board shall institute charges against a person holding a permit by issuing a Complaint and Notice of Hearing in the name of the Board. Such Complaint and Notice of Hearing shall designate the Board as the 'Complainant' and shall designate the permittee involved in the proceedings as the "Respondent"; shall set out the substance of each offense charged with sufficient particularity to reasonably apprise the Respondent of the nature, time and place of conduct or condition complained of in the Complaint and Notice of Hearing; shall state the date, time and place for the hearing; and shall contain a statement of intention of the Board to appoint a hearing examiner.

7.1.6. The Board may amend the charges set forth in a Complaint and Notice of Hearing as it considers proper.

7.1.7. The Board shall serve a Complaint and Notice of Hearing upon the demanding or charging party at least thirty (30) days prior to the date of hearing.

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

7.2. Hearings shall be conducted as follows:

7.2.1. Any party to the hearing may be represented by an attorney-at-law, duly qualified to practice law in the State of West Virginia.

7.2.2. Upon request by the Board, it shall be represented by West Virginia Attorney General's Office.

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

7.2.4. The rules of privilege recognized by the law of this State shall be followed.

7.2.5. Objections to evidentiary offers shall be noted on record. Any party to the hearing may vouch the record as to any excluded testimony or evidence.

7.2.6. Any party to a hearing may appear with witnesses to testify on his or her behalf; may be heard in person, by counsel or both; may present other evidence in support of his or her position as determined appropriate by the Board or its designated hearing examiner; and, when appropriate, may cross-examine witnesses called by the Board in support of the charges or in defense of its decision to deny licensure.

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

7.2.8. The hearing shall be open to the general public.

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

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

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

7.2.12. Where a hearing is held after charges have been brought against a license pursuant to this rule, the board has the burden of proof and shall present its evidence and/or testimony in support of the charges first.

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

7.2.14. Following the conclusion of the Board's presentation of evidence in accordance with subdivision 7.2.12 of this section, the Respondent or charged party has the right to submit his or her evidence.

7.2.15. Following the conclusion of the demanding party's presentation of evidence in accordance with subdivision 7.2.14 of this section, the Board has the right to submit its evidence in rebuttal.

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

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

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

7.2.19. 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.

7.2.20. 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.

7.3. Transcription of Testimony and Evidence.

7.3.1. All testimony, evidence, arguments and rulings on the admissibility of testimony and evidence shall be recorded by stenographic notes and characters or by mechanical means.

7.3.2. All recorded materials shall be transcribed. The Board shall make arrangements for the transcription of the recorded testimony and evidence.

7.3.3. Upon the motion of the Board or any party assuming error or omission in any part of any transcript, the Board or its appointed hearing examiner shall settle all differences arising as to whether the transcript truly discloses what occurred at the hearing and shall direct that the transcript be corrected and/or revised as appropriate so as to make it confirm the truth.

7.3.4. A transcript of the hearing shall be provided to all members of the Board for review at least ten (10) days before the vote is taken on its decision.

7.4. 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.

7.5. Hearing Examiner

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

7.5.2. Hearing examiners appointed by the Board may not grant, suspend, revoke or otherwise take disciplinary action upon any license.

7.5.3. The hearing examiner shall prepare recommended findings of fact and conclusions of law for submission to the Board. The Board may adopt, modify or reject the findings of fact and conclusions of law.

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:

7.6.1.a. To dispose of procedural requests, prehearing motions or similar matters;

7.6.1.b. To simplify or settle issues by consent of the parties; of

7.6.1.c. To provide for informal disposition of cases by stipulation or agreement.

7.6.2. The Board or its duly appointed hearing examiner may cause the conferences to be held on the Board's or the hearing examiner's own motion 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. Evidentiary depositions may be taken and read or otherwise included into evidence as in civil actions in the circuit courts of this State.

7.8. Subpoenas

7.8.1. 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.

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

7.9. Orders

7.9.1. Any final order entered by the Board following a hearing conducted pursuant to this rule shall be made pursuant to the provisions of W. Va. Code §29A-5-3 and §30-1-8 (d). The orders shall be entered within forty-five (45) days following the submission of all documents and materials necessary for the proper disposition of the case, including transcripts, and shall contain findings of fact and conclusions of law.

7.9.2. The findings of fact and conclusions of law shall be approved by a majority of the Board either by a poll or vote at a regular meeting, before the final order is entered. A copy of the final order approved by a majority of the Board shall be served by personal service or by registered or certified mail upon the demanding record, if any within five (5) days after entry by the Board.

7.10. Appeal – An appeal from any final order entered in accordance with this rule shall comply with the provisions of W. Va. Code §30-1-9.

**§15-1-8. Review By Circuit Court and Supreme Court of Board's Refusal to Issue, or Suspend or Revoke Permit.**

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

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

8.3. Upon receipt of the petition copy, the Secretary shall transmit to the clerk of the court, the record of the hearing.

**§15-1-9. Transfer of Legend Drugs.**

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

9.1.1. Transfer of drugs without prescription.

9.1.1.a. Legend 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.

9.1.1.b. The record showing transfers of legend drugs without a prescription shall contain:

9.1.1.b.1. the name of the drug and its quantity;

9.1.1.b.2. the date of transaction;

9.1.1.b.3. the permittee or practitioner to whom the legend drug was transferred; and

9.1.1.b.4. the selling price.

9.1.1.b.4.(a) 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.

9.1.1.b.4.(b) 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.

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

9.1.2.a.1. The patient's name and address and the date the prescription is written;

9.1.2.a.2. The drug's name and quantity; and

9.1.2.a.3. Directions for use.

9.1.2.a.3.A. If the prescription is written on a practitioner's date prescription blank, the order shall contain the following:

9.1.2.a.3.A.1. The practitioner's printed name, address, professional designation and practitioner identifier number; and

9.1.2.a.3.A.2. The practitioner's signature.

9.1.2.a.3.B. If the prescription is written on an institutional prescription blank, the order shall contain the following:

9.1.2.a.3.B.1. The printed name of the practitioner and DEA number with suffix; and

9.1.2.a.3.B.2. The practitioner's signature.

9.1.2.a.3.C. No sticker or other substance shall be allowed to obliterate or cover any of the information required by this subdivision.

9.2. Samples

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

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

9.2.2.a. All prescription drug samples received by the pharmacy are obtained pursuant to a written, signed and 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;

9.2.2.b. the pharmacy retains a copy of all written, signed prescription drug sample requests;

9.2.2.c. prescription drug samples are stored separately from the prescription drug products held for sale (retail stock);

9.2.2.d. records of prescription drug sample receipt are dispensing are maintained separately from records of prescription drug products held for sale and sold (retail stock);

9.2.2.e. a relationship exists between the health care entity and the pharmacy which is evidenced by a written documentation;

9.2.2.f. prescription drug samples are dispensed by the pharmacy to patients in the manufacturer's or distributor's original packaging; and

9.2.2.g. the pharmacy and its employees do not sell, purchase, or trade or offer to sell, purchase, or trade any prescription drug sample.

**§15-1-10. Refilling Prescription Orders.**

10.0. 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 electronic recording is used a daily printout of all prescription orders filled shall be made and verified and signed by each pharmacist responsible for that days work or a log may be kept of each refill number and this log shall be signed by each pharmacist.

10.3. No prescription order may be refilled after twelve (12) months from the original dispensing.

10.4. The refilling of prescription orders for controlled substances is limited by provisions of the Uniform Controlled Substances Act, 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:

11.2.1.a. Writes the word “VOID” on the face of the original prescription order;

11.2.1.b. Records on the reverse of the original prescription the name, address, and Drug Enforcement Administration (DEA) registry number of the pharmacy to which the prescription was transferred and the name of the pharmacist receiving the prescription information; and

11.2.1.c. Records the date and time of the transfer and his or her first and last name;

11.2.2. The pharmacist receiving the transferred prescription order information:

11.2.2.a. Writes the word “TRANSFER” on the face of the transferred prescription; and

11.2.2.b. Provides all the information required to be on a prescription and includes:

11.2.2.b.1. Date of issuance of the original prescription;

11.2.2.b.2. Number of refills on the original prescription;

11.2.2.b.3. The date the original prescription was dispensed;

11.2.2.b.4. The number of valid refills remaining and date of last refill;

11.2.2.b.5. The pharmacy’s name, address, DEA registry number and the original prescription number from which the prescription was transferred; and

11.2.2.b.6. The first and last name of the transferring pharmacist;

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

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

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

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

11.5. Pharmacies accessing a common electronic file of 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.

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. Pharmacy permits and annual registration - A pharmacy shall first secure a permit from the Board and comply fully with W. Va. Code §30-5-14 before it may lawfully conduct a pharmacy.

14.2. Application for permits – The Board shall require and provide for the annual registration of every pharmacy doing business in this state. Any person desiring to operate, maintain, open or establish a pharmacy in West Virginia, shall apply to the Board for a permit to do so. Every 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 permit 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:

14.2.1.a. identification of the owner that is applying for the permit;

14.2.1.b. the name under which the business will be operated and which will be used in advertising;

14.2.1.c. the physical location of the pharmacy including;

14.2.1.c.1. Its street number; and

14.2.1.c.2. The city and county;

14.2.1.d. The mailing address of the pharmacy if different from its physical location;

14.2.1.e. The name and license number of the pharmacist-in-charge;

14.2.1.f. The name and license numbers of other pharmacists regularly employed at the pharmacy;

14.2.1.g. The name and registration numbers of pharmacy technicians and regularly employed at the pharmacy;

14.2.1.h. The pharmacy's hours of operation; and

14.2.1.i. detailed floor plans for the pharmacy made to scale.

14.2.2. Each individual pharmacy shall make separate applications and separate permit shall be issued for each individual pharmacy.

14.2.3. Pharmacies renewing permits shall have the current edition of the three volume set of the USP-DI and its supplements or appropriate texts or electronic media 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. Each initial application for a pharmacy permit shall be accompanied by a fee of one hundred fifty dollars ($150.00), or an amount as set by statute.

14.2.5. Any pharmacy compounding parenteral/enteral compounding permit.

14.3. Issuance of permit.

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

14.3.2. The permit 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. Permits shall be posted in a visibly conspicuous place. The permits may not be in a location that is out of sight of the dispensing area.

14.4. Renewal of permit.

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

14.4.2. If a pharmacy does not make application renewal by the first day of August each year, the permit becomes null and void. To renew a lapsed permit the Board shall re-inspect the pharmacy and the permittee shall pay a fee of one hundred fifty dollars ($150.00) or an amount as set by statute for the permit and one hundred fifty dollars ($150.00) for the re-inspection or an amount set by statute.

14.5. Surrender of permit.

14.5.1. When a pharmacist-in-charge in whose name a pharmacy permit has been issued leave 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 permit to the Board office with the date of the change noted on the permit. For the purposes of this subsection 'full time employment' means working at least 30 hours per week, 3 days per week at one pharmacy. A copy of the permit shall be made and posted in the pharmacy with the newly designated pharmacist-in-charge written on the permit in indelible ink. If the pharmacist-in-charge fails to notify the Board and return the pharmacy permit 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 permit, or any other action which causes the pharmacist-in- charge to cease being in complete and actual charge of the pharmacy. The pharmacy permit holder shall immediately designate a new pharmacist-in-charge and write the name on a copy of the pharmacy permit in indelible ink and post it in the pharmacy. Until a pharmacist-in-charge is designated and written in indelible ink on the pharmacy permit, 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 permit holder shall notify the Board of the replacement in writing within thirty (30) days upon a form provided by the Board with the appropriate fee. Upon receipt of this notification, the Board shall provide a newly printed permit to the pharmacy If an interim pharmacist-in-charge is designated who is not the permanent pharmacist-in-charge listed upon the written form the name of the interim pharmacist-in-charge and the period of time that pharmacist served as pharmacist-in-charge. 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 movies to a new address or a different location within the current building shall apply for a new permit and submit the appropriate fees. The Board shall inspect the facility before a new permit may be issued.

14.5.4. When a pharmacy changes ownership the permit becomes null and void and a new permit 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. All pharmacists 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. Any person who employs any licensed pharmacist shall notify the Board within seven (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 permit holder who fails to notify the Board is subject to disciplinary action.

14.6.4. Any person who employs any licensed pharmacist 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. In the event that a pharmacy is to be operated for a period less than regular business hours of the entire store or institution, the following requirements apply:

14.7.1.a. The pharmacy area shall be separated from other departments of the store or institution by a floor to ceiling, physical barrier or partition, with entry doors that can be securely locked. The Board may approve plans, on a case by case basis, for non-physical barriers. If the pharmacist is always present when other persons are in the store or institution, the pharmacy area need not to be enclosed by a physical barrier. The barrier shall be designated so that only a pharmacist with a key has access to the area where prescription drugs, dangerous drugs, controlled substances, and other drugs and devices restricted to sales by pharmacists are stored, compounded, prepared and/or dispensed;

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

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

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

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

14.7.2.a. The device shall be sound, microwave, photoelectric, ultrasonic, or other accepted and suitable device;

14.7.2.b. The device shall be maintained in operating order and shall have an auxiliary source of power;

14.7.2.c. The device shall fully protect the prescription department and shall be capable of detecting breaking and/or entering by any means when activated;

14.7.2.d. 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 permit 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.

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

14.7.2.f. This subsection does not apple 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:

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

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

14.7.3.c. During times that an institutional pharmacy may be unattended by a pharmacist, 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:

14.7.3.c.1. drugs are properly labels;

14.7.3.c.2. only prepackaged drugs are available, in amounts sufficient for immediate therapeutic requirements;

14.7.3.c.3. whenever access to the cabinet occurs, written practitioner's orders and proof-of-use are provided;

14.7.3.c.4. all drugs in the cabinet are inventoried no less than once per week;

14.7.3.c.5. a complete audit of all activity concerning the cabinet is conducted no less than once per month; and

14.7.3.c.6. written policies and procedures are established to implement the provisions of this subdivision; and

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

14.7.4. In the absence of a pharmacist, a sign with a minimum of four (4) inch letters shall be prominently displayed stating: "Pharmacy Closed. No Pharmacist On Duty", and the pharmacist shall secure the pharmacy by implementing any barriers and security devices prior to leaving the pharmacy;

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

14.7.6. Mobile pharmacy units are prohibited. Completed prescriptions must be picked up at or delivered from the same pharmacy at which they were prepared, except that this subdivision 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 twelve (12) hours within a twenty-four (24) hour period without at least eight (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 twelve (12) hours in order to keep the pharmacy open. The pharmacists would have to document and date and amount of time worked beyond the twelve (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 fifteen (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 permit holder 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 permit 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 permit prior to the effective date of this rule

15.1.2. All standards set by the United States Pharmacopeial Convention shall be the minimum standards followed by all licensed pharmacists and pharmacies during the course of the professional practice of pharmacy.

15.2. Every pharmacy shall continually possess the following:

15.2.1. A sanitary method of measuring and dispensing between five (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 pharmacies compounding ophthalmic preparations, IV additives, enteral nutritional products or other pharmaceuticals requiring more sophisticated techniques, the proper equipment and facilities to prepare sterile products and meet the requirements of good compounding practice;

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 which allows immediate review of at least the following data about the patient which may be reasonably obtained by the pharmacist:

15.2.7.a. The patient's biographical data;

15.2.7.b. The patient's medications;

15.2.7.c. The patient's disease states and drug allergies;

15.2.7.d. The pharmacist's notes; and

15.2.7.e. Any other data necessary to make rational judgments about pharmacist care; 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:

16.4.2.a. The drug's expiration date;

16.4.2.b. The date of preparation; and

16.4.2.c. The drug's control number.

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

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

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

16.5.1.a. A statement in detail of the objectives and operational guidelines of the permittee;

16.5.1.b. A Description of a Quality Assurance Program which monitors:

16.5.1.b.1. personnel qualifications,

16.5.1.b.2. Continuing training and performance of staff;

16.5.1.b.3. Equipment and facilities requirements;

16.5.1.b.4. Standards for compounding and dispensing; and

16.5.1.b.5. Any other requirements of this Board; and

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

16.5.2.a. Utilizing the proper equipment and supplies; and

16.5.2.b. Having a special section of the Policy and Procedure Manual devoted to handling procedures, including:

16.5.2.b.1. A statement that compounding shall be conducted within a properly certified vertical airflow hood;

16.5.2.b.2. A discussion of the proper use of protective garb;

16.5.2.b.3. A description of the proper techniques to prevent all contamination of the prescription and chemical contamination of the person preparing the prescription; and

16.5.2.b.4. Disposal procedures of cytotoxicagents in accordance with accepted professional standards and applicable law.

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

16.6.1. A pharmacy operating under a Sterile Pharmaceutical Permit shall meet the minimum requirements for space, equipment, supplies and reference materials, which are in addition to those required for a regular pharmacy permit, and include the following:

16.6.1.a. Space.

16.6.1.a.1. The area for preparing sterile preparations, as provided for in this rule and referred to as the sterile admixture room, shall be set apart from general work and storage areas.

16.6.1.a.2. Adequate sit conditioning or positive air pressure must be maintained to prevent easy entry of outside air.

16.6.1.a.3. An operating sink with hot and cold running water shall be located in the “clean” anteroom adjoining the buffer room according to United States Pharmacopeia standards.

16.6.1.a.4. The compounding area shall be large enough to allow working room for all personnel to be in the room at one time without interference with each other.

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

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

16.6.1.b.1. Properly certified airflow hood;

16.6.1.b.2. Adequate refrigerator and freezer space;

16.6.1.b.3. A sink and wash area in the anteroom as provided for in this section; and

16.6.1.b.4. Appropriate waste containers for:

16.6.1.b.4.A. Used needles and syringes;

16.6.1.b.4.B. All cytotic waste including disposable apparel used in its preparation;

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

16.6.1.c.1. Cloves, masks, and disposable gowns;

16.6.1.c.2. Disposable syringes and needles in necessary sizes;

16.6.1.c.3. Disinfectant cleaning material for equipment surfaces;

16.6.1.c.4. Disposable towels;

16.6.1.c.5. Liquid bactericidal cleanser for hand washing; and

16.6.1.c. Spill kits for cytotoxic agent spills;

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

16.6.1.d.1. A current edition of the three volume set of the USP-DI with supplements, or referenced texts designated by the Board;

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

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

17.1. General Requirements.

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

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:

17.3.2.a The standard radiation symbol;

17.3.2.b. The words “CAUTION-Radioactive Material”;

17.3.2.c. The name of the radio nucleotide;

17.3.2.d. The chemical form;

17.3.2.e. The amount of radioactive material contained in millicuries or microcuries;

17.3.2.f. The volume in milliliters, if the material is a liquid;

17.3.2.g. The requested calibration time for the amount of radioactivity contained; and

17.3.2.h. The practitioner’s name and the assigned lot number.

17.3.3. The immediate inner container shall be labeled with:

17.3.3.a. The standard radiation symbol;

17.3.3.b. The words “CAUTION-Radioactive Material”; and

17.3.3.c. The prescription number

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

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

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

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

18.2. The prescription counter shall be used for no other purpose than for the compounding and dispensing of prescriptions and shall be maintained free from dust and in orderly condition.

18.3. The sink, with hot and cold running water, in the pharmacy shall be used for no other purpose than the cleaning of equipment and articles used in the preparation of prescriptions and the cleaning of hands of those preparing and dispensing prescriptions.

18.4. All pharmacist and 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 permittees or pharmacy technician trainees, except agents of the Board, may be present in the prescription area when dispensing and 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 reasonable 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:

19.5.1.a. Agents of the Board engaged in the performance of their official duties;

19.5.1.b. Another pharmacist or pharmacy technician when necessary;

19.5.1.c. The patient or his or her authorized representative;

19.5.1.d. The prescriber or other members of the health care team treating the patient; or

19.5.1.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 pharmacist 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:

19.13.1.a. the name of the caller;

19.13.1.b. the time and date of transmission; and

19.13.1.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:

19.13.2.a. To the correct patient (or agent of the patient) for whom the drug or devise was prescribed;

19.13.2.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

19.13.2.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. 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.

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

19.13.6.a.1. The name of and a description of the medication;

19.13.6.a.2. the dosage form, route of administration, degree, and duration of drug therapy;

19.13.6.a.3. Special directions and precautions for preparation, administration, and use by the patient;

19.13.6.a.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;

19.13.6.a.5. Techniques for ser-monitoring drug therapy;

19.13.6.a.6. Proper storage and handling;

19.13.6.a.7. Prescription refill information; and

19.13.6.a.8. Any action to take in the event of a missed dose.

19.13.6.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:

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

19.13.7.b. The patient's individual history including disease states, known allergies and drug reactions, and a comprehensive list of medications and relevant devices; and

19.13.7.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 interns, registered pharmacy technicians and pharmacy technician trainees; and

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

19.13.10.a. Require the knowledge, ability or skill of a licensed pharmacist and

19.13.10.b. Attempt to improve the therapeutic outcome to the patient of the pharmacist care provided by the pharmacist.

19.4. Violation of the rules of professional conduct.

19.4.1. 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, pharmacist 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.**

20.1. 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.

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

20.2.1. 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;

20.2.2. 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;

20.2.3. 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;

20.2.4. 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;

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

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

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

20.2.7.a. Change of employment or responsibility as the PIC;

20.2.7.b. Change of ownership of the pharmacy;

20.2.7.c. Change of address of the pharmacy; or

20.2.7.d. Permanent closing of the pharmacy;

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

20.2.9. 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;

20.2.10. 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

20.2.11. 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:

20.2.11.a. The name and address of the pharmacy;

20.2.11.b. The location of the automated equipment; and

20.2.11.c. The identification of the responsible pharmacist.

20.3. 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.

20.3.1. 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.

20.3.2. 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.

21.1.4.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:

21.1.4.a.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;

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

21.1.4.a.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:

21.1.6.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);

21.1.6.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;

21.1.6.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:

21.1.7.a. the identity of the transmitting agent is included in the order;

21.1.7.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;

21.1.7.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;

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

21.1.7.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.

21.1.8.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.

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

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

21.1.8.b.2. Transmit prescriptions to the pharmacy of the patient’s choice.

21.1.8.b.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.

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:

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

22.1.1.a.1. the name of the drug;

22.1.1.a.2. the route of administration, if other than oral;

22.1.1.a.3. the strength and volume, where appropriate, expressed in the metric system whenever possible;

22.1.1.a.4. the control number and expiration date;

22.1.1.a.5. special storage conditions, if required; and

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

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

22.1.1.c.1. identification of the dispensing pharmacy;

22.1.1.c.2. the patient's name;

22.1.1.c.3. the date of dispensing;

22.1.1.c.4. then name of the drug dispensed; and

22.1.1.c.5. the strength, expressed in the metric system whenever possible.

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

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

22.1.3.a. the name of the solution, the lot number, and the volume of the solution;

22.1.3.b. the patient's name;

22.1.3.c. the infusion rate;

22.1.3.d. the bottle sequence number or other system control number;

22.1.3.e. the name and quantity of each additive;

22.1.3.f. the date of the preparation;

22.1.3.g. the beyond-use date and time of parental admixture; and

22.1.3.h. ancillary precaution labels.

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

22.1.4.a. the name and address of the pharmacy dispensing the drug;

22.1.4.b. the name of the patient for whom the drug is prescribed; or, if the patient is an animal, the name of the owner and species of the animal;

22.1.4.c. the name of the prescribing practitioner;

22.1.4.d. directions stated on the prescription;

22.1.4.e. the date of dispensing;

22.1.4.f. any cautions which may be required by federal or state law;

22.1.4.g. the serial number of the prescription drug order;

22.1.4.h. the name or initials of the dispensing pharmacist;

22.1.4.i. the proprietary or generic name of the drug dispensed and its strength, if more than one strength of the drug is marked;

22.1.4.i.1. when dispensing an equivalent drug product, the word ‘substitution” or the letters ‘sub” shall appear on the label affixed to the container in which the drug is dispensed, followed by the generic name and manufacturer, or reasonable abbreviation, and/or distributor of the chosen product. This requirement only applies to single-entity, multiple-course drugs;

22.1.4.i.2. when dispensing a single-entity, single-source drug, the trade name of the prescribed drug may also appear on the label, and the generic name of the prescribed drug may also appear on the label;

22.1.4.i.3. when dispensing a fixed combination product, the United States Pharmacopeia’s publication of Pharmacy Equivalent Names (PEN) for fixed combination products is the official list of abbreviations for labeling, and is the approved abbreviation for identifying the combination product dispensed;

22.1.4.j. the name of the manufacturer or distributor of the drug; and

22.1.4.k. they beyond- use date

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

22.1.5.a. the standard radiation symbol;

22.1.5.b. the words “Caution- Radioactive Material; and

22.1.5.c. the prescription number.

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

22.1.6.a. the standard radiation symbol;

22.1.6.b. the words “Caution- Radioactive Material”;

22.1.6.c. the radionuclide and chemical form;

22.1.6.d. the activity and date and time of assay;

22.1.6.e. the volume, if in liquid form;

22.1.6.f. the requested activity and the calibrated activity;
22.1.6.g. the prescription number;

22.1.6.h. the patient’s name or space for the patient’s name. When the patient’s name is not available at the time of dispensing, a 72 hour exemption is allowed to obtain the name of the patient. No later than 72 hours after dispensing the radiopharmaceutical, the pharmacist shall obtain the patient’s name and it shall become a part of the prescription to be retained for a period of five years;

22.1.6.i. the name and address of the nuclear pharmacy;

22.1.6.j. the name of the practitioner; and

22.1.6.k. the lot number of the prescription.

**§15-1-23. Pharmacist Consultants.**

23.1. Places needing consultants.

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

23.2. Requirements and registration.

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

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

23.2.2.a. The consultant pharmacist shall file an application with the Board for each institution,

23.2.2.b. place or person to whom consulting services are provided;

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

23.2.2.b.1. The name, address and phone number of the applying consultant and his or her license number;

23.2.2.b.2. The name, address, phone number and type of institution, entity or person receiving the consulting services;

23.2.2.b.3. A description of the services to be provided by the consultant; and

23.2.2.b.4. The name and signature of the facility administrator.

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

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

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

23.4. Responsibilities.

23.4.1. A pharmacist consultant shall document by date and time, in a permanent log book, his or her activities for each place where he or she is registered. This log book shall be present in each facility for which the consultant pharmacist is registered and shall be available for inspection by the Board at any time.

23.4.2. The pharmacist consultant shall initiate and maintain, in each facility, appropriate records and procedures for the receipt, storage and disposition of all drugs including but not limited to:

23.4.2.a. Prescriptions;

23.4.2.b. Floor stock;

23.4.2.c. Emergency boxes or kits;

23.4.2.d. Investigational drugs;

23.4.2.e. Samples; and

23.4.2.f. Outdated or discontinued drugs.

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

23.4.3.a. Transcribing drug orders and prescription ordering;

23.4.3.b. Prescription delivery system and in-house verification;

23.4.3.c. Drug recall;

23.4.3.d. Automatic stop orders;

23.4.3.e. Formulary or standards for drug quality;

23.4.3.f. Systematic review of drug orders;

23.4.3.g. Reconciliation of controlled substances;

23.4.3.h. Disposition by the following means of prescriptions not totally consumed by the patient:

23.4.3.h.1. Return to pharmacy for credit; and

23.4.3.h.2. Destruction by the pharmacist in the presence of a registered nurse; and

23.4.3.i. In-serving drug education for other personnel.

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

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

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

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

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

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

**§15-1-24. Specialized Dispensing Systems.**

24.1. Definition.

24.1.1. Specialized dispensing systems are those systems other than traditional bottle systems used to provide controlled administration of drugs, for oral administration, to 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:

24.2.1.a. The name and strength of the drug;

24.2.1.b. The name of the manufacturer or the packager;

24.2.1.c. The lot number; and

24.2.1.d. The expiration date.

24.2.2. A unit of use system is a system in which all doses containing different medications to be administered at a given time are placed together in a single package, or packet, which is intended to be placed in a larger prescription container which is complete with prescription labeling and contains several unit of use packets. Each unit of use packet shall be labeled with the following:

24.2.2.a. The name and strength of each drug contained in the unit of use packet;

24.2.2.b. The name of the manufacturer or the packager of each drug in the unit of use packet;

24.2.2.c. The lot number of each drug in the unit use packet; and

24.2.2.d. The expiration date of each drug in the unit of use packet;

24.2.3. Punch card packaging is a system, which does not constitute unit does packaging, in which several doses of the same drug are packaged in a card, which is a prescription container, in which each dose has its own space and may be removed without disturbing the packaging for the remaining doses. A punch card shall be labeled with the following:

24.2.3.a. The name and strength of the drug contained in the punch card;

24.2.3.b. The name of the manufacturer or packager of the drug contained in the punch card;

24.2.3.c. The lot number of the drug contained in the punch card;

24.2.3.d. The expiration date of the drug contained in the punch card; and

24.2.3.e. All other information required to be on the label of a completed prescription order.

24.3.1. All extemporaneous unit dose, unit of use, punch card or any other specialized packaging shall be done by pharmacists, 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:

24.4.3.a. Drugs in emergency kits are to be administered only by those persons licensed to administered drugs;

24.4.3.b. The drugs in the emergency kit are of such nature that their absence would threaten the survival of the patients or intended recipients;

24.4.3.c. The contents of the emergency kit are determined by the pharmacist consultant and the medical director and the nursing director;

24.4.3.d. The emergency kit is sealed so that it is obvious if it has been opened and it is stored under secure conditions;

24.4.3.e. Administration of drugs from the kit is ordered by a practitioner and a record kept of administration;

24.4.3.f. Drugs stocked in the emergency kit are unit dose packaged;

24.4.3.g. Any drug used from the kit is replaced only upon a prescription or physician institution order form for the patient to which the dose was administered; and

24.4.3.h. Any emergency kit containing controlled substances is kept only at a facility holding a controlled substance permit from the Board.

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

25.1. Any facility, including any hospital, skilled nursing facility, intermediate nursing facility, personal care home, jail, correctional institution, emergency organization, clinic or any other place which is responsible to administer drugs to in-patients or out-patients which, may or may not, hold a permit from this Board to operate a pharmacy, shall have a permit to handle controlled substances on hand at the facility. A practitioner whose office is his or her primary place of practice is not required to obtain a permit for the office but shall obtain a permit for any satellite offices or clinics with controlled substances on the premises.

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

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

25.3.1. Manufacturer and wholesaler . . . . . .$50.00

25.3.2. Hospital or Clinic . . . . . .$50.00

25.3.3. Extended care facility or nursing home . . . . . .$25.00

25.3.4. Non-government training institution . . . . . .$25.00

25.3.5. Non-government researcher . . . . . .$25.00

25.3.6. Pharmacy . . . . . .$10.00

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

25.3.8. Non-government rescue or emergency squads . . . . .$25.00

25.3.9. Non-government humane societies . . . . . .$25.00

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

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

26.1. A pharmacist may dispense an emergency supply refill of life-sustaining prescription drugs to a patient without a prescription when, in the professional judgment of the pharmacist, the emergency supply is appropriate and the prescribing practitioner is not available. The emergency supply may not be more than a ten (10) days supply and the pharmacist shall immediately document the dispensing indicating the patient name, drug and its strength and amount, date filled, the name of the dispensing pharmacist, and the reasons for emergency dispensing. The dispensing pharmacist shall contact the prescribing practitioner as soon as possible subsequent to the drugs being dispensed.

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

27.1. The purpose of this section is to establish rules for the West Virginia Official Prescription Program Act set forth at West Virginia Code Section §16-5W-1, et seq. for use in writing prescriptions by practitioners.

27.2. Definitions. As used in this rule:

27.2.1. "Program Vendor" means the private contractor or contractors selected to manage the production and delivery of official state prescription paper.

27.2.2. "West Virginia Official Prescription Paper" means prescription paper, which has been authorized by the state for use, and meets the following criteria:

27.2.2.a. Prevention of unauthorized copying;

27.2.2.b. Prevention of erasure or modification;

27.2.3.c. An ability to prevent counterfeit prescription pads; and

27.2.4.d. Capable of supporting automated validation through pharmacy claims processing systems using the official state prescription control number.

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

27.3.1. 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;

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

27.3.2.a. 1-24;

27.3.2.b. 25-49;

27.3.2.c. 50-74;

27.3.2.d. 75-100;

27.3.2.e. 101-150; and

27.3.2.f. 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;

27.3.3. shall contain space for the prescriber to indicate number of refills, if any, or to indicate no refills;

27.3.4. shall provide space for the patient's name and address, the prescribing practitioner's signature;

27.3.5. 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;

27.3.6. 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."; and

27.3.7. each blank must be numbered on the face with a unique identifying control number in both human readable and barcode format.

27.4. The Board will solicit open bids and select a vendor or vendors to provide West Virginia Official Prescription Paper and maintain appropriate records of such product supplied to practitioners based on ability of proposed program to prevent prescription fraud, price and ability to meet these requirements.

27.4.1. Practitioners licensed to practice in this State may purchase West Virginia Official Prescription Paper as per individual orders from the selected vendor(s). The cost of the Official Prescription Paper will be borne by the ordering practitioner/institution, unless the state is successful in securing offsetting funds such as federal grants, risk/reward programs or private funding applied for and received by the state for the express purpose of partially or fully funding the West Virginia Official Prescription Program.

27.4.2. Orders shall be placed through a vendor supplied secure on-line order capture system or on an order form to be supplied by the vendor, and must contain the requesting practitioner's name, specialty, primary address and other practice site address(s), Federal DEA registration number, if any, National Provider Identification number, the State professional practice license number, number of prescriptions requested, and shall be signed by the requesting practitioner.

27.4.3. Records of West Virginia Official Prescription Paper supplied to practitioners will be maintained by the vendor or vendors and will be subject to random and regular audits. Discrepancies shall be reported to the Board in a regular and timely manner.

27.5. On and after January 1, 2012 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 an official state issued prescription form.

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

27.6.1. 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.

27.6.2. The Practitioner must also notify the vendor of any failure to receive Official Prescription Paper within a reasonable time after ordering them. 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:

27.6.2.a. Estimated number of blanks affected;

27.6.2.b. Control numbers if available; and

27.6.2.c. Suspected reason for destruction, theft, or loss.

27.6.3. The program vendor must provide annual SAS70 or SSAE16 third party audits of the prescription paper printing/personalization facility used in the preparation and distribution of West Virginia Official Prescription Paper blanks upon request. The program vendor must be able to provide such report for each year and for two years prior to the term of the contract.

**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.**

1.1. 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.

1.2. Authority. -- W. Va. Code §60A-3-301.

1.3. Filing Date. -- April 4, 2012.

1.4. Effective Date. -- April 4, 2012.

**§15-2-2. Adoption of Federal Law.**

2.1. 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 and all licensed pharmacists and licensed pharmacies shall comply with them.

2.1. 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.**

3.1. Persons required to register.

3.1.a. 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 West Virginia Board of Pharmacy is a "registrant".

3.2. The West Virginia Board of Pharmacy shall exempt from payment of a fee for a controlled substance permit the following registrants:

3.2.a. 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

3.2.b. 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.

3.2.c. 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.

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

3.3. 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.

3.4. 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.

3.5. 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.

3.6. 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.

3.7. Filing of application; joint filings.

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

3.7.b. 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.

3.8. Acceptance for filing; defective applications.

3.8.a. 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 West Virginia Board of Pharmacy 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.

3.9. Additional information.

3.9.a. The West Virginia Board of Pharmacy 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 West Virginia Board of Pharmacy in granting or denying the application.

3.10. Amendments to and withdrawal of applications.

3.10.a. An applicant may amend or withdraw an application without permission of the West Virginia Board of Pharmacy 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 West Virginia Board of Pharmacy at any time where good cause is shown by the applicant or where the amendment or withdrawal is in the public interest.

3.10.b. 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.

3.11. Administrative review generally.

3.11.a. The West Virginia Board of Pharmacy 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 West Virginia Board of Pharmacy regarding an applicant in order to determine whether the applicable standards of W. Va. Code §60A-3-303 have been met by the applicant.

3.12. Applications for research in Schedule I substances.

3.12.a. In the case of an application for registration to conduct research with controlled substances in Schedule I, the West Virginia Board of Pharmacy 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.

3.12.b. 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.

3.13. 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.

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

**§15-2-4. Security Requirements.**

4.1. Security requirements.

4.2. Security requirements generally.

4.2.a. 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 West Virginia Board of Pharmacy shall evaluate the overall security system and needs of the applicant or registrant.

4.2.b. 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.

4.2.c. 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.

4.3. 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.

4.4. 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 West Virginia Board of Pharmacy 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.

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

4.6. Physical security controls.

4.6.a. 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 such 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.

4.6.b. 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 have the following meanings, unless the context otherwise requires:

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

5.1.b. "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.

5.1.c. "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.

5.1.d. "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.

5.1.e. "Label" means any display of written, printed, or graphic matter placed upon the commercial container of any controlled substance by any manufacturer of the substance.

5.1.f. "Labeling" means all labels and other written, printed or graphic matter (1) upon any controlled substance or any of its commercial containers or wrappers, or (2) accompanying the controlled substance.

5.1.g. "Manufacture" means the producing, preparation, propagation, compounding or processing of a drug or other substance or the packaging or repackaging of the substance, or the labeling or relabeling of the commercial container of the substance, but does not include the activities of a practitioner who, as an incident to his or her administration or dispensing the substance in the course of his or her professional practice, prepares, compounds, packages or labels the substance. "Manufacturer" means a person who manufactures a drug or other substance, whether under a registration as a manufacturer or under authority of registration as a researcher or chemical analyst.

5.1.h. “Registrant” means a person who has obtained a controlled substance permit from the Board.

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

5.2. Symbol required; exceptions.

5.2.a. 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.

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

5.2.c. The following symbols shall designate the schedule corresponding thereto:

Schedule I.....CI or C-I.
Schedule II.....CII 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.

5.2.d. 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.

5.2.e. 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.

5.2.f. 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.

5.2.g. 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.

5.3. Location and size of symbol on label.

5.3.a. The symbol shall be prominently located on the right upper corner 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.b. In lieu of locating the symbol in the corner of the label, as prescribed in subsection 5.3.a 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.c. 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.

5.4. Location and size of symbol on labeling.

5.4.a. 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.

5.5. Effective dates of labeling requirements.

5.5.a. 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.

5.5.b. The West Virginia Board of Pharmacy 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.

5.6. Sealing of controlled substances.

5.6.a. On each bottle, multiple dose, vial or other commercial container of any controlled substance listed in Schedules I and/or II, and of any narcotic controlled substance listed in Schedule III or IV, there shall be securely affixed to the stopper, cap, lid, covering or wrapper of the container a seal to disclose upon inspection any tampering or opening of the container.

5.6.b. Any seal accepted for use under Federal Law prior to May 1, 1971, shall be considered acceptable for use under this section.

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

6.1. All records required to be kept shall be readily retrievable. "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.

6.2. Maintenance of records and inventories.

6.2.a. 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 West Virginia Board of Pharmacy.

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

6.2.b.1. 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

6.2.b.2. 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.

6.2.c. 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.b of this rule.

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

6.2.d.1. 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; and

6.2.d.2. 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.

6.3. General requirements for inventories.

6.3.a. 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.

6.3.b. 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.

6.3.c. 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.

6.3.d. 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.

6.3.e. 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.

6.4. Initial inventory date.

6.4.a. 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.

6.5. Biennial inventory date.

6.5.a. 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.

6.6. Inventory date for new controlled substances.

6.6.a. On the effective date of a rule or statutory change by the West Virginia Board of Pharmacy 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.

6.7. Inventories of manufacturers.

6.7.a. Each registered manufacturer shall include the following information in the inventory:

6.7.a.1. 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:

6.7.a.1.A. The name of the substance; and

6.7.a.1.B. The total quantity of the substance to the nearest metric unit weight consistent with unit size (except that for inventories made in 1971, avoirdupois weights may be utilized where metric weights are not readily available).

6.7.a.2. For each controlled substance in the process of manufacture on the inventory date:

6.7.a.2.A. The name of the substance;

6.7.a.2.B. The quantity of the substance in each batch and/or stage of manufacture, identified by the batch number or other appropriate identifying number; and

6.7.a.2.C. 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.

6.7.a.3. For each controlled substance in finished form:

6.7.a.3.A. The name of the substance;

6.7.a.3.B. Each finished form of the substance (e.g., ten (10) milligram tablet or ten (10) milligram concentration per fluid ounce or milliliter);

6.7.a.3.C. 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

6.7.a.3.D. The total quantity of the substance in all forms to the nearest metric unit weight.

6.7.a.4. For each controlled substance not included in Paragraphs (a), (b) or (c) of this subdivision (e.g., damaged, defective or impure substances awaiting disposal, substances held for quality control purposes, or substances maintained for extemporaneous compoundings):

6.7.a.4.A. The name of the substance;

6.7.a.4.B. The total quantity of the substance to the nearest metric unit weight or the total number of units of finished form; and

6.7.a.4.C. 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.

6.8. Inventories of distributors.

6.8.a. Each registered distributor shall include in the inventory the same information required of manufacturers pursuant to paragraph 6.7.a.3. and paragraph 6.7.a.4. of this rule.

6.9. Inventories of dispensers and researchers.

6.9.a. Each person registered to dispense or conduct research with controlled substances and required to keep records pursuant to subsection 6.4 of this rule, shall include in the inventory the same information required of manufacturers pursuant to paragraph 6.7.a.3. and paragraph 6.7.a.4. 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:

6.9.a.1. If the substance is listed in Schedule I or II, the dispenser shall make an exact count or measure of the content; and

6.9.a.2. 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.

6.10. Inventories of importers and exporters.

6.10.a. Each registered importer or exporter shall include in the inventory the same information required of manufacturers pursuant to paragraph 6.7.a.3. and paragraph 6.7.a.4. 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).

6.11. Inventories for chemical analysts.

6.11.a. Each analytical laboratory registered to conduct chemical analysis with controlled substances shall include in its inventory the same information required of manufacturers pursuant to paragraph 6.7.a,3, and paragraph 6.7.a.4. 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 West Virginia Board of Pharmacy 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.

6.12. General requirements for continuing records.

6.12.a. 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.

6.12.b. 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 is responsible.

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

6.12.d. 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).

6.13. Records of manufacturers.

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

6.13.a.1. 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:

6.13.a.1.A. The name of the substance;

6.13.a.1.B. The quantity manufactured in bulk form by the registrant, including the date, quantity and batch or other identifying number of each batch manufactured;

6.13.a.1.C. 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;

6.13.a.1.D. 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;

6.13.a.1.E. The quantity used to manufacture the same substance in finished form, including:

6.13.a.1.E.1. The date and batch or other identifying number of each manufacture;

6.13.a.1.E.2. The quantity used in the manufacture;

6.13.a.1.E.3. The finished form (e.g., ten (10) milligram tablets or ten (10) milligram concentration per fluid ounce or milliliter);

6.13.a.1.E.4. The number of units of finished form manufactured;

6.13.a.1.E.5. The quantity used in quality control;

6.13.a.1.E.6. The quantity lost during manufacturing and the causes therefore, if known;

6.13.a.1.E.7. The total quantity of the substance contained in the finished form;

6.13.a.1.E.8. The theoretical and actual yields; and

6.13.a.1.E.9. Any other necessary information;

6.13.a.1.F. The quantity used to manufacture other controlled and noncontrolled substances, including the name of each substance manufactured and the information required in paragraph 6.13.a.1.E. of this rule;

6.13.a.1.G. 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;

6.13.a.1.H. 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

6.13.a.1.I. 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.

6.13.a.2. For each controlled substance in finished form:

6.13.a.2.A. The name of the substance;

6.13.a.2.B. 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);

6.13.a.2.C. The number of containers of each commercial finished form manufactured from bulk form by the registrant, including the information required pursuant to paragraph 6.13.a.1.E. of this rule;

6.13.a.2.D. 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;

6.13.a.2.E. 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;

6.13.a.2.F. The number of units and/or commercial containers manufactured by the registrant from units in finished form received from others or imported, including:

6.13.a.2.F.1. The date and batch or other identifying number of each manufacture;

6.13.a.2.F.2. The operation performed (e.g., repackaging or relabeling);

6.13.a.2.F.3. 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

6.13.a.2.F.4. Any other information necessary to account for all controlled substances used in the manufacturing process;

6.13.a.2.G. 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;

6.13.a.2.H. 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

6.13.a.2.I. 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.

6.14. Records for distributors.

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

6.14.a.1. The name of the substance;

6.14.a.2. 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);

6.14.a.3. 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;

6.14.a.4. 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;

6.14.a.5. 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;

6.14.a.6. 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

6.14.a.7. 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.

6.15. Records for dispensers and researchers.

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

6.15.a.1. The name of the substance;

6.15.a.2. 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);

6.15.a.3. 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;

6.15.a.4. 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

6.15.a.5. 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.

6.16. Records for importers.

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

6.16.a.1. The name of the substance;

6.16.a.2. 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;

6.16.a.3. 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;

6.16.a.4. 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 paragraph 6.13.a.1.D. or paragraph 6.13.a.2.E. of this rule, including the date and manner of disposal and the quantity disposed.

6.17. Records for chemical analysis.

6.17.a. 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:

6.17.a.1. The name of the substance;

6.17.a.2. 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);

6.17.a.3. 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

6.17.a.4. 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.

6.17.b. 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.

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

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

**§15-2-7. Prescriptions.**

7.1. 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.

7.2. Definitions.

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

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

7.2.a.2. "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.

7.2.a.3. "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.

7.2.a.4. "Pharmacist" or “registered pharmacist” means an individual currently licensed by the jurisdiction in which he or she practices to engage in the practice of pharmacy and pharmaceutical care.

7.2.a.5. "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.

7.2.a.6. Any term not defined in this section has the definition set forth in W. Va. Code §60A-1-101.

7.3. Persons entitled to issue prescriptions.

7.3.a. 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.

7.3.b. 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.

7.4. Purpose of issue of prescription.

7.4.a. 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.

7.4.b. 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.

7.4.c. 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.

7.5. Manner of issuance of prescriptions.

7.5.a. 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.

7.6. Form of controlled substance prescription.

7.6.a. 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 Board of Pharmacy Rule, Rules and Regulations of the Board of Pharmacy, 15.1.2.1.19, 15CSR1. 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.

7.6.b. 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. Provided, that 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 West Virginia Board of Pharmacy.

7.6.c. 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. Provided, that 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 West Virginia Board of Pharmacy.

7.7. Persons entitled to fill prescriptions.

7.7.a. 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).

7.8. Dispensing of narcotic drugs for maintenance purposes.

7.8.a. 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.

7.8.b. 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 or extended.

7.8.c. 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.

7.9. Controlled substances listed in Schedule II.

7.9.a. Requirement of prescription.

7.9.a.1. 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.b 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 Board of Pharmacy Rule, Rules and Regulations of the Board of Pharmacy, §15-1-21, 15CSR1. 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.

7.9.a.2. 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 subdivision 7.8.a. of this rule.

7.9.a.3. 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.

7.9.b. 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:

7.9.b.1. the quantity prescribed and dispensed is limited to the amount adequate to treat the patient during the emergency period. Dispensing beyond the emergency period shall be pursuant to a prescription issued in the normal course of practice as permitted in subsection 15-2-7.9.a.

7.9.b.2. 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;

7.9.b.3. 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 West Virginia Board of Pharmacy if the prescribing practitioner fails to deliver a written prescription.

7.10. Refilling Schedule II prescriptions; issuance of multiple prescriptions.

7.10.a. 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" followed by the earliest date on which it may be dispensed, or other such language.

7.11. Partial filling of Schedule II prescriptions.

7.11.a. 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.

7.12. Labeling of Schedule II prescriptions.

7.12.a. 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 prescription or required by law.

7.13. Filing of prescriptions.

7.13.a. All written prescriptions and written records of emergency oral prescriptions shall be kept in accordance with requirements of the Uniform Controlled Substances Act and this rule.

7.14. Controlled substances listed in Schedules III, IV, and V.

7.14.a. Requirement of prescription.

7.14.a.1. A pharmacist may dispense a controlled substance listed in Schedule III, IV, or V, which is a prescription drug as determined under the Federal Food, Drug and Cosmetic Act, only pursuant to either a paper prescription manually signed by a prescribing individual practitioner, a facsimile of a paper prescription or order for medication, an electronic prescription, or an oral prescription made by a prescribing individual practitioner and promptly reduced to writing by the pharmacist containing all information required by this rule, except for the signature of the prescribing individual practitioner.

7.14.a.2. An individual practitioner may administer or dispense a controlled substance listed in Schedule III, IV, or V in the course of his or her professional practice without a prescription, subject to the provisions of subsection 7.8 of this rule.

7.14.a.3. An institutional practitioner may administer or dispense directly, but not prescribe, a controlled substance listed in Schedules III, IV, or V pursuant to a paper prescription signed by a prescribing individual practitioner, an electronic prescription, or an oral prescription made by a prescribing individual practitioner and promptly reduced to writing by the pharmacist containing all information required in subsection 7.5 of this rule, except for the signature of the prescribing individual practitioner, or pursuant to an order for medication made by an individual practitioner which is dispensed for immediate administration to the ultimate user, subject to subsection 7.8 of these rules.

7.15. Refilling of Schedule III or IV prescriptions.

7.15.a. A pharmacist shall not fill or refill a prescription for a controlled substance listed in Schedule III or IV more than six (6) months after the date on which the prescription was issued and any prescription authorized to be refilled may not be refilled more than five (5) times. Each refilling of a prescription shall be entered on the back of the prescription, or on another uniformly maintained appropriate record, such as medication records, which indicate prescription refills, initialed, and dated by the pharmacist as of the date of dispensing, and shall state the amount dispensed. If the pharmacist merely initials and dates the back of the prescription, he or she shall be considered to have dispensed a refill for the full face amount of the prescription. Additional quantities of controlled substances listed in Schedule III or IV may only be authorized by a prescribing practitioner through issuance of a new prescription as provided in subsection 7.14 of this rule, which shall be a new and separate prescription. The number of partial fills may be more than five times as 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.

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

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

7.16.a.1. Each partial filling is recorded in the same manner as a refilling;

7.16.a.2. The total quantity dispensed in all partial fillings does not exceed the total quantity prescribed; and

7.16.a.3. No dispensing occurs after 6 months after the date on which the prescription was issued.

7.17. Labeling of Schedule III, IV, or V prescriptions.

7.17.a. 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.

7.18. Filing of Schedule III, IV, or V prescriptions.

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

7.19. Dispensing without prescription.

7.19.a. 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: Provided, That

7.19.a.1. The dispensing is made only by a pharmacist and not by a nonpharmacist 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 nonpharmacist;

7.19.a.2. 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;

7.19.a.3. The purchaser is at least eighteen (18) years of age;

7.19.a.4. 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;

7.19.a.5. 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 subsection 6.2 of this rule; and

7.19.a.6. 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.**

8.1. Distribution upon discontinuance or transfer of business.

8.1.a. 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.

8.2. Disposal of controlled substances.

8.2.a. 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.

8.3. Reporting theft of drugs.

8.3.a. 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.

8.4. Ordering of Controlled Substances.

8.4.a. 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.

8.4.b. 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.

**TITLE 15**
**LEGISLATIVE RULE**
**BOARD OF PHARMACY**

**SERIES 4**
**COMPUTER REGULATIONS**

## §15-4-1. General.

1.1. Scope. -- To outline the proper use of the automated Data Processing System.

1.2. Authority. -- W. Va. Code ' 30-5-19.

1.3. Filing Date. -- April 9, 1992.

1.4. Effective Date. -- April 9, 1992.

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

2.1. A pharmacy may establish and use an automated data processing system to keep records of prescription drugs which it dispenses. A pharmacy is not required to establish and use such a system but if it does the pharmacy must comply with the provisions of this rule.

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

## §15-4-3. Definitions.

3.1. An Automated Data Processing System (ADP) is a system utilizing computer software and hardware for the purpose of recordkeeping.

3.2. A Cathode Ray Tube (CRT) is a vacuum tube in which a hot negatively charged electrode is used to impose visual information on a screen.

3.3. A computer, is a programmable electronic device capable of multifunctions including but not limited to storage, retrieval and processing of information.

3.4. Downtime is that period of time when a computer is not operable.

3.5. A printout is a readable printed copy of the output of a computer.

3.6. A common data base is a file or collection of information created by the automated data processing system that enables authorized users to have common access to the file regardless of physical location.

3.7. A computer operator is the person charged with the responsibility of entry and retrieval of patient information.

3.8. The Drug Enforcement Administration (DEA) is the Lead Federal Law Enforcement Agency charged with the responsibility for combating controlled substance abuse.

3.9. On-line retrieval means the producing of sight-readable documents on the CRT.

3.10. A Prescription Drug Order means a lawful written or verbal order by a prescribing practitioner for a drug.

3.11. Hardware is the fixed components of a computer.

3.12. Software is the program, procedure and storage of required information data.

3.13. A refill of a drug order is continued dispensing of the medicine authorized by the practitioner in the original prescription.

3.14. A renewal of a precription is that which is authorized by the practitioner after the original prescription has had the authorized number of refills.

**§15-4-4. Record of Dispensing Prescription Drugs.**

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

4.1. The quantity dispensed

4.2. The date of dispensing

4.3. The serial number of the prescription (or equivalent if an institution)

4.4. The identification of the pharmacist responsible for dispensing the drug

4.5. A record of renewals to date

4.6. The name, and strength of the dispensed drug (name of manufacturer if a generic drug)

**§15-4-5. Record of Retrieval (Documentation of Activity)**

5.1. An ADP system must provide by CRT display and/or printout a current history of all authorized prescription activity. This information shall include, but not be limited to:

5.1.1. The serial number of the prescription (or equivalent if an institution).

5.1.2. The date of dispensing.

5.1.3. The quantity dispensed.

5.1.4. The identification of the pharmacist responsible for dispensing the drug.

5.1.5. The prescription drug dispensed.

5.2. An ADP system may be used for the storage and retrieval of refill information for prescription orders for controlled substances in Schedule III and IV, subject to the following conditions:

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

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

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

5.2.4. A ADP system shall have the capability of producing a printout of any refill data which the user pharmacy is responsible for maintaining under W. Va. Code '30-5-1 et seq. and its implementing regulations. For example, this would include a refill-by-refill audit trail for any specified strength and dosage form of any controlled substance (by either brand or generic name or both). Such a printout must include the name of the prescribing practitioner, the name and address of the patient, the quantity dispensed on each refill, the date of dispensing for each refill, the name or identification code of the dispensing pharmacist, and the number of the original prescription order. Any recordkeeping location must be capable of sending the Special Agent or Compliance Investigator a copy of such printout from the user pharmacy if requested to do so by the Agent or Investigator and must verify the printout transmittal capability of its system by documentation. (e.g., postmark).

5.2.5. In the 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.

5.2.6. 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 a registered pharmacist may have access to the Automated Data Processing System.

**TITLE 15**
**LEGISLATIVE RULE**
**BOARD OF PHARMACY**

**SERIES 5**
**LICENSURE OF WHOLESALE DRUG DISTRIBUTORS**

**§15-5-1. General.**

1.1. Scope. -- To establish rules for the federal Prescription Drug Marketing Act, as amended, for the licensing by this State of persons who engage in wholesale distributions in interstate commerce of prescription drugs into this State.

1.2. Authority. -- W. Va. Code §60A-8-9.

1.3. Filing Date. -- April 4, 2012.

1.4. Effective Date. -- April 4, 2012.

**§15-5-2. Definitions.**

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

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

2.3. "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.

2.4. "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.

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

2.6. "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.

2.7. "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:

2.7.a. Intracompany sales, (defined as any transaction or transfer between any division, subsidiary, parent and/or affiliated or related company under the common ownership and control of a corporate entity;)

2.7.b. 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);

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

2.7.d. The sale, purchase, or trade of blood and blood components intended for transfusion;

2.7.e. 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;

2.7.f. 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;

2.7.g. 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;

2.7.h. 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;

2.7.i. 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

2.7.j. 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).

2.8. “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 Licensing Requirement.**

3.1. Every wholesale distributor, wherever located, who engages in the wholesale distribution of drugs into, out of, or within the State of West Virginia must be licensed by the West Virginia Board of Pharmacy in

accordance with the laws and regulations of this state before engaging in the wholesale distribution of prescription drugs.

**§15-5-4. Minimum Required Information For Licensure.**

4.1. The West Virginia Board of Pharmacy requires the following from each wholesale drug distributor as part of the initial licensing procedure and as part of any renewal of license:

4.1.a. The name, full business address, and telephone number of the licensee;

4.1.b. All trade or business names used by the licensee;

4.1.c. 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;

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

4.1.e. The name of the owner and/or operator of the licensee, including:

4.1.e.1. If a person, the name of the person;

4.1.e.2. If a partnership, the name of each partner, and the name of the partnership;

4.1.e.3. 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;

4.1.e.4. If a sole proprietorship, the full name of the sole proprietor and the name of the business entity.

4.2. Where operations are conducted at more than one (1) location by a single wholesale drug distributor, each location shall be licensed by the West Virginia Board of Pharmacy. However, the West Virginia Board of Pharmacy may provide for a single license 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.

4.3. A wholesale drug distributor shall submit changes in any of the information required by this section to the West Virginia Board of Pharmacy within thirty (30) days after the change.

**§15-5-5. Minimum Qualifications.**

5.1. The West Virginia Board of Pharmacy shall consider, at a minimum the following factors in reviewing the qualifications of persons who engage in wholesale distribution of prescription drugs within the state:

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

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

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

5.1.d. The furnishing by the applicant of false or fraudulent material in any application made in connection with drug manufacturing or distribution;

5.1.e. Suspension or revocation by Federal, State, or local government of any license currently or previously held by the applicant for the manufacture or distribution of any drugs, including controlled substances;

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

5.1.g. Compliance with requirements to maintain and/or make available to the West Virginia Board of Pharmacy or to Federal, State, or local law enforcement officials those records required under this section; and

5.1.h. Any other factors or qualifications the West Virginia Board of Pharmacy considers relevant to and consistent with the public health and safety.

5.2. The West Virginia Board of Pharmacy has the right to 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 license, the licensee 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.**

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

7.2. The West Virginia Board of Pharmacy may reprimand, suspend, restrict, or revoke any license granted under this section for willful and serious violations of these regulations.

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

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

The following constitutes the minimum 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.

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

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

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

8.1.c. 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;

8.1.d. Be maintained in a clean and orderly condition; and

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

8.2. Security.

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

8.2.a.1. Access from outside the premises shall be kept to a minimum and be well controlled.

8.2.a.2. The outside perimeter of the premises shall be well-lighted.

8.2.a.3. Entry into areas where prescription drugs are held shall be limited to authorized personnel.

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

8.2.c. 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.

8.3. 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).

8.3.a. 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.

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

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

8.4. Examination of materials.

8.4.a. 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.

8.4.b. 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.

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

8.5. Returned, damaged, and outdated prescription drugs.

8.5.a. 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.

8.5.b. 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.

8.5.c. 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, identify, 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.

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

8.6. Recordkeeping.

8.6.a. 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:

8.6.a.1. 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;

8.6.a.2. The identity and quantity of the drugs received and distributed or disposed of; and

8.6.a.3. The dates of receipt and distribution or other disposition of the drugs.

8.6.b. 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.

8.6.c. 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.

8.7. 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:

8.7.a. 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.

8.7.b. 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:

8.7.b.1. 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 West Virginia Board of Pharmacy;

8.7.b.2. Any voluntary action by the manufacturer to remove defective or potentially defective drugs from the market; or

8.7.b.3. Any action undertaken to promote public health and safety by replacing of existing merchandise with an improved product or new package design.

8.7.c. 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.

8.7.d. 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.

8.8. 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.

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

8.9.a. Wholesale drug distributors shall permit the West Virginia Board of Pharmacy'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.

8.9.b. Wholesale drug distributors that deal in controlled substances shall register with the West Virginia Board of Pharmacy and with the Drug Enforcement Administration (DEA), and shall comply with all applicable State, local, and DEA regulations.

8.10. 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.

**TITLE 15**
**LEGISLATIVE RULE**
**BOARD OF PHARMACY**

**SERIES 6**
**MAIL ORDER HOUSE**

## §15-6-1. General.

1.1. Scope. -- To establish rules for the Mail Order House.

1.2. Authority. -- W. Va. Code '30-5-6a.

1.3. Filing Date. -- April 9, 1992.

1.4. Effective Date. -- April 9, 1992.

## §15-6-2. Definitions.

2.1. Mail Order House means a pharmacy which dispenses drugs or medicines through the United States mail or otherwise.

2.2. Mail Order Prescription means the drug or medicine prescribed by a practitioner on a prescription order as authorized under W. Va. Code '30-5-1(6) and '30-5-12(5)(6).

2.3. Board means the West Virginia Board of Pharmacy.

## §15-6-3. Permits for Mail Order Houses.

3.1. A Mail Order House is required to apply for a permit for authorization to dispense prescription drugs or medicines in West Virginia.

3.2. A Mail Order House shall submit the application for the permit to the West Virginia Board of Pharmacy. The application shall contain the following information:

3.2.1. The owner of the Mail Order House, whether an individual, a partnership, or a corporation.

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

3.2.3. The pharmacy manager.

3.2.4. The pharmacist-in-charge.

3.2.5. The complete address, telephone number and fax number of the Mail Order House.

3.3. The Mail Order House shall obtain separate permits if it operates more than one pharmacy.

3.4. The Mail Order House shall maintain a permit or license as required by the state where located.

3.5. The manager-in-charge shall certify that the Mail Order House 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 House.

**§15-6-4.**

The Mail Order House shall maintain prescription records which are available for review if required by the Board.

**§15-6-5.**

Mail Order Houses 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 one the prescription container label.

**§15-6-6.**

Mail Order Houses soliciting, receiving, and dispensing and delivering orders comprising legend drugs and scheduled controlled drug substances as defined in 21 UCS 1 et seq., and 21 CFR 1 et seq., (1989) and delivered to ultimate consumers in West Virginia constitutes doing business in West Virginia.

**§15-6-7.**

Mail Order Houses 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.

**TITLE 15**
**LEGISLATIVE RULE**
**WEST VIRGINIA BOARD OF PHARMACY**

**SERIES 7**
**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 16, 2015.

1.4. Effective Date. -- May 17, 2015.

## §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:

3.1.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

3.1.b. for those obtaining registration beginning July 1, 2014, and forward:

3.1.b.1. has either:

3.1.b.1.A. graduated from a competency-based pharmacy technician education and training program of a learning institution or training center approved by the Board; or

3.1.b.1.B completed a pharmacy-provided, on-the-job, competency-based education and training program approved by the Board; and

3.1.b.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;

3.1.b.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

3.1.b.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.

3.1.b.4.A. The criminal history records must have been requested within the twelve (12) months immediately before the application is filed with the board.

3.1.b.4.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.

3.1.b.4.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:

3.2.a. the steps in receiving prescriptions;

3.2.b. the creation of or updating of patient profiles;

3.2.c. the entering of prescription information into the computer;

3.2.d. the updating of files and the printing of labels;

3.2.e. the pulling of stock packages from shelves;

3.2.f. the checking of medications;

3.2.g. the preparing of medications;

3.2.h. refill procedures and regulations; and

3.2.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. The training program shall, at a minimum contain the following:

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

4.1.a.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

4.1.a.2. specify duties which may and may not be performed by pharmacy technicians; and

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

4.1.b.1. Orientation;

4.1.b.2. Job descriptions;

4.1.b.3. Communication techniques;

4.1.b.4. Legislative rules of the West Virginia Board of Pharmacy;

4.1.b.5. Security and safety;

4.1.b.6. Prescription drugs, including:

4.1.b.6.A. Basic pharmaceutical nomenclature; and

4.1.b.6.B. Dosage forms;

4.1.b.7. Prescription drug orders, including:

4.1.b.7.A. Prescribers;

4.1.b.7.B. Directions for use;

4.1.b.7.C. Commonly used abbreviations and symbols;

4.1.b.7.D. Number of dosage units;

4.1.b.7.E. Strengths and systems of measurement;

4.1.b.7.F. Routes of administration;

4.1.b.7.G. Frequency of administration;

4.1.b.7.H. Interpreting directions for use; and

4.1.b.8. Prescription drug order preparation, including:

4.1.b.8.A. the creation or updating of patient medication records;

4.1.b.8.B. the entering of prescription drug order information into the computer or typing the label in a manual system;

4.1.b.8.C. the selection of the correct stock bottle and the accurate counting of or pouring of the appropriate quantity of drug product;

4.1.b.8.D. the selection of the proper container; and

4.1.b.8.E. the preparation of the finished drug product for inspection, labelling, and final check by pharmacists;

4.1.b.9. Drug product prepackaging;

4.1.b.10. the compounding of non-sterile pharmaceuticals; and

4.1.b.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:

4.3.a. has graduated from a high school or obtained a Certificate of General Educational Development (GED) or its equivalent;

4.3.b. is not an alcohol or drug abuser;

4.3.c. has not been convicted of a felony in any jurisdiction within ten years preceding the date of application;

4.3.d. 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.

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.

4.4.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.

4.4.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.

4.4.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.

4.4.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.

4.4.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:

4.4.f.1. provide an extension of time for completion of the training program upon a showing of special circumstances; or

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

4.4.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:

4.4.g.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

4.4.g.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:

4.5.a. the name of the person receiving the training;

4.5.b. the date of the training;

4.5.c. a general description of the topics covered;

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

4.5.e. the name of the person supervising the training; and

4.5.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:

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

5.1.b. interpret and evaluate prescription drug orders;

5.1.c. select drug products;

5.1.d. interpret patient medication records and perform drug regimen reviews;

5.1.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;

5.1.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;

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

5.1.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:

5.2.a. the placement, receipt, unpacking and storage of drug orders;

5.2.b. maintenance of the work area and equipment in a clean and orderly condition;

5.2.c. the ordering and stocking of all pharmacy supplies;

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

5.2.e. the operation of the cash register. However the pharmacy technician shall

5.2.e.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;

5.2.e.2. only handle the transactions on new prescriptions after counseling by the pharmacist has been offered; and

5.2.e.3. refer all questions regarding over the counter and prescription drug product selection or advice to the pharmacist;

5.2.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;

5.2.g. the placement of completed prescription orders on the will-call shelf;

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

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

5.2.j. the reconciliation of third-party payments;

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

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

5.2.m. the handling of non-professional phone calls to or from:

5.2.m.1. patients requesting refills of prescriptions by number and patient name;

5.2.m.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;

5.2.m.3. patients concerning price information that has been calculated by computer;

5.2.m.4. patients concerning business hours, mailing and delivery services, and the availability of goods and services;

5.2.m.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;

5.2.m.6. wholesalers and distributors dealing with the ordering of goods and supplies; and

5.2.m.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.

5.2.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;

5.2.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:

5.2.o.1. Monitor the label printing; and

5.2.o.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.

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

5.2.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;

5.2.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

5.2.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:

7.2.a. the pharmacies are under common ownership and control and have a common training program; or

7.2.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**

**§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 30, 2014.

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

**§15-8-2. Definitions.**

2.1. Except as otherwise indicated, 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" refers to the central 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. "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.c "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.d. “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 duly authorized representative of the covered person or entity to access the central repository on behalf of the covered person or entity.

2.2.e “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.f. “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.

2.2.g. “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.h. “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.i. "Medical Services Provider" means a licensed practitioner with the legal authority to dispense controlled substances.

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

2.2.k. "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.l. "Reporter" means any 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.m. "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.n. "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.o. "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 is dispensed for out-patient use, the medical services provider, health care facility, or pharmacy that dispensed the controlled substance 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 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 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. If the reporter is unable to input this information to the central repository at the time of reporting, this information shall be retained in either print or electronic form. If the reporter electronically reports the individual's first name, last name, official government-issued photo identification card number and the card's issuing authority or jurisdiction (e.g. United State military, State driver's license, Passport, Green Card, etc.) into the central repository, the reporter shall retain the additional information in print or electronic form for a period of ninety (90) days. If the reporter does not file the listed information into the central repository, the information shall be retained in print or electronic form for a period of at least two (2) years; and

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

3.2. Any person reporting more than twenty (20) controlled substance prescriptions in any given month shall transmit to the central repository the information outlined in section 4 of this rule using one of the following methods:

3.2.a. An electronic device compatible with the receiving device of the central repository;

3.2.b. A computer compact disc; or

3.2.c. A magnetic tape.

3.3. Any person reporting less than twenty (20) Schedule II, III, or IV controlled substance dispensings in any given month may submit data using a Universal Claim Form or transmit the information using the methods outlined in subsection 3.2 of this section.

3.4. The board may grant a waiver to a reporter who does not have an automated recordkeeping system capable of producing an electronic report in the established format. A reporter requesting a waiver shall make the request to the board in writing and the board shall grant the request if the reporter agrees to report the data by submitting a completed Universal Claim Form.

3.5. 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 required to be submitted by the provisions of this rule may be transmitted at any time, but shall be transmitted at least within twenty-four (24) hours of the dispensing, Provided that, 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 there was no dispensing of any Schedule II, III, or IV controlled substances within up to seven days of the last report, the reporter shall submit a "zero" report no later than seven days after the last date and time reported on the previous report. 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 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 W. Va. Code §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, 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 properly filed with and 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 for the purpose of dispensing.

4.3. The board may not penalize a reporter for failure to comply with the program if the board or the central repository cannot secure adequate funding to implement the program and recover the cost.

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

The information required to be transmitted by this rule 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 notify the board of the inaccuracy and the necessary corrections in writing as soon as possible, but in no event longer than fourteen (14) days after the discovery of the inaccurate reporting, so that the board may take the necessary steps to correct the error within the database.

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

6.1. The central repository shall create 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;

7.3.d. Authorized agents of the federal Drug Enforcement Administration;

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;

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 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.

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.

**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 NETWORKS**

**§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**

**§15-12-1. General.**

1.1. Scope. -- To amend the rules for pharmacists licensed in West Virginia to administer immunizations to patients in this State, providing for additional immunizations through joint rulemaking by the West Virginia Board of Pharmacy, Board of Medicine, and Board of Osteopathy.

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

1.3. Filing Date. -- April 4, 2012.

1.4. Effective Date. -- April 4, 2012.

**§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 may administer to any person eighteen years of age or older, including:

2.2.a. Influenza;

2.2.b. Pneumonia;

2.2.c. Hepatitis A;

2.2.d. Hepatitis B;

2.2.e. Herpes Zoster; and

2.2.f. Tetanus, tetanus-diphtheria (commonly referred to as "Td"), or tetanus-diphtheria-and-pertussis (commonly referred to as "Tdap").

**§15-12-3. Qualifications.**

3.1. A pharmacist licensed by the Board may administer immunizations to any person eighteen years of age or older provided the pharmacist has met all of the following requirements:

3.1.a. registered with the board to administer immunizations;

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;

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

3.1.d. completed a minimum of two (2) hours annually of continuing education related to immunizations. The continuing education must be by a provider approved by the Accreditation Council for Pharmacy Education (A.C.P.E.).

3.2. It is unprofessional conduct for a pharmacist 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 3.1 have been met. The application must be submitted along with a required fee of $10.00. Provided all requirements of Section 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.

**§15-12-5. Immunizations.**

5.1. Immunizations authorized by this rule shall be administered:

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", including the footnotes provided for each schedule (available at www.cdc.gov/vaccines/recs/schedules/adult-schedule.htm); or

5.1.b. in accordance with a proper order from a properly authorized practitioner.

5.2. Administration must be done in accordance with the training required by Section 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;

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.

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. 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 must document such in the immunization record, and provide a record of the immunization administration to the patient.

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 who administered the immunization is employed 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. 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 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 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:

8.1.a. basic immunology, including the human immune response;

8.1.b. adverse reactions, contraindications, warnings and precautions;

8.1.c. response to emergency situations, including administration of epinephrine and diphenhydramine;

8.1.d. storage and handling requirements;

8.1.e. recordkeeping and reporting requirements, including screening and informed consent documentation;

8.1.f. proper environment for administration and observation;

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

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.

# DEA PHARMACIST'S MANUAL

Can be viewed and downloaded at the below listed website:

http://www.deadiversion.usdoj.gov/pubs/manuals/pharm2/