PHARMACY LAWS
AND
LEGISLATIVE RULES
OF WEST VIRGINIA

GOVERNING

THE PRACTICE OF PHARMACY

CONTROLLED SUBSTANCES ACT

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2024 EDITION

WEST VIRGINIA

BOARD OF PHARMACY

Reprinted from the West Virginia Code and Rules

Note: WV Code updated with legislation passed through the 2024 Sessions
This is a copy of the annotated WV Code, provided as a convenience to locate Law or Rule by the use of WORD search

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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Repealed.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Repealed.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Repealed.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Repealed.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:

“Ambulatory health care facility” includes any facility defined in §16-5B-1 *et seq*. of this code, that also has a pharmacy, offers pharmacist care, or is otherwise engaged in the practice of pharmacist care.

“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.

“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.

“Board” means the West Virginia Board of Pharmacy.

“Board authorization” means a license, registration, or permit issued under this article.

“Chain Pharmacy Warehouse” means a permanent physical location for drugs 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.

“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.

“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.

“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, or for a medical provider in training where the agreement is signed by the supervising physician or chairperson of the medical department where the medical provider in training is practicing, and an individual pharmacist or pharmacists that provides for collaborative pharmacy practice for the purpose of drug therapy management of a patient.

“Common Carrier” means any person or entity who undertakes, whether directly or by any other arrangement, to transport property including prescription drugs for compensation.

“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.

“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.

“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.

“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.”

“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.

“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.

“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.

“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.

“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.

“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 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.

“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) Performing patient evaluations that are mutually agreed upon in the collaborative agreement;

(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.

"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.

"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".

"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.

"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.

"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.

"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.

"FDA" means the Food and Drug Administration, a federal agency within the United States Department of Health and Human Services.

"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.

“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.

“Heath care system” means an organization of people, institutions, and resources that deliver health care services to meet the health needs of a target population.

“HIPAA” is the federal Health Insurance Portability and Accountability Act of 1996 (Public Law 104-191).

“Immediate container” means a container and does not include package liners.

“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.

“Intracompany sales” means any transaction between a division, subsidiary, parent, or affiliated or related company under the common ownership and control of a corporate or other legal business entity.

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

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

“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.

“Mail-order pharmacy” means a pharmacy, regardless of its location, which dispenses greater than 25 percent of its prescription drugs via the mail or other delivery services.

“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.

“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.

“Medical order” means a lawful order of a practitioner that may or may not include a prescription drug order.

“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.

"Misbranded" means a drug or device that has a label that is false or misleading in any particular manner; 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.

"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.

"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.

"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.

"Pedigree" means a statement or record in 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.

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

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

"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.

"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.

"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.

"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.

"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.

"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.

"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.

"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.

“Practice notification” means a written notice to the appropriate licensing board that an individual physician or physician group or a medical provider in training where the agreement is signed by the supervising physician or chairperson of the medical department where the medical provider in training is practicing, and an individual pharmacist or pharmacists will practice in collaboration.

“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.

“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.

“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.

“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.

“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.

“Repackage” means changing the container, wrapper, quantity, or product labeling of a drug or device to further the distribution of the drug or device.

“Repackager” means a person who repackages.

“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.

“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.

“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.

“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 this section;

(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 12 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.

“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.

§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.

(a) (1) The board has all the powers and duties set forth in this article, by rule, in §30-1-1 et seq. of this code and elsewhere in law, including the power to:

(2) Hold meetings;

(3) Establish additional requirements for a license, permit, and registration;

(4) Establish procedures for submitting, approving, and rejecting applications for a license, permit, and registration;

(5) Determine the qualifications of any applicant for a license, permit, and registration;

(6) Establish a fee schedule;

(7) Issue, renew, deny, suspend, revoke, or reinstate a license, permit, and registration;

(8) 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;

(9) Contract with third parties to administer the examinations required under the provisions of this article;

(10) 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;

(11) Regulate mail order pharmacies;

(12) 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;

(13) Investigate alleged violations of the provisions of this article, legislative rules, orders, and final decisions of the board;

(14) Conduct disciplinary hearings of persons regulated by the board;

(15) Determine disciplinary action and issue orders;

(16) Institute appropriate legal action for the enforcement of the provisions of this article;

(17) Maintain an accurate registry of names and addresses of all persons regulated by the board;

(18) Keep accurate and complete records of its proceedings, and certify the same as may be necessary and appropriate;

(19) Propose rules in accordance with the provisions of §29A-3-1 et seq. of this code to implement the provisions of this article;

(20) Sue and be sued in its official name as an agency of this state;

(21) Confer with the Attorney General or his or her assistant in connection with legal matters and questions; and

(22) Take all other actions necessary and proper to effectuate the purposes of this article.

(b) The board is exempt from state purchasing laws, legislative rules, and policies for the purposes of spending grant money if the grant is in relation to substance use and controlled substances.

§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 §29A-3-1 *et seq*. of this code, to implement the provisions of this article and §60A-2-201 *et seq*., §60A-3-301 *et seq*., §60A-8-1 *et seq*., §60A-9-1 *et seq*., and §60A-10-1 *et seq*. of this code, 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 who 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 §16-5-27 of this code;

(27) Regulations on controlled substances as provided in §60A-2-201 *et seq*. of this code;

(28) Regulations on manufacturing, distributing, or dispensing any controlled substance as provided in §60A-3-301 of this code;

(29) Regulations on wholesale drug distribution as provided in §60A-8-1 *et seq*. of this code;

(30) Regulations on controlled substances monitoring as provided in §60A-9-1 *et seq*. of this code;

(31) Regulations on Methamphetamine Laboratory Eradication Act as provided in §60A-10-1 *et seq*. of this code;

(32) Establish and maintain an official prescription paper program; and

(33) Any other rules necessary to effectuate the provisions of this article.

(b) The board may provide an exemption to the pharmacist-in-charge requirement for the opening of a new retail pharmacy or during a declared emergency.

(c) The board, the Board of Medicine, and the Board of Osteopathic Medicine shall jointly agree and propose rules concerning collaborative pharmacy practice for legislative approval in accordance with the provisions of §29A-3-1 *et seq*. of this 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 §29A-3-1 *et seq*. of this code to perform influenza and pneumonia immunizations on a person of 18 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;

(7) That a pharmacist may not delegate the authority to administer immunizations to any other person, unless administered by a licensed pharmacy intern or registered pharmacy technician under the direct supervision of a pharmacist of whom the pharmacist, the pharmacist technician and intern have successfully completed all board-required training; and

(8) Any other provisions necessary to implement the provisions of this section.

(e) The Board of Medicine and the Board of Osteopathic Medicine shall propose joint rules, by July 1, 2023, for legislative approval in accordance with the provisions of §29A-3-1 *et seq*. of this code to permit a licensed pharmacist, pharmacy technician or pharmacy intern to administer immunizations 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, the

CDC's recommended immunization schedule for adults, children, and adolescents. In addition, the joint rules shall permit a licensed pharmacist, pharmacy technician or pharmacy intern to administer immunizations in accordance with definitive treatment guidelines for immunizations promulgated by the latest notice from the CDC, including, but not limited to, the CDC's recommended immunization schedule for adults, children, and adolescents to a person age 3 through 17, with written informed parental consent and there are no contraindications to that patient receiving that vaccine. These rules shall provide, at a minimum, the same provisions contained in subsections (d)(1) through (d)(8), inclusive, 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., c. 148.

§30-5-7c.

Repealed.

Acts 2013, Reg. Sess., c. 148.

§30-5-8. Fees; special revenue account; administrative fines.

(a) All fees and other moneys, except fines, received by the board shall be deposited in a separate special revenue fund in the State Treasury designated the "Board of Pharmacy Fund", which fund is continued. The fund is used by the board for the administration of this article. Except as may be provided in article one of this chapter, the board shall retain the amounts in the special revenue account from year to year. Any compensation or expense incurred under this article is not a charge against the General Revenue Fund.

(b) The board shall deposit any amounts received as administrative fines imposed pursuant to this article into the General Revenue Fund of the State Treasury.

§30-5-9. Qualifications for licensure as pharmacist;

(a) To be eligible for a license to practice pharmacist care under the provisions of this article, the applicant shall:

(1) Submit a written application to the board;

(2) Be eighteen years of age or older;

(3) Pay all applicable fees;

(4) Graduate from an accredited school of pharmacy;

(5) Complete at least fifteen hundred hours of internship in a pharmacy under the instruction and supervision of a pharmacist;

(6) Pass an examination or examinations approved by the board;

(7) Not be an alcohol or drug abuser, as these terms are defined in section eleven, article one-a, chapter twenty-seven of this code: Provided, That an applicant in an active recovery process, which may, in the discretion of the board, be evidenced by participation in a twelve-step program or other similar group or process, may be considered;

(8) Present to the board satisfactory evidence that he or she is a person of good moral character, has not been convicted of a felony involving the sale or distribution of controlled substances;

(9) Not been convicted in any jurisdiction of any other felony or crime which bears a rational nexus to the individual's ability to practice pharmacist care, Provided, That an applicant with a felony conviction other than the felony conviction specified in subdivision eight of this section may apply to the board for licensure no sooner than five years after the date of the conviction. The board shall evaluate each applicant on a case by case basis; and

(10) Has fulfilled any other requirement specified by the board in rule.

(b) An applicant from another jurisdiction shall comply with all the requirements of this article.

§30-5-9a.

Repealed.

Acts, 2013 Reg. Sess., Ch. 148.

§30-5-10. Scope practice for licensed pharmacist;

(a) A licensed pharmacist may:

(1) Provide care related to the interpretation, evaluation, and implementation of medical orders;

(2) Dispense of prescription drug orders; participate in drug and device selection;

(3) Provide drug administration;

(4) Provide drug regimen review;

(5) Provide drug or drug-related research;

(6) Perform patient counseling;

(7) Provide pharmacy related primary care;

(8) Provide pharmacist care in all areas of patient care, including collaborative pharmacy practice;

(9) Compound and label drugs and drug devices;

(10) Proper and safe storage of drugs and devices;

(11) Maintain proper records;

(12) Provide patient counseling concerning the therapeutic value and proper use of drugs and devices;

(13) Order laboratory tests in accordance with drug therapy management; and

(14) Provide medication therapy management.

(b) A licensee meeting the requirements as promulgated by legislative rule may administer immunizations.

(c) The sale of any medicine, if the contents of its container, or any part thereof, taken at one time, are likely to prove poisonous, deleterious, or habit-forming is prohibited by any person other than a registered pharmacist, who shall take precautions to acquaint the purchaser of the nature of the medicine at the time of sale.

§30-5-10a.

Repealed.

Acts, 2013 Reg. Sess., Ch. 148.

§30-5-11. Registration of pharmacy technicians.

(a) To be eligible for registration as a pharmacy technician to assist in the practice of pharmacist care, the applicant shall:

(1) Submit a written application to the board;

(2) Pay the applicable fees;

(3) Have graduated from high school or obtained a Certificate of General Educational Development (GED) or equivalent.

(4) Have:

(A) Graduated from a competency-based pharmacy technician education and training program as approved by legislative rule of the board;

(B) Completed a pharmacy-provided, competency-based education and training program approved by the board; or

(C) Obtained a national certification as a pharmacy technician and have practiced in another jurisdiction for a period of time as determined by the board.

(5) 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 §27-1A-11 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 12-step program or other similar group or process, may be considered;

(7) Not have been convicted of a felony in any jurisdiction within 10 years preceding the date of application for license, which conviction remains unreversed;

(8) 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

(9) 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) To be eligible to obtain a nuclear pharmacy technician endorsement, 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 successfully completed a pharmacy provided, competency-based nuclear pharmacy technician education and training program approved by the board;

(5) Have all applicable national certifications and comply with all federal rules and regulations;

(6) Not be an alcohol or drug abuser, as these terms are defined in §27-1A-11 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 12-step program or other similar group or process, may be considered;

(7) Not have been convicted of a felony in any jurisdiction within 10 years preceding the date of application for license, which conviction remains unreversed;

(8) 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

(9) Has fulfilled any other requirement specified by the board in any rule.

(d) 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 nuclear pharmacy technician.

§30-5-11a. Pharmacy technician trainee qualifications.

(a) To be eligible for registration as a pharmacy technician trainee 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) (A) Have graduated from a high school or obtained a Certificate of General Educational Development (GED), or

(B) Be currently enrolled in a high school competency based pharmacy technician education and training program;

(4) (A) Be currently enrolled in a competency-based pharmacy technician education and training program of a learning institution or training center approved by the board; or

(B) Be an employee of a pharmacy in an on-the-job competency-based pharmacy technician training program.

(5) Not be an alcohol or drug abuser as these terms are defined in section 11, 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;

(6) Not have been convicted of a felony in any jurisdiction within ten years preceding the date of application for registration, which conviction remains unreversed;

(7) Not have been convicted of a misdemeanor or felony in any jurisdiction which bears a rational nexus to the practice of pharmacist care, which conviction remains unreversed; and

(8) Have requested and submitted to the board the results of a fingerprint-based state and a national electronic criminal history records check.

(b) The rules, authorized duties and unauthorized prohibitions as set out in section twelve of this article for pharmacy technicians apply to pharmacy technician trainees.

(c) The board shall promulgate an emergency rule and legislative rule pursuant article two, chapter twenty-nine-a, to authorize the requirements of this section to permit pharmacy technician trainees.

§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;

(4) Stock medications;

(5) Complete a list of a patient’s current prescription and nonprescription medications to provide for medication reconciliation;

(6) Supervise registered pharmacy technicians and pharmacy technician trainees;

(7) Medical records screening;

(8) Administer immunizations, as provided by legislative rule; and

(9) Perform pharmacy technician product verification, where no clinical judgment is necessary and the pharmacist makes the final verification; if the registered pharmacy technician furnishes to the Board an affidavit signed and dated by the supervising pharmacist-in-charge of the facility which will employee the applicant attesting to the applicant's competency in the advanced areas of practice that he or she will practice; and has either:

(A) Worked as a full-time registered pharmacy technician holding a pharmacy technician endorsement in West Virginia for at least the previous two years; or

(B) Worked as a full-time registered pharmacy technician holding a pharmacy technician license in good standing in another jurisdiction for at least the previous two years.

(b) A registered pharmacy technician may perform the following under indirect supervision of a licensed pharmacist:

(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;

(7) Receive new oral prescription drug orders;

(8) An act within the practice of pharmacist care that involves discretion or independent professional judgment; or

(9) A function which the registrant has not been trained and the function has not been specified in a written protocol with competency established.

(d) Indirect supervision of a registered pharmacy technician is permitted to allow a pharmacist to take one break of no more than 30 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.

(g) A registered pharmacy technician who has obtained a nuclear pharmacy technician endorsement, may under the direct supervision of the licensed nuclear pharmacist, perform the following:

(1) Assist in the dispensing process;

(2) Receive new written or electronic prescription drug orders;

(3) Mix compound ingredients for liquid products, suspensions, ointments, mixes, or blend for tablet granulations and capsule powders;

(4) Prepare radiopharmaceuticals;

(5) Record keeping;

(6) File and organize prescriptions;

(7) Create reports;

(8) Inventory tasks;

(9) Handle raw materials and intermediate or finished products;

(10) Perform general maintenance as required on pumps, homogenizers, filter presses, tablet compression machines, and other like machines;

(11) Perform standard operating procedures to meet current good manufacturing practices (GMP);

(12) Maintain records;

(13) Monitor and verify quality in accordance with statistical process or other control procedures; and

(14) Stock medications.

(h) A registered pharmacy technician who has obtained a nuclear pharmacy technician endorsement 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) Receive new oral prescription drug orders.

§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) "Covered entity" means:

(A) Any hospital or medical service organization, insurer, health coverage plan, or health maintenance organization licensed in the state that contracts with another entity to provide prescription drug benefits for its customers or clients;

(B) Any health program administered by the state in its capacity as provider of health coverage; or

(C) Any employer, labor union, or other group of persons organized in the state that contracts with another entity to provide prescription drug benefits for its employees or members.

(3) "Covered individual" means a member, participant, enrollee, contract holder, policy holder, or beneficiary of a covered entity who is provided a prescription drug benefit by a covered entity. The term "covered individual" includes a dependent or other person provided a prescription drug benefit through a policy, contract, or plan for a covered individual.

(4) "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.

(5) "Substitute" means to dispense a therapeutically equivalent generic drug product in the place of the drug ordered or prescribed.

(6) "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 a substitution may not 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 indicates 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) A person may not 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. An employer or his or her agent may not 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 may 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 is subject to the penalties prescribed §30-5-34 of this code.

(f) A pharmacist may substitute a drug pursuant to the provisions of this section only where there will be a savings to the purchaser. 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) If a pharmacist substitutes a drug pursuant to the provisions of this section, the patient shall receive the savings which shall be equal to the difference in the patient's acquisition cost of the product prescribed and the acquisition cost of the substituted product: Provided, That this subsection may not apply if the patient is a covered individual.

(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. The 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 an 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 §29A-3-1 et seq. 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 90 days of the date of passage of this section and may be amended in accordance with the provisions of that chapter.

(m) A pharmacist may not 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 the substitution. The person presenting the prescription may 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 §29A-3-1 et seq. of this code setting standards for substituted drug products and obtaining compliance with the provisions of this section. The board has the primary responsibility for enforcing the provisions of this section.

(q) Any person may file a complaint with the West Virginia Board of Pharmacy regarding any violation of the provisions of this article. The 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 the 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 §30-5-22 of this code, suspend or revoke the permit of any person, firm, corporation, or copartnership to operate a pharmacy.

(s) A pharmacist or pharmacy complying with the provisions of this section may not 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 may 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 may 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. Substitution of biological product: Definitions; selection of interchangeable biological products; exceptions; records; labels; manufacturing standards; emergency rules; complaints; and immunity.

(a) As used in this section:

“Biological product” means the same as that term is defined in 42 U.S.C.§ 262.

“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.

“Interchangeable biological product” means a biological product that the federal Food and Drug Administration has:

(1) Licensed and determined meets the standards for interchangeability pursuant to 42 U.S.C § 262(k)(4); or

(2) Determined is therapeutically equivalent as set forth in the latest edition of or supplement to the federal Food and Drug Administration’s Approved Drug Products with Therapeutic Equivalence Evaluations.

“Proper name” means the nonproprietary name of a biological product.

“Substitute” means to dispense without the prescriber’s express authorization an interchangeable biological product in the place of the drug ordered or prescribed.

(b) Except as limited by subsection (c) and unless instructed otherwise by the patient, a pharmacist who receives a prescription for a specific biological product shall select a less expensive interchangeable biological 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. The pharmacist shall provide notice to the patient or the patient’s designee regarding the selection of a less expensive interchangeable biological product.

(c) If, in the professional opinion of the prescriber, it is medically necessary that an equivalent drug product or interchangeable biological product not be selected, the prescriber may so indicate by certifying that the specific brand-name drug product prescribed, or the specific brand-name biological product prescribed, is medically necessary for that particular patient. In the case of a prescription transmitted orally, the prescriber must expressly indicate to the pharmacist that the specific brand-name drug product prescribed, or the specific biological product prescribed is medically necessary.

(d) (1) Within five business days following the dispensing of a biological product, the dispensing pharmacist or the pharmacist’s designee shall communicate the specific product provided to the patient, including the name of the product and the manufacturer, to the prescriber through any of the following electronic records systems:

(A) An interoperable electronic medical records system;

(B) An electronic prescribing technology;

(C) A pharmacy benefit management system; or

(D) A pharmacy record.

(2) Communication through an electronic records system as described in §30-5-12c(d)(1) of this code is presumed to provide notice to the prescriber.

(3) If the pharmacist is unable to communicate pursuant to an electronic records system the pharmacist shall communicate to the prescriber which biological product was dispensed to the patient using facsimile, telephone, electronic transmission, or other prevailing means.

(4) Communication is not required under this subsection when:

(A) There is no Federal Food and Drug Administration approved interchangeable biological product for the product prescribed; or

(B) A refill prescription is not changed from the product dispensed on the prior filling of the

prescription.

(e) The pharmacist shall maintain a record of the biological product dispensed for at least two years. Such record shall include the manufacturer and proper name of the interchangeable biological product selected.

(f) All biological products shall be labeled in accordance with the instructions of the practitioner.

(g) Unless the practitioner directs otherwise, the prescription label on all biological products dispensed by the pharmacist shall indicate the proper 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.

(h) A pharmacist may not dispense a product under the provisions of this section unless the manufacturer has shown that the biological product 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.

(i) The West Virginia Board of Pharmacy shall promulgate emergency rules pursuant to the provisions of §29A-3-15 of this code setting standards for substituted interchangeable biological products, obtaining compliance with the provisions of this section, and enforcing the provisions of this section.

(j) 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.

(k) No pharmacist or pharmacy complying with the provisions of this section shall be liable in any way for the dispensing of an interchangeable biological product substituted under the provisions of this section, unless the interchangeable biological product was incorrectly substituted.

(l) In no event where the pharmacist substitutes an interchangeable biological product 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 biological product unless the original biological product was incorrectly prescribed.

(m) 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.

§30-5-13. Pharmacist interns.

(a) To be eligible for a license to assist in the practice of pharmacist care as a pharmacy intern, the applicant shall be:

(1) Enrolled and progressing to obtain a degree in a professional degree program of a school or college of pharmacy that has been approved by the board, and is satisfactorily progressing toward meeting the requirements for licensure as a pharmacist; or

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

(3) A qualified applicant awaiting examination for licensure or meeting board requirements for relicensure; or

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

§30-5-14. Prohibiting the dispensing of prescription orders in absence of practitioner-patient relationship.

A pharmacist may not compound or dispense any prescription order when he or she has knowledge that the prescription was issued by a practitioner without establishing a valid practitioner-patient relationship. An online or telephonic evaluation by questionnaire, or an online or telephonic consultation, is inadequate to establish a valid practitioner-patient relationship: Provided, That this prohibition does not apply:

(1) In a documented emergency;

(2) In an on-call or cross-coverage situation;

(3) For the treatment of sexually transmitted diseases by expedited partner therapy as set forth in article four-f, chapter sixteen of this code; or

(4) Where patient care is rendered in consultation with another practitioner who has an ongoing relationship with the patient and who has agreed to supervise the patient's treatment, including the use of any prescribed medications.

§30-5-14a.

Repealed.

Acts, 2013 Reg. Sess., Ch. 148.

§30-5-14b.

Repealed.

Acts, 2013 Reg. Sess., Ch. 148.

§30-5-15. Reciprocal licensure of pharmacists from other states or countries.

(a) The board may by reciprocity license pharmacists in this state who have been authorized to practice pharmacist care in another state: Provided, That the applicant for licensure meets the requirements of the rules for reciprocity promulgated by the board in accordance with the provisions of chapter twenty-nine-a of this code: Provided, however, That reciprocity is not authorized for pharmacists from another state where that state does not permit reciprocity to pharmacists licensed in West Virginia.

(b) The board may refuse reciprocity to pharmacists from another country unless the applicant qualifies under the legislative rules as may be promulgated by the board for licensure of foreign applicants.

§30-5-16. Renewal requirements.

(a) All persons regulated by this article shall annually or biannually, renew his or her board authorization by completing a form prescribed by the board and submitting any other information required by the board.

(b) The board shall charge a fee for each renewal of an board authorization and shall charge a late fee for any renewal not paid by the due date.

(c) The board shall require as a condition of renewal that each licensee or registrant complete continuing education.

(d) The board may deny an application for renewal for any reason which would justify the denial of an original application.

(e) After June 30, 2014, a previously registered pharmacy technician may renew his or her current registration without having successfully completed the requirements of subdivision six, subsection (a), of section eleven. The previously registered pharmacist may continue to renew his or her registration under this provision.

§30-5-16a.

Repealed.

Acts, 2013 Reg. Sess., Ch. 148.

§30-5-16b.

Repealed.

Acts, 2013 Reg. Sess., Ch. 148.

§30-5-16c.

Repealed.

Acts, 2013 Reg. Sess., Ch. 148.

§30-5-17. Special volunteer pharmacist license; civil immunity for voluntary services rendered to indigents.

(a) There is a special volunteer pharmacist license for pharmacists retired or retiring from the active practice of pharmacist care who wish to donate their expertise for the pharmacist care and treatment of indigent and needy patients in the clinical 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, but may donate to the clinic the proceeds of any reimbursement 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 person engaged in the active practice of pharmacist care in this state whose license is in good standing may donate their expertise for the care and treatment of indigent and needy patients pursuant to an arrangement with a clinic organized, in whole or in part, for the delivery of health care services without charge to the patient. Services rendered pursuant to an arrangement may be performed in either the pharmacist's office or the clinical setting.

(c) 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 or pursuant to an arrangement with a clinic as authorized pursuant to subsection (b) 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.

(d) 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 or who renders such care and treatment pursuant to an arrangement with a clinic as authorized pursuant to subsection (b) of this section.

(e) 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.

(f) 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.

(g) 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 or who renders such care and treatment pursuant to an arrangement with a clinic as authorized pursuant to subsection (b) of this section.

§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 and practice notification.

(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 after informed consent of the patient and noted in the patient's medical record, that is entered into between an individual physician or physician group and an individual pharmacist or pharmacists. A pharmacist may not diagnose.

(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;

(4) The laboratory tests that may be ordered in accordance with drug therapy management; and

(5) The mutually agreed upon patient evaluations the pharmacist may conduct.

(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 30 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 pharmacy setting and ambulatory care clinics. The pharmacist shall be employed by or under contract to provide services to the hospital, community pharmacy, nursing home, ambulatory care clinic, or medical school, or hold a faculty appointment with one of the schools of pharmacy or medicine in this state.

(f) Notwithstanding any other provision to the contrary, a pharmacist or group of pharmacists may practice in collaboration with physicians in any practice setting, including but not limited to a health care system, pursuant to a practice notification which has been filed with the appropriate board: *Provided*, That a pharmacist who is currently in collaboration with physicians pursuant to a practice agreement which was approved prior to June 1, 2023, may continue to practice under that agreement until the practice agreement terminates or until June 1, 2024.

(g) The practice notification shall be filed with the appropriate licensing board and becomes effective immediately upon filing. The board retains jurisdiction to investigate any complaints filed regarding a practice notification with respect to their respective license holders.

(h) 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 is 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.

(j) The provisions of this section do not apply to the sale or distribution of dialysate, drugs or devices necessary to perform home peritoneal renal dialysis to patients with end state renal disease, provided the requirements of §30-5-29 of this code are met.

§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.

(d) This article may not be construed to prevent, restrict or in any manner interfere with the sale or distribution of dialysate, drugs or devices necessary to perform home peritoneal renal dialysis to patients with end state renal disease, nor may any legislative rule be adopted by the board which shall require the sale or distribution of such peritoneal dialysis products by a licensed pharmacist or in a pharmacy, provided the following criteria are met:

(1) The dialysate, drugs or devices are approved or cleared by the Food and Drug Administration, as required by federal law.

(2) The dialysate, drugs or devices are lawfully held by a manufacturer or a manufacturer’s agent that has obtained the proper permit from the board as a manufacturer or wholesale distributor, or third-party logistics provider.

(3) The dialysate, drugs or devices are held and delivered in their original, sealed packaging from the manufacturing facility.

(4) The dialysate, drugs or devices are delivered only upon receipt of a physician’s prescription by a licensed pharmacy, and the transmittal of an order from the licensed pharmacy to the manufacturer or the manufacturer’s agent; and

(5) The manufacturer or a manufacturer’s agent delivers the dialysate, drugs, or devices directly to:

(A) A patient with chronic kidney failure, or his/her designee, for the patient's self-administration of the dialysis therapy; or

(B) A health care provider or institution for administration or delivery of the dialysis therapy to a patient with chronic kidney failure.

(e) The provisions of §30-5-29(d) of this code shall not alter the manner in which dialysate, drugs, devices necessary to perform home peritoneal renal dialysis to patients with end state renal disease are billed by Medicaid under the current pharmacy benefit structure.

(f) A person who handles a prescription drug only during the point of sale to provide the prescription drug to a patient and accept payment is not subject to the licensure requirements of this article. This handling process includes the cashier having access to the pharmacy's operating system to verify unique information for each patient. A pharmacy may require an individual to complete a criminal background check before he or she is hired.

§30-5-30. Actions to enjoin violations.

(a) If the board obtains information that any person has engaged in, is engaging in or is about to engage in any act which constitutes or will constitute a violation of the provisions of this article, the rules promulgated pursuant to this article, or a final order or decision of the board, it may issue a notice to the person to cease and desist in engaging in the act and/or apply to the circuit court in the county of the alleged violation for an order enjoining the act.

(b) The circuit court may issue a temporary injunction pending a decision on the merits, and may issue a permanent injunction based on its findings in the case.

(c) The judgment of the circuit court on an application permitted by the provisions of this section is final unless reversed, vacated or modified on appeal to the West Virginia Supreme Court of Appeals.

§30-5-31. Complaints; investigations; due process procedure; grounds for disciplinary action.

(a) The board may initiate a complaint upon receipt of credible information, and shall upon the receipt of a written complaint of any person, cause an investigation to be made to determine whether grounds exist for disciplinary action under this article or the legislative rules promulgated pursuant to this article.

(b) After reviewing any information obtained through an investigation, the board shall determine if probable cause exists that the licensee, registrant or permittee has violated subsection (g) of this section or rules promulgated pursuant to this article.

(c) Upon a finding of probable cause to go forward with a complaint, the board shall provide a copy of the complaint to the licensee, registrant or permittee.

(d) Upon a finding that probable cause exists that the licensee, registrant or permittee has violated subsection (g) of this section or rules promulgated pursuant to this article, the board may enter into a consent decree or hold a hearing for disciplinary action against the licensee, registrant or permittee. Any hearing shall be held in accordance with the provisions of this article, and shall require a violation to be proven by a preponderance of the evidence.

(e) Any member of the board or the executive director of the board may issue subpoenas and subpoenas duces tecum to obtain testimony and documents to aid in the investigation of allegations against any person regulated by the article.

(f) Any member of the board or its executive director may sign a consent decree or other legal document on behalf of the board.

(g) The board may, after notice and opportunity for hearing, deny or refuse to renew, suspend, restrict or revoke the license, registration or permit of, or impose probationary conditions upon or take disciplinary action against, any licensee, registrant or permittee for any of the following reasons:

(1) Obtaining a board authorization by fraud, misrepresentation or concealment of material facts;

(2) Being convicted of a felony, other crime involving moral turpitude or a violation of chapter sixty-a of this code.

(3) Being guilty of unprofessional conduct which placed the public at risk, as defined by legislative rule of the board;

(4) Intentional violation of a lawful order or legislative rule of the board;

(5) Having had a board authorization revoked or suspended, other disciplinary action taken, or an application for a board authorization revoked or suspended by the proper authorities of another jurisdiction;

(6) Aiding or abetting unlicensed practice;

(7) Engaging in an act while acting in a professional capacity which has endangered or is likely to endanger the health, welfare or safety of the public;

(8) Incapacity that prevents a licensee or registrant from engaging in the practice of pharmacist care or assisting in the practice of pharmacist care, with reasonable skill, competence, and safety to the public;

(9) Violation of any laws, including rules pertaining thereto, of this or any other jurisdiction, relating to the practice of pharmacist care, drug samples, drug manufacturing, wholesale or retail drug or device distribution, or controlled substances;

(10) Committing fraud in connection with the practice of pharmacist care;

(11) Disciplinary action taken by another state or jurisdiction against a board authorization to practice pharmacist care based upon conduct by the licensee, registrant or permittee similar to conduct that would constitute grounds for actions as defined in this section;

(12) Failure to report to the board any adverse action taken by another licensing jurisdiction, government agency, law-enforcement agency, or court for conduct that would constitute grounds for action as defined in this section;

(13) Failure to report to the board one's surrender of a license or authorization to practice pharmacist care in another jurisdiction while under disciplinary investigation by any of those authorities or bodies for conduct that would constitute grounds for action as defined in this section;

(14) Failure to report to the board any adverse judgment, settlement, or award arising from a malpractice claim related to conduct that would constitute grounds for action as defined in this section;

(15) Knowing or suspecting that a licensee or registrant is incapable of engaging in the practice of pharmacist care or assisting in the practice of pharmacist care, with reasonable skill, competence, and safety to the public, and failing to report any relevant information to the board;

(16) Illegal use or disclosure of protected health information;

(17) Engaging in any conduct that subverts or attempts to subvert any licensing examination or the administration of any licensing examination;

(18) Failure to furnish to the board or its representatives any information legally requested by the board, or failure to cooperate with or knowingly engaging in any conduct which obstructs an investigation being conducted by the board;

(19) Agreeing to participate in a prescription drug product conversion program promoted or offered by a manufacturer, wholesaler or distributor of such product for which the pharmacist or pharmacy received any form of financial remuneration, or agreed to participate in a prescription drug program in which the pharmacist or pharmacy is promoted or offered as the exclusive provider of prescription drug products or whereby in any way the public is denied, limited or influenced in selecting pharmacist care or counseling;

(20) Violation of any of the terms or conditions of any order entered in any disciplinary action.

(h) For the purposes of subsection (g) of this section, effective July 1, 2013, disciplinary action may include:

(1) Reprimand;

(2) Probation;

(3) Restrictions;

(4) Suspension;

(5) Revocation;

(6) Administrative fine, not to exceed $1,000 per day per violation;

(7) Mandatory attendance at continuing education seminars or other training;

(8) Practicing under supervision or other restriction; or

(9) Requiring the licensee, registrant or permittee to report to the board for periodic interviews for a specified period of time.

(i) In addition to any other sanction imposed, the board may require a licensee, registrant or permittee to pay the costs of the proceeding.

(j) The board may defer disciplinary action with regard to an impaired licensee or registrant who voluntarily signs an agreement, in a form satisfactory to the board, agreeing not to practice pharmacist care and to enter an approved treatment and monitoring program in accordance with the board's legislative rule. This subsection, provided that this section should not apply to a licensee or registrant who has been convicted of, pleads guilty to, or enters a plea of nolo contendere or a conviction relating to a controlled substance in any jurisdiction.

(k) A person authorized to practice under this article, who reports or otherwise provides evidence of the negligence, impairment or incompetence of another member of this profession to the board or to any peer

review organization, is not liable to any person for making such a report if such report is made without actual malice and in the reasonable belief that such report is warranted by the facts known to him or her at the time.

§30-5-32. Procedures for hearing; right of appeal.

(a) Hearings are governed by the provisions of section eight, article one of this chapter.

(b) The board may conduct the hearing or elect to have an administrative law judge conduct the hearing.

(c) If the hearing is conducted by an administrative law judge, at the conclusion of a hearing he or she shall prepare a proposed written order containing findings of fact and conclusions of law. The proposed order may contain proposed disciplinary actions if the board so directs. The board may accept, reject or modify the decision of the administrative law judge.

(d) Any member or the executive director of the board has the authority to administer oaths, examine any person under oath and issue subpoenas and subpoenas duces tecum.

(e) If, after a hearing, the board determines the licensee, registrant or permittee has violated provisions of this article or the board's rules, a formal written decision shall be prepared which contains findings of fact, conclusions of law and a specific description of the disciplinary actions imposed.

§30-5-33. Judicial review.

Any person adversely affected by a decision of the board entered after a hearing may obtain judicial review of the decision in accordance with section four, article five, chapter twenty-nine-a of this code, and may appeal any ruling resulting from judicial review in accordance with article six, chapter twenty-nine-a of this code.

§30-5-34. Criminal offenses.

(a) When, as a result of an investigation under this article or otherwise, the board has reason to believe that a person authorized under this article has committed a criminal offense under this article, the board may bring its information to the attention of an appropriate law-enforcement official.

(b) Any person who intentionally practices, or presents himself or herself out as qualified to practice pharmacist care or to assist in the practice of pharmacist care, or uses any title, word or abbreviation to indicate to or induce others to believe he or she is licensed to practice as a pharmacist or pharmacist technician without obtaining an active, valid West Virginia license to practice that profession; or

With a license that is:

(1) Expired, suspended or lapsed; or

(2) Inactive, revoked, suspended as a result of disciplinary action, or surrendered;

is guilty of a misdemeanor and, upon conviction thereof, shall be fined not more than ten thousand dollars.

§30-5-35. Conversion of prescriptions authorizing refills.

(a) If a prescription authorizes a drug to be dispensed by refilling the prescription one or more times and the total quantity of the drug does not exceed a 90-day supply of the drug, a pharmacist who is filling or refilling the

prescription may dispense a quantity of the drug that varies from the quantity or amount of the drug originally written on the prescription, if all of these conditions are met:

(1) The action taken by the pharmacist does not result in a quantity or amount of the drug being dispensed that exceeds the total quantity that may be dispensed by filling and refilling the prescription.

(2) The prescription is for one of the following:

(A) A maintenance drug to be taken on a regular, recurring basis to treat a chronic condition;

(B) A drug to be taken on a regular, recurring basis to prevent disease; or

(C) A contraceptive.

(3) If the prescription is for a maintenance drug, the patient has used an initial 30-day supply of the drug, or a 90-day supply of the drug has previously been prescribed to the patient, and the pharmacist determines, after consulting with the patient, that the drug has stabilized the patient's condition.

(4) The prescription is not for a controlled substance, as set forth in §60A-1-1 et seq.; and

(5) The pharmacist consults with the patient, and the pharmacist determines the action authorized by this section is appropriate for the patient.

(b) When a licensed practitioner authorizes a drug to be dispensed in a certain dosage, and the pharmacist is unable to dispense the drug in the same dosage as specified, the pharmacist may substitute the same drug in a different dosage, if the aggregate dosage of the prescription remains the same and the following conditions are met:

(1) The pharmacist counsels the patient on the differences; and

(2) The pharmacist notifies the patient's prescriber of the drug product substitution within five business days of the substitution.

(c) This section does not require a health care insurer, government health care program, pharmacy benefit manager, or other entity that offers health benefit plans to provide coverage for a drug in a manner that is inconsistent with the patient's benefit plan.

§30-5-36. Emergency prescriptions for life-sustaining medication

(a) A pharmacist may distribute or sell a dangerous drug, other than a schedule II-controlled substance as defined in §60A-2-206, without a written or oral prescription from a licensed health professional authorized to prescribe drugs if all the following conditions are met:

(1) The pharmacy at which the pharmacist works has a record of a prescription for the drug in the name of the patient who is requesting it, but the prescription does not provide for a refill or the time permitted by the rules adopted by the state board of pharmacy for providing refills has elapsed;

(2) The pharmacist is unable to obtain authorization to refill the prescription from a health care professional who issued the prescription or another health professional responsible for the patient's care;

(3) In the exercise of the pharmacist's professional judgment:

(A) The drug is essential to sustain the life of the patient or continue therapy for a chronic condition of the patient.

(B) Failure to dispense or sell the drug to the patient could result in harm to the health of the patient.

(4) Except as provided in this section, the amount of the drug that is dispensed or sold under this section does not exceed a seventy-two-hour supply as provided in the prescription; and

(5) If the drug sold or dispensed under this section is not a controlled substance and the patient has been on a consistent drug therapy as demonstrated by records maintained by a pharmacy, the amount of the drug dispensed or sold does not exceed a thirty-day supply as provided in the prescription or, if the standard unit of dispensing for the drug exceeds a thirty-day supply, the amount of the drug dispensed or sold does not exceed the standard unit of dispensing. A pharmacist shall not dispense or sell a particular drug to the same patient in an amount described in this section more than once in any twelve-month period.

(b) A Pharmacist who dispenses or sells a drug under this section shall:

(1) For one year after the date of dispensing or sale, maintain a record in accordance with this chapter of the drug dispensed or sold, including the name and address of the patient and the individual receiving the drug, if the individual receiving the drug is not the patient, the amount dispensed or sold, and the original prescription number;

(2) Notify the health professional who issued the initial prescription or another health professional responsible for the patient’s care not later than seventy-two hours after the drug is sold or dispensed; and within seven 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-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.

(3) If applicable, obtain authorization for additional dispensing from one of the health professionals in division (A) (1) of this section.

(4) A pharmacist who dispenses or sells a drug under this section may do so once for each prescription described here.

60A Uniform Controlled Substance Act

§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) “Fentanyl analog or derivative” means any substance which has a chemical structure which is substantially similar to the chemical structure of fentanyl, including any of its salts, isomers, or salts of isomers, including any chemical compound or mixture. For purposes of this chapter, the term “fentanyl derivative or analog” includes any fentanyl analog that is not otherwise scheduled in this chapter.

(o) “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.

(p) “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.

(q) “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.

(r) “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.

(s) “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.

(t) “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.

(u) “Opium poppy” means the plant of the species “Papaver somniferum L.”, except its seeds.

(v) “Person” means individual, corporation, government or governmental subdivision or agency, business trust, estate, trust, partnership or association, or any other legal entity.

(w) “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.

(x) “Poppy straw” means all parts, except the seeds, of the opium poppy after mowing.

(y) “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.

(z) “Production” includes the manufacture, planting, cultivation, growing or harvesting of a controlled substance.

(aa) “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.

(bb) “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.

§60A-2-201. Authority of Board of Pharmacy; recommendations to Legislature.

(a) The 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 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 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 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 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 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.

(f) Notwithstanding any provision of this chapter to the contrary, the sale, wholesale, distribution or prescribing of a cannabidiol or nabiximols in a product approved by the Food and Drug Administration is permitted and shall be placed on the schedule or descheduled as provided for by the Drug Enforcement Administration.

§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 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.

(b) Opiates.

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

Acetylmethadol;

Allylprodine;

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

Alphameprodine;

Alphamethadol;

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

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

Benzethidine;

Betacetylmethadol;

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

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

Betameprodine;

Betamethadol;

Betaprodine;

Clonitazene;

Dextromoramide;

Diampromide;

Diethylthiambutene;

Difenoxin;

Dimenoxadol;

Dimepheptanol;

Dimethylthiambutene;

Dioxaphetyl butyrate;

Dipipanone;

Ethylmethylthiambutene;

Etonitazene;

Etoxeridine;

Furethidine;

Hydroxypethidine;

Ketobemidone;

Levomoramide;

Levophenacylmorphan;

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

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

Morpheridine;

N-Methylnorfentanyl (N-(1-Methyl-4-piperidinyl)-N-phenyl-propanamide, monohydrochloride);

Norfentanyl (N-Phenyl-N-4-piperidinyl-propanamide);

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

Noracymethadol;

Norlevorphanol;

Normethadone;

Norpipanone;

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

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

Phenadoxone;

Phenampromide;

Phenomorphan;

Phenoperidine;

Piritramide;

Proheptazine;

Properidine;

Propiram;

Racemoramide;

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

Tilidine;

Trimeperidine.

(c) Opium derivatives,

Acetorphine;

Acetyldihydrocodeine;

Benzylmorphine;

Codeine methylbromide;

Codeine-N-Oxide;

Cyprenorphine;

Desomorphine;

Dihydromorphine;

Drotebanol;

Etorphine (except HCl Salt);

Heroin;

Hydromorphinol;

Methyldesorphine;

Methyldihydromorphine;

Morphine methylbromide;

Morphine methylsulfonate;

Morphine-N-Oxide;

Myrophine;

Nicocodeine;

Nicomorphine;

Normorphine;

Pholcodine;

Thebacon.

(d) Hallucinogenic substances.

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

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

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

N-(2-Methoxybenzyl)-4-bromo-2, 5-dimethoxyphenethylamine. The substance has the acronym 25B-NBOMe;

2-(4-chloro-2,5-dimethoxyphenyl)-N-(2-methoxybenzyl) ethanamine (25C-NBOMe);

2-(4-iodo-2,5-dimethoxyphenyl)-N-(2-methoxybenzyl) ethanamine (25I-NBOMe);

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

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

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

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

3-Hydoxy-phencyclidine (other name hydroxy PCP);

5-methoxy-3, 4-methylenedioxy-amphetamine;

4-methyl-2,5-dimethoxy-amphetamine; some trade and other names: 4-methyl-2,5-dimethoxy-alpha-methylphenethylamine; “DOM”; and “STP”;

3,4-methylenedioxy amphetamine;

3,4-methylenedioxymethamphetamine (MDMA);

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

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

3,4,5-trimethoxy amphetamine;

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

Alpha-methyltryptamine (other name: AMT);

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

Diethyltryptamine; sometrade and other names: N, N-Diethyltryptamine; DET;

Dimethyltryptamine; some trade or other names: DMT;

5-Methoxy-N,N-disopropyltryptamine (5-MeO-DIPT);

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;

Lysergic acid diethylamide;

Marihuana; Marijuana (Cannabis, sp.);

Mescaline;

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;

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;

N-ethyl-3-piperidyl benzilate;

N-methyl-3-piperidyl benzilate;

Psilocybin;

Psilocyn;

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 including, but not limited to 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;

delta-8 Cis or trans tetrahydrocannabinol and its optical isomers; and

delta-10 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.)

Delta-8-tetrahydrocannabinol-O (delta-8-THC-0), Delta-9-tetrahydrocannabinol (delta-9-THC-0) and Synthetic and non-naturally occurring cannabinoids.

The provisions of this section related to tetrahydrocannabinols are inapplicable to products or substances lawfully manufactured, distributed, or possessed under the provisions of §19-12E-1 *et seq*. and Chapter 16H of this code.

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

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

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

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

4-methylmethcathinone (Mephedrone);

3,4-methylenedioxypyrovalerone (MDPV);

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

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

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

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

2-[4-(Ethylthio)-2,5-dimethoxyphenyl]ethanamine (2C-T-2);

2-[4-(Isopropylthio)-2,5-dimethoxyphenyl]ethanamine (2C-T-4);

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

2-(2,5-Dimethoxy-4-nitro-phenyl)ethanamine (2C-N);

2-(2,5-Dimethoxy-4-(n)-propylphenyl)ethanamine (2C-P);

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

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

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

Alpha-methyltryptamine (other name: AMT);

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

Synthetic Cannabinoids as follows:

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

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

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

(dexanabinol);

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

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

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

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

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

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

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

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

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

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

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

1-(1-(2-cyclohexylethyl) -1H-indol-3-yl) -2-(2-methoxyphenyl) ethanone {also known as RCS-8};

1-pentyl-3-[1-(4-methoxynaphthoyl)]indole (JWH-081);

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

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

Synthetic cannabinoids:

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

YL)phenol);

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

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

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

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

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

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

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

Methyl 2-(1-(5-fluoropentyl)-1H-indazole-3-carboxamido)-3,3-dimethylbutanoate (5F-ADB);

Methyl 2-(1-(5-fluoropentyl)-1H-indazole-3-carboxamido)-3-methylbutanoate (5F-AMB);

Methyl 2-(1-(4-fluorobenzyl)-1H-indazole-3-carboxamido)-3-methylbutanoate (FUB-AMB);

N-(adamantan-1-yl)-1-(5-fluoropentyl)-1H-indazole-3-carboxamide (5F-APINACA);

N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-(4-fluorobenzyl)-1H-indazole-3-carboxamide (ADB-FUBINACA);

Methyl 2-(1-(cyclohexylmethyl)-1H-indole-3-carboxamido)-3,3-dimethylbutanoate (MDMB-CHMICA);

Methyl 2-(1-(4-fluorobenzyl)-1H-indazole-3-carboxamido)-3,3-dimethylbutanoate (MDMB-FUBINACA);

Tetrahydrocannabinols:

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 their trans tetrahydrocannabinol and their optical isomers.

Synthetic Phenethylamines

2-(4-iodo-2,5-dimethoxyphenyl)-N-(2-methoxybenzyl)ethanamine (25I-NBOMe/ 2C-I-NBOMe);

2-(4-chloro-2,5-dimethoxyphenyl)-N-(2-methoxybenzyl)ethanamine (25C-NBOMe/2C-C-NBOMe);

2-(4-bromo-2,5-dimethoxyphenyl)-N-(2-methoxybenzyl)ethanamine (25B-NBOMe/ 2C-B-NBOMe);

Synthetic Opioids (including their isomers, esters, ethers, salts and salts of isomers, esters and ethers):

N-(1-phenethylpiperidin-4-yl)-N-phenylacetamide (acetyl fentanyl);

furanyl fentanyl;

3,4-dichloro-N-[2-(dimethylamino)cyclohexyl]-N-methylbenzamide (also known as U-47700);

N-(1-phenethylpiperidin-4-yl)-N-phenylbutyramide, also known as N-(1-phenethylpiperidin-4-yl)-N-phenylbutanamide, (butyryl fentanyl);

N-[1-[2-hydroxy-2-(thiophen-2-yl)ethylpiperidin-4-yl]-N-phenylpropionamide, also known as N-[1-[2-hydroxy-2-(2-thienyl)ethyl]-4-piperidinyl]-N-phenylpropanamide, (beta-hydroxythiofentanyl);

N-(1-phenethylpiperidin-4-yl)-N-phenylacrylamide (acryl fentanyl);

N-(1-phenethylpiperidin-4-yl)-N-phenylisobutyramide (isobutyryl fentanyl);

N-(1-phenethylpiperidin-4-yl)-N-phenylcyclopentanecarboxamide (cyclopropyl fentanyl);

2-(2,4-dichlorophenyl)-N-((1S,2S)-2-(dimethylamino)cyclohexyl)-N-methylacetamide (also known as U-48800);

Trans-3,4-dichloro-N-[2-(diethylamino)cyclohexyl]-N-methyl-benzamide (also known as U-49900);

Trans-3,4-dichloro-N-[2-(dimethylamino)cyclohexyl]-N-methyl-benzeneacetamide (also known as U-51754);

2-(2-(4-butoxybenzyl)-5-nitro-1H-benzimidazol-1-yl)-N,N-diethylethan-1-amine (butonitazene);

2-(2-(4-ethoxybenzyl)-1H-benzimidazol-1-yl)-N,N-diethylethan-1-amine (etodesnitazene);

N,N-diethyl-2-(2-(4-fluorobenzyl)-5-nitro-1H-benzimidazol-1-yl)ethan-1-amine (flunitazene);

N,N-diethyl-2-(2-(4-methoxybenzyl)-1H-benzimidazol-1-yl)ethan-1-amine (metodesnitazene);

N,N-diethyl-2-(2-(4-methoxybenzyl)-5-nitro-1H-benzimidazol-1-yl)ethan-1-amine (metonitaze);

2-(4-ethoxybenzyl)5-nitro-1-(2-(pyrrolidin-1-yl)ethyl)-1 H-benzimidazole (N-pyrrolidino etoitazene, etonitazepyne);

N,N-diethyl-2-(5-nitro-2-(4- propoxybenzyl)-1H-benzimidazol-1- yl)ethan-1-amine (protonitazene);

N-pyrrolidino etonitazene;

Etodesnitazene;

Isotonitazene;

Protonitazene;

Metonitazene;

Butonitazene;

Metodesnitazene;

Flunitazene;

Opioid Receptor Agonist

AH-7921 (3,4-dichloro-N- (1dimethylamino)cyclohexylmethyl]benzamide).

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:

JWH 015;

JWH 018;

JWH 019;

JWH 073;

JWH 081;

JWH 122;

JWH 200;

JWH 210;

JWH 398;

AM 2201; and

WIN 55,212.

Naphylmethylindoles or any compound containing a 1hindol-3-yl-(1-naphthyl) methane structure with a 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, but not be limited to, JWH 175 and JWH 184.

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.

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.

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:

RCS-8, SR-18 OR BTM-8;

JWH 250;

JWH 203;

JWH 251; and

JWH 302.

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:

CP 47,497 and its homologues and analogs;

Cannabicyclohexanol; and

CP 55,940.

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:

AM 694;

Pravadoline WIN 48,098;

RCS 4; and

AM 679.

[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.

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.

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.

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.

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

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.

Tryptamines:

5- methoxy- N- methyl-N-isopropyltryptamine (5-MeO-MiPT);

4-hydroxy-N,N-diisopropyltryptamine (4-HO-DiPT);

4-hydroxy-N-methyl-N-isopropyltryptamine (4-HO-MiPT);

4-hydroxy-N-methyl-N-ethyltryptamine (4-HO-MET);

4-acetoxy-N,N-diisopropyltryptamine (4-AcO-DiPT);

5-methoxy-α-methyltryptamine (5-MeO-AMT);

4-methoxy-N,N-Dimethyltryptamine (4-MeO-DMT);

4-hydroxy Diethyltryptamine (4-HO-DET);

5- methoxy- N,N- diallyltryptamine (5-MeO-DALT);

4-acetoxy-N,N-Dimethyltryptamine (4-AcO DMT);

4-hydroxy Diethyltryptamine (4-HO-DET);

FDU-PB-22 (1-Naphthyl 1-(4-fluorobenzyl)-1H-indole-3-carboxylate);

FUB-PB-22 (Quinolin-8-yl 1-(4-fluorobenzyl)-1H-indole-3-carboxylate);

5-Fluoro-MN-24 (1-(5-Fluoropentyl)-N-(naphthalen-1-yl)-1H-indole-3-carboxamide);

MN-24 (N-(naphthalen-1-yl)-1-pentyl-1H-indole-3-carboxamide);

SDB-005 (Naphthalen-1-yl 1-pentyl-1H-indazole-3-carboxylate);

SDB-006 (1-Pentyl-N-(phenylmethyl)-1H-indole-3-carboxamide);

Methyl-Ethylaminopentiophenone;

FUB-AMB (Methyl(1-(4-fluorobenzyl)-1H-indazole-3-carbonyl)-L-valinate);

5-Fluoro-SDB-005 Indole (Naphthalen-1-yl 1-(5-fluoropentyl)-1H-indole-3-carboxylate);

5F-AB-PINACA (N-(1-Amino-3-methyl-1-oxobutan-2-yl)-1-(5-fluoropentyl)-1H-indazole-3- carboxamide);

MMB-CHMICA (Methyl 2-(1-(cyclohexylmethyl)-1H-indole-3-carboxamido)-3-methylbutanoat);

MN-24 (N-(naphthalen-1-yl)-1-pentyl-1H-indole-3-carboxamide);

SDB-005 (Naphthalen-1-yl 1-pentyl-1H-indazole-3-carboxylate);

SDB-006 (1-Pentyl-N-(phenylmethyl)-1H-indole-3-carboxamide);

Ethcathinone (2-(ethylamino)-1-phenyl-1-propanone, monohydrochloride);

Methyl-Ethylaminopentiophenone;

FUB-AMB (Methyl(1-(4-fluorobenzyl)-1H-indazole-3-carbonyl)-L-valinate);

5-Fluoro-SDB-005 Indole (Naphthalen-1-yl 1-(5-fluoropentyl)-1H-indole-3-carboxylate);

5F-AB-PINACA (N-(1-Amino-3-methyl-1-oxobutan-2-yl)-1-(5-fluoropentyl)-1H-indazole-3- carboxamide);

MMB-CHMICA (Methyl 2-(1-(cyclohexylmethyl)-1H-indole-3-carboxamido)-3-methylbutanoat);

Bromazolam (8-bromo-1-methyl-6-phenyl-4H-[1,2,4]triazolo[4,3-a][1,4]benzodiazepine);

Clonazolam (6-(2-chlorophenyl)-1-methyl-8-nitro-4 H-[1,2,4]triazolo[4,3-a][1,4]benzodiazepine);

Cloniprazepam (5-(2-chlorophenyl)-1-(cyclopropylmethyl)-1,3-dihydro-7-nitro-2H-1,4-benzodiazepin-2-one);

Etizolam (4-(2-chlorophenyl)-2-ethyl-9-methyl-6H-thieno[3,2-f] [1,2,4]triazolo[4,3-a][1,4]diazepine);

Flualprazolam (8-chloro-6-(2-fluorophenyl)-1-methyl-4H-[1,2,4]triazolo[4,3-a][1,4]benzodiazepine);

Flubromazepam (7-bromo-5-(2-fluorophenyl)-1,3-dihydro-2H-1,4-benzodiazepin-2-one);

Flubromazolam (8-bromo-6-(2-fluorophenyl)-1-methyl-4H-[1,2,4]triazolo[4,3-a][1,4]benzodiazepine);

Flunitrazolam (6-(2-fluorophenyl)-1-methyl-8-nitro-4H-benzo[f][1,2,4]triazolo[4,3-a][1,4]diazepine);

Nifoxipam (5-(2-fluorophenyl)-1,3-dihydro-3-hydroxy-7-nitro-2H-1,4-benzodiazepin-2-one) ;

Nitrazolam (1-methyl-8-nitro-6-phenyl-4H-[1,2,4]triazolo[4,3-a][1,4]benzodiazepine); and

Pyrazolam (8-bromo-1-methyl-6-(2-pyridinyl)-4H-[1,2,4]triazolo[4,3-a][1,4]benzodiazepine).

(e) Depressants.

4-CN-CUMYL-BUTINACA (1-(4-Cyanobutyl)-N-(2-phenylpropan-2- yl)-1H-indazole-3-carboxamide);

Alpha-Phenylacetoacetonitrile (3-Oxo-2-phenylbutanenitrile);

2-Fluoro Deschloroketamine (2-(2-Fluorophenyl)-2-(methylamino)-cyclohexanone, monohydrochloride);

4-MEAP (2-(Ethylamino)-1-(4-methylphenyl)pentan-1-one);

Mecloqualone;

Methaqualone;

Bromazolam (8-bromo-1-methyl-6-phenyl-4H-[1,2,4]triazolo[4,3-a][1,4]benzodiazepine);

Clonazolam (6-(2-chlorophenyl)-1-methyl-8-nitro-4 H-[1,2,4]triazolo[4,3 a][1,4]benzodiazepine);

Cloniprazepam (5-(2-chlorophenyl)-1-(cyclopropylmethyl)-1,3-dihydro-7-nitro-2H-1,4-benzodiazepin-2-one);

Etizolam (4-(2-chlorophenyl)-2-ethyl-9-methyl-6H-thieno[3,2-f] [1,2,4]triazolo[4,3-a][1,4]diazepine);

Flualprazolam (8-chloro-6-(2-fluorophenyl)-1-methyl-4H-[1,2,4]triazolo[4,3-a][1,4]benzodiazepine);

Flubromazepam (7-bromo-5-(2-fluorophenyl)-1,3-dihydro-2H-1,4-benzodiazepin-2-one);

Flubromazolam (8-bromo-6-(2-fluorophenyl)-1-methyl-4H-[1,2,4]triazolo[4,3-a][1,4]benzodiazepine);

Flunitrazolam (6-(2-fluorophenyl)-1-methyl-8-nitro-4H-benzo[f][1,2,4]triazolo[4,3-a][1,4]diazepine);

Nifoxipam (5-(2-fluorophenyl)-1,3-dihydro-3-hydroxy-7-nitro-2H-1,4-benzodiazepin-2-one);

Nitrazolam (1-methyl-8-nitro-6-phenyl-4H-[1,2,4]triazolo[4,3-a][1,4]benzodiazepine);

Pyrazolam (8-bromo-1-methyl-6-(2-pyridinyl)-4H-[1,2,4]triazolo[4,3-a][1,4]benzodiazepine);

Declazepam (7-Chloro-5-(2-chlorophenyl)-1-methyl-1,3-dihydro-2H-1,4-benzodiazepin-2-one); and

Deschloroetizolam (2-Ethyl-9-methyl-4-phenyl-6H-thieno[3,2- f][1,2,4]triazolo[4,3-a][1,4]diazepine);

(f) Stimulants.

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

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

Fenethylline;

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—-methylaminopropiophenone; monomethylpropion; 3,4-methylenedioxypyrovalerone and/or mephedrone;3,4-methylenedioxypyrovalerone (MPVD); ephedrone; N-methylcathinone; methylcathinone; AL-464; AL-422; AL- 463 and UR1432;

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

N-ethylamphetamine;

N,N-dimethylamphetemine; also known as N,N-alpha- trimethyl-benzeneethanamine; N,N-alpha-trimethylphenethylamine;

Alpha-pyrrolidinopentiophenone, also known as alpha-PVP, optical isomers, salts and salts of isomers;

Substituted amphetamines:

2-Fluoroamphetamine;

3-Fluoroamphetamine;

4-Fluoroamphetamine;

2-chloroamphetamine;

3-chloroamphetamine;

4-chloroamphetamine;

2-Fluoromethamphetamine;

3-Fluoromethamphetamine;

4-Fluoromethamphetamine;

4-chloromethamphetamine;

Ethcathinone (2-(ethylamino)-1-phenyl-1-propanone, monohydrochloride);

Alpha-PHP (1-Phenyl-2-(pyrrolidin-1-yl)hexan-1-one);

MPHP (1-(4-Methylphenyl)-2-(pyrrolidin-1-yl)hexan-1-one);

PV8 (1-Phenyl-2-(pyrrolidin-1-yl)heptan-1-one);

4-Chloro-Alpha-PVP (1-(4-chlorophenyl)-2-(pyrrolidin-1-yl)pentan-1-one);

N-Ethylhexedrone (2-(Ethylamino)-1-phenylhexan-1-one);

Methoxetamine (2-(Ethylamino)-2-(3-methoxyphenyl)-cyclohexanone); and

3-Fluorophenmetrazine (2-(3-Fluorophenyl)-3-methylmorpholine);

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

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

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

N-benzylpiperazine, also known as BZP;

Cyclopentyl fentanyl (N-(1-phenethylpiperidin-4-yl)-N-phenylcyclopentanecarboxamide);

4-fluorobutyryl fentanyl (N-(4-fluorophenyl)-N-[1-(2-phenylethyl)piperidin-4-yl]-butyramide);

Isobutyryl fentanyl (2-methyl-N-phenyl-N-[1-(2-phenylethyl)piperidin-4-yl]-propanamide);

Methoxyacetyl fentanyl (2-methoxy-N-phenyl-N-[1-(2-phenylethyl)piperidin-4-yl]-acetamide);

3-methylbutyryl fentanyl (N-[3-methyl-1-(2-phenylethyl)piperidin-4-yl]-N-phenylbutyramide);

4-methoxybutyryl fentanyl (N-(4-methoxyphenyl)-N-(1-phenethylpiperidin-4-yl)butyramide);

Ocfentanil (N-(2-fluorophenyl)-2-methoxy-N-[1-(2-phenylethyl)piperidin-4-yl]-acetamide);

Tetrahydrofuran fentanyl (N-(1-phenethylpiperidin-4-yl)-N-phenyltetrahydrofuran-2-carboxamide); and

Valeryl fentanyl (N-phenyl-N-[1-(2-phenylethyl)piperidin-4-yl]pentanamide).

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

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:

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;

By substitution at the 3-position with an acyclic alkyl substituent;

By substitution at the 2-amino nitrogen atom with alkyl, dialkyl, benzyl or methoxybenzyl groups;

By inclusion of the 2-amino nitrogen atom in a cyclic structure; or

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. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following

substances, 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.

(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:

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:

Raw opium;

Opium extracts;

Opium fluid;

Powdered opium;

Granulated opium;

Tincture of opium;

Codeine;

Dihydroetorphine;

Ethylmorphine;

Etorphine hydrochloride;

Hydrocodone;

Hydromorphone;

Metopon;

Morphine;

Oripavine;

Oxycodone;

Oxymorphone; and

Thebaine;

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;

Opium poppy and poppy straw;

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;

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.

Alfentanil;

Alphaprodine;

Anileridine;

Bezitramide;

Bulk dextropropoxyphene (nondosage forms);

Carfentanil;

Dihydrocodeine;

Diphenoxylate;

Fentanyl;

Isomethadone;

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

Levomethorphan;

Levorphanol;

Metazocine;

Methadone;

Methadone-Intermediate, 4-cyano-2-dimethylamino-4, 4-diphenyl butane;

Moramide-Intermediate, 2-methyl-3-morpholino-1;

Norfentanyl;

Oliceridine;

1-diphenylpropane-carboxylic acid;

Pethidine; (meperidine);

Pethidine-Intermediate-A, 4-cyano-1-methyl-4- phenylpiperidine;

Pethidine-Intermediate-B, ethyl-4-phenylpiperidine-4-carboxylate;

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

Phenazocine;

Piminodine;

Racemethorphan;

Racemorphan;

Remifentanil;

Sufentanil;

Tapentadol; and

Thiafentanil (4-(methoxycarbonyl)-4-(N-phenmethoxyacetamido)-1-2-(thienyl)ethylpiperidine), including its isomers, esters, ethers, salts and salts of isomers, esters and ethers.

(d) Stimulants.

Amphetamine, its salts, optical isomers, and salts of its optical isomers;

Methamphetamine, its salts, isomers, and salts of its isomers;

Methylphenidate;

Phenmetrazine and its salts; and

Lisdexamfetamine.

(e) Depressants.

Amobarbital;

Glutethimide;

Pentobarbital;

Phencyclidine; and

Secobarbital.

(f) Hallucinogenic substances:

Dronabinol [(-)-delta-9-trans tetrahydrocannabinol] if in an FDA approved oral solution; and

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:

Immediate precursor to amphetamine and methamphetamine:

Phenylacetone;

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

Immediate precursors to phencyclidine (PCP):

1-phenylcyclohexylamine; and

1-piperidinocyclohexanecarbonitrile (PCC).

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;

(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).

(i) Human chorionic gonadotropin, except when used for injection or implantation in cattle or any other nonhuman species and when that use is approved by the Food and Drug Administration.

§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. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances, 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.

(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:

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

Dextropropoxyphene (alpha-( )-4-dimethylamino-1,2-diphenyl-3-methyl-2-propionoxybutane).

(c) Depressants.

Alprazolam;

Barbital;

Bromazepam;

Camazepam;

Carisoprodol;

Chloral betaine;

Chloral hydrate;

Chlordiazepoxide;

Clobazam;

Clonazepam;

Clorazepate;

Clotiazepam;

Cloxazolam;

Delorazepam;

Diazepam;

Dichloralphenazone;

Estazolam;

Ethchlorvynol;

Ethinamate;

Ethyl loflazepate;

Fludiazepam;

Flunitrazepam;

Flurazepam;

Fospropofol;

Halazepam;

Haloxazolam;

Ketazolam;

Lemborexant.

Loprazolam;

Lorazepam;

Lormetazepam;

Mebutamate;

Medazepam;

Meprobamate;

Methohexital;

Methylphenobarbital (mephobarbital);

Midazolam;

Nimetazepam;

Nitrazepam;

Nordiazepam;

Oxazepam;

Oxazolam;

Paraldehyde;

Petrichloral;

Phenobarbital;

Pinazepam;

Prazepam;

Quazepam;

Remimazolam.

Temazepam;

Tetrazepam;

Triazolam;

Xylazine;

Zaleplon;

Zolpidem;

Zopiclone; and

Suvorexant ([(7R)-4-(5-chloro-1,3-benzoxazol-2-yl)-7-methyl-1,4-diazepan-1-yl] [5-methyl-2-(2H-1,2,3-triazol-2-yl)phenyl]methanone).

(d) Any material, compound, mixture, or preparation which contains any quantity of Fenfluramine and Dexfenfluramine.

(e) Stimulants.

Cathine (( )-norpseudoephedrine);

Diethylpropion;

Fencamfamin;

Fenproporex;

Mazindol;

Mefenorex;

Modafinil;

Pemoline (including organometallic complexes and chelates thereof);

Phentermine;

Pipradrol;

Serdexmethylphenidate;

Sibutramine;

SPA ((-)-1-dimethylamino-1,2-diphenylethane); and

Eluxadoline (5-[[[(2S)-2-amino-3-[4-aminocarbonyl)-2,6-dimethylphenyl]-1-oxopropyl [(1S)-1-(4-phenyl-1H-imidazol-2-yl)ethyl]amino]methyl]-2-methoxybenzoic acid);

(f) Other substances.

Pentazocine;

Butorphanol;

Tramadol (2-[(dimethylamino)methyl]-1-(3-methoxyphenyl) cyclohexanol); and

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. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture or preparation which contains any quantity of the following substances, 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.

(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.

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

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

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

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

Not more than 100 milligrams of opium per 100 milliliters or per 100 grams; and

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

(c) Stimulants:

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 12: *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:

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

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

Brivaracetam ((2S)-2-[(4R)-2-oxo-4-propylpyrrolidin-1-yl] butanamide) (also referred to as BRV; UCB-34714; Briviact).

(f) Other substances:

Gabapentin;

Pregabalin;

Cenobamate; and

Lasmiditan.

§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.

§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, $50; for registration of a wholesaler, $50; for registration of a retailer, $15; for registration of a hospital or clinic, $15; and for registration of a research institution, $5.

§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; 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 or which is methamphetamine, is guilty of a felony and, upon conviction thereof, may be imprisoned in a state correctional facility for not less than one year nor more than 15 years, or fined not more than $25,000, or both fined and imprisoned: *Provided*, That any person who violates this section knowing that the controlled substance classified in Schedule II is fentanyl, either alone or in combination with any other substance shall be fined not more than $50,000, or be imprisoned in a state correctional facility for not less than 3 nor more than 15 years, or both fined and imprisoned;

(ii) Any other controlled substance classified in Schedule I, II, or III is guilty of a felony and, upon conviction thereof, may be imprisoned in a state correctional facility for not less than one year nor more than five years, or fined not more than $15,000, or both fined and imprisoned;

(iii) A substance classified in Schedule IV is guilty of a felony and, upon conviction thereof, may be imprisoned in a state correctional facility for not less than one year nor more than three years, or fined not more than $10,000, or both fined and imprisoned;

(iv) A substance classified in Schedule V is guilty of a misdemeanor and, upon conviction thereof, may be confined in jail for not less than six months nor more than one year, or fined not more than $5,000, or both fined and confined: *Provided,* That for offenses relating to any substance classified as Schedule V in §60A-10-1 *et seq.* of this code, 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, or methamphetamine, is guilty of a felony and, upon conviction thereof, may be imprisoned in a state correctional facility for not less than one year nor more than 15 years, or fined not more than $25,000, or both fined and imprisoned;

(ii) Any other counterfeit substance classified in Schedule I, II, or III is guilty of a felony and, upon conviction thereof, may be imprisoned in a state correctional facility for not less than one year nor more than five years, or fined not more than $15,000, or both fined and imprisoned;

(iii) A counterfeit substance classified in Schedule IV is guilty of a felony and, upon conviction thereof, may be imprisoned in a state correctional facility for not less than one year nor more than three years, or fined not more than $10,000, or both fined and imprisoned;

(iv) A counterfeit substance classified in Schedule V is guilty of a misdemeanor and, upon conviction thereof, may be confined in jail for not less than six months nor more than one year, or fined not more than $5,000, or both fined and confined: *Provided,* That for offenses relating to any substance classified as Schedule V in §60A-10-1 *et seq.* of this code, 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 or her 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 §60A-4-407 of this code, subject to the limitations specified in said section, or upon conviction thereof, the person may be confined in jail not less than 90 days nor more than six months, or fined not more than $1,000, or both fined and confined: *Provided,* That notwithstanding any other provision of this act to the contrary, any first offense for possession of synthetic cannabinoids as defined by §60A-1-101(d)(32) of this code; 3,4-methylenedioxypyrovalerone (MPVD) and 3,4-methylenedioxypyrovalerone and/or mephedrone as defined in §60A-1-101(f) of this code; or less than 15 grams of marijuana, shall be disposed of under §60A-4-407 of this code.

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

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

(2) To create, possess, sell, or otherwise transfer any equipment with the intent that the 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 thereof, may be confined in jail for not less than six months nor more than one year, or fined not more than $5,000, or both fined and confined. Any person 18 years old or more who violates subdivision (1) of this subsection and distributes or delivers an imitation controlled substance to a minor child who is at least three years younger than that person is guilty of a felony and, upon conviction thereof, may be imprisoned in a state correctional facility for not less than one year nor more than three years, or fined not more than $10,000, or both fined and imprisoned.

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

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

(1) To adulterate another controlled substance using fentanyl as an adulterant;

(2) To create a counterfeit substance or imitation controlled substance using fentanyl; or

(3) To cause the adulteration or counterfeiting or imitation of another controlled substance using fentanyl.

(4) Any person who violates this subsection is guilty of a felony and, upon conviction thereof, shall be imprisoned in a state correctional facility for not less than three nor more than 15 years, or fined not more than $50,000, or both fined and imprisoned.

(5) For purposes of this section:

(i) A controlled substance has been adulterated if fentanyl has been mixed or packed with it; and

(ii) Counterfeit substances and imitation controlled substances are further defined in §60A-1-101 of this code.

§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 $25,000, 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, theft, 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 a correctional facility for not less than one year nor more than four years, or fined not more than $30,000, 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.

[Repealed.]

§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 18 by persons over the age of 21; distribution by persons 18 or over in, on, or within 1,000 feet of, school or college; distribution by persons 18 or over in, on, or within 200 feet of a public library; 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 and Rehabilitation, for service of a sentence of incarceration and is convicted of a felony violation under the provisions of §60A-4-401(a)(i) of this code for distribution of a controlled substance and:

(1) Is 21 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 18 years at the time of the distribution;

(2) Is 18 years of age or older and the distribution upon which the conviction is based occurred in, on, or within 1,000 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; or

(3) Is 18 years of age or older and the distribution upon which the conviction is based occurred in, on, or within 200 feet of, the real property comprising a public library 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 and Rehabilitation, for service of a sentence of incarceration and is convicted of a felony violation under the provisions of §60A-4-401(a)(ii) of this code for distribution of a controlled substance and:

(1) Is 21 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 18 years at the time of the distribution;

(2) Is 18 years of age or older and the distribution upon which the conviction is based occurred in, on, or within 1,000 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; or

(3) Is 18 years of age or older and the distribution upon which the conviction is based occurred in, on, or within 200 feet of, the real property comprising a public library 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 limits 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-4-407a. Authorizing additional requirements to obtain a final order of discharge and dismissal for persons charged with possession of controlled substances.

(a) Notwithstanding any provision of this code to the contrary, when a person pleads guilty or is found guilty of a violation of §60A-4-401(c) of this code, or a municipal ordinance containing the same elements where the controlled substance possessed is listed in §60A-2-204 of this code, other than marijuana, or is a controlled substance listed in §60A-2-206, §60A-2-208, or §60A-2-210 of this code, the court may, as an additional condition for the entry of a final order of discharge or dismissal under §60A-4-407 of this code or a municipal ordinance containing the same or substantially the same provision, require the defendant to be:

(1) Evaluated for admission into a drug court program; or

(2) Participate in a drug treatment program.

(b) If a defendant is determined to be an appropriate candidate for admission to drug court or a drug treatment program, the court may make successful completion of a drug court or a drug treatment program a requirement for obtaining a final order of discharge and dismissal.

§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 is unlawful for any person to transport or cause to be transported 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 thereof, may be imprisoned in the state correctional facility for not less than one year nor more than 15 years, or fined not more than $25,000, or both: *Provided*, That any person who violates this section knowing that the controlled substance classified in Schedule II is fentanyl, either alone or in combination with any other substance shall be fined not more than $50,000 or imprisoned in a state correctional facility for a definite term of not less than 10 nor more than 20 years, or both fined and imprisoned.

(2) Any other controlled substance classified in Schedule I, II or III shall be guilty of a felony and, upon conviction thereof, may be imprisoned in the state correctional facility for not less than one year nor more than 10 years, or fined not more than $15,000, or both: *Provided*, That for the substance marijuana, as scheduled in

subdivision (24) subsection (d), §60A-2-204 of this code, the penalty, upon conviction of a violation of this subsection, shall be that set forth in subdivision (3) of this subsection.

(3) A substance classified in Schedule IV shall be guilty of a felony and, upon conviction thereof, may be imprisoned in the state correctional facility for not less than one year nor more than five years, or fined not more than $10,000, or both;

(4) A substance classified in Schedule V shall be guilty of a misdemeanor and, upon conviction thereof, may be confined in jail for not less than six months nor more than one year, or fined not more than $5,000, or both: *Provided*, That for offenses relating to any substance classified as Schedule V in §60A-10-1 *et seq.* of this code, the penalties established in said article apply.

(c) Notwithstanding the provisions of subsection (b) of this section, any person violating or causing a violation of subsection (a) of this section involving one kilogram or more of heroin, five kilograms or more of cocaine or cocaine base, 100 grams or more of phencyclidine, 10 grams or more of lysergic acid diethylamide, or 50 grams or more of methamphetamine or 500 grams of a substance or material containing a measurable amount of methamphetamine, is guilty of a felony and, upon conviction thereof, shall be imprisoned in a state correctional facility for a determinate sentence of not less than two nor more than 30 years.

(d) Notwithstanding the provisions of subsection (b) of this section, any person violating or causing a violation of subsection (a) of this section involving 100 but fewer than 1,000 grams of heroin, not less than 500 but fewer than 5,000 grams of cocaine or cocaine base, not less than ten but fewer than 99 grams of phencyclidine, not less than one but fewer than 10 grams of lysergic acid diethylamide, or not less than five but fewer than 50 grams of methamphetamine or not less than 50 grams but fewer than 500 grams of a substance or material containing a measurable amount of methamphetamine, is guilty of a felony and, upon conviction thereof, shall be imprisoned in a state correctional facility for a determinate sentence of not less than two nor more than 20 years.

(e) Notwithstanding the provisions of subsection (b) of this section, any person violating or attempting to violate the provisions of subsection (a) of this section involving not less than 10 grams nor more than 100 grams of heroin, not less than 50 grams nor more than 500 grams of cocaine or cocaine base, not less than two grams nor more than 10 grams of phencyclidine, not less than 200 micrograms nor more than one gram of lysergic acid diethylamide, or not less than 499 milligrams nor more than five grams of methamphetamine or not less than 20 grams nor more than 50 grams of a substance or material containing a measurable amount of methamphetamine is guilty of a felony and, upon conviction thereof, shall be imprisoned in a state correctional facility for a determinate sentence of not less than two nor more than 15 years.

(f) 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 $5,000 nor more than $25,000, or both.

(b) Any person who operates or attempts to operate a clandestine drug laboratory and who as a result of, or in the course of doing so, causes to be burned any dwelling, outbuilding, building or structure of any class or character is guilty of a felony and, upon conviction thereof, shall be fined not less than $1,000 nor more than $5,000, or imprisoned in a state correctional facility for not less than one nor more than five years, or both fined and imprisoned.

(c) 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.

(d) The offenses in subsections (a) and (b) of this section are separate and distinct offenses and subsection (a) of this section shall not be construed to be a lesser included offense of subsection (b) of this section.

(e) For purposes of section one, article two of this chapter, both subsection (a) and (b) of this section shall be deemed qualifying felony offenses of manufacturing and delivery of a controlled substance.

(f) Any person convicted of a violation of subsection (a) or (b) 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 $1,000;

(2) For a second offense is guilty of a misdemeanor and, upon conviction, be fined not more than $5,000; and

(3) For a third or subsequent offense is guilty of a misdemeanor and, upon conviction, be fined not more than $10,000 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.

§60A-4-414. Conspiracy.

(a) Any person who willfully conspires with one or more persons to commit a felony violation of section four hundred one of this article, if one or more of such persons does any act to effect the object of the conspiracy, is guilty of a felony and, upon conviction thereof, shall be imprisoned in a state correctional facility for a determinate sentence of not less than two nor more than ten years: Provided, That the provisions of this subsection are inapplicable to felony violations of section four hundred one of this article prohibiting the manufacture, delivery or possession with intent to manufacture or deliver marijuana.

(b) Notwithstanding the provisions of subsection (a) of this section, any person who willfully conspires with one or more persons to manufacture, deliver or possess with intent to manufacture or deliver one kilogram or more of heroin, five kilograms or more of cocaine or cocaine base, one hundred grams or more of phencyclidine, ten grams or more of lysergic acid diethylamide, or fifty grams or more of methamphetamine or five hundred grams of a substance or material containing a measurable amount of methamphetamine, if one or more of such persons does any act to effect the object of the conspiracy, is guilty of a felony and, upon conviction thereof, shall be imprisoned in a state correctional facility for a determinate sentence of not less than two nor more than thirty years.

(c) Notwithstanding the provisions of subsection (a) of this section, any person who willfully conspires with one or more persons to manufacture, deliver or possess with intent to manufacture or deliver not less than one hundred but fewer than one thousand grams of heroin, not less than five hundred but fewer than five thousand grams of cocaine or cocaine base, not less than ten but fewer than one hundred grams of phencyclidine, not less than one but fewer than ten grams of lysergic acid diethylamide, or not less than five but fewer than fifty grams of methamphetamine or not less than fifty grams but fewer than five hundred grams of a substance or material containing a measurable amount of methamphetamine, if one or more of such persons does any act to effect the object of the conspiracy, is guilty of a felony and, upon conviction thereof, shall be imprisoned in a state correctional facility for a determinate sentence of not less than two nor more than twenty years.

(d) Notwithstanding the provisions of subsection (a) of this section, any person who willfully conspires with one or more persons to manufacture, deliver, possess with intent to manufacture or deliver not less than ten grams nor more than one hundred grams of heroin, not less than fifty grams nor more than five hundred grams of cocaine or cocaine base, not less than two grams nor more than ten grams of phencyclidine, not less than two hundred micrograms nor more than one gram of lysergic acid diethylamide, or not less than four hundred ninety-nine milligrams nor more than five grams of methamphetamine or not less than twenty grams nor more than fifty grams of a substance or material containing a measurable amount of methamphetamine, if one or more of such persons does any act to effect the object of the conspiracy, is guilty of a felony and, upon conviction thereof, shall be imprisoned in a state correctional facility for a determinate sentence of not less than two nor more than fifteen years.

(e) The trier of fact shall determine the quantity of the controlled substance attributable to the defendant beyond a reasonable doubt based on evidence adduced at trial.

(f) The determination of the trier of fact as to the quantity of controlled substance attributable to the defendant in a charge under this section may include all of the controlled substances manufactured, delivered or possessed with intent to deliver or manufacture by other participants or members of the conspiracy.

(g) Offenses in this section proscribing conduct involving lesser quantities are lesser included offenses of offenses proscribing conduct involving larger quantities.

(h) No person may be charged under the provisions of section thirty-one, article ten, chapter sixty-one of this code for conduct that is charged under this section.

(i) Nothing in this section may be construed to place any limitation whatsoever upon alternative sentencing options available to a court.

§60A-4-415. Unlawful manufacture, delivery, transport into state, or possession of fentanyl.

[Repealed.]

§60A-4-416. Drug delivery resulting in death; failure to render aid.

(a) Any person who knowingly and willfully delivers a controlled substance or counterfeit controlled substance in violation of the provisions of section four hundred one, article four of this chapter for an illicit purpose and the use, ingestion or consumption of the controlled substance or counterfeit controlled substance alone or in combination with one or more other controlled substances, proximately causes the death of a person using, ingesting or consuming the controlled substance, is guilty of a felony and, upon conviction thereof, shall be imprisoned in a state correctional facility for a determinate sentence of not less than three nor more than fifteen years.

(b) Any person who, while engaged in the illegal use of a controlled substance with another, who knowingly fails to seek medical assistance for such other person when the other person suffers an overdose of the controlled substance or suffers a significant adverse physical reaction to the controlled substance and the overdose or adverse physical reaction proximately causes the death of the other person, is guilty of a felony and, upon conviction thereof, shall be imprisoned for not less than one year nor more than five years.

§60A-4-417. Sale of dextromethorphan.

(a) As used in this section, "finished drug product" means a drug legally marketed under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 321 et seq.) that is in finished dosage form.

(b) A person may not knowingly or willfully sell or trade a finished drug product containing any quantity of dextromethorphan to a person under 18 years of age.

(c) A person under 18 years of age, unless an emancipated minor, may not purchase a finished drug product containing any quantity of dextromethorphan.

(d) A person making a retail sale of a finished drug product containing any quantity of dextromethorphan shall require and obtain proof of age from the purchaser before completing the sale, unless from the purchaser’s outward appearance the person making the sale would reasonably presume the purchaser to be at least 25 years of age.

(e) This section does not apply to a medication containing dextromethorphan that is sold pursuant to a valid prescription.

(f) Any person violating the provisions of this section is guilty of a misdemeanor and shall be fined not less than $100 nor more than $250.

§60A-4-418. Use of a minor to commit a felony drug offense; penalties.

Any person over the age of 21 who knowingly and intentionally causes, aids, abets, or encourages a person under the age of 18 to distribute, dispense, manufacture, or possess with the intent to distribute a controlled substance in violation or the provisions of this chapter is guilty of a felony and, upon conviction thereof, shall be fined not more than $10,000 or imprisoned in a state correctional facility for not more than five years, or both fined and imprisoned.

§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.

§60A-5-509. Unlawful retaliation against health care providers.

(a) A health care provider has the right to exercise his or her professional judgment to decline to administer, dispense, or prescribe narcotics without being subject to actual or threatened acts of reprisal.

(b) It shall be unlawful for any person or entity to engage in any form of threats or reprisal, or to engage in, or hire, or conspire with, others to commit acts or activities of any nature, the purpose of which is to punish, embarrass, deny, or reduce privileges or compensation, or cause economic loss or to aid, abet, incite, compel, or coerce any person to engage in such threats or reprisal, against a health care provider as a result of, or in retaliation for, the refusal of that health care provider to administer, dispense, or prescribe narcotics.

(c) Any person or entity who violates the foregoing shall be subject to a private right of action by the affected health care provider and shall be liable in the amount of three times the economic loss sustained as a direct and proximate result of the reprisal.

(d) A health care provider that prevails in an action brought pursuant to this section shall be entitled to an award of costs and attorney fees.

§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.

§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.

§60A-7-708. Bookkeeping procedures and internal controls.

(a) Any law-enforcement agency or office in this state, including, but not limited to, an “appropriate person” as identified in §60A-7-703(b), excluding prosecuting attorneys, who seizes or receives forfeited moneys, securities, negotiable instruments, items subject to forfeiture in accordance with §60A-7-703(a) of this code, or other property under the provisions of this article shall account for the same in the following manner:

(1) Maintain any items of property subject to forfeiture in accordance with §60A-7-704(d) of this code, including, but not limited to, moneys, securities, negotiable instruments, or other items and property identified in the same manner as the agency’s appropriated funds. Bank accounts, checkbooks, purchase cards, and other financial instruments or documents must be maintained in the same manner as appropriated funds;

(2) Establish a segregated account or accounting codes to track both revenues and expenditures for each respective program. No other funds may be commingled in these accounts or with these accounting codes;

(3) Process all expenditures and payments in the same manner as appropriated funds, including procurement and payment transactions;

(4) In accordance with the provisions of §60A-7-704(d)(4) of this code, in the case of seized moneys, securities, or other negotiable instruments, place the assets in an interest-bearing depository insured by an agency of the federal government. Deposit all interest earned on equitable sharing funds into the respective account or accounting code. All interest is subject to the same use restrictions as equitable sharing funds. Losses to funds maintained in investment accounts in accordance with the jurisdiction’s policies may not be allocated to or deducted from the equitable sharing account;

(5) Develop, maintain, and follow written policies for accounting, bookkeeping, inventory control, and procurement that comply with the applicable jurisdiction policies. Ensure distribution of relevant policies to all appropriate personnel;

(6) Maintain records of all revenue and expenditures posted to the account or accounting code, to include bank/ledger statements, invoices, receipts, required jurisdiction approvals, or any other documents used or created during the procurement and disposition process;

(7) Report all transactions using cash-based accounting methods;

(8) Dispose of items purchased with shared funds in accordance with the agency’s disposal policies. To the extent practicable and, if consistent with the agency’s procurement and disposal polices, deposit proceeds from the sale of such property into the agency’s sharing account or accounting code. If an item has minimal or no value, an agency may donate the item to a recipient of its choice if permitted under the agency’s disposal policies;

(9) Ensure the agency head, or designee, authorizes all expenditures from the sharing accounts; and

(10) Obtain approval for expenditures from the governing body, such as the county commission, town council, or city manager's office, when required under normal established jurisdiction accounting procedures.

(b) Any law-enforcement agency or office in this state, excluding prosecuting attorneys, receiving forfeited moneys, securities, negotiable instruments, real property, personal property, or other property under the provisions of this article shall report the same to the State Auditor. For each seizure only one report shall be filed by the agency that made the seizure. All agencies receiving forfeited property shall report disposition and expenditures of any proceeds of that property. Reports shall be filed in the following manner:

(1) Name of the law-enforcement agency or office that seized the property, or if seized by a multijurisdictional task force, the name of the lead agency;

(2) The time and date the property was seized;

(3) The type of property seized, whether real or personal;

(4) The actual or estimated value of the property seized;

(5) The property's final disposition, including the amount received if the property was sold, or if the property was put to use on behalf of a law-enforcement agency or office, the identity of the agency or office that took possession and use of the property;

(6) Whether forfeiture was made by settlement agreement;

(7) Whether any procedure for forfeiture was initiated in accordance with the provisions of §60A-7-705 of this code, or other identifying information sufficient to permit acquisition of any available public records related to the forfeiture procedure and disposition of the forfeited property;

(8) The disposition of any action under the provisions of §60A-7-705 of this code;

(9) If an arrest was made;

(10) Whether any charges brought against a defendant in conjunction with a seizure pursuant to this article resulted in deferred action, conviction, plea deal, acquittal, or ongoing criminal case;

(11) When an administrative forfeiture procedure has been initiated pursuant to the provisions of §60A-7-705a of this code, provide designated information contained in the administrative forfeiture notice;

(12) The total value of seized and forfeited or property held by the agency at the end of the reporting period; and

(13) A copy of the United States Department of Justice's Equitable Sharing Agreement and Certification - Annual Certification Report shall be provided to the State Auditor no later than October 31 each calendar year.

(c) The State Auditor shall establish and maintain a searchable public website that includes the aggregate information submitted by any law-enforcement agency or office required under subsection (b) of this section: *Provided*, That the State Auditor's website must not provide individual case details on its public website.

(d) The State Auditor, before December 31 of each year, shall submit to the Speaker of the House of Delegates, the President of the Senate, the Attorney General, and the Governor a written report summarizing activity in the state for the preceding fiscal year on the type, approximate value, and disposition of the property forfeited and/or seized and the amount of any proceeds received or expended at the state and local levels. The

report shall provide a categorized accounting of all proceeds expended. Summary data on seizures, forfeitures and expenditures of forfeiture proceeds shall be disaggregated by agency.

(e) In the course of preparing its annual report, the State Auditor may, in its discretion or for good cause shown, perform a financial audit of records related to inventory of seized property and expenditures of forfeiture proceeds by any law-enforcement agency or office in this state. This audit shall be conducted under the Generally Accepted Government Auditing Standards (GAGAS). A copy of the financial audit report shall be submitted to the State Auditor no later than 90 days after its initiation. The State Auditor shall submit a copy of the financial audit report to the Speaker of the House of Delegates, the President of the Senate, the Attorney General and the Governor.

(f) If, in the course of a calendar year, any law enforcement agency or office that secures seized or forfeited assets valued in excess of 50 percent of the prior year's total seized or forfeited assets, or expends more than 50 percent of the prior year's total expenditures of forfeited assets, shall so advise the State Auditor, who shall perform a financial audit under the Generally Accepted Government Auditing Standards (GAGAS) of records related to inventory of seized property and expenditures of forfeiture proceeds. A copy of the final audit report shall be submitted to the State Auditor no later than 90 days after the end of the fiscal year and shall be made public.

(g) The State Auditor may recoup its costs under this section by charging a fee.

(h) The State Auditor may include in its aggregate report required by subsection (d) of this section recommendations to improve statutes, rules, and policies related to seizure, forfeiture, and expenditures. The aggregate report shall be made available on the State Auditor's website.

(i) If a law-enforcement agency fails to timely file the report identified in subsection (b) of this section the State Auditor shall immediately notify the law-enforcement agency that the report has not been received.

(j) The State Auditor may propose rules for legislative approval in accordance with the provisions of §29A-3-1 *et seq.* of this code to implement this section.

(k) The data and reports compiled and prepared under this section are public information under the West Virginia Freedom of Information Act, chapter 29B of this code.

(l) This section is effective for the reporting period starting January 1, 2021.

(m) Nothing provided in this section would prevent a court of competent jurisdiction from sealing records otherwise made available under the provisions of this section.

§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 $1,000. 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 $1,000 nor more than $5,000.

§60A-8-6a. Distribution of safety net drugs to contract pharmacies; penalties; and preemption.

(a) Definitions. — As used in this section:

(1) "340B drug" means a drug that:

(A) Is a covered outpatient drug within the meaning of 42 U.S.C. §256b;

(B) Has been subject to any offer for reduced prices by a manufacturer under 42 U.S.C. §256b(a)(1); and

(C) Is purchased by a covered entity within the meaning of 42 U.S.C. §256b.

(2) "340B entity" has the same meaning as that term is defined in §33-51-3 of this code.

(3) "Biological product" has the same meaning as that term is defined in 42 U.S.C. §262.

(4) "Board of Pharmacy" means the West Virginia Board of Pharmacy, which is the agency of this state authorized to issue and condition licensure and permitting of wholesale drug distributors, third-party logistics providers, and manufacturers.

(5) "Commissioner" means the West Virginia Insurance Commissioner, his or her deputies, or the West Virginia Offices of the Insurance Commissioner.

(6) "Manufacturer" has the same meaning as that term is defined in §60A-8-5 of this code, except that such definition shall include manufacturers of biological products.

(7) "Package" has the same meaning as that term is defined in 21 U.S.C. §360eee(11)(A).

(8) "Pharmacy" has the same meaning as that term is defined in §30-5-4 of this code.

(b) Distribution of drugs to safety net providers and contract pharmacies. —

(1) A manufacturer, agent, or affiliate of such manufacturer shall not, either directly or indirectly, deny, restrict, or prohibit the acquisition of a 340B drug by, or delivery of a 340B drug to, a location authorized by a 340B entity to receive such 340B drug, unless the receipt of the 340B drug is prohibited by the United States Department of Health and Human Services.

(2) A manufacturer, agent, or affiliate of such manufacturer shall not, either directly or indirectly, require a 340B entity to submit any claims or utilization data as a condition for allowing the acquisition of a 340B drug by, or delivery of a 340B drug to, a 340B entity unless the claims or utilization data sharing is required by the United States Department of Health and Human Services.

(c) Penalties and investigations. —

(1) The commission of any act prohibited by subsection (b) of this section constitutes:

(A) A violation of §46A-6-104 of this code and shall subject the violator to a civil penalty of $50,000 per each violation, as well as any and all actions, including investigative demands, remedies, and penalties provided for in §46A-7-101 *et seq*. of this code, except that there shall be no right to bring a private cause of action; and

(B) A violation of §33-11-1 *et seq*. of this code and shall subject the violator to any and all actions, including cease and desist orders, civil penalties, and restitution provided for in §33-11-6 of this code, except that there shall be no right to bring a private cause of action.

(2) Each package of 340B drugs determined to be subject to a prohibited act under subsection (b) of this section constitutes a separate violation under this section.

(3) Upon receipt by the Board of Pharmacy of a complaint that a manufacturer has violated subsection (b) of this section, the Board of Pharmacy:

(A) May investigate the complaint, including by investigating the manufacturer or any agent, affiliate, or contractor thereof, including any wholesaler or third-party logistics provider that may possess evidence supporting such complaint; and

(B) Shall consider appropriate penalties, including imposing discipline, or suspending, or revoking the license or permit of any manufacturer; and

(C) Shall share the results of the investigation with the Attorney General and commissioner if an investigation is conducted.

(3) The Board of Pharmacy and commissioner may promulgate rules to implement the provisions of subsection (b) of this section.

(d) Preemption. —

(1) Nothing in this section is to be construed or applied to be less restrictive than any federal law as to any person or other entity regulated by this section. Nothing in this section is to be construed or applied to be in conflict with any of the following:

(A) Applicable federal law and related regulations.

(B) Other laws of this state, if the state law is compatible with applicable federal law.

(2) Limited distribution of a drug required under 21 U.S.C. §355-1 is not to be construed as a violation of this section.

§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.

§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 July 1, of each calendar year by the board. All licenses issued under this section are not transferable and expire on June 30 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 September 14, 1992. 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 $200 nor more than $1,000.

§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.

§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 continued 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. A veterinarian is exempt from the requirements of this article.

§60A-9-3. Reporting system requirements; implementation; central repository requirement.

(a) The Board of Pharmacy shall implement a program wherein a central repository is established and maintained which shall contain such information as is required by the provisions of this article regarding Schedule II, III, and IV controlled substance prescriptions written or filled in this state. In implementing this program, the Board of Pharmacy shall consult with the West Virginia State Police, the licensing boards of practitioners affected by this article and affected practitioners.

(b) The program authorized by subsection (a) of this section shall be designed to minimize inconvenience to patients, prescribing practitioners and pharmacists while effectuating the collection and storage of the required information. The board shall allow reporting of the required information by electronic data transfer where feasible, and where not feasible, on reporting forms promulgated by the board. The information required to be submitted by the provisions of this article shall be required to be filed no more frequently than within twenty-four hours.

(c) (1) The board shall provide for the electronic transmission of the information required to be provided by this article by and through the use of a toll-free telephone line.

(2) A dispenser, who does not have an automated record-keeping system capable of producing an electronic report in the established format may request a waiver from electronic reporting. The request for a waiver shall be made to the board in writing and shall be granted if the dispenser agrees in writing to report the data by submitting a completed "Pharmacy Universal Claim Form" as defined by legislative rule.

§60A-9-4. Required information.

(a) The following individuals shall report the required information to the Controlled Substances Monitoring Program Database when:

(1) A medical services provider dispenses a controlled substance listed in Schedule II, III, IV, or V;

(2) A prescription for the controlled substance or opioid antagonist is filled by:

(A) A pharmacist or pharmacy in this state;

(B) A hospital, or other health care facility, for outpatient use; or

(C) A pharmacy or pharmacist licensed by the Board of Pharmacy, but situated outside this state for delivery to a person residing in this state; and

(3) A pharmacist or pharmacy sells an opioid antagonist.

(b) The above individuals shall, in a manner prescribed by rules promulgated by the Board of Pharmacy pursuant to 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, IV, and V controlled substance or opioid antagonist dispensed;

(5) The quantity and dosage of the Schedule II, III, IV, and V controlled substance or opioid antagonist dispensed;

(6) The date the prescription was written and the date filled;

(7) The number of refills, if any, authorized by the prescription;

(8) If the prescription being dispensed is being picked up by someone other than the patient on behalf of the patient, information about 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.

(c) Whenever a medical services provider treats a patient for an overdose that has occurred as a result of illicit or prescribed medication, the medical service provider shall report the full legal name, address, and birth date of the person who is being treated, including any known ancillary evidence of the overdose. The Board of Pharmacy shall coordinate with the Division of Justice and Community Services and the Office of Drug Control Policy regarding the collection of overdose data.

(d) The Board of Pharmacy may prescribe, by rule promulgated pursuant to this article, the form to be used in prescribing a Schedule II, III, IV, and V substance or opioid antagonist if, in the determination of the Board of Pharmacy, the administration of the requirements of this section would be facilitated.

(e) Products regulated by the provisions of §60A-10-1 *et seq*. of this code shall be subject to reporting pursuant to the provisions of this article to the extent set forth in said article.

(f) 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. The quantity dispensed by a prescribing practitioner to his or her own patient may not exceed an amount adequate to treat the patient for a maximum of 72 hours with no greater than two 72-hour cycles dispensed in any 15-day period of time: *Provided*, That an advanced practice registered nurse who is participating in a clinical trial, with institutional review board approval, for the rural expansion of medication-assisted treatment for opioid use disorder may exceed the 3-day supply for the time frame of the clinical trial, after registering with the Board of Pharmacy: *Provided, however*, That this exemption only permits one program to participate once in CTN-0102-XR, which is also the same program as provided for in §30-7-15a of this code.

(g) The Board of Pharmacy shall notify a physician prescribing buprenorphine or buprenorphine/naloxone within 60 days of the availability of an abuse deterrent or a practitioner-administered form of buprenorphine or buprenorphine/naloxone if approved by the Food and Drug Administration as provided in FDA Guidance to Industry. Upon receipt of the notice, a physician may switch his or her patients using buprenorphine or buprenorphine/naloxone to the abuse deterrent or a practitioner-administered form of the drug.

§60A-9-4a. Verification of identity.

Prior to releasing a Schedule II, III, or IV controlled substance sold at retail, a pharmacist or pharmacy shall verify the full legal name, address and birth date of the person picking up the controlled substance dispensed by requiring the presentation of a valid government-issued photo identification card. This information shall be reported in accordance with the provisions of this article.

§60A-9-5. Confidentiality; limited access to records; period of retention; no civil liability for required reporting.

(a)(1) The information required by this article to be kept by the Board of Pharmacy is confidential and not subject to the provisions of §29B-1-1 *et seq*. of this code or obtainable as discovery in civil matters absent a court order and is open to inspection only by inspectors and agents of the Board 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 the Office of Health Facility Licensure and Certification for use in certification, licensure, and regulation of health facilities, duly authorized agents of licensing boards of practitioners in this state and other states authorized to prescribe Schedules II, III, IV, and V controlled substances, prescribing practitioners and pharmacists, a dean of any medical school or

his or her designee located in this state to access prescriber level data to monitor prescribing practices of faculty members, prescribers, and residents enrolled in a degree program at the school where he or she serves as dean, a physician reviewer designated by an employer of medical providers to monitor prescriber level information of prescribing practices of physicians, advance practice registered nurses, or physician assistants in their employ, and a chief medical officer of a hospital or a physician designated by the chief executive officer of a hospital who does not have a chief medical officer, for prescribers who have admitting privileges to the hospital or prescriber level information, and persons with an enforceable court order or regulatory agency administrative subpoena. All law-enforcement personnel who have access to the Controlled Substances Monitoring Program Database shall be granted access in accordance with applicable state laws and the Board of Pharmacy's rules, shall be certified as a West Virginia law-enforcement officer and shall have successfully completed training approved by the Board of Pharmacy. All information released by the 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*, That the West Virginia Controlled Substances Monitoring Program Database Review Committee established in §60A-9-5(b) of this code is authorized to query the database to comply with §60A-9-5(b) of this code.

(2) Subject to the provisions of §60A-9-5(a)(1) of this code, the Board of Pharmacy shall also review the West Virginia Controlled Substances Monitoring Program Database and issue reports that identify abnormal or unusual practices of patients and practitioners with prescriptive authority who exceed parameters as determined by the advisory committee established in this section. The Board of Pharmacy shall communicate with practitioners and dispensers to more effectively manage the medications of their patients in the manner recommended by the advisory committee. All other reports produced by the Board of Pharmacy shall be kept confidential. The Board of Pharmacy 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 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 §60A-9-4 of this code 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 of Pharmacy shall establish an advisory committee to develop, implement, and recommend parameters to be used in identifying abnormal or unusual usage patterns of patients and practitioners with prescriptive authority in this state. This advisory committee shall:

(A) Consist of the following members: A physician licensed by the West Virginia Board of Medicine; a dentist licensed by the West Virginia Board of Dental Examiners; a physician licensed by the West Virginia Board of Osteopathic Medicine; a licensed physician certified by the American Board of Pain Medicine; a licensed physician board certified in medical oncology recommended by the West Virginia State Medical Association; a licensed physician board certified in palliative care recommended by the West Virginia Center on End of Life Care; a pharmacist licensed by the West Virginia Board of Pharmacy; a licensed physician member of the West Virginia Academy of Family Physicians; an expert in drug diversion; and such other members as determined by the Board of Pharmacy.

(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 §60A-9-5(a)(2) of this code.

(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 24-hour reporting requirement for the Controlled Substances Monitoring Program set forth in §60A-9-3 of this code, 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 practitioners or dispensers under consideration. The licensing board having jurisdiction over the practitioner or dispenser under consideration shall report back to the Board of Pharmacy regarding any findings, investigation, or discipline resulting from the findings of the review committee within 30 days of resolution of any action taken by the licensing board resulting from the information provided by the Board of Pharmacy. The review committee shall also review notices provided by the chief medical examiner pursuant to §61-12-10(h) of this code and determine on a case-by-case basis whether a practitioner who prescribed or dispensed a controlled substance resulting in or contributing to the drug overdose may have breached professional or occupational standards or committed a criminal act when prescribing the controlled substance at issue to the decedent. Only in those cases in which there is reasonable cause to believe a breach of professional or occupational standards or a criminal act may have occurred, the review committee shall notify the appropriate professional licensing agency having jurisdiction over the applicable practitioner or dispenser and appropriate law-enforcement agencies and provide pertinent information from the database for their consideration. The number of cases identified shall be determined by the review committee based on a number that can be adequately reviewed by the review committee. The information obtained and developed may not be shared except as provided in this article and is not subject to the provisions of §29B-1-1 *et seq*. 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 of Pharmacy shall promulgate rules with advice and consent of the advisory committee, after consultation with the licensing boards set forth in §60A-9-5(d)(4) of this code and in accordance with the provisions of §29A-3-1 *et seq*. of this code. The legislative rules must include, but shall not be limited to, the following matters:

(1) Identifying parameters used in identifying abnormal or unusual prescribing or dispensing patterns;

(2) Processing parameters and developing reports of abnormal or unusual prescribing or dispensing patterns for patients, practitioners, and dispensers;

(3) Establishing the information to be contained in reports and the process by which the reports will be generated and disseminated;

(4) Dissemination of these reports at least quarterly to:

(A) The West Virginia Board of Medicine codified in §30-3-1 *et seq*. of this code;

(B) The West Virginia Board of Osteopathic Medicine codified in §30-14-1 *et seq*. of this code;

(C) The West Virginia Board of Examiners for Registered Professional Nurses codified in §30-7-1 *et seq*. of this code;

(D) The West Virginia Board of Dentistry codified in §30-4-1 *et seq*. of this code; and

(E) The West Virginia Board of Optometry codified in §30-8-1 *et seq*. of this code; and

(5) Setting up processes and procedures to ensure that the privacy, confidentiality, and security of information collected, recorded, transmitted, and maintained by the review committee is not disclosed except as provided in this section.

(e) Persons or entities with access to the West Virginia Controlled Substances Monitoring Program Database pursuant to this section may, pursuant to rules promulgated by the Board of Pharmacy, delegate appropriate personnel to have access to said database.

(f) Good faith reliance by a practitioner on information contained in the West Virginia Controlled Substances Monitoring Program Database in prescribing or dispensing or refusing or declining to prescribe or dispense a Schedule II, III, IV, or V controlled substance shall constitute an absolute defense in any civil or criminal action brought due to prescribing or dispensing or refusing or declining to prescribe or dispense.

(g) A prescribing or dispensing practitioner may notify law enforcement of a patient who, in the prescribing or dispensing practitioner's judgment, may be in violation of §60A-4-410 of this code, based on information obtained and reviewed from the Controlled Substances Monitoring Program Database. A prescribing or dispensing practitioner who makes a notification pursuant to this subsection is immune from any civil, administrative, or criminal liability that otherwise might be incurred or imposed because of the notification if the notification is made in good faith.

(h) Nothing in the article may be construed to require a practitioner to access the West Virginia Controlled Substances Monitoring Program Database except as provided in §60A-9-5 of this code.

(i) The Board of Pharmacy shall provide an annual report on the West Virginia Controlled Substances Monitoring Program to the Legislative Oversight Commission on Health and Human Resources Accountability with recommendations for needed legislation no later than January 1 of each year.

§60A-9-5a. Practitioner requirements to access database and conduct annual search of the database; required rulemaking.

(a) All practitioners, as that term is defined in §60A-2-201 of this code who prescribe or dispense Schedule II, III, IV or V controlled substances shall register with the West Virginia Controlled Substances Monitoring Program and obtain and maintain online or other electronic access to the program database: *Provided*, That compliance with the provisions of this subsection must be accomplished within 30 days of the practitioner obtaining a new license: *Provided, however*, That the Board of Pharmacy may renew a practitioner's license without proof that the practitioner meet the requirements of this subsection.

(b) 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 §30-3-1 *et seq*. of this code, the Board of Registered Professional Nurses as set forth in §30-7-1 *et seq*. of this code, the Board of Dental Examiners as set forth in §30-4-1 *et seq*. of this code, the Board of Osteopathic Medicine as set forth in §30-14-1 *et seq*. of this code, the West Virginia Board of Optometrists as set forth in §30-8-1 *et seq*. of this code, and a pharmacist licensed by the West Virginia Board of Pharmacy as set forth in §30-5-1 *et seq*. upon initially prescribing or dispensing any Schedule II controlled substance, any opioid or any benzodiazepine to a patient who is not suffering from a terminal illness, and at least annually thereafter should the practitioner or dispenser continue to treat the patient with a controlled substance, shall access the West Virginia Controlled Substances Monitoring Program Database for information regarding specific patients. 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 maintained by a private prescriber or any inpatient facility licensed pursuant to the provisions of chapter 16 of this code. A pain-relieving controlled substance shall be defined as set forth in §30-3A-1 of this code.

(c) The various boards mentioned in §60A-9-5(b) of this code shall amend its legislative rules pursuant to the provisions of §29A-3-1 *et seq*. of this code to effectuate the provisions of this article.

§60A-9-6. Promulgation of rules.

The state Board of Pharmacy shall promulgate legislative rules to effectuate the purposes of this article in accordance with the provisions of chapter twenty-nine-a of this code.

§60A-9-7. Criminal penalties; and administrative violations.

(a) Any person who is required to submit information to the state Board of Pharmacy pursuant to the provisions of this article who fails to do so as directed by the board is guilty of a misdemeanor and, upon conviction thereof, shall be fined not less than $100 nor more than $500.

(b) Any person who is required to submit information to the state Board of Pharmacy pursuant to the provisions of this article who knowingly and willfully refuses to submit the information required by this article is guilty of a misdemeanor and, upon conviction thereof, shall be confined in a county or regional jail not more than six months or fined not more than $1,000, or both confined and fined.

(c) Any person who is required by the provisions of this article to submit information to the state Board of Pharmacy who knowingly submits thereto information known to that person to be false or fraudulent is guilty of a misdemeanor and, upon conviction thereof, shall be confined in a county or regional jail not more than one year or fined not more than $5,000, or both confined and fined.

(d) Any person granted access to the information required by the provisions of this article to be maintained by the state Board of Pharmacy, who shall willfully disclose the information required to be maintained by this article in a manner inconsistent with a legitimate law-enforcement purpose, a legitimate professional regulatory purpose, the terms of a court order or as otherwise expressly authorized by the provisions of this article is guilty of a misdemeanor and, upon conviction thereof, shall be confined in a county or regional jail for not more than six months or fined not more than $1,000, or both confined and fined.

(e) Unauthorized access or use or unauthorized disclosure for reasons unrelated to the purposes of this article of the information in the database is a felony punishable by imprisonment in a state correctional facility for not less than one year nor more than five years or fined not less than $3,000 nor more than $10,000, or both imprisoned or fined.

(f) Any practitioner who fails to register with the West Virginia Controlled Substances Monitoring Program and obtain and maintain online or other electronic access to the program database as required in subsection (a), section five-a, article nine of this chapter, shall be subject to an administrative penalty of $1,000 by the licensing board of his or her licensure. All such fines collected pursuant to this subsection shall be remitted by the applicable licensing board to the Fight Substance Abuse Fund created under section eight of this article. The provisions of this subsection shall become effective on July 1, 2016.

(g) Any practitioner or dispenser who is required to access the information contained in the West Virginia Controlled Substances Monitoring Program database as set forth in subsection (a), section five-a of this article and fails to do so as directed by the rules of his or her licensing board shall be subject to such discipline as the licensing board deems appropriate and on or after July 1, 2016, be subject to a $100 administrative penalty per violation by the applicable licensing board. All such fines collected pursuant to this subsection shall be transferred by the applicable licensing board to the Fight Substance Abuse Fund created under section eight of this article.

(h) Lack of available internet connectivity is a defense to any action brought pursuant to subsections (d) or (f) of this section.

§60A-9-8. Creation of Fight Substance Abuse Fund.

There is created a special revenue account in the state treasury, designated the Fight Substance Abuse Fund, which shall be an interest-bearing account. The fund shall consist of all moneys received from whatever source to further the purpose of this article. The fund shall be administered by the West Virginia Bureau for Public Health to provide funding for substance abuse prevention, treatment, treatment coordination, recovery and education. Any moneys remaining in the fund at the close of a fiscal year shall be carried forward for use in the next fiscal year. Fund balances shall be invested with the state's consolidated investment fund and any and all interest earnings on these investments shall be used solely for the purposes that moneys deposited in the fund may be used pursuant to this article. There is created within the Office of the Secretary of the Department of Health and the Department of Human Services the Grant Writer Pilot Project. The Secretary shall hire a person as a grant writer, who shall be placed within the Office of the Secretary. This person shall identify, application and monitoring policies and procedures to increase grant applications and improve management and oversight of grants. The grant writer shall focus his or her abilities on obtaining grants concerning the prevention and treatment of substance abuse. The grant writer is not eligible for civil service. The department shall report to the Legislative Oversight Commission on Health and Human Resources Accountability on the implementation of the new grant policy; the number of grants obtained; and an analysis examining the costs associated with obtaining a grant verses the federal money received.

§60A-9-9. Drugs of concern designation.

(a) The Board of Pharmacy may designate certain drugs as drugs of concern which must be reported to the database established pursuant to this article. The designation of a drug of concern shall be reserved for drugs which have a high potential for abuse. Whenever a medical services provider dispenses a drug of concern or whenever a prescription for a drug of concern is filled by: (i) A pharmacist or pharmacy in this state; (ii) a hospital, or other health care facility, for outpatient 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 number of the drug of concern dispensed;

(5) The quantity and dosage of the drug of concern 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, information about 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 drug of concern dispensed.

(b) The penalties set forth in section seven of this article shall not apply to drugs listed as drugs of concern. Failure to report may be considered a violation of the practice act of the prescriber and may result in discipline by the appropriate licensing board.

(c) The Board of Pharmacy may promulgate emergency rules pursuant to the provisions of section fifteen, article three, chapter twenty-nine-a of this code to effectuate the provisions of this section.

§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 $5,000.

(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 30-day period, or more than 86 and four-tenths 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 knowingly purchases, receives, or otherwise possesses more than seven and two-tenths grams in a 30-day period of ephedrine, pseudoephedrine, or phenylpropanolamine in any form without a

prescription is guilty of a misdemeanor and, upon conviction thereof, 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 thereof, 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 (1), subsection (a), 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 thereof, 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 12;

(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 thereof, shall be imprisoned in a state correctional facility for not less than two nor more than 10 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 §60A-10-6 of this code. Any such pharmacy, wholesaler, manufacturer, or distributor shall keep complete records of all sales and transactions as provided in §60A-10-8 of this code. 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 $100 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 thereof, shall be imprisoned in a state correctional facility for not less than two nor more than ten years, fined not more than $10,000, or both.

(b) Notwithstanding the provisions of subsection (a) of this section, 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 and the child thereby suffers serious bodily injury is guilty of a felony and, upon conviction thereof, shall be imprisoned in a state correctional facility for not less than three nor more than fifteen years, fined not more than $25,000, or both imprisoned and fined.

(c) As used in subsection (b) of this section, “serious bodily injury” shall have the same meaning as this term is defined in section one, article eight-b, chapter sixty-one of this code.

§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 $5,000 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 $10,000, 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 $10,000.

(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 $10,000.

(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.

The provisions of this article establishing the Multi–State Real-Time Tracking System shall expire on June 30, 2023.

§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 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.

(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 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 to do such work;

(4) Requiring licensed contractors to notify the Department of Health 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.

Donated Drug Repository Program

§60B-1-1. Definitions.

As used in this chapter:

“Board” means the West Virginia Board of Pharmacy.

“Controlled substance” means a drug, substance, or immediate precursor in Schedules I through V of §60A-2-1 *et seq*. of this code, and Schedules I through V of 21 CFR Part 1308.

“Donor” means any person, including an individual member of the public, or any entity legally authorized to possess drugs with a license or permit in good standing in the state in which it is located, including, but not limited to, a wholesaler or distributor, third party logistic provider, pharmacy, dispenser, clinic, surgical or health center, detention and rehabilitation center, laboratory, medical or pharmacy school, prescriber or other health care professional, or healthcare facility. Donor also means government agencies and entities that are federally authorized to possess drugs including, but not limited to, drug manufacturers, repackagers, relabelers, outsourcing facilities, Veteran Affairs hospitals, and prisons.

“Drugs” means both prescription and nonprescription (“over-the-counter”) drugs.

“Eligible patient” means an indigent person. However, if the recipient’s supply of donated drugs exceeds the need for donated drugs by indigent patients, then any other person in need of a particular drug can be an eligible patient.

“Eligible recipient” means a pharmacy, wholesaler, reverse distributor, hospital, federally qualified health center, nonprofit clinic, healthcare facility, an entity participating in a drug donation or repository program pursuant to another state’s law, or private office of a healthcare professional that has been authorized by the West Virginia Board of Pharmacy.

“Healthcare facility” means a facility licensed by the State of West Virginia as a:

(1) Nursing home;

(2) Personal care home;

(3) Assisted living community;

(4) Residential care facility for the elderly;

(5) Hospice;

(6) Hospital;

(7) Home health agency; or

(8) A similar entity licensed in the state in which it is located.

“Health care professional” means a person who is licensed by the State of West Virginia to practice as a:

(1) Physician;

(2) Registered nurse or licensed practical nurse;

(3) Physician assistant;

(4) Dentist or dental hygienist;

(5) Optometrist; or

(6) Pharmacist

“Indigent patient” means a patient whose income is at or below the income eligibility requirements of the West Virginia Medicaid program, or who is uninsured, underinsured, or enrolled in a public assistance health benefits program.

“Program” means the donated drug repository program established by rule pursuant to §60B-1-8 of this code.

“Transaction date” means the date on which ownership of the drugs is transferred between two participants of the program as established by contract or other arrangement. If no such contract or arrangement exists, the transaction date shall be the date the drug was accepted into inventory by the recipient.

§60B-1-2. Authority and waivers.

(a) A donor or eligible recipient may request a waiver or variance from the board with regard to any rule related to this program upon a showing that such action would be in the interest of public health and safety.

(b) The board and its rules have sole regulatory authority over the program. Notwithstanding any rule to the contrary:

(1) A person or entity may dispose of an eligible drug by donating it to an eligible recipient in accordance with the rules of this program.

(2) An eligible recipient including, but not limited to, a pharmacy may receive drugs from a donor in accordance with the rules of this program.

(3) An eligible recipient may accept donated drugs that are in tamper-evident packaging, including, but not limited to, drugs that have a tamper-evident seal on either their immediate, outer, secondary, or shipping container.

(4) An eligible recipient, including, but not limited to, a pharmacy, may receive, accept, replenish, repackage, and store donated drug samples in accordance with the rules of this program.

§60B-1-3. Eligible drugs.

(a) Drugs may only be dispensed pursuant to the program if:

(1) For prescription drugs, they do not expire before the completion of the medication by the eligible patient based on the prescribing health care professional’s directions for use and, for over-the-counter drugs, they do not expire before use by the eligible patient based on the directions for use on the manufacturer’s label; and

(2) The drugs were donated in unopened tamper-evident packaging as defined by United States Pharmacopeia General Chapter 659, Packaging and Storage Requirements, including, but not limited to, unopened unit-dose and multiple-dose packaging.

(b) The following drugs may not be donated to the program:

(1) Controlled substances;

(2) Drugs subject to a federal Food and Drug Administration managed risk evaluation and mitigation strategy pursuant to 21 U.S.C. §355-1 if inventory transfer is prohibited by such strategy; or

(3) Drugs that there is reason to believe are adulterated.

§60B-1-4. Eligible recipients.

(a) A pharmacy, hospital, wholesaler, reverse distributor, federally qualified health center, nonprofit clinic, healthcare facility, an entity participating in a drug donation or repository program pursuant to another state's law, or healthcare professional that is otherwise legally authorized to possess prescription drugs may become an eligible recipient for a period of one year by giving written notice to the board. That notice serves as authority for the recipient to participate in the program for a period of one year, unless revoked by the board. An eligible recipient may renew its authority by sending written notice in subsequent years.

(b) The board shall publish on its website the list of authorized recipients.

(c) An entity which chooses to participate in the program shall comply with this chapter and shall make all records available for audit by the board within five business days. Failure to comply with any provision of this chapter or statutes governing prescription drugs may result in revocation of authority to participate in the program. Such revocation shall be provided as a written notice to the recipient and shall include the specific requirements that were violated and the corrective actions necessary for the recipient to reinstate its authority to participate in the program.

§60B-1-5. Receipt, storage, and handling of donated drugs by an eligible recipient.

(a) A donor may donate drugs to an eligible recipient.

(b) An eligible recipient may receive, accept, donate, dispose, replenish, and store drugs that were either donated or repackaged as provided in subsection (f) of this section.

(c) Prior to the first donation from a new donor, a recipient shall verify and record the following:

(1) The donor meets the definition of "donor" as provided in §60B-1-1 of this code;

(2) The donor's name, address, phone number, and license number if applicable;

(3) The donor shall only make donations of drugs in accordance with the program;

(4) The donor shall ensure integrity of any drug requiring temperature control other than "room temperature storage" that is delivered by enclosing in the drug's packaging a USP-recognized method by which the eligible recipient can easily detect improper storage or temperature variations; and

(5) If applicable, the donor shall remove or redact any patient names and prescription numbers on donated drugs or otherwise maintain patient confidentiality by executing a confidentiality agreement with the eligible recipient.

(d) An eligible recipient shall store and maintain donated drugs in a secure and temperature-controlled environment that meets the drug manufacturers' recommendations and United States Pharmacopeial Convention (USP) standards.

(e) A participating eligible recipient shall keep all donated drugs physically or electronically separated from other inventory. Donated inventory may be used to replenish purchased inventory with the same drug name and strength that was previously dispensed or administered to an eligible patient. Replenishment shall follow applicable provisions of the federal 340B Drug Pricing Program.

(f) Drugs may be repackaged as necessary for storage, replenishment, dispensing, administration, or further donation. Repackaged drugs shall be labeled with the drug name, strength, and expiration date, and shall be kept in a separate designated area until inspected and initialed by a health care professional authorized to dispense.

(g) All donations received but not yet accepted into inventory shall be kept in a separate designated area.

(h) Prior to or upon accepting a donation into inventory, an eligible recipient shall maintain a written or electronic inventory of the donation, including:

(1) The transaction date;

(2) The name, strength, and quantity of each accepted drug; and

(3) The name, address, and phone number of the donor.

(i) No record of a donation other than as described in subsection (h) of this section may be required.

(j) All records required by this chapter shall be retained in physical or electronic format, on or off the recipient's premise for a period of six years.

(k) A donor or eligible recipient may contract with one another or a third-party to create and/or maintain records on each other's behalf.

(l) An identifier, such as a serial number or barcode, may be used in place of any or all information required by a record or label pursuant to this chapter if it allows for such information to be readily retrievable. Upon audit by the board the identifier on requested records shall be replaced with the original information. An identifier may not be used on patient labels when dispensing or administering a drug.

(m) A drug wholesaler, distributor, supplier, or outsourcing facility registered pursuant to state law except reverse distributors, shall comply with the requirements of 21 U.S.C. §§ 360eee-1 - 360eee-4 relating to drug supply chain security. If a donation's transaction history is required, the record of transaction history begins with the donor of the drugs, shall include all prior donations, and, if the drug was previously dispensed, may not include drug information that is not otherwise required to be on the drug's label.

§60B-1-6. Dispensing and distribution of donated drugs.

(a) An eligible recipient may only dispense or administer prescription drugs if otherwise permitted by law.

(b) Donation and the brokering or other facilitation of a donation of a drug pursuant to this program may not be considered wholesale distribution and may not require licensure as a wholesaler.

(c) Donated prescription drugs may only be dispensed to eligible patients pursuant to a valid prescription drug order. That patient shall be provided with appropriate counseling on the use of the prescription drug, including any potential side effects and the fact that the drug was donated.

(d) An eligible recipient may further donate unused prescription drugs to or receive unused prescription drugs from another eligible recipient in the program when one has the need for a drug, and another has it available. An inventory of such donations shall be created in accordance with the program unless both eligible recipients are under common ownership or common control.

(e) An eligible recipient shall dispose of any drug that does not meet all of the requirements of the program in one of the following ways:

(1) Return the drug to the donor;

(2) Destroy the drug through an incinerator licensed with the Environmental Protection Agency or other lawful method; or

(3) Transfer the drug to a reverse distributor.

(f) All such donated drugs to be disposed shall be quarantined in a separately designated area.

(g) An eligible recipient shall maintain a written or electronic record of disposal, including:

(1) The disposal method as described in subdivision (2), subsection (e) of this section;

(2) The date of disposal or quarantine; and

(3) The name, strength, and quantity of each drug disposed.

(h) No record of disposal other than as described in subsection (g) of this section may be required.

(i) Donated drugs may not be resold and shall be considered nonsalable. However, reimbursement for any handling fee authorized pursuant to this chapter does not constitute reselling.

(j) Before dispensing a donated drug, an eligible recipient shall inspect the drug to determine that it has not adulterated. The drug shall be repackaged into a new container or all previous patient information and pharmacy labeling shall be redacted or removed from the donated container.

(k) Dispensed drugs shall clearly indicate the final dispensers information and current patient information, and shall be properly labeled in accordance with the regulations of the board.

(l) An eligible recipient that provides donated drugs to an eligible patient shall maintain patient-specific written or electronic records in accordance with West Virginia law and the rules of the board. If also providing patients with purchased drugs, the eligible recipient shall also note, either on the face of a written prescription or in the electronic record of prescription, that a donated drug was dispensed to the patient.

(m) An expiration date is required on all donated drugs dispensed. The expiration date shall be brought forward to the filled prescription. If multiple packaged donated drugs are used to fill a single prescription with varied expiration dates, the shortest expiration date shall be used for the dispensed prescription.

(n) Dispensed drugs may not expire before the use by the patient based on the prescribing practitioners directions for use or, for over-the-counter medicine not dispensed pursuant to a prescription, the directions for use on the packages label.

(o) Dispensed drugs subject to a United States Food and Drug Administration managed risk evaluation and mitigation strategy pursuant to 21 U.S.C. §355-1 shall be managed and dispensed according to the requirements of that strategy.

(p) When complying with the provisions of this article and the rules and regulations adopted pursuant to this article, unless an action or omission constitutes willful or wanton misconduct, the following persons or entities shall not be subject to criminal or civil prosecution, criminal or civil liability for injury, death, or loss to person or property, other criminal or civil action, or disciplinary actions by licensing, professional, or regulatory agencies:

(1) A person that donates or gives drugs to an eligible recipient, including a drug wholesaler, drug manufacturer, reverse distributor pharmacy, third-party logistics provider, government entity, hospital, or health care facility;

(2) An eligible recipient;

(3) A health care professional who prescribes or dispenses a donated drug;

(4) The Board of Pharmacy;

(5) An intermediary that helps administer the program by facilitating the donation or transfer of drugs to eligible recipients;

(6) A repackager or manufacturer of a donated drug; and

(7) Any employee, volunteer, trainee, or other staff of individuals and entities listed in subdivisions (1) through (6).

(q) An entity participating in a drug donation or repository program operated by another state may participate in this program, and in the case of a pharmacy, may dispense donated drugs to residents of this state. This entity is required to comply with all laws and rules in this state unless such laws or rules differ or conflict with the laws or rules of the state in which the entity is located.

§60B-1-7. Handling fees.

(a) An eligible recipient may not charge or collect any fees from an eligible patient for drugs dispensed pursuant to this program. However, an eligible recipient may charge a handling fee for each donated drug that is dispensed. A handling fee may not exceed the reasonable costs of participating in the program including, but not limited to, the current and anticipated costs of educating eligible donors, providing technical support to participating donors, shipping and handling, labor, storage, licensing, utilities, advertising, technology, supplies, and equipment.

(b) Nothing in the preceding paragraph limits an eligible recipient from charging fees, including, but not limited to, a usual and customary charge, to donors, eligible recipients, health plans, pharmacy benefit managers, and other entities.

§60B-1-8. Rule-making.

The board shall propose rules for legislative approval in accordance with §29A-3-1 *et seq*. of this code to implement this chapter.

TITLE 15
LEGISLATIVE RULE
WEST VIRGINIA BOARD OF PHARMACY

SERIES 1
LICENSURE AND PRACTICE OF PHARMACY

§15-1-1. General.

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

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

1.3. Filing date -- May 3, 2024.

1.4. Effective date -- May 3, 2024.

1.5. Sunset Provision-- This rule shall terminate and have no further force or effect on August 1, 2034.

§15-1-2. Definitions.

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

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

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

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

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

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

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

2.1.7. "Compounding" means:

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

2.1.7.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

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

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

2.1.7.c. The following are not “compounding” and are exempt from USP 795 Compounding Standards:

2.1.7.c.1. the reconstitution of a drug pursuant to a manufacturer’s directions;

2.1.7.c.2. the act of tablet splitting, crushing, or capsule opening; except those prohibited by USP General Chapter 800 Hazardous Drugs;

2.1.7.c.3. upon the request of the prescribing practitioner and/or the patient for whom the prescription is ordered or such patient’s agent, the addition of therapeutically inert, nonallergenic flavoring agents to a commercially manufactured product, not in excess of five percent (5%) of the preparation’s total volume;

2.1.7.c.4. the combining of commercially manufactured ready to use products under the following conditions:

2.1.7.c.4.A. no more than four (4) commercially manufactured ready-to-use products are combined;

2.1.7.c.4.B. all products combined are FDA approved;

2.1.7.c.4.C. combining is not done in anticipation of medication orders;

2.1.7.c.4.D. USP 795 beyond use dating (BUDs) is followed;

2.1.7.c.4.E. combining with hazardous drugs from final dosage forms, listed in NIOSH List Tables 2 and 3 requires assessment of risk, the pharmacist or pharmacy technician should wear personal protective equipment as described in USP Chapter 800 and must use compounding equipment dedicated solely for hazardous drugs;

2.1.7.c.4.F. a valid prescription shall serve as the combining record, including the name and amount or concentration, lot number, and expiration date of each ingredient; and

2.1.7.c.4.G. the prescription label shall comply with the labeling requirements as set forth in West Virginia CSR § 15-1-18.

2.1.8. "Confidential information" means patient-identifiable information maintained by any person in connection with the practice of pharmacist care in the patient record or which is communicated to the patient as part of patient counseling, or which is communicated by the patient to the person providing pharmacist care.

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

2.1.10. "Cosmetic" means:

2.1.10.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;

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

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

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

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

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

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

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

2.1.15.a. To dispense or administer;

2.1.15.b. 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;

2.1.15.b.1. 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;

2.1.15.b.2. Intracompany sales.

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

2.1.17. "Drug" means:

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

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

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

2.1.17.d. Articles intended for use as a component of any articles specified in paragraph 2.1.17.a., 2.1.17.b. or 2.1.17.c. of this subdivision.

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

2.1.18.a. Evaluation of the prescription drug orders and, if available, patient records for:

2.1.18.a.1. Known allergies;

2.1.18.a.2. Rational therapy-contraindications;

2.1.18.a.3. Reasonable dose and route of administration; and

2.1.18.a.4. Reasonable directions for use.

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

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

2.1.18.c.1. Drug-drug;

2.1.18.c.2. Drug-food;

2.1.18.c.3. Drug-disease; and

2.1.18.c.4. Adverse drug reactions.

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

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

2.1.19.a. An electronic prescription order;

2.1.19.b. A refill authorization request;

2.1.19.c. A communication; or

2.1.19.d. Other patient care information.

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

2.1.21. “Electronic supervision” means that a licensed pharmacist provides supervision of the pharmacy through the utilization of audio and visual technology, which may be used with both direct and indirect supervision tasks of a pharmacy technician or pharmacy technician trainee.

2.1.22. “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.

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

2.1.24. “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.

2.1.25. “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.

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

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

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

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

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

2.1.31. "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.

2.1.32. “Nuclear pharmacist” means a pharmacist who has been certified in the specialty of nuclear pharmacy.

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

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

2.1.34.a. the applicant is a new business;

2.1.34.b. the applicant is an established business that is transferred to a successor;

2.1.34.c. the applicant is an established business in which fifty percent (50%) ownership or

more is transferred to a new owner;

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

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

2.1.35. "Outpatient pharmacy" means any pharmacy, apothecary, or place within this state where drugs are dispensed and sold at retail or displayed for sale at retail and where the practice of pharmacy is conducted and pharmacist care is provided; and any place outside of this state where drugs are dispensed and the practice of pharmacy and pharmacist care is provided to residents of this state.

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

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

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

2.1.39. "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.

2.1.40. "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.

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

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

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

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

2.1.42.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

2.1.42.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.

2.1.42.d.1. 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

2.1.43. "Pharmacy technician" means registered supportive personnel who work under the direct or electronic 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.

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

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

2.1.46. "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.

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

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

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

2.1.50. “Refill” means a subsequent dispensing of the medicine ordered by the practitioner in the original prescription order, based upon the practitioner’s authorization for the subsequent dispensing in that original prescription order.

2.1.51. “Renewal” means a new prescription drug order for the same medication previously prescribed

for a patient, authorized by the practitioner without change or modification from the original prescription order after the authorized number of refills of the original prescription order has been exhausted.

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

2.1.53. “Secretary" means the Secretary of the West Virginia Board.

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

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

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

2.1.56.a. Prevention of unauthorized copying;

2.1.56.b. Prevention of erasure or modification; and

2.1.56.c. An ability to prevent counterfeit prescriptions or prescription pads.

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

§15-1-3. General Provisions.

3.1. Officers of the Board. – The members of the board shall annually elect as officers of the Board one (1) member to serve as President of the Board, one (1) to serve as Vice-president and one (1) to serve as Secretary, all to serve a one (1) year term or until their successors are elected. The election is to be held in June each year.

3.2. Official Seal – The Board hereby reaffirms and readopts, as the official seal of the Board the following: The outer circle of the seal has inscribed in it ‘West Virginia Board of Pharmacy’; and the inner circle of the seal consists of a base upon which rests a graduate entwined about which there is an Aesculapius serpent and holding in balance a set of scales, an impression of which is affixed to it.

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

3.4. Record of proceedings; registration of applicant; certified copies of records prima facie evidence, report to governor. – The Secretary of the Board shall keep a record of its proceedings and a register of all applicants for license or registration, showing for each, the date of his or her application, name, age, educational and other qualifications, place of residence, whether an examination was required, whether the applicant was rejected or a certificate of licensure or registration granted, the license or registration number, if required, and any suspension or revocation of any license or registration. The books and register of the Board shall be open to public inspection at all reasonable times, and the books and register, or a copy of any part of them, certified by the Secretary and attested by the seal of the Board, is prima facie evidence of all matters recorded by the Board.

3.5. Roster of licensed or registered persons. – The Secretary shall prepare and maintain a complete roster of all persons, granted a board authorization, alphabetically and by class or type and by whether within

or without the state.

3.6. Power of Inspection and Investigation – The authorized agents of the Board may inspect and investigate in a lawful manner and during regular business hours all places or persons holding a board authorization. The investigation may include, but not be limited to, all inventories, invoices for prescription drugs, selling prices, and other records required by law, acts of individuals and facilities, but shall not extend to financial data or sales data other than shipment data or pricing data; unless the owner, operator or agent in charge of the controlled premises consents in writing. The board authorization holder shall allow access to selling prices only when needed for a specific investigation or inquiry by the Board regarding a particular drug.

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

3.7.1. the ability of the pharmacist to practice pharmacist care with reasonable skill, competency, or safety to the public is impaired because the board authorization holder's cognitive, interpersonal, or psychomotor skills are affected by psychiatric, psychological, or emotional problems, or excessive alcohol or drug use or addiction; or

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

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

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

§15-1-4. Internship Requirements.

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

4.2. To be eligible to practice as a pharmacy intern, an applicant must:

4.2.1. make application to the board on a form provided by the Board;

4.2.2. pay the required application fee;

4.2.3. meet all other requirements for licensure; and

4.2.4. complete a criminal history records check as prescribed in § 29.

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

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

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

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

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

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

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

4.6.4 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.

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

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

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

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

§15-1-5 Confidential Information.

5.1. All licensees and registrants must comply with the Health Insurance Portability and Accountability Act ("HIPAA"), 45 CFR § 160, 45 CFR § 162, and 45 CFR § 164.

§15-1-6 Transfer of Prescription Drugs.

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

6.1.1. Transfer of drugs without prescription.

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

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

6.1.1.b.1. the name of the drug and its quantity;

6.1.1.b.2. the date of transaction;

6.1.1.b.3. the permittee or practitioner to whom the prescription drug was transferred; and

6.1.1.b.4. the selling price.

6.1.1.c. The record of the transfer shall be kept in the pharmacy and be immediately accessible within one year from the date of transfer, and available within seventy-two (72) hours if between one year and five years from the date of transfer.

6.1.1.d. Any pharmacy with transfers of prescription drugs that exceed the five percent restriction set forth in paragraph 9.6.1.1a 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.

6.1.2. Transfer of drugs with a Prescription.

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

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

6.1.2.a.2. The drug's name and quantity; and

6.1.2.a.3. Directions for use.

6.1.2.a.3.A. If the prescription is written on a practitioner's date prescription blank, the order shall contain the following:

6.1.2.a.3.A.1. The practitioner's printed name, address, professional designation and practitioner identifier number; and

6.1.2.a.3.A.2. The practitioner's signature.

6.1.2.a.3.B. If the prescription is written on an institutional prescription blank, the order shall contain the following:

6.1.2.a.3.B.1. The printed name of the practitioner and DEA number with suffix; and

6.1.2.a.3.B.2. The practitioner's signature.

6.1.2.a.3.C. No sticker or other substance shall be allowed to obliterate or cover any of the information required by this subdivision.

6.2. Samples

6.2.1. Pharmacies may not sell, purchase, or trade or offer to sell, purchase, or trade any prescription

drug sample.

§15-1-7. Refilling Prescription Orders.

7.1. A pharmacist may not refill any prescription order containing a drug if the label of the original container bears the statement, “CAUTION: Federal Law Prohibits Dispensing Without Prescription”, or “RX Only”, unless the practitioner has authorized the refill by written notation on the original prescription order. Subsequent refill authorization shall be treated as a new prescription order.

7.2. If a prescription order is refillable, the date of the refill and the handwritten initials of the pharmacist shall be recorded upon the original written prescription order; if an Automated Data Processing System is used to document the refill, such documentation shall be completed in accordance with West Virginia Title 15 Code of State Rules Series 4.

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

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

§15-1-8. Transferring Prescription Orders Between Pharmacies.

8.1. The pharmacist or pharmacy intern shall, upon the request of the patient, transfer the prescription information to the pharmacy designated by the patient. Pharmacy interns are prohibited from transferring controlled substances.

8.2. The transfer of original prescription order information is permissible between pharmacies if the transfer is communicated directly between pharmacists or pharmacy interns, and the following occurs:

8.2.1. The transferring pharmacist or pharmacy intern:

8.2.1.a. Writes the word “VOID” on the face of the original prescription order; for electronic prescriptions, information that the prescription has been transferred must be added to the prescription record;

8.2.1.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 or pharmacy intern receiving the prescription information; for electronic prescriptions, information that the prescription has been transferred must be added to the prescription record; and

8.2.1.c. Records the date and time of the transfer and his or her first and last name;

8.2.2. The pharmacist or pharmacy intern receiving the transferred prescription order information:

8.2.2.a. Writes the word “TRANSFER” on the face of the transferred prescription; and

8.2.2.b. Provides all the information required to be on a prescription and includes:

8.2.2.b.1. Date of issuance of the original prescription;

8.2.2.b.2. Number of refills on the original prescription;

8.2.2.b.3. The date the original prescription was dispensed;

8.2.2.b.4. The number of valid refills remaining and date of last refill;

8.2.2.b.5. The pharmacy's name, address, DEA registry number and the original prescription number from which the prescription was transferred; and

8.2.2.b.6. The first and last name of the transferring pharmacist or pharmacy intern;

8.2.3. A pharmacist or pharmacy intern may give a copy of a prescription clearly marked "For Information Only" to a patient; and

8.2.4. 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.

8.3. 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.

8.4. 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 seventy-two (72) hours of request if date of last refill is between one (1) and five (5) years.

8.5. Pharmacies accessing a common electronic file or database used to maintain required dispensing information are not required to transfer prescription drug orders or information for dispensing purposes between or among pharmacies participating in the same common prescription file. Provided, the common electronic file or database shall contain complete records of each prescription drug order and refill dispensed, and the system shall have the capability at the pharmacy refilling the prescription drug order or at the pharmacy where the prescription is transferred to generate a hard copy record of each prescription drug order transferred or accessed for purposes of refilling.

§15-1-9. Returning Drugs and Devices.

9.1. 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:

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

9.1.2. 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

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

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

9.3. 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.

9.4 Drugs must be returned in compliance with a Donated Drug Repository Program as permitted in W.Va. Code 60B-1-1 *et seq*. and W. Va. 15 CSR 20.

§15-1-10. Drug Product Selection and Substitution.

10.1. 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 and any authorized generics 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.

§15-1-11. Equipment, Facilities and Record Systems.

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

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

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

11.2. A pharmacy shall continually possess the following:

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

11.2.2. Supplies necessary to ensure the physical, equipment, and environmental requirements established by USP;

11.2.3. For a pharmacy compounding ophthalmic preparations, IV additives, enteral nutritional products or other pharmaceuticals requiring more sophisticated techniques, the proper equipment and facilities to prepare sterile products and meet the requirements of good compounding practice;

11.2.4. 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;

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

11.2.6. 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;

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

11.2.8. The most currently available Pharmacy Law Book and book of Rules and Regulations published by the Board, provided that a readily retrievable electronic copy may suffice.

§15-1-12. Sterile Pharmaceutical Compounding.

12.1. Permitting and Control.

12.1.1. A pharmacy compounding or mixing prescription orders for sterile solutions or suspensions 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.

12.1.2. 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.

12.1.3. 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.

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

12.2.1. A completed Board application form;

12.2.2. A copy of the Policy and Procedure Manual;

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

12.3. 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 the following standards of:

12.3.1. The 2023 United States Pharmacopeia (USP) Chapter 797 Pharmaceutical Compounding – Sterile Preparations;

12.3.2 The 2023 United States Pharmacopeia (USP) Chapter 800 Hazardous Drugs; and

12.3.3. The Controlled Environment Testing Association's (CETA) Certification Guide for Sterile Compounding Facilities or a substantially similar standard for certification completed by a qualified independent certifier indicating that the compounding area is meeting its design and air quality specifications.

12.4. General Requirements.

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

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

12.4.2.a. The drug's expiration date;

12.4.2.b. The date of preparation; and

12.4.2.c. The drug's control number.

12.4.3. 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.

12.5. Reference Works. Minimum reference works required in a pharmacy with a Sterile Pharmaceutical Compounding:

12.5.1. A current edition, in either print or electronic media, of a drug information and reference compendium such as Elsevier Gold Standard/Clinical Pharmacology, Facts & Comparisons, or other appropriate compendium approved by the board; and

12.5.2. Handbook of Injectable Drugs published by the American Society of Health System Pharmacists, or its equivalent.

§15-1-13. Licensure and Control of Nuclear Pharmacies.

13.1. General Requirements.

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

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

13.2. Space.

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

13.2.2. A pharmacy handling radiopharmaceuticals shall provide a radioactive storage and product decay area which meets the requirements of the appropriate federal agency and the 2023 United States Pharmacopeia (USP) Chapter 825 Radiopharmaceuticals.

13.3. Dispensing and labeling.

13.3.1. 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.

13.3.2. 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:

13.3.2.a. the standard radiation symbol;

13.3.2.b. The words "CAUTION-Radioactive Material";

13.3.2.c. the name of the radio nucleotide;

13.3.2.d. the chemical form;

13.3.2.e. The amount of radioactive material contained in millicuries or microcuries;

13.3.2.f. The volume in milliliters, if the material is a liquid;

13.3.2.g. The requested calibration time for the amount of radioactivity contained; and

13.3.2.h. The practitioner's name and the assigned lot number.

13.3.3. The immediate inner container shall be labeled with:

13.3.3.a. The standard radiation symbol;

13.3.3.b. The words "CAUTION-Radioactive Material"; and

13.3.3.c. The prescription number

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

13.4. 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.

§15-1-14. Sanitary Regulation of Pharmacies.

14.1. The pharmacy shall have undergone a pharmacy inspection by the Board or authorized agent thereof; and possess the following minimum requirements for a pharmacy:

14.1.1. Each Pharmacy shall be of sufficient size, as determined by the Board, to allow for the safe and proper storage of Prescription Drugs and for the safe and proper Compounding and/or preparation of Prescription Drug Orders.

14.1.2. Each Pharmacy shall maintain an area designated for the provision of Patient Counseling services. This area shall be designed to provide a reasonable expectation of privacy of Protected Health Information.

14.1.3. 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 an orderly condition.

14.1.4. All pharmacist and pharmacy interns when providing pharmacist care, shall wear 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. Provided, that only pharmacists and pharmacy interns may wear a white coat or jacket.

14.1.5. 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 United States Pharmacopeia–National Formulary (USP-NF) and/or the Manufacturer's or Distributor's Product Labeling unless otherwise indicated by the Board.

14.1.6. Each Pharmacy shall have access to a sink with hot and cold running water that is convenient to the prescription preparation, patient care, and compounding area for the purpose of hand scrubs prior to pharmacist care.

14.1.7 The Pharmacy shall carry and utilize the equipment and supplies necessary to conduct a Pharmacy in a manner that is in the best interest of the patients served and to comply with all State and Federal laws.

14.1.8. The Pharmacy shall provide a means for patients to prevent disclosure of Confidential Information or personally identifiable information that was obtained or collected by the Pharmacist or Pharmacy incidental to the Delivery of Pharmacist Care Services other than as authorized by law or rules of the Board.

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

15.1. Statement of purpose

15.1.1. 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.

15.1.2. 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.

15.2. Freedom of practice.

15.2.1. 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.

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

15.3. Uncertain Prescription orders.

15.3.1. No pharmacist, pharmacy intern, or pharmacy technician shall compound or dispense any prescription order which, in his or her judgment and/or 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.

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

15.5. Confidential information.

15.5.1. 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:

15.5.1.a. Agents of the Board engaged in the performance of their official duties;

15.5.1.b. Another pharmacist or pharmacy technician when necessary;

15.5.1.c. The patient or his or her authorized representative;

15.5.1.d. The prescriber or other members of the health care team treating the patient; or

15.5.1.e. Any person authorized by law to receive the information.

15.6. 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.

15.7. 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.

15.8. 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.

15.9. Promotion of and reliability of drugs.

15.9.1. 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.

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

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

15.11 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.

15.12. 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.

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

15.13.1. 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:

15.13.1.a. the name of the caller;

15.13.1.b. the time and date of transmission; and

15.13.1.c. the hand-written initials of the receiver.

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

15.13.2.a. To the correct patient (or agent of the patient) for whom the drug or devise was prescribed;

15.13.2.b. with the correct drug in the correct strength, quantity, and dosage form ordered by the practitioner, unless converting a prescription order in accordance with W. Va. Code § 30-5-35; a pharmacist may substitute a generic drug pursuant to W. Va. Code § 30-5-12b; and

15.13.2.c. With correct labeling (including directions for use) as ordered by the practitioner;

15.13.3. 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;

15.13.4. 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;

15.13.5. 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;

15.13.6. To counsel or inform patients about their drugs, which may include supplemental media according to the pharmacist's professional judgment, to the patient, care giver, or agent. An offer to counsel shall be made by the pharmacist or designee in an oral communication with the patient, care giver or agent who presents a new prescription order, unless in the professional judgment of the pharmacist it is permissible for the offer to counsel to be made in a written communication, by telephone, in person, or in a manner determined by the pharmacist to be appropriate. The exercise of and reasons for this judgment shall be documented including the hand-written pharmacist's initials. An offer to counsel has not been made by a mere question of whether the patient has any questions.

15.13.6.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:

15.13.6.a.1. The name of and a description of the medication;

15.13.6.a.2. the dosage form, route of administration, degree, and duration of drug therapy;

15.13.6.a.3. Special directions and precautions for preparation, administration, and use by the patient;

15.13.6.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;

15.13.6.a.5. Techniques for self-monitoring drug therapy;

15.13.6.a.6. Proper storage and handling;

15.13.6.a.7. Prescription refill information; and

15.13.6.a.8. Any action to take in the event of a missed dose.

15.13.6.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;

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

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

15.13.7.b. The patient's individual history including disease states, known allergies and drug reactions, and a comprehensive list of medications and relevant devices; and

15.13.7.c. The pharmacist's comments regarding the patient's therapy;

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

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

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

15.13.10.a. Require the knowledge, ability or skill of a licensed pharmacist and

15.13.10.b. Attempt to improve the therapeutic outcome to the patient of the pharmacist care provided by the pharmacist.

15.14. Violation of the rules of professional conduct.

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

15.14.2. 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 may result in disciplinary action. To the extent not otherwise provided, pharmacy interns and pharmacy technicians must comply with the requirements of subsection 19.15.13 of this section to the extent permitted by his or her scope of practice.

15.14.3. 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.

15.15. 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.

§15-1-16. Duties and Responsibilities of the Pharmacist-in-Charge.

16.1. 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.

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

16.2.1. 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;

16.2.2. The pharmacist-in-charge shall document and notify the pharmacy permit holder of potential violations of any statute, rule or court order existing within the pharmacy. The PIC shall provide the permit holder verbal or electronic mail communication of any violations. Documentation shall be kept on file at the pharmacy. If appropriate action has not been taken within a reasonable amount of time the pharmacist-in-charge shall provide the pharmacy permit holder written notification of the violation(s) and a copy shall be retained in the pharmacy. If appropriate action has not been taken or significant progress achieved within a reasonable amount of time the pharmacist-in-charge shall provide a written notice to the permit holder with a copy submitted to the Chief Compliance Officer at 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 documented notice to the pharmacy permit holder as outlined in this section. The pharmacy permit holder shall be responsible for such violations. Nothing precludes the pharmacist-in-charge from immediately notifying the Board of any violations;

16.2.3. 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;

16.2.4. 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;

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

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

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

16.2.7.a. Change of employment or responsibility as the PIC;

16.2.7.b. Change of ownership of the pharmacy;

16.2.7.c. Change of address of the pharmacy;

16.2.7.d. Permanent closing of the pharmacy which shall be accompanied with a statement of the location where records will be retained for the required time period; or

16.2.7.e. The separation of employment of any pharmacist, pharmacy intern, pharmacy technician, or pharmacy technician trainee for any confirmed drug-related reason, including but not limited to, adulteration, abuse, theft, or diversion.

16.2.7.f. Notification shall include the reason for the termination. If it is the employment of the Pharmacist-in-Charge that is terminated, the owner and/or pharmacy permit holder shall immediately notify the Board of Pharmacy.

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

16.2.9. 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;

16.2.10. 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

16.2.11. 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:

16.2.11.a. The name and address of the pharmacy;

16.2.11.b. The location of the automated equipment; and

16.2.11.c. The identification of the responsible pharmacist.

16.3. 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.

16.3.1. 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.

16.3.2. 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.

§15-1-17. Manner of Issuance of a Prescription.

17.1. 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.

17.1.1. 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.

17.1.2. 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.

17.1.3. 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.

17.1.4. 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.

17.1.4.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:

17.1.4.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;

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

17.1.4.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.

17.1.6. 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:

17.1.6.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);

17.1.6.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;

17.1.6.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.

17.1.7. 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:

17.1.7.a. the identity of the transmitting agent is included in the order;

17.1.7.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;

17.1.7.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;

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

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

17.1.8 Electronic Data Intermediaries.

17.1.8.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.

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

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

17.1.8.b.2. Transmit prescriptions to the pharmacy of the patient’s choice.

17.1.8.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.

§15-1-18. Labeling.

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

18.1.1. 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:

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

18.1.1.a.1. the name of the drug;

18.1.1.a.2. the route of administration, if other than oral;

18.1.1.a.3. the strength and volume, where appropriate, expressed in the metric system whenever possible;

18.1.1.a.4. the control number and expiration date;

18.1.1.a.5. special storage conditions, if required; and

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

18.1.1.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:

18.1.1.c.1. identification of the dispensing pharmacy;

18.1.1.c.2. the patient's name;

18.1.1.c.3. the date of dispensing;

18.1.1.c.4. then name of the drug dispensed; and

18.1.1.c.5. the strength, expressed in the metric system whenever possible.

18.1.2. All drugs dispensed to inpatients for self-administering shall be labeled in accordance with subdivision 22.18.1.4 of this section.

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

18.1.3.a. the name of the solution, the lot number, and the volume of the solution;

18.1.3.b. the patient's name;

18.1.3.c. the infusion rate;

18.1.3.d. the bottle sequence number or other system control number;

18.1.3.e. the name and quantity of each additive;

18.1.3.f. the date of the preparation;

18.1.3.g. the beyond-use date and time of parental admixture; and

18.1.3.h. ancillary precaution labels.

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

18.1.4.a. the name (including store number, if any), address, and telephone number of the pharmacy dispensing the drug;

18.1.4.b. the name of the patient for whom the drug is prescribed; or, if the patient is an animal, the last name of the owner, name and species of the animal; Provided that, if the prescription is for expedited partner therapy as permitted by West Virginia Code Chapter 16, Article 4F, then the words “Expedited Partner Therapy” or the designation “EPT” may be written for the name of the patient;

18.1.4.c. the name of the prescribing practitioner;

18.1.4.d. directions stated on the prescription order, and medication purpose/indication if included on the prescription order;

18.1.4.e. the date filled;

18.1.4.f. any cautions which may be required by federal or state law;

18.1.4.g. the prescription number of the prescription drug order;

18.1.4.h. the name or initials of the dispensing pharmacist;

18.1.4.i. the proprietary or generic name of the drug dispensed, and its strength;

18.1.4.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-source drugs;

18.1.4.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;

18.1.4.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;

18.1.4.j. drug quantity;

18.1.4.k. number of remaining refills;

18.1.4.l. auxiliary information;

18.1.4.m. the name of the manufacturer or distributor of the drug; and

18.1.4.n. the beyond-use date.

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

18.1.5.a. the standard radiation symbol;

18.1.5.b. the words “Caution- Radioactive Material; and

18.1.5.c. the prescription number.

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

18.1.6.a. the standard radiation symbol;

18.1.6.b. the words “Caution- Radioactive Material”;

18.1.6.c. the radionuclide and chemical form;

18.1.6.d. the activity and date and time of assay;

18.1.6.e. the volume, if in liquid form;

18.1.6.f. the requested activity and the calibrated activity;

18.1.6.g. the prescription number;

18.1.6.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;

18.1.6.i. the name and address of the nuclear pharmacy;

18.1.6.j. the name of the practitioner; and

18.1.6.k. the lot number of the prescription.

§15-1-19. Pharmacist Consultants.

19.1. Locations requiring a pharmacist to serve as a pharmacy consultant:

19.1.1. Hospital or medical clinic without a pharmacy;

19.1.2. Humane society;

19.1.3. Weight loss clinic (registered as a facility);

19.1.4. Urgent care clinic;

19.1.5. Long Term Care Facility, including but not limited to, skilled nursing facilities, intermediate nursing facilities, nursing homes, extended care facilities, assisted living facilities, rest homes, and personal care centers;

19.1.6. Opioid Treatment Facility or Medication Assisted Treatment Facility;

19.1.7. Jails and correctional facilities.

19.2. Locations not required to have a pharmacist consultant;

19.2.1 Teaching institutions/researcher;

19.2.2 Emergency services;

19.2.3 Law enforcement;

19.2.4 Veterinary hospital/clinic

19.3. Requirements and registration.

19.3.1. 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.

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

19.3.2.a. The consultant pharmacist shall file an application with the Board for each institution, place or person to whom consulting services are provided;

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

19.3.2.b.1. The name, address and phone number of the applying consultant and his or her license number;

19.3.2.b.2. The name, address, phone number and type of institution, entity or person receiving the consulting services;

19.3.2.b.3. A description of the services to be provided by the consultant; and

19.3.2.b.4. The name and signature of the facility administrator.

19.3.3. 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.

19.3.4. The fee for registration as a consultant is forty dollars ($40.00) for each registration.

19.4. 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.

19.5. Responsibilities.

19.5.1. 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.

19.5.2. 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:

19.5.2.a. Prescriptions;

19.5.2.b. Floor stock;

19.5.2.c. Emergency boxes or kits;

19.5.2.d. Investigational drugs;

19.5.2.e. Samples; and

19.5.2.f. Outdated or discontinued drugs.

19.5.3. 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:

19.5.3.a. Transcribing drug orders and prescription ordering;

19.5.3.b. Prescription delivery system and in-house verification;

19.5.3.c. Drug recall;

19.5.3.d. Automatic stop orders;

19.5.3.e. Formulary or standards for drug quality;

19.5.3.f. Systematic review of drug orders;

19.5.3.g. Reconciliation of controlled substances;

19.5.3.h. Disposition by the following means of prescriptions not totally consumed by the patient:

19.5.3.h.1. Return to pharmacy for credit; and

19.5.3.h.2. Destruction by the pharmacist in the presence of a registered nurse; and

19.5.3.i. In-serving drug education for other personnel.

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

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

19.5.6. 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.

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

19.5.6.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.

19.5.7. 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.

§15-1-20. Specialized Dispensing Systems.

20.1. Definition.

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

20.2. Types.

20.2.1. 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:

20.2.1.a. The name and strength of the drug;

20.2.1.b. The name of the manufacturer or the packager;

20.2.1.c. The lot number; and

20.2.1.d. The expiration date.

20.2.2. 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:

20.2.2.a. The name and strength of each drug contained in the unit of use packet;

20.2.2.b. The name of the manufacturer or the packager of each drug in the unit of use packet;

20.2.2.c. The lot number of each drug in the unit use packet; and

20.2.2.d. The expiration date of each drug in the unit of use packet;

20.2.3. 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:

20.2.3.a. The name and strength of the drug contained in the punch card;

20.2.3.b. The name of the manufacturer or packager of the drug contained in the punch card;

20.2.3.c. The lot number of the drug contained in the punch card;

20.2.3.d. The expiration date of the drug contained in the punch card; and

20.2.3.e. All other information required to be on the label of a completed prescription order.

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

20.3.2. 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.

20.3.3. 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.

20.4. Methods of supplying drugs and devices.

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

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

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

20.4.3.a. Drugs in emergency kits are to be administered only by those persons licensed to administered drugs;

20.4.3.b. The drugs in the emergency kit are of such nature that their absence would threaten the survival of the patients or intended recipients;

20.4.3.c. The contents of the emergency kit are determined by the pharmacist consultant and the medical director and the nursing director;

20.4.3.d. The emergency kit is sealed so that it is obvious if it has been opened and it is stored under secure conditions;

20.4.3.e. Administration of drugs from the kit is ordered by a practitioner and a record kept of administration;

20.4.3.f. Drugs stocked in the emergency kit are unit dose packaged;

20.4.3.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

20.4.3.h. Any emergency kit containing controlled substances is kept only at a facility holding a controlled substance permit from the Board.

§15-1-21. Institutions and Other Places Needing a Controlled Substance Permit.

21.1. 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 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.

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

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

21.3.1. Manufacturer and wholesaler $50.00

21.3.2. Hospital or Clinic $50.00

21.3.3. Extended care facility or nursing home $25.00

21.3.4. Non-government training institution $25.00

21.3.5. Non-government researcher $25.00

21.3.6. Pharmacy $10.00

21.3.7. Non-government jails and correctional facilities $25.00

21.3.8. Non-government rescue or emergency squads $25.00

21.3.9. Non-government humane societies $25.00

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

§15-1-22. Emergency Dispensing by Pharmacists.

22.1. If a pharmacist is unable to obtain a refill authorization from a health care professional who issued the prescription and the pharmacy at which the pharmacist works has a record of the prescription for the drug in the name of the patient who is requesting it, a pharmacist may dispense an emergency supply of a prescription drug of life-sustaining medication or continue therapy for a chronic condition of the patient, when in the professional judgement of the pharmacist, failure to dispense could result in harm to the health of the patient. An amount not to exceed a thirty (30) day supply or the standard unit of dispensing of a non-controlled substance may be provided to the patient as demonstrated by records maintained by the pharmacy. An amount not to exceed a seventy-two (72) hour supply of a Schedule III, IV or V may be provided to the patient

as demonstrated by records maintained by the pharmacy. A pharmacist shall not dispense a particular drug to a patient as an emergency supply more than once in any twelve-month period.

22.1.1. A pharmacist who dispenses under §15-1-22 shall:

22.1.1.a. maintain a record of the dispensing for one (1) year from the date of dispensing;

22.1.1.b. notify the health professional who prescribed the initial professional within seventy-two (72) hours after the drug is dispensed;

22.1.1.c. if possible, obtain authorization for additional dispensing from one of the health professionals responsible for the patients care; and

22.1.1.d. a pharmacist who dispenses under this section may do so once per year for each particular drug.

§15-1-23. West Virginia Official Prescription Paper Program Rules.

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

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

23.2.1. 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;

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

23.2.2.a. 1-24;

23.2.2.b. 25-49;

23.2.2.c. 50-74;

23.2 2.d. 75-100;

23.2.2.e. 101-150; and

23.2.2.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;

23.2.3. shall contain space for the prescriber to indicate number of refills, if any, or to indicate no refills;

23.2.4. shall provide space for the patient's name and address, the prescribing practitioner's signature;

23.2.5. 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; Provided that, if a practitioner does not have authority to prescribe controlled substances, then no

DEA number shall be required, and, instead, the following statement shall be printed: “No Controlled Substances Authority”; and, Provided further that, if a practitioner is a veterinarian, no NPI number shall be required;

23.2.6. 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.".

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

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

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

23.5.1. 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.

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

23.5.2.a. Estimated number of blanks affected;

23.5.2.b. Control numbers if available; and

23.5.2.c. Suspected reason for destruction, theft, or loss.

23.5.3. West Virginia Official Prescription Paper does not have to come pre-printed from a vendor, but may also be created at the point of prescribing with software-generated prescriptions by printing on plain paper with secure technology accessible only by the prescriber and his or her authorized agent that results in a tamper resistant prescription as required by subsection 23.3 of this section.

§15-1-24. Practice of Telepharmacy.

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

24.1.1. for a pharmacist to provide direct patient-care activities, when the patient is unable to be present in the pharmacy for a personal, face-to-face interaction, provided the pharmacist is:

24.1.1.a. licensed to practice pharmacist care in West Virginia; or,

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

24.1.2. for drug regimen review of prescription orders for a patient in an institutional facility, for the pharmacist to authorize the dispensing and administration, provided the pharmacist is licensed to practice pharmacist care in West Virginia.

§15-1-25. Criminal History Record Check.

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

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

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

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

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

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

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

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

25.9. An initial licensure application is not complete until the Board receives the results of a state and criminal history record check conducted by the State Police or another entity duly authorized by the Board. The Board shall not grant an application for licensure submitted by any applicant who fails or refuses to submit the criminal history record check required by this section.

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

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

25.11. 1. To the individual who is the subject of the criminal history record check;

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

25.11. 3. Pursuant to a court order.

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

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. -- This rule relates 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. -- May 2, 2023

1.4. Effective Date. -- May 2, 2023

1.5. Sunset Date -- This rule shall terminate and have no further force or effect on August 1, 2033.

§ 15-2-2. Definitions.

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

2.1.1. "Act" means the Uniform Controlled Substances Act as provided in W. Va. Code §60A-1-101 et. seq.

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

2.1.3. "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.

2.1.4. "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.

2.1.5. "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.

2.1.6. "Individual Practitioner" means a physician, dentist, veterinarian or other individual authorized 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.

2.1.7 "Institutional Practitioner" means a hospital or other person, not including an individual, authorized by the jurisdiction in which it practices, to dispense a controlled substance in the course of professional practice, but does not include a pharmacy.

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

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

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

2.1.10.a. 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

2.1.10.b. 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.

2.1.11. "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.

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

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

2.1.14. "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.

2.1.15. "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.

2.1.16. “Registrant” means a person who has obtained a controlled substance registration from the Board.

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

§ 15-2-3. Adoption of Federal Law.

3.1. The requirements of the federal regulations, Drug Enforcement Administration, Department of Justice, 21 CFR Parts 1300-1321 (2020), and the federal Controlled Substances Act, 21 U.S.C. 801, as revised, are adopted by reference.

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

§ 15-2-4. Controlled Substance Registration.

4.1. Persons required to register.

4.1.1. A person who manufactures, distributes, reverse distributes, 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 registration unless exempted by law or pursuant to Section 4.2 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 registration from the Board is a “registrant”.

4.2. The Board shall exempt from payment of a fee for a controlled substance registration the following registrants:

4.2.1. An 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

4.2.2. An 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.

4.3. 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.

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

4.5. 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.

4.6. An individual applicant shall sign the 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 accompanies the application.

4.7. If an 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 4.6. of this rule in addition to any other persons required to sign the application.

4.8. If the applicant is at a 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.

4.9. Filing of application; joint filings.

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

4.9.2. A person required to obtain more than one registration may submit all applications in one package. An application must be complete and should not refer to an accompanying application for required information.

4.10. Acceptance for filing; defective applications.

4.10.1. Upon receipt, the Board shall date the application. If found to be complete, the Board will accept the application for filing. The Board does not accept an application failing to comply with the requirements of this rule. If an application has minor defects as to completeness, the Board may accept the application for filing with a request to the applicant for additional information. The Board shall return a defective application to the applicant within ten 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.

4.11. Additional information.

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

4.12. Amendments to and withdrawal of applications.

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

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

4.13. Administrative review generally.

4.13.1. The Board may inspect, or cause to be inspected, the establishment of an applicant or registrant, pursuant to W. Va. Code §60A-5-501. The Board shall review the application for registration and other information gathered by the Board regarding an applicant in order to determine whether the applicable standards of W. Va. Code §60A-3-303 have been met by the applicant.

4.14. Applications for research in Schedule I substances.

4.14.1. In the case of an application for registration to conduct research with controlled substances in Schedule I, the Board shall determine the qualifications and competency of the applicant as well as the merits

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

4.14.2. 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.

4.15. The controlled substance registration 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 registration at the registered location.

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

§ 15-2-5. Security Requirements.

5.1. Security requirements.

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

5.1.2. 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.

5.1.3. A registrant who receives or transfers substantial quantities of controlled substances in normal business operations shall employ security procedures to guard against in-transit losses.

5.2. Before distributing a controlled substance to a 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.

5.3. A wholesale drug distributor shall design and operate a system to disclose to the wholesale drug distributor suspicious orders of controlled substances. A wholesale drug distributor shall inform the Office of the Board on the Board supplied form of suspicious orders of controlled substances when discovered by the wholesale drug distributor by providing a copy of the information which the wholesale drug distributor provides to the U.S. Drug Enforcement Administration regarding such suspicious orders. The notification shall include the contact information for the wholesale drug distributor's department or staff responsible for coordinating with state regulatory or enforcement entities, unless such information has previously been provided in writing, including electronic or internet based means, to the Office of the Board. If a wholesale distributor detects no suspicious orders in a calendar month, then the wholesale drug distributor shall inform the Office of the Board in writing within fifteen days of the end of such month stating it is reporting no suspicious orders for that month. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency. The Board supplied form is available at www.wvbop.com.

5.3.1. A wholesale drug distributor that ceases distribution of Schedule II through V controlled substances to a customer located in West Virginia due to concerns that the customer may be involved in dispensing controlled substances for other than a legitimate medical purpose shall notify the Office of the Board within 5 days of the cessation. The notification shall include the contact information for the wholesale drug distributor's department or staff responsible for coordinating with state regulatory or enforcement entities, unless such information has previously been provided in writing to the Office of the Board.

5.3.2. A wholesale drug distributor that decides not to commence distribution of Schedule II through V controlled substances to a customer in West Virginia due to a concern that the customer may be involved in dispensing controlled substances for other than a legitimate medical purpose shall notify the Office of the Board within 5 days of that decision. The notification shall include the contact information for the wholesale drug distributor's department or staff responsible for coordinating with state regulatory or enforcement entities, unless such information has previously been provided in writing to the Office of the Board.

5.4. The registrant shall notify the Office of the Board of any theft or significant loss of any controlled substances upon discovery of the theft or loss as provided in subsection 9.3.

5.5. Physical security controls

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

5.5.2. 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.

§ 15-2-6. Labeling And Packaging Requirements For Controlled Substances.

6.1 Symbol required; exceptions.

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

6.1.2. A manufacturer shall print upon the labeling of a controlled substance distributed the symbol designating the schedule in which the controlled substance is listed.

6.1.3. 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" does not need to be used. There is no distinction made between narcotic and nonnarcotic substances.

6.1.4. 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.

6.1.5. 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.

6.1.6. 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.

6.1.7. 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.

6.2. Location and size of symbol on label.

6.2.1. 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 times as large as the largest type otherwise printed on the label.

6.2.2. In lieu of locating the symbol in the corner of the label, as prescribed in subsection 6.2.1. of this rule, the symbol may be overprinted on the label, in which case the symbol shall be printed at least one half the height of the label and in a contrasting color providing clear visibility against the background color of the label.

6.2.3. 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.

6.3. Sealing of controlled substances.

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

§ 15-2-7. Records And Reports Of Registrants.

7.1. Records required to be kept shall be readily retrievable.

7.2. Maintenance of records and inventories.

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

7.2.2. A registrant shall maintain inventories and records of controlled substances as follows:

7.2.2.a. 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

7.2.2.b. 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.

7.2.3. 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 7.2.2. of this rule.

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

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

7.2.4.b. 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 utilizes 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.

7.3. General requirements for inventories.

7.3.1. 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.

7.3.2. 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.

7.3.3. A registrant shall make a separate inventory for each independent activity for which he or she is registered, except as provided in subsection 7.10. of this rule.

7.3.4. 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.

7.3.5. 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.

7.4. Initial inventory date.

7.4.1. 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 7.4. through 7.7 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.

7.5. Biennial inventory date.

7.5.1. 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.

7.6. Inventory date for new controlled substances.

7.6.1. On the effective date of a rule or statutory change by the Board or the DEA adding a substance to any schedule of controlled substances, when the substance was, immediately prior to that date, not listed on any such schedule, every registrant required to keep records who is manufacturing, distributing or dispensing that substance, shall take an inventory of all stocks of the substance on hand. Thereafter the substance shall be included in each inventory made by the registrant pursuant to subsection 7.5. of this rule.

7.7. Inventories of manufacturers.

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

7.7.1.a. 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:

7.7.1.a.1. The name of the substance; and

7.7.1.a.2. The total quantity of the substance to the nearest metric unit weight consistent with unit size.

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

7.7.1.b.1. The name of the substance;

7.7.1.b.2. The quantity of the substance in each batch and/or stage of manufacture, identified by the batch number or other appropriate identifying number; and

7.7.1.b.3. The physical form which the substance is to take upon completion of the manufacturing process, identified by the batch number or other appropriate identifying number, and if possible the finished form of the substance and the number or volume of the substance.

7.7.1.c. For each controlled substance in finished form:

7.7.1.c.1. The name of the substance;

7.7.1.c.2. Each finished form of the substance;

7.7.1.c.3. The number of units or volume of each finished form in each commercial container; and

7.7.1.c.4. The total quantity of the substance in all forms to the nearest metric unit weight.

7.7.1.d. For each controlled substance not included in Subdivisions (a), (b) or (c) of this subsection:

7.7.1.d.1. The name of the substance;

7.7.1.d.2. The total quantity of the substance to the nearest metric unit weight or the total number of units of finished form; and

7.7.1.d.3. 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.

7.8. Inventories of distributors.

7.8.1. Each registered distributor shall include in the inventory the same information required of manufacturers pursuant to subdivision 7.7.1.c. and subdivision 7.7.1.d. of this rule.

7.9. Inventories of dispensers and researchers.

7.9.1. Each person registered to dispense or conduct research with controlled substances and required to keep records pursuant to section 7.4. of this rule, shall include in the inventory the same information required of manufacturers pursuant to subdivision 7.7.1.c. and subdivision 7.7.1.d. of this rule. In determining the number of units of each finished form of a controlled substance in a commercial container which has been opened, the dispenser shall do as follows:

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

7.9.1.b. 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 tablets or capsules in which case the dispenser shall make an exact count of the contents.

7.10. Inventories of importers and exporters.

7.10.1. Each registered importer or exporter shall include in the inventory the same information required of manufacturers pursuant to subdivision 7.7.1.c. and subdivision 7.7.1.d. of this rule. Each registered importer and exporter who is also registered as a manufacturer or as a distributor shall include in the inventory as an importer or exporter only those stocks of controlled substances that are actually separated from the stocks as a manufacturer or as a distributor.

7.11. Inventories for chemical analysts.

7.11.1. Each analytical laboratory registered to conduct chemical analysis with controlled substances shall include in its inventory the same information required of manufacturers pursuant to subdivision 7.7.1.c. and subdivision 7.7.1.d. of this rule, as to substances which have been manufactured, imported or received by the laboratory conducting the inventory. If less than one kilogram of any controlled substance, other than a hallucinogenic controlled substance listed in Schedule I, or less than twenty grams of a hallucinogenic substance listed in Schedule I, other than lysergic acid diethylamide, or less than five tenths gram of lysergic acid diethylamide, is on hand at the time of inventory, that substance need not be included in the inventory.

Laboratories of the Board may possess up to one hundred fifty grams of any hallucinogenic substance in Schedule I without regard to a need for an inventory of those substances.

7.12. General requirements for continuing records.

7.12.1. Every registrant required to keep records pursuant to subsection 7.3. 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.

7.12.2. 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.

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

7.12.4. 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.

7.13. Records of manufacturers.

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

7.13.1.a. 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:

7.13.1.a.1. The name of the substance;

7.13.1.a.2. The quantity manufactured in bulk form by the registrant, including the date, quantity and batch or other identifying number of each batch manufactured;

7.13.1.a.3. 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;

7.13.1.a.4. 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;

7.13.1.a.5. The quantity used to manufacture the same substance in finished form, including:

7.13.1.a.5.A. The date and batch or other identifying number of each manufacture;
7.13.1.a.5.B. The quantity used in the manufacture;

7.13.1.a.5.C. The finished form;

7.13.1.a.5.D. The number of units of finished form manufactured;

7.13.1.a.5.E. The quantity used in quality control;

7.13.1.a.5.F. The quantity lost during manufacturing and the causes therefore, if known;

7.13.1.a.5.G. The total quantity of the substance contained in the finished form;

7.13.1.a.5.H. The theoretical and actual yields; and

7.13.1.a.5.I. Any other necessary information;

7.13.1.a.6. The quantity used to manufacture other controlled and noncontrolled substances, including the name of each substance manufactured and the information required in subdivision 7.13.1.a.5. of this rule;

7.13.1.a.7. 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;

7.13.1.a.8. 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

7.13.1.a.9. The quantity distributed or disposed of in any other manner by the registrant, for example, 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.

7.13.1.b. For each controlled substance in finished form:

7.13.1.b.1. The name of the substance;

7.13.1.b.2. Each finished form and the number of units or volume of finished form in each commercial container;

7.13.1.b.3. The number of containers of each commercial finished form manufactured from bulk form by the registrant, including the information required pursuant to subdivision 7.13.1.a.5. of this rule;

7.13.1.b.4. 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;

7.13.1.b.5. 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;

7.13.1.b.6. The number of units and/or commercial containers manufactured by the registrant from units in finished form received from others or imported, including:

7.13.1.b.6.A. The date and batch or other identifying number of each manufacture;

7.13.1.b.6.B. The operation performed;

7.13.1.b.6.C. 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

7.13.1.b.6.D. Any other information necessary to account for all controlled substances used in the manufacturing process;

7.13.1.b.7. 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;

7.13.1.b.8. 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

7.13.1.b.9. The number of units of finished forms and/or commercial containers distributed or disposed of in any other manner by the registrant, 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.

7.14. Records for distributors.

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

7.14.1.a. The name of the substance;

7.14.1.b. Each finished form, for example, ten milligram tablet or ten milligram concentration per fluid ounce or milliliter and the number of units or volume of finished form in each commercial container, for example, one hundred tablet bottle or three milliliter vial;

7.14.1.c. 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;

7.14.1.d. 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;

7.14.1.e. 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;

7.14.1.f. 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

7.14.1.g. The number of units or volume of finished forms and/or commercial containers distributed or disposed of in any other manner by the registrant, for example, 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.

7.15. Records for dispensers and researchers.

7.15.1. Each person registered to dispense or conduct research with controlled substances and required to keep records pursuant to section 7.3. of this rule, shall maintain records with the following information for each controlled substance:

7.15.1.a. The name of the substance;

7.15.1.b. Each finished form, for example, ten milligram tablet or ten milligram concentration per fluid ounce or milliliter and the number of units or volume of finished form in each commercial container, for example, one hundred bottle or three milliliter vial;

7.15.1.c. 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;

7.15.1.d. 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

7.15.1.e. 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.

7.16. Records for importers.

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

7.16.1.a. The name of the substance;

7.16.1.b. 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;7.1.6.1.c. 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;

7.16.1.d. The quantity disposed of in any other manner by the registrant except quantities used in manufacturing by an importer under a registration as a manufacturer, which is to be recorded pursuant to subdivision 7.13.1.a.4. or subdivision 7.13.1.b.5. of this rule, including the date and manner of disposal and the quantity disposed.

7.17. Records for chemical analysis.

7.17.1. 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:

7.17.1.a. The name of the substance;

7.17.1.b. The form or forms in which the substance is received, imported or manufactured by the registrant, for example, powder, granulation, tablet, capsule or solution and the concentration of the substance in that form,such as C.P., U.S.P., N.F., ten milligram tablet or ten milligram concentration per milliliter;

7.17.1.c. The total number of the forms received, imported or manufactured, for example, one hundred tablets, thirty one milliliter vial, or ten 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

7.17.1.d. 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.

7.17.2. 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.

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

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

§ 15-2-8. Prescriptions.

8.1. 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.

8.2. Reserved.

8.3. Persons entitled to issue prescriptions.

8.3.1. 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, class or specific substance which he or she is authorized by that jurisdiction to prescribe.

8.3.2. 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.

8.4. Purpose of issue of prescription.

8.4.1. 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.

8.4.2. 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. 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.

8.4.3. 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.

8.5. Manner of issuance of prescriptions. 8.5.1. 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, for example, J.H. Smith or John H. Smith. Where an oral order is not authorized, prescriptions shall be written, typed, or computer-generated and printed with ink, and shall be manually signed by the practitioner. The prescriptions may be prepared by a secretary or agent for the signature of a practitioner, but the prescribing practitioner is responsible in case the prescription does not conform in all essential respects to the law and legislative rules. A corresponding liability rests upon the pharmacist who fills a prescription not prepared in the form prescribed in this rule, Provided that: a pharmacist may make changes to a prescription order written for a controlled substance in accordance with the following:

8.5.1.a. the pharmacist may add or change the patient's address upon verification;

8.5.1.b. the pharmacist may add or change the dosage form, drug strength, drug quantity, directions for use, or issue date only after consultation with and agreement of the prescribing practitioner.

8.5.1.c. such consultations and corresponding changes should be noted by the pharmacist on the prescription; and

8.5.1.d. the pharmacist is never authorized to make changes to the patient's name, controlled substance prescribed, except for generic substitution authorized by state law or the prescriber's signature.

8.6. Form of controlled substance prescription.

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

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

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

8.7. Persons entitled to fill prescriptions.

8.7.1. 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, for example, a hospital, nursing home, home for the aged, clinic, orphanage, governmental agency or institution or other place of similar character which dispenses controlled substances.

8.8. Dispensing of narcotic drugs for maintenance purposes.

8.8.1. The administering or dispensing directly, but not prescribing, of narcotic drugs listed in any schedule to a narcotic drug dependent person for “detoxification treatment” or “maintenance treatment” shall be considered to be within the meaning of the term "in the course of his or her professional practice or research." The practitioner shall be 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 comply with the regulatory standards imposed relative to treatment qualification, security, records and unsupervised use of drugs pursuant to the Act.

8.8.2. 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.

8.8.3. 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.

8.9. Controlled substances listed in Schedule II.

8.9.1. Requirement of prescription.

8.9.1.a. 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 8.9.2. of this rule. A prescription for a Schedule II controlled substance may be transmitted by the practitioner or the practitioner’s agent to a pharmacy via facsimile equipment or other electronic transmission other than electronic prescribing, provided that the original paper, manually signed prescription is presented to the pharmacist for review prior to the actual dispensing of the controlled substance, except as provided by West Virginia Code of State Rules § 15-1-21, 15 CSR 1. A prescription for a Schedule II controlled substance is valid for ninety days from the date issued. A pharmacist may fill the prescription after ninety 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.

8.9.1.b. An individual practitioner may administer or dispense a controlled substance listed in Schedule II in the course of his or her professional practice without a prescription, subject to subsection 8.8.1. of this rule.

8.9.1.c. 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.

8.9.2. 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:

8.9.2.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 shall be pursuant to a prescription issued in the normal course of practice as authorized in subsection 8.9.1. of this rule.

8.9.2.b. 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;

8.9.2.c. within seven 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 day period; if sent by electronic prescription, it must be transmitted by the prescriber within the seven day period. Upon receipt, the dispensing pharmacist shall attach this written prescription to the emergency oral prescription which had earlier been reduced to writing or to the hard copy of the electronically transmitted prescription. The pharmacist shall notify the nearest office of the U.S. Drug Enforcement Administration and the Board if the prescribing practitioner fails to deliver a written prescription.

8.10. Refilling Schedule II prescriptions; issuance of multiple prescriptions.

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

8.11. Partial filling of Schedule II prescriptions.

8.11.1. 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 hours of the first partial filling, however, if the remaining portion is not or cannot be filled within the seventy-two hour period, the pharmacist shall notify the prescribing individual practitioner. No further quantity of controlled substances may be supplied beyond seventy-two hours without a new prescription.

8.12. Labeling of Schedule II prescriptions.8.12.1. 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.

8.13. Filing of prescriptions.

8.13.1. 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.

8.14. Controlled substances listed in Schedules III, IV, and V.

8.14.1. Requirement of prescription.

8.14.1.a. 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.

8.14.1.b. 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 section 8.8. of this rule.

8.14.1.c. 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 section 8.5. 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 section 8.8. of this rule.

8.15. Refilling of Schedule III, IV, or V prescriptions.

8.15.1. A pharmacist shall not fill or refill a prescription for a controlled substance listed in Schedule III, IV, or V more than six months after the date on which the prescription was issued and any prescription authorized to be refilled may not be refilled more than five 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, IV, or V may only be authorized by a prescribing practitioner through issuance of a new prescription as provided in section 8.14. 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.

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

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

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

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

8.16.1.c. No dispensing occurs after six months after the date on which the prescription was issued.

8.17. Labeling of Schedule III, IV, or V prescriptions.

8.17.1. 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.

8.18. Filing of Schedule III, IV, or V prescriptions.

8.18.1. All prescriptions for controlled substances listed in Schedules III, IV, or V shall be kept in accordance with section 7.15. of this rule.

8.19. Dispensing without prescription.

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

8.19.1.a. 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;

8.19.1.b. Not more than 240 cc. of any controlled substance containing opium, nor more than 120 cc. 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 48 hour period;

8.19.1.c. The purchaser is at least 18 years of age;

8.19.1.d. 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;

8.19.1.e. A bound record book for distributions of controlled substances under this section, other than by prescription, is maintained by the pharmacist. The book shall contain the name and address of the purchaser, the name and quantity of controlled substance purchased, the date of each purchase and the name or initials of the pharmacist who dispensed the substance to the purchaser. The book shall be maintained in accordance with the record keeping requirement of section 7.2. of this rule; and

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

15-2-9. Miscellaneous.

9.1. Distribution upon discontinuance or transfer of business.

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

9.2. Disposal of controlled substances.

9.2.1. 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 registered or licensed health care professionals with a record of the destruction indicating the two witnesses with their signatures.

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

9.3. Reporting theft of drugs.

9.3.1. In the event of any controlled substances being lost or stolen, the registrant shall immediately submit DEA Form 106 to the Board.

9.4. Ordering of Controlled Substances.

9.4.1. A registrant shall complete DEA Form 222 for each transfer of a Schedule II controlled substance to another registrant without a prescription.

9.4.2. 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. -- May 3, 2024.

1.4. Effective Date. -- May 3, 2024.

1.5. Sunset Date -- This rule shall terminate and have no further force or effect upon August 1, 2034.

§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 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~~.~~ which promotes problem-solving and critical thinking and is applicable to the practice of pharmacy.

2.4. "Continuing Pharmacy Education Committee" ("CPE Committee") means that committee appointed by the board responsible for approval of the content of each CPE activity, which is not otherwise automatically approved by this rule for CPE credit, offered by a non-accredited ACPE 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 activities and licensure renewal requirements.

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

represents 1.0 continuing pharmacy education contact hour, but Continuing Pharmacy Education activities of less than one hour may be approved as Continuing Pharmacy Education activities in fifteen-minute increments worth one quarter contact hour per fifteen-minute period.

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

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 activities.

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-year licensure period beginning on July 1 of a given year through June 30 two 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 current or former pharmacists duly licensed by the board.

2.12. "West Virginia Society of Health System Pharmacists" means a statewide professional organization representing the interests of current and former 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 CPE hours every two 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 hours of the thirty CPE hours required every two years shall be obtained through a live presentation requiring the direct presence of the pharmacist at the CPE activity.

4.4. Every pharmacist shall complete a minimum of two hours of drug diversion training and best practice prescribing of controlled substances training within one year of receiving his or her initial license from the Board.

4.4.a. Said two hours of CPE shall be a part of the 30 hours of CPE required and is not two 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 two CPE hours which includes drug diversion training, best-practice prescribing of controlled substances training, and training on prescribing and administration of an opioid antagonist that has been approved by the Board.

§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:

5.1.a. Live Activities, 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 activities 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 activities granted credit by other states; and

5.1.e. Any activity approved by ACPE.

5.2. ACPE approved providers do not have to give a statement of credit to pharmacists. Non-ACPE approved providers shall provide the pharmacist a statement of credit or statement of attendance.

§15-3-6. Activity 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.

§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 Pharmacists.

7.2. The members of the CPE Committee shall be selected by the board and shall serve for a period of three 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 activity offered by a non-accredited ACPE provider of CPE credit.

7.5. The CPE Committee shall:

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

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

7.6 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 activities to the board for approval.

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

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

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 activity shall require the provider to submit a new application for the activity.

8.6. Providers shall retain a file of participants of each accredited activity for four years.

8.7. Providers not accredited by ACPE 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 an activity. 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 board CPE number.

§15-3-9. Responsibilities of Pharmacists.

9.1. Pharmacists shall keep valid records, receipts, and certifications of continuing pharmacy education activities completed for four 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 activities 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 activities 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 only transfer CPE hours from another state if that state accepts the transfer of West Virginia CPE hours to its state.

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 activity attended or completed.

§15-3-10. Approval of Continuing Pharmacy Activities.

10.1. Providers shall submit all CPE activities for approval by the board except as provided for in subsections 10.2 and 10.3 of this section.

10.2. The board has approved all activities developed and presented by ACPE accredited providers.

10.3. Approval of a CPE activity is valid for a three-year period if the content remains the same.

10.4. All activities shall meet the criteria utilized by ACPE and additionally shall meet the following criteria:

10.4.a. The activity shall be relevant, timely, and applicable to pharmacy practice;

10.4.b. The activity content shall be well organized with stated objectives, and an orderly flow of material, with appropriate examples and/or illustrations; and

10.4.c. The activity shall be appropriately presented, with the mode/method of presentation appropriate to the topic.

§15-3-11. Activity Evaluation.

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

11.2. 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 CPE improvement by the provider or sponsor.

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

§15-3-12. Credits and Records.

12.1. Credits and records of CPE shall be based on a CPE hour or approved fifteen-minute increments.

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

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

12.4. Graduates 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 graduate 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
RECORD KEEPING AND AUTOMATED DATA PROCESSING SYSTEMS

§15-4-1. General.

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

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

1.3. Filing Date. -- April 27, 2020.

1.4. Effective Date. -- April 27, 2020.

1.5. Sunset Provision-- This rule shall terminate and have no further force or effect on April 27, 2030.

§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.

2.2. Two or more pharmacies may establish and use an automated data processing system as a common data file or database 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 of each prescription and renewal dispensed.

§15-4-3. Definitions.

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

3.2. “Automated Data Processing System (ADP)” means a system utilizing computer software and hardware for the purpose of recordkeeping.

3.3. “Printout” means a readable printed copy of the output of a computer.

3.4. “Common database” means 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.

3.5. “On-line retrieval” means the producing of sight-readable documents on a suitable computer screen or monitor.

3.6. “Hardware” is the fixed components of a computer, server, or other such devices used for the electronic storage and retrieval of data.

3.7. “Software” is a computer program used to direct the operation of a computer, as well as the documentation giving instructions on how to use it, and directs the storage of required data on the hardware.

§15-4-4. Record of Dispensing Prescription Drugs.

Records of dispensing of prescription 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 from the date of last dispensing. Information beyond one (1) year but up to five (5) years from the date of dispensing may be maintained other than on-line, but must be produced within seventy-two (72) hours upon request by proper authorities. The information contained in the records shall include, but not be limited to:

4.1. the information required to be placed upon the label for the dispensed medication as set forth in Title 15, Series 1, Section 18;

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

4.3. a record of renewals to date.

§15-4-5. Record of Retrieval (Documentation of Activity)

5.1. The pharmacy must be able to provide a current history of all authorized prescription activity required to be kept by section 4. In addition, this information must be capable of production on a patient-by-patient basis in the form of patient profiles which allows immediate review of any other data necessary to make rational judgments about pharmacist care.

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

5.3. 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:

5.3.1. The ADP system shall provide on-line retrieval (via computer screen or monitor display or printout) of the original prescription order information for those prescription orders which are currently authorized for refilling. Order information includes, but is not limited to: 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.

5.3.2. The ADP system shall provide on-line retrieval (via computer screen or monitor display or printout) of the current refill history for Schedule III, IV, or V 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.

5.3.3. 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, IV, or V Controlled Substance. A verified record of the day's controlled substance prescription order refill data must be retrievable by each pharmacy within seventy-two (72) hours of the date on which the refill was dispensed.

5.3.4. The 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. This includes 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). The 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 the 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).

5.3.5. 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, IV, and V 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.

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

§15-4-6. Auxiliary Recordkeeping System.

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

§15-4-7. Operating the ADP System.

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

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

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

(a) provide accountability and an audit trail;

(b) be provided to the Board upon request;

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

TITLE 15
LEGISLATIVE RULE
BOARD OF PHARMACY

SERIES 5
LICENSURE OF WHOLESALE DRUG DISTRIBUTORS, THIRD PARTY LOGISTICS PROVIDERS, AND MANUFACTURERS

§15-5-1. General.

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

1.2. Authority. -- W. Va. Code §60A-8-9.

1.3. Filing Date. -- May 11, 2021

1.4. Effective Date. -- June 11, 2021

1.5. Sunset Date -- This rule shall terminate and have no further force or effect upon June 11, 2031.

§15-5-2. Definitions.

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

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

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

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

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

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

2.5. "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.

2.6. "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 (2020), a person cannot simultaneously be a "healthcare entity" and a retail pharmacy or wholesale drug distributor.

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

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

2.9. “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.

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

2.11. “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:

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

2.11.2. 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 percent of the total prescription drug sales revenue of either the transferor or transferee pharmacy during any consecutive twelve month period);

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

2.11.4. The sale, purchase, or trade of blood and blood components intended for transfusion;

2.11.5. 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;

2.11.6. 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;

2.11.7. 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;

2.11.8. 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;

2.11.9. 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 (2020); or

2.11.10. 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 percent of the total prescription drug sales revenue of either the transferor or transferee pharmacy during any consecutive twelve month period).

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

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

3.1. Every wholesale distributor, wherever located, who engages in the wholesale distribution of drugs into, out of, or within the state must be licensed by the West Virginia Board of Pharmacy (hereinafter, the "Board") in accordance with the laws and regulations of this state before engaging in the wholesale distribution of prescription drugs. Every wholesale distributor, wherever located, who engages in the wholesale distribution of drugs into, out of, or within the state shall report discipline from any jurisdiction within thirty days of the entry of the final order.

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

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

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

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

4.1.1. The name, full business address, and telephone number of the licensee;

4.1.2. All trade or business names used by the licensee;

4.1.3. 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;

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

4.1.5. The name of the owner and/or operator of the licensee, including:

4.1.5.a. If a person, the name of the person;

4.1.5.b. If a partnership, the name of each partner, and the name of the partnership;

4.1.5.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 the name of the parent company, if any;

4.1.5.d. 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 location by a single wholesale drug distributor, third-party logistics provider, or manufacturer, each location shall be licensed or permitted by the Board. However, the Board may provide for a single license or permit for a business entity operating more than one facility within this state, or for a parent entity with divisions, subsidiaries, and/or affiliate companies within this state when operations are conducted at more than one location and there exists joint ownership and control among all entities.

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

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

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

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

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

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

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

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

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

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

§15-5-5. Minimum Qualifications.

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

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

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

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

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

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

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

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

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

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

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

§15-5-6. Personnel.

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

§15-5-7. Violations and Penalties.

7.1. The Board may reprimand, suspend, restrict, or revoke any licenses or permits granted under this series upon conviction of violations of Federal, State, or local drug laws or regulations. Before any license or permit may be reprimanded, suspended, restricted, or revoked, a licensee or permittee under this series shall have a right to prior notice and a hearing pursuant to Chapter 29A-1-1 et seq., Administrative Procedures Act of the Code of West Virginia.

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

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

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

The following constitutes the 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:

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

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

8.1.3. 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;

8.1.4. Be maintained in a clean and orderly condition; and

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

8.2. Security.

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

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

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

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

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

8.2.3. 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).

8.3.1. 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.

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

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

8.4. Examination of materials.

8.4.1. 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.

8.4.2. 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.

8.4.3. 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.

8.5.1. 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.

8.5.2. 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.

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

8.5.4. 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.

8.6.1. 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:

8.6.1.a. 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;

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

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

8.6.2. 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 years following disposition of the drugs.

8.6.3. 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 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:

8.7.1. 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.

8.7.2. 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:

8.7.2.a. Any action initiated at the request of the Food and Drug Administration or other Federal, State, or local law enforcement or other government agency, including the Board;

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

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

8.7.3. 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.

8.7.4. 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 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 and provide the board with such list upon licensure and renewal.

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.

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

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

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 (2020).

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

9.1. Third-party logistics providers and manufacturers shall meet the minimum requirements for the storage and handling of prescription drugs, and for the establishment and maintenance of prescription drug distribution records as required by the Federal Food and Drug Administration.

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

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

10.2. Licensees and permittees under this series may keep records regarding purchase and sales transactions at a central location apart from the principal office of the licensee or permittee or the location at which the drugs were manufactured, housed, or stored by the licensee or permittee, and from which they were

shipped: Provided, That such records shall be made available for inspection within two working days after a request to inspect by the board is made. Such records may be kept in any form permissible under federal law applicable to prescription drugs record keeping.

TITLE 15
LEGISLATIVE RULE
BOARD OF PHARMACY

SERIES 6
MAIL-ORDER AND NON-RESIDENT PHARMACIES

§15-6-1. General.

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

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

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

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

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

§15-6-2. Definitions.

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

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

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

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

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

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

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

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

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

3.2.c. The pharmacy manager.

3.2.d. The pharmacist-in-charge.

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

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

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

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

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

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

§15-6-5.

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

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

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

§15-6-7. Resident Agent

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

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

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

TITLE 15
LEGISLATIVE RULE
WEST VIRGINIA BOARD OF PHARMACY

SERIES 7
BOARD OF PHARMACY RULES FOR REGISTRATION OF PHARMACY TECHNICIANS

§15-7-1. General.

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

1.2. Authority. -- W. Va. Code§§ 30-5-7 and 30-5-11a.

1.3. Filing Date. -- May 3, 2024.

1.4. Effective Date. -- May 3, 2024.

1.5. Sunset Provision -- This rule shall terminate and have no further force or effect on August 1, 2034.

§15-7-2. Definitions.

2.1 “Cashier” means a pharmacy employee who only handles a prescription drug at the point of sale to provide the prescription drug to a patient and handles the financial transaction of the pharmacy.

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

2.3. “Medication Reconciliation” means the process of identifying the most accurate list of all medications that the patient is taking, including name, dosage, frequency, and route, by comparing the medical record to an external list of medications obtained from a patient, hospital, or other provider.

2.4. “National Healthcare 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.

2.5. "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.

2.6. “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).

2.7. "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 unless the individual qualifies for a fee waiver, 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;

3.1.b.1.B. completed a pharmacy-provided, on-the-job, competency-based education and training program approved by the Board; or

3.1.b.1.C. Obtained a national certification as a pharmacy technician and have practiced in another jurisdiction for at least one year; 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. complete a criminal history records check as prescribed in § 29 of Title 15, Series 1.

3.1.b.4.A. The criminal history records must have been requested within the 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.

3.1.c. If the individual is seeking registration pursuant to 3.1.b.1.C. then the individual must provide satisfactory proof to the Board of his or her licensure status with the board of pharmacy in the state in which the individual is licensed. In states where there is no Board oversight, then a notarized document of proof of satisfactory employment by previous pharmacist-in-charge will suffice.

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. 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. The training program shall be outlined in a training manual which shall be used throughout the program. A competency-based pharmacy technician education and training program shall, at a minimum contain the following:

4.1.a. written procedures and guidelines for the use and supervision of pharmacy technicians and pharmacy technician trainees. 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 and pharmacy technician trainees, shall supervise the pharmacy technicians and pharmacy technician trainees, 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 pharmacy technician trainees; and

4.1.b. instruction in the following areas and any additional areas appropriate to the duties of pharmacy technicians and pharmacy technician trainees 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 repackaging;

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. The on-the-job, competency-based pharmacy technician training program shall consist of a minimum of 500 hours of employment within a 12-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 500-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, or is currently enrolled in a high school competency-based pharmacy technician education and training program;

4.3.b. is not an alcohol or drug abuser;

4.3.c. has not been convicted of a crime bearing a rational nexus to the practice duties of a pharmacy technician. For other convictions not bearing a rational nexus to the practice of pharmacy, the Board shall permit the applicant to apply for initial licensure if:

4.3.c.1. a period of five years has elapsed from the date of conviction or the date of release from incarceration, whichever is later;

4.3.c.2. the individual has not been convicted of any other crime during the period of time following the disqualifying offense; and

4.3.c.3. the conviction was not for an offense of a violent or sexual nature: Provided, that a conviction for an offense of a violent or sexual nature may subject an individual to a longer period of disqualification from licensure, to be determined by the individual board.

4.3.d. has completed a criminal history records check as prescribed in § 29 of Title 15, Series 1.

4.4. 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.a. 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.b. Within 12 months of approval of his or her application to begin working as a pharmacy technician trainee 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.c. 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.d. If the pharmacy technician trainee fails to complete the required training program and hours within the 12 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.d.1. provide an extension of time for completion of the training program upon a showing of special circumstances; or

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

4.4.e. 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.e.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.e.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 trainee 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 and Pharmacy Technician Trainee.

5.1. A pharmacy technician or pharmacy technician trainee 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;

5.1.h. receive or place a call for a transferred prescription;

5.1.i. perform any act within the practice of pharmacist care that involves discretion or independent professional judgment; or

5.1.j. perform all pharmacy related functions which the registrant has not been trained and the function has not been specified in a written protocol with competency established.

5.2. The duties of a registered pharmacy technician or pharmacy technician trainee 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, in numerical order;

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 or pharmacy technician trainee 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 or pharmacy technician trainee may assist in the preparation of compounded sterile and non-sterile preparations under the direct supervision of a pharmacist. In all cases, the pharmacist shall check and verify the accuracy of the pharmacy technician or pharmacy technician trainee;

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;

5.2.t. under the direct supervision of a licensed pharmacist, a pharmacy technician may perform the following:

5.2.t.1. Perform pharmacy technician product verification where no clinical judgment is necessary and the pharmacist provides the final verification;

5.2.t.2. Complete a list of a patient's current prescription and nonprescription medications to provide for medication reconciliation;

5.2.t.3. Supervise registered pharmacy technicians and pharmacy technician trainees;

5.2.t.4. Medical records screening;

5.2.t.5. Administer immunizations per W. Va. 15 CSR 12.

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 six pharmacy technicians and/or pharmacy technician trainees per on-duty pharmacist operating in any pharmacy shall be maintained, to be determined by the discretion of the pharmacist-in-charge (PIC). This ratio shall not include pharmacy interns. The PIC shall have final approval of the ratio of pharmacy technicians operating in the pharmacy. Any decisions overriding such control of the PIC may be grounds for disciplinary action against the pharmacy permit.

5.4. A registered pharmacy technician or pharmacy technician trainee 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.

5.5. A person who handles a prescription drug only during the point of sale to provide the prescription drug to a patient and accept payment is not subject to the licensure requirements of West Virginia Code of State Rules §15-7. This handling process includes the cashier having access to the pharmacy's operating system to verify unique information for each patient. A pharmacy may require an individual to complete a criminal background check before he or she is hired.

§15-7-6. Nuclear Pharmacy Technician Endorsement Requirements.

6.1. Submit a written application to the board;

6.2. Pay the applicable fees;

6.3. Have graduated from high school or obtained a Certificate of General Educational Development (GED) or equivalent;

6.4. Have successfully completed a pharmacy provided, competency-based nuclear pharmacy technician education and training program approved by the board;

6.5. Have all applicable national certifications and comply with all federal rules and regulations;

6.6. Not be an alcohol or drug abuser, as these terms are defined in §27-1A-11 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 12-step program or other similar group or process, may be considered;

6.7. Not have been convicted of a felony in any jurisdiction within 10 years preceding the date of application for license, which conviction remains unreversed;

6.8. 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

6.9. Have fulfilled any other requirement specified by the board in any rule.

6.10. 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 nuclear pharmacy technician.

§15-7-7. Nuclear Pharmacy Technician Endorsement Scope of Practice.

7.1. A registered pharmacy technician who has obtained a nuclear pharmacy technician endorsement, may under the direct supervision of the licensed nuclear pharmacist, perform the following:

7.1.a. Assist in the dispensing process;

7.1.b. Receive new written or electronic prescription drug orders;

7.1.c. Mix compound ingredients for liquid products, suspensions, ointments, mixes, or blend for tablet granulations and capsule powders;

7.1.d. Prepare radiopharmaceuticals;

7.1.e. Record keeping;

7.1.f. File and organize prescriptions;

7.1.g. Create reports;

7.1.h. Inventory tasks;

7.1.i. Handle raw materials and intermediate or finished products;

7.1.j. Perform general maintenance as required on pumps, homogenizers, filter presses, tablet compression machines, and other like machines;

7.1.k. Perform standard operating procedures to meet current good manufacturing practices (GMP);

7.1.l. Maintain records;

7.1.m. Monitor and verify quality in accordance with statistical process or other control procedures; and

7.1.n. Stock medications.

7.2. A registered pharmacy technician who has obtained a nuclear pharmacy technician endorsement may not perform the following:

7.2.a. Drug regimen review;

7.2.b. Clinical conflict resolution;

7.2.c. Contact a prescriber concerning prescription drug order clarification or therapy modification;

7.2.d. Receive new oral prescription drug orders.

§15-7-8. Identification of Technicians and Technician Trainees.

8.1. Pharmacy technicians shall wear a name tag 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.

8.2. During the period of training, a pharmacy technician trainee shall wear a name tag which contains the designation "Pharmacy Technician Trainee."

§15-7-9. Certificate of Registration; Transfer of Registration.

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

9.2. The registration of the pharmacy technician or pharmacy technician trainee may not be transferred to another pharmacy unless:

9.2.a. the pharmacies are under common ownership and control and have a common training program; or

9.2.b. the pharmacist-in-charge of the pharmacy at which the pharmacy technician or pharmacy technician trainee intends to work certifies that the pharmacy technician or pharmacy technician trainee 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 or pharmacy technician trainee has adequately completed the pharmacy-specific 20-hour training program as outlined in subsection 3.2 of this rule.

TITLE 15
LEGISLATIVE RULE
WEST VIRGINIA BOARD OF PHARMACY

SERIES 8
CONTROLLED SUBSTANCES MONITORING PROGRAM

§15-8-1. General.

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

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

1.3. Filing Date. -- April 14, 2022

1.4. Effective Date. -- April 14, 2022

1.5. Sunset Date. -- This rule shall terminate and have no further force or effect upon August 1, 2027.

§15-8-2. Definitions.

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

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

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

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

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

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

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

2.2.f. “Drugs of concern” means prescription drugs which are not controlled substances but which have a high potential for abuse.

2.2.g. “Authorized agent” means an individual, who is an employee of any of the covered persons or entities permitted to have access to the central repository pursuant to Rule 15-8-7.3 of this rule, who is specifically designated by the covered person or authorized representative of the covered entity to access the central repository on behalf of the covered person or entity.

2.2.h. “Electronic access” means the ability to connect with and view the information in the central repository maintained by the board using electronic means permits real-time connectivity to the central repository.

2.2.i. “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 United 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 (2020).

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

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

2.2.n. “Patient” means an individual who:

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

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

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

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

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

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

2.2.r. "Schedule II, III, IV, or V Controlled Substance" means a controlled substance classified in those categories under W. Va. Code §§60A-2-206, 208, 210, and 212.

2.2.s. "Security prescription blank" means a prescription blank that complies with the requirements of §15-1-2~~7~~3 of the West Virginia Code of State Rules.

2.2.t. "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, IV, or V Controlled Substance, drug of concern, or opioid antagonist is dispensed for out-patient use, the medical services provider, health care facility, or pharmacy that dispensed the controlled substance, drug of concern, or opioid antagonist shall transmit to the central repository the information required by West Virginia Code § 60A-9-4 in the appropriate American Society for Automation in Pharmacy format used by the central repository for reporting to it. 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 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 his or her 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, IV, or V controlled substance, drug of concern, or opioid antagonist dispensed. By providing this NDC number, the Controlled Substances Monitoring Program database will extract the name and dosage or strength of the controlled substance required by the statute such that the reporters do not need to additionally supply the name and dosage;

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

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

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

3.1.h. If the prescription being dispensed is being picked up by a recipient representative on behalf of the recipient, the first and last name of the recipient representative as set forth on the person's government-issued photo identification card, the appropriate code for the type of ID, the ID number, the appropriate code indicating the relationship of the recipient representative to the patient, and the appropriate code for the issuing jurisdiction of the ID; and

3.1.i. The source of payment for the controlled substance, drug of concern, or opioid antagonist dispensed.

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

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

4.1. The information may be transmitted at any time, but shall be transmitted at least within twenty-four hours of the dispensing. If the dispensing is done by mail or other postal, courier, or logistics services such as United Parcel Service or Federal Express, then the information shall be submitted at least within forty-eight hours of the time the dispensing is placed in the mail for delivery. If a reporter is closed for a holiday, or week-end day, the reporter shall make the required report as soon as is practicable upon reopening, or within forty-eight hours, whichever occurs first. If there are no dispensings of any Schedule II, III, IV, or V controlled substances, drug of concern, or opioid antagonists, then the reporter shall submit a daily "zero" report If there are no such dispensings within up to seven days of the last report, the reporter may submit a weekly "zero" report no later than seven days after the last date and time reported on the previous report. If a reporter is unable to make the required reporting in a timely manner due to an emergency, the reporter shall inform the board of the emergency and provide the board with information on when the reporter believes it will return to full compliance. Such notification may be taken into consideration by any agency, licensing board, or court, when determining if the reporter is in compliance with reporting requirements of West Virginia Code §60A-9-3 and section three of this rule, 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, IV, or V controlled substances, drug of concern, or opioid antagonists, the dispenser may notify the board in writing by requesting a waiver from reporting on a form supplied by the board. If the waiver is granted by the board, the reporter is not required to submit a zero report unless and until the reporter possesses a Schedule II, III, IV, or V controlled substance or opioid antagonist for the purpose of dispensing.

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

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

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

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

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

6.3. The central repository shall secure the information collected and the database maintained 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.

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 a 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. An authorized agent of a board in this state or another state that licenses practitioners authorized to prescribe Schedule II, III, IV, or V 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 engaged in an investigation, an adjudication, or a prosecution of a violation under any state or federal law that involves a controlled substance;

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

7.3.e. Authorized agents of the West Virginia Bureau for Medical Services;

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

7.3.g. Authorized agents of the West Virginia Office of Health Facility Licensure and Certification for use in certification, licensure and regulation of health facilities;

7.3.h. A dean of a medical school located in this State or his or her designee to access prescriber level data to monitor prescribing practices of faculty members, prescribers and residents enrolled in a degree program at the school where he or she serves as dean;

7.3.i. A physician reviewer designated by an employer of medical providers to monitor prescriber level information of prescribing practices of physicians, advance practice registered nurses, or physician assistants in their employ;

7.3.j. A chief medical officer of a hospital, or a physician designated by the chief executive officer of a hospital which does not have a chief medical officer, to monitor prescriber level information of prescribing practices of prescribers who have admitting privileges to the hospital;

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

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

7.3.m. Prescribing practitioners or their authorized agents for purposes of treating a patient;

7.3.n. Pharmacists or a registered pharmacy technician as the agent of the pharmacist for purposes of

treating a patient; and

7.3.o. 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 (n) of this section except that practitioners who prescribe or dispense controlled substances may also request specific data related to all dispensings reported to the database as prescribed and/or dispensed under their drug enforcement administration controlled substance registration number or for the purpose of providing treatment to a patient.

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

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

7.5. 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 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. A person or entity having access to the central repository and who is permitted to designate an 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 ensure that the designated agent maintains the confidentiality of the information in the central repository as required. If the designating individual remove the authority of the designated agent to act as the authorized agent, or should the designated agent leave the employment of the designating individual or entity then the designating individual shall immediately notify the board, at which time the designee's access to the central repository shall be removed.

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

7.8. The board shall review records in the CSMP in accordance with parameters set by the Advisory Committee to identify abnormal or unusual practices of patients who exceed those parameters and are therefore outliers in the CSMP data. The board shall issue reports of the results of these searches to the Review Committee for its regular review and action. The board shall communicate with prescribers and dispensers of the patients who exceed the parameters to inform them of each practitioner's patient's activities as demonstrated in the CSMP reports. Reports and communications produced by the board shall be kept confidential by the board and the Review Committee.

7.9. The Review Committee may query the CSMP based on parameters established by the advisory committee to identify abnormal or unusual practices of patients who are outliers in the data according to their

controlled substance prescribing, dispensing, or usage patterns or other indicators available in the system. The Review Committee may also query the CSMP based on parameters established by the advisory committee to identify abnormal prescribing and/or dispensing patterns of practitioners indicated by outliers in the system. The Review Committee may also query the CSMP for any relevant prescribing or dispensing records of involved patients or practitioners as it carries out its duty to review notices provided by the chief medical examiner pursuant to West Virginia Code § 61-12-10(h) and determine on a case-by-case basis whether a practitioner who prescribed or dispensed a controlled substance may have resulted in or contributed to the drug overdose, and, if so, if the practitioner may have breached professional or occupational standards or committed a criminal act when prescribing the controlled substance at issue to the decedent. The Review Committee, in accordance with parameters established by the Advisory Committee, may provide any pertinent information in its discretion from the CSMP to the relevant practitioner, the practitioner's licensing board, or law enforcement as permitted by West Virginia Code § 60A-9-5(b). The Review Committee, in accordance with parameters established by the Advisory Committee, may also communicate with pertinent practitioners or patients to make them aware of the practitioner's own prescribing or dispensing patterns or history, or the patient's own usage patterns or history as reflected in the CSMP in an effort to reduce inappropriate use of prescription drugs in accordance with West Virginia Code § 60A-9-5(a)(3)(C). The information obtained and developed by or on behalf of the Review Committee may not be shared except as provided in West Virginia Code § 60A-9-5(b) and as provided specifically in subsection 7.8 and this subsection of this section.

§15-8-8. Pharmacist Requirement to Check the Controlled Substances Monitoring Program Database.

8.1. A pharmacist shall access the West Virginia Controlled Substances Monitoring Program Database for information regarding specific patients in the following scenarios:

8.1.a. upon initially dispensing any Schedule II controlled substance, any opioid, or any benzodiazepine to a patient who is not suffering from a terminal illness; and

8.1.b. at least annually thereafter should the pharmacist continue to dispense the patient with a controlled substance.

TITLE 15
PROCEDURAL RULE
WEST VIRGINIA BOARD OF PHARMACY

SERIES 9
DISCIPLINARY 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. – August 26, 2020

1.4. Effective Date. -- September 27, 2020

§15-9-2. Complaint Procedures.

2.1. Any individual may make a complaint to the board concerning a licensee or registrant. The Board may also file a complaint against 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 may accept a complaint in writing, online via the Board's website, or in person. The board may provide a form for the purpose of submitting a written complaint or online complaint.

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 to it.

2.6. Upon receipt of a 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 and prosecution of a case.

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

2.6.3. 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 4. 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 the 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. 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 shall make a formal recommendation of discipline to the full Board for its consideration.

2.9. The full Board shall vote on the Complaint Committee's recommendation. The Board may accept the recommendations or amend the recommendations. The Board representative may draft a consent agreement reflecting the discipline voted upon by the full Board. The Board may vote to give the Board representative discretion in settling the case within certain discipline parameters voted upon by the Board.

2.10. If the licensee or registrant contests the allegations and refuses to enter into a consent agreement,~~.~~ the Board representative may present the Board with an amended discipline charge or recommend that the case be set for hearing. All hearings shall be in accordance with W. Va. Code § 29A-1-1 et seq. and 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.

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 and the Board is set to hear the case.

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.

§ 15-9-3. Proceedings for Disciplinary Action.

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

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

3.3. Motions for a continuance of a hearing may be granted upon a showing of good cause. Motions for continuance shall be in writing and received in the office of the board or with the delegated hearing examiner no later than seven (7) days prior to the hearing date. In determining whether good cause exists, the board or delegated hearing examiner shall give consideration to the ability of the party requesting the continuance to proceed effectively without a continuance. The board or designated hearing examiner 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.

3.4. All motions related to a case set for hearing before the board, except motions for continuance shall be received in the office of the board or with the designated hearing examiner 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.

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

§ 15-9-4. Conferences; Informal Disposition of Cases.

4.1. 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:

4.1.1. To dispose of procedural requests, prehearing motions or similar matters;

4.1.2. To simplify or settle issues by consent of the parties; or

4.1.3. To provide for informal disposition of cases by stipulation or agreement.

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

4.3. 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.

4.4. Subpoenas to compel the attendance of witnesses and subpoenas duces tecum to compel the production of documents in connection with a hearing may be issued by any member of the board or the board's executive director.

TITLE 15
LEGISLATIVE RULE
WEST VIRGINIA BOARD OF PHARMACY

SERIES 10
BOARD OF PHARMACY RULES FOR PHARMACIST RECOVERY NETWORKS

§15-10-1. General.

1.1. Scope -- This rule provides for the operation of Pharmacist Recovery Networks.

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

1.3. Filing date -- April 2, 2018.

1.4. Effective date -- April 2, 2018

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

§15-10-2. Definitions.

2.1. "Applicant" means a person applying to the Board for licensure as a pharmacist, licensed intern, or registered pharmacy technician.

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

2.3. "Committee" means the Board of Directors established to function as a supervisory and advisory body to the WVPRN, made up of professional peers actively licensed or registered to practice pharmacist care in West Virginia.

2.4. "Executive Director" means a person selected by the committee to administer the WVPRN.

2.5. "Facility" means a residential or in-patient treatment hospital or institution, a partial hospital programming hospital or institution with a housing component, or an intensive outpatient programming hospital or institution, all of which have a specific program with expertise in treating healthcare professionals.

2.6. "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.

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

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

§15-10-3. Board of Directors.

3.1. The Board of Directors shall consist, at a minimum, of the following:

3.1.a. Six licensed pharmacists various practice settings and state regions, a minimum of two shall be past clients of the WVPRN in recovery, or if not past clients of the WVPRN, otherwise be in recovery from alcohol or drug dependency or other mental impairment;

3.1.b. One pharmacy technician actively registered with the Board; and

3.1.c. One actively licensed intern from each ACPE accredited school of pharmacy located in the state.

§15-10-4. Pharmacist Recovery Network Agreements.

4.1. Pharmacist Recovery Network Agreements with the board require the following:

4.1.a. Upon receiving information about possible impairment of a licensee or applicant from a person the Executive Director shall contact the licensee or applicant to verify the information.

4.1.b. 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 or applicant to present himself or herself to a WVPRN-approved evaluator's office within seven days of initial contact for a complete substance abuse assessment.

4.1.b.1. If the licensee or applicant resists coming in for an assessment, the Executive Director shall pursue one repeat contact.

4.1.b.2. After two unsuccessful interventions within a period not to exceed 14 days, the Executive Director shall inform the licensee or applicant of the WVPRN's intent to close the file and disclose all evidence of impairment allowed by law to the board. If the licensee or applicant still refuses to cooperate, then the WVPRN shall inform the board of any and all findings of the WVPRN developed during the course of its investigation.

4.1.c. The evaluator shall conduct an in-person substance abuse evaluation to include among other things, a psychoactive substance use history, administration of a Substance Abuse Subtle Screening Inventory (SASSI) or other diagnostic tool the evaluator deems necessary, and urinalysis utilizing a minimum of a 14-panel screen and Ethyl Glucuronide Test (ETG);

4.1.d. If a diagnosis of substance abuse or dependence or an impairing mental disorder 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 WVPRN. If there is insufficient evidence to warrant a diagnosis of substance abuse or dependence, or an impairing mental disorder, the Executive Director shall place the file in an inactive status, and destroy the file after five years.

4.1.e. The Executive Director shall draw up a final agreement or "contract" between the licensee and the WVPRN 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;

4.1.f. 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, or any other treatment documentation, including recommendations to return to practice, if applicable;

4.1.g. The Executive Director 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

4.1.h. Upon the completion of treatment and rehabilitation, and the expiration of the recovery contract, the network shall conclude involvement with the licensee.

§15-10-5. Due Process.

5.1. Any action taken pursuant to the WVPRN shall afford the licensee all due process rights enumerated in W. Va. Code §§29A-1-1 et. seq.

§15-10-6. Receipt and Use of Information of Suspected Impairment.

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

6.2. Upon receipt of information of a suspected impairment, the WVPRN shall initiate an investigation.

6.3. The WVPRN may conduct routine inquiries regarding suspected impairments.

6.4. The WVPRN may require a licensee suspected of impairment to submit to personal interviews before any person authorized by the WVPRN, including but not limited to evaluators or treatment centers.

§15-10-7. Intervention and Referral.

7.1. 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 request the licensee to surrender their license to the WVPRN to be put into inactive status at the Board, and then refer the licensee to an appropriate treatment source acceptable to the WVPRN.

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

7.3. The WVPRN shall arrange and conduct interventions as soon as possible.

7.4. The WVPRN shall evaluate treatment sources before making case referrals for treatment.

7.5. The WVPRN shall record intervention outcomes including treatment contracts that result from the administration of the case.

§15-10-8. Monitoring Treatment.

8.1. The WVPRN shall monitor a treatment source by receiving updates from it as to the treatment source's ability to provide:

8.1.a. adequate medical and non-medical staffing, facilities, and experience with health professional clients;

8.1.b. appropriate treatment;

8.1.c. affordable treatment; and

8.1.d. appropriate post-treatment support.

§15-10-9. Monitoring Rehabilitation and Performance.

9.1. The WVPRN shall designate monitoring requirements for each licensee participating in the WVPRN. Licensees may be required to be tested regularly or randomly on demand of the WVPRN.

9.2. The WVPRN may require treatment sources to submit reports regarding a licensee's rehabilitation and performance to the WVPRN.

9.3. The WVPRN may require impaired licensees to submit to periodic personal interviews before any person authorized by the WVPRN.

9.4. The WVPRN shall maintain appropriate case records in a HIPPA encrypted data file regarding each licensee that is a participant.

§15-10-10. Monitoring Post-Treatment Support.

10.1. Post-treatment support may include family counseling, advocacy and other services and programs considered appropriate to the licensee's recovery.

10.2. The WVPRN shall monitor the post-treatment support of treatment sources on an ongoing basis.

10.3. The WVPRN's own post-treatment support shall be monitored by the WVPRN on an ongoing basis utilizing recognized performance measures.

§15-10-11. Reports of Cases of Impairment to the Board.

11.1. A voluntary agreement entered into between the WVPRN and a licensee is not considered a disciplinary action or order by the Board, shall not be disclosed to the Board, and shall not be public information if:

11.1.a. The voluntary agreement is the result of the licensee or applicant self-enrolling or voluntarily participating in the WVPRN;

11.1.b. The Board has not received nor filed any written complaints regarding the licensee or applicant relating to an alcohol, chemical dependency or major mental illness affecting the care and treatment of patients; and

11.1.c. The licensee or applicant is in compliance with the voluntary treatment program and the conditions and procedures to monitor compliance.

11.2. If a licensee or applicant enters into a voluntary agreement with the WVPRN, and then fails to comply with or fulfill the terms of said agreement, the Executive Director shall report the noncompliance to the Board within twenty-four hours, so the Board may determine whether to initiate disciplinary proceedings.

11.3. If the board has not instituted a disciplinary proceeding, any information received, maintained or developed by the WVPRN relating to the alcohol or chemical dependency impairment or mental impairment of a licensee or applicant and the voluntary agreement shall be confidential and not available for public information, discovery or court subpoena, nor for introduction into evidence in any medical professional liability action or other action for damages arising out of the provision of or failure to provide health care services.

11.4. If WVPRN becomes aware that the licensee or applicant has diverted controlled substances to a person other than himself or herself, or the individual constitutes an immediate danger to the public or himself or herself, the WVPRN 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.

§15-10-12 Periodic Reporting of Statistical Information.

12.1. The WVPRN shall 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. The WVPRN may not disclose any personally identifiable information relating to any pharmacist, intern, pharmacy technician, or pharmacy technician trainee participating in a voluntary agreement as provided herein.

12.2. The WVPRN shall, on a quarterly basis, report on the status of licensees subject to monitoring by the WVPRN by Order of the Board.

§15-10-13. Confidentiality.

13.1. All information, interviews, reports, statements, memoranda, or other documents furnished to or produced by the WVPRN, all communications to or from the WVPRN, and all proceedings, findings, and conclusions of the WVPRN, 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.

13.2. All records and proceedings of the WVPRN that pertain or refer to a person participating in a pharmacist recovery network shall be privileged and confidential, used by the WVPRN 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 subsections 4.1.b.2 and 11.4. of this rule.

13.3. The WVPRN may only disclose the information relative to an impaired licensee if:

13.3.a. it is essential to disclose the information to a person or an organization needing the information in order to address the intervention, treatment, or rehabilitation needs of the impaired licensee and a release by the licensee has been executed;

13.3.b. the release is authorized in writing by the impaired licensee; or

13.3.c. the WVPRN is required to make a report to the board pursuant to subsections 4.1.b.2 or 11.4. of this rule.

§15-10-14. Discretionary Authority of the Board to Designate Program

14.1. The board has the sole discretion to designate pharmacy recovery programs for licensees of the board and no provision of this rule may be construed to entitle any pharmacist, pharmacy intern, pharmacy technician, or pharmacy technician trainee to the creation or designation of a pharmacy recovery program for any individual qualifying illness or group of qualifying illnesses.

§15-10-15. Fees.

15.1. 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:

15.1.a. Pharmacist - $20 with each biennial renewal;

15.1.b. Intern - $5 with each annual renewal; and

15.1.c. 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 FOR IMMUNIZATIONS ADMINISTERED BY PHARMACISTS,

§15-12-1. General.

1.1. Scope. -- To provide the rules for pharmacists, pharmacy interns, and pharmacy technicians to administer immunizations to patients in this State through joint rulemaking by the West Virginia Board of Pharmacy, Board of Medicine, and Board of Osteopathy.

1.2. Authority. -- W. Va. Code § 30-5-7 and 29A-3-15.

1.3. Filing Date. -- May 3, 2024.

1.4. Effective Date. -- May 3, 2024.

1.5. Sunset Date -- This rule shall terminate and have no further force or effect on August 1, 2034.

§15-12-2. Definitions.

2.1 “ACPE” means American Council for Pharmacy Education.

2.2. “Board” means the West Virginia Board of Pharmacy.

2.3. “CDC” means the United States Centers for Disease Control and Prevention.

2.4 “CPR” means cardiopulmonary resuscitation.

2.5. “Direct supervision” means the supervising immunizing pharmacist is physically present and readily and immediately available during the administration of an immunization.

2.6. "Immunizations" means the action of making a person immune to infection, typically by inoculation.

2.7. “VAERS” means vaccine adverse event reporting system which is the 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.

§15-12-3. Qualifications.

3.1. A licensed pharmacist may order and administer immunizations as permitted by this rule provided that the pharmacist:

3.1.a. is registered with the board to administer immunizations;

3.1.b. has successfully completed the American Pharmacists Association's (APhA) immunization training program or Board-approved training program, as provided in section 8, which courses shall be based

on the standards established for immunization training by the Centers for Disease Control and Prevention (CDC) 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), from the American Heart Association, or the American Red Cross or other Board-approved course; and

3.1.d. completed a minimum of two hours of continuing pharmacy education related to immunizations each licensing year for a total of four hours each renewal period. The continuing education shall be by a provider approved by the Accreditation Council for Pharmacy Education (ACPE).

3.2. A pharmacy intern licensed by the Board may administer immunizations as permitted by this rule provided that the pharmacy intern:

3.2.a. is under the direct supervision of a pharmacist who is registered with the board to administer immunizations; and

3.2.b. has completed all of the training and current certification required by subsections 3.1.b. and 3.1.c. of this section.

3.3. A pharmacy technician licensed by the Board may administer immunizations as permitted by this rule provided that the pharmacy technician:

3.3.a. is registered with the Board to administer immunizations;

3.3.b. is under the direct supervision of a pharmacist who is registered with the Board to administer immunizations; and

3.3.c. has successfully completed a practical training program approved by the ACPE and the Board. This training must include hands-on injection technique and the recognition and treatment of emergency reactions to vaccines; and

3.3.d. maintains current certification in basic life-support training, including basic CPR, from the American Heart Association, or the American Red Cross or other Board-approved course; and

3.3.e. complete a minimum of two hours of continuing pharmacy education related to immunizations each licensing renewal period. The continuing education shall be by a provider approved by the ACPE.

3.4. It is unprofessional conduct for a pharmacist, pharmacy intern, or pharmacy technician to administer an immunization in violation of 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 shall 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 the pharmacist a registration to administer immunizations. Registrations shall expire biennially on June 30 of year in which the pharmacist's license to practice pharmacy expires.

4.2. The registration shall be posted conspicuously at all locations at which the pharmacist administers an immunization.

4.3. Prior to administering immunizations, a pharmacy intern shall provide to his or her supervising pharmacist documentation that the pharmacy intern has completed all of the training and current certification required by subsections 3.1.b. and 3.1.c. of this rule. The supervising pharmacist shall maintain this documentation in the pharmacy where the pharmacist and pharmacy intern who administers an immunization is employed or otherwise practicing at the time any immunization is administered by a pharmacy intern.

4.4 Prior to administering immunizations, a pharmacy technician shall submit an application supplied by the Board providing that all of the requirements of Section 3.3 have been met. Providing all requirements of Section 3.3 have been met, the Board shall issue a registration to administer immunizations. Registrations shall expire biennially on June 30 of the year in which the pharmacy technician's license expires.

§15-12-5. Immunizations.

5.1. A licensed pharmacist may order and a licensed pharmacist, pharmacy intern or pharmacy technician may administer immunizations in accordance with this rule.

5.2. Immunizations authorized by this rule shall be administered:

5.2.a. in accordance with a prescription order from a healthcare provider for a person age 3 years and up; or

5.2.b. in accordance with definitive treatment guidelines for immunizations promulgated by the latest notice from the U.S. Department of Health and Human Services, CDC, including, but not limited to, CDC's recommended immunization schedule for adults and children and adolescents, including the footnotes provided for each schedule, available at https://www.cdc.gov/vaccines/ or a successor webpage created for the same purpose. Such immunizations administered to a person age three to seventeen years shall be given only:

5.2.b.1. with parental written, informed consent;

5.2.b.2. provided there are no contraindications to that person receiving that vaccine; and

5.2.b.3. after informing the patient and the adult caregiver accompanying the patient of the importance of a well-child visit with a pediatrician or other licensed primary-care provider and referral for patients as appropriate.

5.3. Administration shall be done in accordance with the training required by section 3.1.b. including, but not limited to indications, contraindications, route of administration, sanitary environment for administration, specifics regarding administration, and storage requirements for each specific immunization authorized by this rule, and, when done pursuant to a prescription, in accordance therewith;

5.4. Administration shall include implementation of the CDC's recommended appropriate observation for an adverse reaction of an individual following an immunization.

5.5. A pharmacist may not delegate the authority to administer immunizations to any other person, unless administered by a licensed pharmacy intern or registered pharmacy technician under the direct supervision of a pharmacist of whom the pharmacist, the pharmacist technician and intern have successfully completed all required training.

5.6. A current Vaccine Information Statement, as provided by CDC, shall be provided to each person receiving an immunization for each immunization administered.

§15-12-6. Record-keeping and reporting.

6.1. An immunization questionnaire and consent form shall be completed for each person receiving an immunization. When the immunization is for a minor age three through seventeen years of age, the questionnaire and consent form shall include written informed parental consent for the minor.

6.2. 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 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, pharmacy intern, or pharmacy technician shall document such in the immunization record and provide a record of the immunization administration to the patient. The record shall contain the name of the pharmacist, and, where applicable, the name of the pharmacy intern or pharmacy technician administering the immunization.

6.3. The pharmacist shall 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 30 days of the date of the administration.

6.4. The immunization questionnaire, 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 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, pharmacy intern, or pharmacy technician who administered the immunization is employed or otherwise practicing at the time the immunization is given.

6.5. A pharmacist shall report all adverse events to the Vaccine Adverse Events Reporting System (VAERS), and promptly provide a copy of all reports to the Board; the West Virginia Department of Health and Human Resources Bureau for Public Health, Office of Epidemiology and Prevention Services, Division of Immunization Services; and the patient's primary care physician or other licensed health care provider as identified by the person receiving the immunization in accordance with subsection 6.2.

§15-12-7. Emergencies.

7.1. A pharmacist, pharmacy intern, or pharmacy technician 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.

7.2. A pharmacist, pharmacy intern, or pharmacy technician shall have a readily retrievable emergency response plan as outlined 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 shall approve a course or program in immunization administration for pharmacists and pharmacy interns 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, shall 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. A course approved by the Board for pharmacists and pharmacy interns shall include a minimum of fifteen hours of didactic and practical based components of instruction and training, including self-study and live instruction. The live instruction shall be a minimum of six hours and shall include documented and supervised instruction on physical administration of vaccinations.

8.3 The Board shall approve a course or program in immunization administration for pharmacy technicians to be used to meet the qualification requirement of section 3.3.c. In order to be approved by the Board, the course or program, at a minimum shall include practical training and instruction on the following:

8.3.a. proper technique of drawing up and administering immunizations;

8.3.b. commonly used vaccines and their corresponding routes of administration;

8.3.c. proper needle length selection based on vaccine, patient age, and patient size;

8.3.d. proper vaccine storage requirements;

8.3.e. safety measures to avoid accidental needle stick injuries; and

8.3.f. appropriate actions to take in emergency situations.

8.4 A course approved by the Board shall include a self-study component combined with a practical component that teaches hands-on immunization techniques.

TITLE 15
LEGISLATIVE RULE
WEST VIRGINIA BOARD OF PHARMACY

SERIES 13
REGULATION OF CHARITABLE CLINIC PHARMACIES

§15-13-1. General.

1.1. Scope. -- This rule establishes the requirements for charitable clinic pharmacies to operate in West Virginia to prepare and dispense prescriptions to patients of the clinics in this State.

1.2. Authority. -- W. Va. Code §§ 30-5-14 and 30-5-19.

1.3. Filing Date. -- June 9, 2009.

1.4. Effective Date. -- July 1, 2009.

§15-13-2. Definitions.

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

2.1.1. "Charitable clinic pharmacy" means a clinic or facility organized as a not-for-profit corporation that offers pharmaceutical care and dispenses prescriptions free of charge to appropriately screened and qualified patients. A charitable clinic pharmacy shall meet the minimum standards for a pharmacy as set forth in W. Va. Code §30-5-1, et seq., and by this rule, but may not be charged any applicable licensing fees. A charitable clinic pharmacy may have pharmacists-in-charge, as that term is defined in this section, who volunteers his or her services. A charitable clinic may also receive donated drugs. It is not the intent of this rule to affect any organizations which are merely operating a prescribing practitioner's or clinic's free sample drug room.

2.1.2. "Charitable organization" means an organization which operates a clinic or facility organized as a not-for-profit corporation which is qualified as a charitable organization pursuant to Section 501(c)(3) of the Internal Revenue Code, or its successor.

2.1.3. "Legend drug sample" for purposes of this Series means an unopened package of a manufacturers legend drug product that has been distributed to either a practitioner or the charitable clinic pharmacy in accordance with the provisions of the Prescription Drug Marketing Act of 1987, 21 U.S.C. §301 et seq, or its successor.

2.1.4. "Qualified patient" means a patient of the charitable clinic pharmacy that has been screened and approved by the charitable organization as meeting the organization's mission of providing pharmaceutical care to those who are without sufficient funds to obtain needed legend drugs. The requirements and screening process employed by the charitable organization must be in accordance with the "Guidelines" and other program requirements developed by the West Virginia Department of Health and Human Resources, Office of Community Health Systems, Division of Primary Care, for eligibility to receive funding as a "Free Clinic" for "Uncompensated Care and Equipment and Capital Costs Funding".

§15-13-3. Charitable Clinic Pharmacy Permit Required.

3.1. A charitable clinic pharmacy is considered to be a pharmacy and must follow all federal and state laws, rules, and regulations that pertain to pharmacies and the practice of pharmacy, except as otherwise provided specifically herein. A charitable clinic pharmacy permit is required for a charitable organization to operate a

pharmacy in this State to dispense prescription drugs to qualified patients. No fee is required to apply for or obtain the permit.

3.2. Permits obtained pursuant to this section expire on June 30 of each calendar year. Renewal will be conducted in accordance with the laws and rules for renewing pharmacy permits as outlined in this rule.

3.3. Charitable Clinic Pharmacies may petition the Board for exemptions from portions of the requirements set forth in this rule which are not addressed here on a case by case basis, including, but not limited to, such things as the requirement for weights and measures if no compounding is to be done, the requirement for separate security features and alarms if they are available on the clinic building as a whole, and other such requirements.

§15-13-4. Controlled Substances Restricted; Prescriptions to qualified patients.

4.1. A charitable clinic pharmacy shall not purchase, possess, trade, distribute, or dispense controlled substances.

4.2. Patient Dispensing. Prescriptions filled in a charitable clinic pharmacy may only be dispensed to qualified patients of that pharmacy on lawful orders or prescriptions of practitioners authorized by law to prescribe or administer said drugs.

4.2.1. All prescriptions filled by the charitable clinic pharmacy must be checked by a pharmacist or a prescribing practitioner licensed as such in the State of West Virginia prior to being dispensed; Provided That any prescribing practitioner licensed in this State may access the charitable clinic pharmacy to fill, check, or dispense prescriptions when no pharmacist is present, provided that he or she insures proper labeling and documentation of the dispensing.

4.2.2. Any other rule notwithstanding, in the absence of a pharmacist, a prescribing practitioner who is licensed in the State of West Virginia may also supervise the work of pharmacy technicians within the pharmacy, so that they may continue to work during that period of time.

4.2.3. Any other rule notwithstanding, if there is no pharmacist or prescribing practitioner who is licensed in the State of West Virginia present to supervise the pharmacy technicians, the pharmacy technicians may continue to process and fill prescriptions, and perform all other duties which may be performed by a pharmacy technician, for up to two hours during the charitable clinic pharmacy's regular hours of operation provided that no actual dispensing may occur until the prescriptions filled are checked in accordance with subsection 4.2.1 above.

4.3. The charitable clinic pharmacy may not charge any fee for dispensing prescription drug samples or prescription legend drugs to qualified patients of the charitable clinic pharmacy. However, this rule does not prevent a charitable clinic or charitable clinic pharmacy from requesting voluntary donations from its patients who receive prescriptions, provided that a sign is posted in a conspicuous location where it can be seen by all patients stating that a donation is not required to receive prescription drugs.

4.4. Any other rule notwithstanding, a charitable clinic pharmacy may allow completed prescription orders to be dispensed to its patients by permitting a pharmacy technician or other licensed health care provider working on behalf of the charitable clinic to transport the completed prescription to another remote clinic operated by the charitable clinic, Provided That:

4.4.1. the completed prescriptions are kept in a locked tote or other such storage container and remain in the possession of the licensed health care provider until such time as they are actually dispensed directly to the patient or someone picking up on behalf of the patient;

4.4.2. the completed prescriptions are accompanied by a manifest indicating the contents of the tote at the time they leave the pharmacy;

4.4.3. the patient or person picking up the prescription on behalf of the patient signs for receipt of the prescription; and

4.4.4. any prescriptions which are not dispensed at the remote clinic site are returned in the locked tote to the charitable clinic pharmacy, along with the manifest, by a licensed health care provider working on behalf of the charitable clinic, and are reconciled by the pharmacy.

4.5. Charitable clinic pharmacies are exempt from the restrictions in Section 15-1.19.10 insofar as the charitable clinic pharmacy may provide prescription blanks imprinted with its name for prescribers working in the clinic to write prescriptions to be filled at the charitable clinic pharmacy.

§15-13-5. Prescription Drug Samples.

5.1. Except insofar as it may conflict with federal law, charitable clinic pharmacies are exempt from any State law or rule which restricts who may receive sample drugs from a manufacturer. Specifically, unless it conflicts with federal law, a charitable clinic pharmacy may accept donated prescription drugs in their unbroken original packaging from pharmacies, licensed prescribers, wholesalers, or manufacturers provided appropriate records of transfer, donation, and receipt are maintained: Provided That the samples have been stored under the proper conditions required by the manufacturer and applicable law to prevent deterioration or contamination. However, a charitable clinic pharmacy may only receive, possess, and dispense prescription drug samples if the following conditions are satisfied:

5.1.1. The samples are dispensed at no charge to qualified patients of that charitable clinic pharmacy;

5.1.2. The samples are possessed in compliance with the Federal Prescription Drug Marketing Act of 1987, 21 U.S.C. §301 et seq, or its successor;

5.1.3. The samples are in the original container in which they were placed by the manufacturer and the container is clearly marked sample;

5.1.4. Prior to being furnished or dispensed, the samples have been stored under the proper conditions to prevent deterioration or contamination;

5.1.5. The samples are clearly marked with an expiration date and lot number;

5.1.6. The samples are not expired; and

5.1.7. The samples are not a controlled substance.

5.2. If donated samples are received which do not comply with Section 15-13-5.1, then they must be refused, returned, or properly disposed of by the charitable clinic pharmacy.

5.3. A charitable clinic pharmacy may not sell, purchase, or trade prescription drug samples.

5.4. A Charitable Clinic Pharmacy dispensing a sample drug shall comply with the following:

5.4.1. A pharmacist in a charitable clinic pharmacy must have a valid prescription prior to dispensing a sample drug to a patient.

5.4.2. The charitable clinic pharmacy must determine the eligibility requirements for a patient to receive a sample drug.

5.4.3. The sample drug is dispensed:

5.4.3.a. In the original container in which it was placed by its manufacturer where the container is clearly marked as sample; or

5.4.3.b. By removing the sample drug from the original container only if the prescription label on the appropriate container clearly states that the drug dispensed is a sample drug.

5.4.4. Nothing is this rule shall restrict a prescribing practitioner from providing samples in their original container from being given to the practitioner's patients in accordance with federal law.

§15-13-6. Pharmacist-In-Charge Responsibilities.

6.1. The pharmacist-in-charge at the charitable clinic pharmacy is responsible for implementing policies and procedures and a quality assurance program for operation of the charitable clinic pharmacy.

6.2. The pharmacist-in-charge at the charitable clinic pharmacy shall ensure through implementation of policies and procedures that the following occurs at the charitable clinic pharmacy:

6.2.1. donated drugs dispensed from pharmacy are properly labeled;

6.2.2. donated drugs that are expired, adulterated, misbranded, recalled, deteriorated, not kept under proper conditions, or did not have the identifying drug information on them as required are not dispensed to patients;

6.2.3. donated drugs are inspected prior to dispensing to determine that the donated drugs meet all federal and state requirements for product integrity;

6.2.4. donated drugs that are expired, adulterated, misbranded, recalled, deteriorated, not kept under proper conditions, or did not have the identifying drug information on them as required are destroyed; and

6.2.5. manifests for donated drugs that are dispensed pursuant to prescriptions from the charitable clinic pharmacy are created and maintained at the charitable clinic pharmacy as required for all prescription records.

§15-13-7. Limitations of Charitable Clinic Pharmacies.

Charitable Clinic Pharmacies shall comply with the following:

7.1. All drug therapies and prescriptions shall be prescribed on an individual basis.

7.2. A Charitable Clinic Pharmacy may not accept lost identity or unknown drugs.

7.3. Misbranded drugs may not be accepted by the Charitable Clinic Pharmacy.

7.4. A Charitable Pharmacy may accept donated and unadulterated prescription drugs in their unbroken original manufacturer packaging from pharmacies, licensed prescribers, wholesalers or manufacturers, the State of West Virginia, the Board of Pharmacy or by other means, provided appropriate records of receipt are maintained.

§15-13-8. Continuing Education Credits for Volunteering in Charitable Clinic Pharmacy.

A pharmacists who volunteers as a pharmacist-in-charge or a staff pharmacist in a charitable clinic pharmacy may earn up to a maximum of six live continuing education credits for such activities. For every eight hours worked in a charitable clinic pharmacy as the PIC, the PIC may earn one hour of live continuing education credit.

For every ten hours worked in a charitable clinic pharmacy as a staff pharmacist, the pharmacist may earn one hour of live continuing education credit.

§15-13-9. Inspection and Investigation of Charitable Clinic Pharmacies.

9.1. The Board of Pharmacy will use an Inspection Form which is consistent with the requirements under which a Charitable Clinic Pharmacy shall operate as contemplated by W. Va. Code §30-5-1b.

9.2. Upon receipt of the completed inspection form, the Board of Pharmacy and any appointed Quality Control Committee or other such body of the Charitable Clinic Pharmacy may meet and confer to address and resolve issues which may impact the health and safety of the pharmacy's patients. To the extent necessary, corrective plans may result from such meeting(s) with timeframes established by the Board of Pharmacy for the resolution of Quality control issues.

TITLE 15
LEGISLATIVE RULE
WEST VIRGINIA BOARD OF PHARMACY

SERIES 14
BOARD OF PHARMACY RULES FOR CENTRALIZED PRESCRIPTION PROCESSING

§15-14-1. General.

1.1. Scope -- To establish standards for central prescription processing.

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

1.3. Filing date -- May 3, 2024.

1.4. Effective date -- May 3, 2024.

1.5. Sunset Date -- This rule shall terminate and have no further force or effect on August 1, 2034.

§15-14-2. Definitions.

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

2.1.a. "Central fill pharmacy" means a pharmacy or central filling operation registered as a pharmacy by the Board acting as an agent of or under contract with the originating or delivering pharmacy to fill or refill a prescription.

2.1.b. "Central prescription filling" means filling of a new or refilling of a prescription drug order by a central fill pharmacy at the request of an originating or delivering pharmacy for delivery to the patient or patient's agent pursuant to the lawful order of a practitioner.

2.1.c. "Originating pharmacy" means a pharmacy registered with the Board that uses a central fill pharmacy to fill or refill a prescription order received by or transferred to that pharmacy by the patient, the patient's agent, or the patient's prescriber.

§15-14-3. General Requirements.

3.1. Any other rule notwithstanding, a pharmacy may outsource a prescription drug order filling, excluding prescription drug orders for Schedule II controlled substances listed in West Virginia Code § 60A-2-206, to another pharmacy via central prescription filling provided the pharmacies:

3.1.a. Have the same owner; or

3.1.b. Have entered into a written contract or agreement which outlines the services to be provided and responsibilities and accountabilities of each pharmacy in compliance with federal and state laws and regulations, and include confidentiality of patient information; and

3.1.c. Share a common electronic file or have appropriate technology or interface to allow secure access to sufficient information necessary or required to fill or process a prescription drug order.

3.2. The pharmacist in charge of the central fill pharmacy shall assure that:

3.2.a. The pharmacy maintains and uses adequate storage or shipment containers and shipping processes to ensure drug stability and potency. Such shipping processes shall include the use of appropriate

packaging material and/or devices to ensure that the drug is maintained at an appropriate temperature range to maintain the integrity of the medication through the delivery process; and

3.2.b. The filled prescriptions are shipped in containers which are sealed in a manner as to show evidence of opening or tampering.

3.3. The filling, processing, and delivering of a drug order by a central fill pharmacy for an originating or delivering pharmacy pursuant to this series is not to be considered a drug order transfer or a wholesale distribution.

3.4. Any filled prescription which was not picked up by or actually delivered to the patient must be put into the originating or delivering pharmacy's inventory.

3.5. Prior to outsourcing the filling of a prescription to a central fill pharmacy, the originating or delivering pharmacy must notify patients that their prescription may be outsourced to a central fill pharmacy and provide the name and address of the central fill pharmacy. Such notice may be provided through a one-time written notice to the patient or through the use of a sign in the pharmacy.

3.6. The originating or delivering pharmacy is responsible for making the offer to counsel to the patient or patient's agent picking up the prescription on behalf of the patient.

3.7. Pharmacies that perform central prescription filling shall create operating policies and procedures. The policies and procedures must include:

3.7.a. an audit trail that records and documents the central prescription filling process and the individuals accountable at each step in the process for complying with Federal and State laws and regulations including recordkeeping; and

3.7.b. provisions for dispensing prescription drug orders when the filled order is not received from the central fill pharmacy, or the patient or patient's representative comes into the originating or delivering pharmacy before the order is received from the central fill pharmacy. The standard of care must not be altered by the pharmacies' central fill program. Ultimately the patient's therapy cannot be unreasonably delayed.

3.8. The prescription label of a centrally filled prescription shall display the name and address of the originating or delivering pharmacy and may include the name of the central fill pharmacy, as well as all other information required by Rule § 15-1-22.

3.9. Each pharmacy engaging in central prescription filling shall be jointly responsible for:

3.9.a. Maintaining manual or electronic records that identify, individually for each drug order processed, the name, initials, or other unique identifier of each pharmacist, intern or pharmacy technician who took part in the central prescription filling functions performed at that pharmacy;

3.9.b. Maintaining manual or electronic records that identify, individually for each drug order filled or dispensed, the name, initials, or other unique identifier of each pharmacist, pharmacy intern, pharmacy technician, and pharmacy technician trainee who took part in the filling and dispensing functions performed at that pharmacy;

3.9.c. Maintaining a mechanism for tracking the drug order during each step of the processing and filling procedures performed at the pharmacy. The central fill pharmacy must keep a record of the date the filled prescription was delivered to the originating or delivering pharmacy and the method of delivery (i.e., private, common or contract carrier). The originating or delivering pharmacy must keep a record of receipt of the filled prescription, including the date of receipt, the method of delivery (i.e. private, common or contract carrier) and the name of the originating or delivering pharmacy employee accepting delivery;

3.9.d. Providing for adequate security to protect the confidentiality and integrity of patient information; and

3.9.e. Providing for inspection of any required record or information within 72 hours of any request by the Board or its designee.

15-14-4. Remote Order Entry and Remote Order Review.

4.1. Remote-order-entry or remote-order-review of prescription orders for prescriptions received at a pharmacy registered by this state is permitted to be performed by another pharmacy registered by the state, Provided that:

4.1.a. for purposes of data entry, the data entry must be performed by a licensed pharmacist, licensed pharmacy intern, or registered pharmacy technician or pharmacy technician trainee who is located at the other pharmacy registered by the state which shares a common automated data processing system, and such system creates an audit trail of which pharmacist, pharmacy intern, or pharmacy technician or pharmacy technician trainee entered the data; and

4.1.b. for purpose of drug regimen review, the review must be performed by a licensed pharmacist who is located at the other pharmacy registered by the state which shares a common automated data processing system, and such system creates an audit trail of which pharmacist provided the drug regimen review.

4.1.c. Nothing in this Section shall prohibit an individual licensed pharmacist licensed in the state, who is an employee of or under contract with a licensed pharmacy, or a licensed pharmacy technician or pharmacy intern, working under the supervision of the pharmacist, from accessing that pharmacy's electronic database from inside or outside the pharmacy and performing the prescription drug order processing functions permitted by the W.Va. Code 30-5.1 *et seq*., if the following conditions are met:

4.1.c.1. The pharmacy establishes controls to protect the confidentiality and integrity of Protected Health Information; and

4.1.c.2. No part of the database is duplicated, downloaded, or removed from the pharmacy's electronic database; and

4.1.c.3. The pharmacy's electronic database shall only be accessed outside of the pharmacy via a virtual private network (VPN).

TITLE 15
LEGISLATIVE RULE
WEST VIRGINIA BOARD OF PHARMACY

SERIES 15
REGULATIONS GOVERNING PHARMACY PERMITS

§15-15-1. General.

1.1. Scope. -- Licensure and regulations governing pharmacy permits.

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

1.3. Filing date -- May 3, 2024.

1.4. Effective date -- May 3, 2024.

1.5. Sunset Date -- This rule shall terminate and have no further force or effect on August 1, 2034.

§15-15-2. Registration.

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

2.2. A pharmacy shall obtain a registration biennially. Not more than one registration may be issued in any one name in more than one location. Every registered pharmacy shall be under the direct charge of a pharmacist, designated the Pharmacist-in-charge, and shall operate in compliance with the state and federal laws and rules and regulations.

2.2.1. The application for a new registration shall be completed on a form prescribed and furnished by the Board.

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

2.2.3. A pharmacy shall have applicable current references readily available according to practice setting as required by this rule.

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

2.2.5. A pharmacy compounding compounded sterile preparations shall also apply for a compounding permit as required by this rule.

§15-15-3. Issuance of Permit.

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

3.2. The registration 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, rules and regulations.

3.3. A registration shall be posted in a visibly conspicuous place.

§15-15-4. Renewal of registration.

4.1. The biennial renewal of a registration takes place on the first day of July of each year. The fee for the biennial renewal is $150.00. Registrations expire on the thirtieth day of June of each calendar year. Renewal applications shall be completed and submitted to the Board office by the fifteenth day of June to allow time for processing. Pharmacies shall have a grace period for renewal until July 31 of the year in which the permit expires; however, renewal applications received in the Board office after June 30 of the year in which the registration expires shall require the payment of a late fee in the amount of $150.00 in addition to the application fee of $150.00, for a total amount of $300.00.

4.2. If a pharmacy does not make application for renewal by the first day of August biennially, to renew an expired registration the Board shall re-inspect the pharmacy and the permittee shall pay the required renewal fee and late fee totaling $300.00 for the registration, and $300.00 for the re-inspection, for a total amount of $600.00.

§15-15-5. Surrender of registration.

5.1. When a pharmacist-in-charge changes at a pharmacy, both the pharmacist-in-charge and pharmacy must notify the Board in writing within fourteen (14) days. The original permit should be copied and the change in pharmacist-in-charge written on the original and copy of the permit. The copy of the modified permit shall be posted in the pharmacy. The original modified permit should be surrendered to the Board along with a ten-dollar ($10.00) fee for the new registration reflecting the new pharmacist-in-charge. Upon receipt of the notification, the Board shall provide for the new registration to the pharmacy. An Interim pharmacist-in-charge may be designated for a period not to exceed sixty (60) days. If an interim pharmacist-in-charge is designated who is not the permanent pharmacist-in-charge, the fee shall not be charged, and a new permit shall not be issued until a permanent pharmacist-in-charge is designated.

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

5.3. When a pharmacy changes ownership the registration expires, and a new registration shall be obtained from the Board.

§15-15-6. Security.

6.1. A board approved operating plan shall be implemented if a pharmacy is to be operated for a period less than regular business hours of the entire store or institution.

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

6.2.1. The device shall be maintained in functioning order and shall have an auxiliary source of power;

6.2.2. Deactivation of the alarm system for the prescription department shall be restricted to the pharmacists working at the pharmacy, and the system shall be activated whenever a pharmacist is not on duty. The pharmacy registration holder may deactivate the system for security or surveillance purposes as long as the reason for the deactivation, the person deactivating the system, and time and date of deactivation are documented and readily retrievable to the Board; and

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

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

the following:

6.3.1. Only licensed pharmacists may possess any keys to the prescription area;

6.3.2. During times that an institutional pharmacy may be unattended by a pharmacist, arrangements shall be made in advance by the pharmacist-in-charge for provision of drugs to the medical staff and other authorized personnel and shall ensure that:

6.3.2.a. drugs are properly labels;

6.3.2.b. only prepackaged drugs are available, in amounts sufficient for immediate therapeutic requirements;

6.3.2.c. whenever access to the cabinet occurs, written practitioner's orders and proof-of-use are provided;

6.3.2.d. all drugs in the cabinet are inventoried no less than once per week;

6.3.2.e. a complete audit of all activity concerning the cabinet is conducted no less than once per month; and

6.3.2.f. written policies and procedures are established to implement the patient care provisions of this subdivision.

6.3.3. 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";

6.4. 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;

6.5. Except as provided in Title 15, Series 14, for central prescription filling, completed prescription orders shall be bagged and kept in the pharmacy and cannot be removed from the pharmacy unless the pharmacist is present and the removal is for the immediate delivery to the patient, the patient's authorized designee picking up the prescription for the patient, or person delivering the prescription to the patient at his or her residence or other place designated by the patient or the patient's authorized designee. If the patient or the patient's designee is unknown to the pharmacist, then his or her identity shall be established by photo identification card;

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

6.7. 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.

§15-15-7. Professional Work Environment

7.1 A pharmacist, pharmacy intern, and pharmacy technician who works eight continuous hours or longer per day shall take, at a minimum, one thirty-minute uninterrupted meal break during that work period. If such a pharmacist, pharmacy intern, or pharmacy technician is required to work twelve continuous hours per twenty-four hours, at a minimum, the individual qualifies for an additional twenty-minute break. A pharmacist, pharmacy intern, or pharmacy technician, who is entitled to take such breaks shall not be required to work more than five continuous hours, excluding a twenty-minute break, before being given the opportunity to take a thirty-minute uninterrupted meal break.

7.2 A pharmacy shall not require a pharmacist, pharmacy intern, or pharmacy technician to work longer than twelve continuous hours per twenty-four-hour period, inclusive of the required breaks under 7.1.

7.3 A pharmacy shall keep and maintain a complete and accurate record showing its pharmacists' daily break periods.

7.4 In the case of an emergency, as deemed by the professional judgement of the pharmacist, a pharmacist, pharmacy intern, or pharmacy technician may work longer than twelve continuous hours, work without taking meal breaks, or have a break interrupted in order to minimize immediate health risks for patients. The pharmacist must document and date the amount of time worked beyond the twelve hours limit or breaks missed along with the reason and make it available to the Board.

7.5 The pharmacist-in-charge or designee shall determine the work schedule for pharmacy technicians based upon prior dispensing records. The pharmacist shall ensure adequate staffing levels based on prior dispensing records and patient care tasks. The pharmacist-in-charge shall have final approval of the work schedule. Any decision overriding such control of the PIC may be grounds for disciplinary action against the pharmacy permit.

7.6 The pharmacist on duty or the pharmacy registrant shall notify the pharmacist-in-charge via telephone, e-mail, or text message whenever a prescription error, loss of drugs, or a violation of any statute or rule occurs and the pharmacist-in-charge is not present.

7.7 A pharmacy shall not use advertisements or make solicitations that may jeopardize the health, safety, or welfare of patients, including, but not limited to, the use of advertisements or solicitations that:

7.7.1 Are false, fraudulent, deceptive, or misleading;

7.7.2 Include any claim regarding a professional service or product or the cost or price thereof that cannot be substantiated by the licensee.

7.8 A pharmacy shall not require a pharmacist to participate in the use or distribution of advertisements.

7.9. A pharmacy shall provide a working environment for all pharmacy personnel that protects the health, safety, and welfare of a patient, which includes, but is not limited to:

7.9.1 employing sufficient personnel to prevent fatigue, distraction or other conditions that interfere with a pharmacist’s ability to practice with competency and safety or creates an environment that jeopardizes patient care as determined by the pharmacist-in-charge or pharmacists based on prior dispensing records and current patient care responsibilities;

7.9.2 Providing appropriate opportunities for uninterrupted rest periods and meal breaks;

7.9.3 Providing adequate time for a pharmacist to complete professional duties and responsibilities, including but not limited to:

7.9.3.a. drug utilization review;

7.9.3.b. immunization;

7.9.3.c. counseling;

7.9.3.d. verification of the accuracy of a prescription;

7.9.3.e. all other duties and responsibilities of a pharmacist as listed in the rules of the Board.

§15-15-8. Notification.

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

8.2. An employer who employs a licensed pharmacist shall notify the Board within fourteen (14) days, in writing, of any discharge or termination of the licensed pharmacist or change of the status of the pharmacist-in-charge.

8.3. A person who employs a licensed pharmacist shall, within three business days from the time of discovery, notify the Board, in writing, of any violations of board rules or laws by the licensed pharmacist.

§15-15-9. Whistleblower protection

9.1 A permit or license holder of the Board who is found to be in violation of 11 (c) CFR 1977.3 or §6C-1 known as the “Whistle-blower law” may be subject to disciplinary action by the Board.

9.2 Nothing in this Section shall be deemed to diminish the rights, privileges, or remedies of an employee of a pharmacy under any other federal or State law, rule, or regulation or under any employment contract.

§15-15-10 Temporary, Permanent, or Emergency Closure of a Pharmacy

10.1. For a temporary closure of a pharmacy, the pharmacy shall:

10.1.1. Post notification of closure on each pharmacy entrance as soon as the need to deviate from the posted hours is known by the pharmacy, but no later than 2 hours after the temporary closure begins. The posting must include:

10.1.1.a. Estimated period of time the pharmacy will be closed; and

10.1.1.b. Options for prescription pick-up (e.g., another local pharmacy, contact prescriber for new prescription, reverse processed prescriptions).

10.1.2. Post notification of closure on each telephone greeting and pharmacy operated internet (e.g., website, social media, mobile applications) as soon as possible. The posting must include:

10.1.2.a. Estimated period of time the pharmacy will be closed; and

10.1.2.b. Options for prescription pick-up (e.g., another local pharmacy, contact prescriber for new prescription, reverse processed prescriptions).

10.1.3. If the pharmacy is temporarily closed greater than two consecutive business days or has

planned closures greater than two days in a 7-day period deviating from the regular business hours, notify the board office as soon as possible but no later than 72 hours after the temporary closure begins with the date and time the closure began, anticipated date and time of re-opening, and the reason for the temporary closure.

10.2. For a permanent closure of a pharmacy, the pharmacy shall:

10.2.1. Prior to closing, the pharmacy must comply with the following:

10.2.1.a. Provide notification of the closing to each patient who has filled a prescription at that pharmacy within the previous 12 months. This notification must be made a minimum of 14 calendar days prior to closing and must include:

10.2.1.a.1. The last day the pharmacy will be open;

10.2.1.a.2. Name, address, and telephone number of the pharmacy that will take possession of the pharmacy records or the person who will serve as the custodian of records;

10.2.1.a.3. Instructions on how patients can arrange for transfer of their pharmacy records to a pharmacy of their choice; and

10.2.1.a.4. The last day a transfer may be initiated.

10.2.1.b. The notification must be made via:

10.2.1.b.1. Distribution by direct mail, electronic mail, phone, text, or written notice with each prescription dispensed; and

10.2.1.b.2. Public notice in a newspaper, online, or print, of general circulation, if available, in the area served by the pharmacy; and

10.2.1.b.3. Posting a closing notice on each pharmacy entrance, on each telephone greeting, and pharmacy-operated internet (e.g., website, social media, mobile applications).

10.2.1.c. Provide any new patients filling prescriptions during the 14-calendar day period prior to the pharmacy closing with written notification that includes:

10.2.1.c.1. The last day the pharmacy will be open;

10.2.1.c.2. Name, address, and telephone number of the pharmacy to which pharmacy records will be transferred or the person who will serve as the custodian of pharmacy records;

10.2.1.c.3. Instructions on how patients can arrange for transfer of their pharmacy records to a pharmacy of their choice; and

10.2.1.c.4. The last day a transfer may be initiated.

10.2.1.d. Notify DEA of any controlled substances, as defined by W. Va. Code 60A-2.201 *et seq.,* being transferred to another registrant as specified in 21 CFR 1301.52.

10.2.2. On the date of closing or up to 24 hours after the permanent closure begins, the pharmacist-in-charge must comply with the following:

10.2.2.a. Complete and document an inventory of all controlled substances.

10.2.2.b. If the pharmacy dispenses prescriptions:

10.2.2.b.1. Transfer the prescription drug order files, including refill information, and patient medication records to a licensed pharmacy pursuant to W.Va. 15 CSR 15-2 *et seq.* who will serve as the custodian of records;

10.2.2.b.2. Update the pharmacy operating status with each electronic prescribing vendor; and

10.2.2.b.3. Remove all signs and symbols indicating the presence of the pharmacy including pharmacy-operated internet (e.g., website, social media, mobile applications).

10.2.2.c. Notify the Board of the closing of the pharmacy.

10.2.3. After closing. Within 30 calendar days after the closing of the pharmacy, the pharmacist-in-charge must:

10.2.3.a. Complete and document an inventory of all non-controlled drugs and devices.

10.2.3.b. Remove all prescription and non-prescription drugs, devices, and related supplies from the pharmacy by one or a combination of the following methods:

10.2.3.b.1. Return to manufacturer or supplier (credit or disposal);

10.2.3.b.2. Transfer to a licensed healthcare professional or outlet who is legally authorized to possess drugs; or

10.2.3.b.3. Destroy and document the destruction by two Board licensees. For controlled substances, the registrant must comply with 21 CFR 1304.21, 21 CFR 1304.22, 21 CFR 1317.05, 21 CFR 1317.90 and 21 CFR 1317.95.

10.2.3.c. Provide the board a written notice of the closing on a Board prescribed form available at www.wvbop.com which includes the following information:

10.2.3.c.1. Date of closing to the public and discontinuance of the business;

10.2.3.c.2. Date and time the inventory of all prescription drugs and devices was conducted;

10.2.3.c.3. Name, address, phone number, and applicable registration number where all legend and controlled substances possessed by the pharmacy were transferred or disposed;

10.2.3.c.4. If drugs were destroyed, name and license numbers of individuals that who witnessed the destruction;

10.2.3.c.5. If the pharmacy is registered to possess controlled substances, confirmation that the pharmacy complied with all applicable federal requirements in 21 CFR 1301.52 for discontinuing operation as a pharmacy that dispenses controlled substances.

10.2.3.c.6. The name, address, and phone number of the pharmacy that took possession of the pharmacy records or the licensed pharmacist who is serve as the custodian of pharmacy records which must be maintained according to W.Va. 15 CSR 4.1 *et seq*.;

10.2.3.c.7. Confirmation all pharmacy labels and blank prescriptions were destroyed;

10.2.3.c.8. Confirmation all signs and symbols indicating the presence of the pharmacy including pharmacy-operated internet (e.g., website, social media, mobile applications) have been removed; and

10.2.3.c.9. Confirmation that each registration certificate issued to the pharmacy by the Board has been mailed to the board office.

10.2.3.d. Once the pharmacy has notified the Board that the pharmacy is permanently closed, the license may not be renewed.

10.2.3.e. Unless a registration has expired, the registration will remain active until the board has notified the registrant that the notice of permanent closure has been received and the registration has been lapsed.

10.2.3.f. The pharmacist-in-charge may be permitted, by written permission from the Board, an extension for compliance with Section 10.2.3 if the requestor shows good cause for the extension.

10.3. Emergency closing. If a pharmacy is closed suddenly due to fire, destruction, natural disaster, death, property seizure, eviction, bankruptcy, inclement weather, or other emergency circumstances and the pharmacist-in-charge cannot provide notification as required in subsection 10.1, the pharmacist-in-charge must comply with the provisions of subsection 10.1 as far in advance or as soon after the closing as allowed by the circumstances.

10.4. Non-resident pharmacies, as defined by W.Va. 15 CSR 6-2.2, are exempt from subsections 10.1, 10.2, and 10.3 and must follow laws and rules in the pharmacy's state of residence pertaining to temporary, permanent and emergency closures. The non-resident pharmacy must provide the Board a written notice of the closing within 30 calendar days on a form prescribed by the board available at www.wvbop.com which includes the following information:

10.4.1. Date of closing to the public and discontinuance of the business;

10.4.2. If the pharmacy dispenses prescriptions, the name, address and phone number of the pharmacy or licensed pharmacist who will serve as the custodian of records for West Virginia patients to which the prescriptions, including refill information, and patient medication records were transferred; and

10.4.3. Confirmation that each registration certificate issued to the pharmacy by the Board has been mailed to the board office.

10.5. The Board may conduct an inspection of the pharmacy and records to verify all requirements in this subsection.

TITLE 15
LEGISLATIVE RULE
WEST VIRGINIA BOARD OF PHARMACY

SERIES 16
REGULATIONS GOVERNING PHARMACISTS

§15-16-1. General.

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

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

1.3. Filing date -- April 14, 2022.

1.4. Effective date -- April 14, 2022.

1.5. Sunset Date -- This rule shall terminate and have no further force or effect upon August 1, 2027.

§ 15-16-2. Examination for Licensure and Registration and Annual Renewal Requirements.

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

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

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

2.2.2. An applicant shall present to the Board satisfactory evidence that he or she is a person of good moral character and has not been convicted of a crime that bears a rational nexus to the practice of pharmacy. For other convictions not bearing a rational nexus to the practice of pharmacy, the Board shall permit the applicant to apply for initial licensure if;

2.2.2.a.. a period of five years has elapsed from the date of conviction or the date of release from incarceration, whichever is later;

2.2.2.b. the individual has not been convicted of any other crime during the period of time following the disqualifying offense; and

2.2.2.c. the conviction was not for an offense of a violent or sexual nature: Provided, that a conviction for an offense of a violent or sexual nature may subject an individual to a longer period of disqualification from licensure, to be determined by the individual board.

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

2.2.4. An applicant shall have acquired 1500 hours of internship under the supervision of a licensed pharmacist.

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

§ 15-16-3. Examinations.

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

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.

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

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

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

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

§ 15-16-4. Certificate of Licensure.

4.1. An applicant for licensure who has successfully passed all the required examinations may receive a letter signed by the Secretary prior to preparation of a permanent certificate, or a permanent certificate evidencing that he or she is a licensed pharmacist. The permanent certificate of licensure shall bear a serial number, the full name of the applicant, the date of its issuance, the seal of the Board, and shall be signed by at least four (4) member of the Board, and attested by the President and Secretary. For any duplicate of this certificate the Board shall charge $25.00. A certificate is not assignable.

§ 15-16-5. License and registration renewal.

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

5.1.1. Biennial renewal of license of pharmacist: $100.00, provided that if the applicant is sixty-five (65) years of age or older at the time of renewal then the fee shall be $50.00;

5.1.2. License of pharmacy intern: $10.00 for the original license; $5.00 for each renewal for the remaining periods of his or her internship;

5.1.3. Registration of a consultant pharmacist: $20.00 for each application; and

5.1.4. Registration of a pharmacy technician: $25.00 for the original registration; $20.00 for each biennial renewal

5.2. All licenses of pharmacists and registrations of pharmacy technicians expire on the thirtieth day of June. One half of all licenses for pharmacists and registrations for pharmacy technicians shall be renewed for a period of one year to expire on the thirtieth day of June, and shall be biennially thereafter. The Board shall

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

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

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

§ 15-16-6. Reciprocity; Licensure of Pharmacists From Other States or Countries.

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

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

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

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

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

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

6.1.6. The applicant originally passed a written examination in subjects determined by the Board as being reasonable; and

6.1.7. The applicant passes the West Virginia MPJE.

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

6.2. An applicant may serve all or part of his or her internship in another state and up to one-third (1/3) of his or her internship in another country. In order to receive credit for that service an affidavit shall be signed by the supervising pharmacist and attested by the secretary of the board of pharmacy of the state or country where the internship was served.

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

6.4. A foreign pharmacy graduate whose undergraduate pharmacy degree was conferred by a school of pharmacy outside of the United States, and its territories, may establish educational equivalency by obtaining a Foreign Pharmacy Graduate Examination Committee Certificate (FPGEC) from the National Association of Boards of Pharmacy (NABP). An applicant for licensure who receives FPGEC certification meets the educational requirement for licensure and may sit for the NAPLEX and MPJE examinations provided he or she has completed 1500 hours of internship, of which 500 hours may have been earned in a foreign country, as certified on a letter of credit or certification from the Board of Pharmacy or other regulatory body of the foreign state, province, or country responsible for regulation of the practice of pharmacy in the foreign location, and must complete a criminal history records check as prescribed in § 29.

§ 15-16-7. Application.

7.1. The applicant shall complete a preliminary application form obtained from the National Association of Boards of Pharmacy and return it to that organization. After the preliminary application data has been verified by the National Association of Boards of Pharmacy and the Board receives notification to that effect, the Board shall supply the applicant who possesses the necessary qualifications with application forms. An applicant must complete the forms and submit a fee of $250.00.

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

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

7.2.2. 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

7.2.3. A signed waiver from the applicant allowing the Board to obtain a certified criminal records check on the applicant.

7.3 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.

TITLE 15
LEGISLATIVE RULE
WEST VIRGINIA BOARD OF PHARMACY

SERIES 17
BOARD OF PHARMACY RULES FOR THE SUBSTITUTION OF BIOLOGICAL PHARMACEUTICALS

§15-17-1. General.

1.1. Scope. -- To establish standards for the substitution of biological pharmaceuticals.

1.2. Authority. -- W. Va. Code§§ 30-5-7 and 30-5-12c.

1.3. Filing Date. -- April 25, 2024

1.4. Effective Date. -- April 25, 2024

1.5. Sunset Date -- This rule shall terminate and have no further force or effect upon August 1, 2034.

§15-17-2. Definitions.

2.1. “Biological product” means a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein (except any chemically synthesized polypeptide), or analogous product, or arsphenamine or derivative or arsphenamine (or any other trivalent organic arsenic compound), applicable to the prevention, treatment, or cure of a disease or condition of human beings.

2.2. “Biosimilar” means a biological product that has been licensed as a biosimilar pursuant to 42 U.S.C. § 262(k), reflecting that it is highly similar to the specific reference biological product notwithstanding minor differences in clinically inactive components, and that there are no clinically meaningful differences between the reference biological product in terms of safety, purity, and potency of the product.

2.3. “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.

2.4. “Interchangeable biological product” means a biological product that the federal Food and Drug Administration has licensed and determined meets the standards for interchangeability pursuant to 42 U.S.C § 262(k)(4) or determined is therapeutically equivalent as set forth in the latest edition of or supplement of the federal Food and Drug Administration’s Approved Drug Products with Therapeutic Equivalence Evaluations.

2.5. “Original prescription” means either the original written prescription drug order, or the original verbal or electronic prescription drug orders reduced to writing either manually or electronically by the pharmacist.

2.6. “Proper name” means the nonproprietary name of a biological product.

2.7. “Reference biological product” means the single biological product licensed pursuant to 42 U.S.C. § 262(a) against which a biological product is evaluated in an application submitted to the U.S. Food and Drug Administration for licensure of biological products as biosimilar or interchangeable pursuant to 42 U.S.C. § 262(k).

2.8. “Substitute” means to dispense without the prescriber's express authorization an interchangeable biological product in the place of the drug ordered or prescribed.

2.9. “Therapeutically equivalent” means pharmaceutically equivalent drug products that, if administered in the same amounts, will provide the same therapeutic effect, identical in duration and intensity.

§15-17-3. Substitution Requirements.

3.1. A pharmacist may dispense an interchangeable biological product if:

3.1.1. The interchangeable biological product costs the patient less than or the same amount as the prescribed drug
product;

3.1.2. The patient does not refuse the substitution; and

3.1.3. The practitioner does not certify on the prescription form that a specific prescribed brand is medically necessary as specified in a dispensing directive described in subsection (c) of this section.

3.2. Dispensing directive.

3.2.1. General requirements. The following is applicable to the dispensing directive outlined in this subsection.

3.2.1.a. When a prescription is issued for a brand name product that has no interchangeable biological equivalent, the pharmacist must dispense the brand name product. If an interchangeable biological product becomes available, a pharmacist may substitute the interchangeable biological product unless the practitioner has specified on the initial prescription that the brand name product is medically necessary.

3.2.1.b. If the practitioner has prohibited substitution through a dispensing directive in compliance with this subsection, a pharmacist shall not substitute an interchangeable biological product unless the pharmacist obtains verbal or written authorization from the practitioner, notes such authorization on the original prescription drug order, and notifies the patient.

3.2.2 Written prescriptions.

3.2.2.a A practitioner may prohibit the substitution of an interchangeable biological product for a brand name drug product by writing across the face of the written prescription, in the practitioner’s own handwriting, the phrase “brand necessary” or “brand medically necessary.”

3.2.2.b. The dispensing directive shall comply with federal and state law, including rules, with regard to formatting and security requirements

3.2.2.c. The dispensing directive specified in this section may not be preprinted, rubber stamped, or otherwise reproduced on the prescription form.

3.2.2.d. A practitioner may prohibit substitution on a written prescription only by following the dispensing directive specified in this section. Two-line prescription forms, check boxes, or other notations on an original prescription drug order which indicate “substitution instructions” are not valid methods to prohibit substitution, and a pharmacist may substitute on these types of written prescriptions.

3.2.3. Verbal prescription.

3.2.3.a. If a prescription drug order is transmitted to a pharmacist orally, the practitioner or practitioner's agent shall prohibit substitution by specifying "brand necessary" or "brand medically necessary." The pharmacist shall note any substitution instructions by the practitioner or practitioner's agent, on the file copy of the prescription drug order.

3.2.3.b. If the practitioner's or practitioner's agent does not clearly indicate that the brand name is medically necessary, the pharmacist may substitute a generically equivalent drug or interchangeable biological product.

3.2.4. Electronic prescription drug orders.

3.2.4.a. To prohibit substitution, the practitioner or practitioner's agent shall clearly indicate substitution instructions in the electronic prescription drug order.

3.2.4.b. If the practitioner or practitioner's agent does not indicate or does not clearly indicate in the electronic prescription drug order that the brand is necessary, the pharmacist may substitute an interchangeable biological product.

3.2.5. Refills. All refills shall follow the original substitution instructions unless otherwise indicated by the practitioner or practitioner's agent.

§15-17-4. Patient Notification.

4.1. Substitution notification. Before delivery of a prescription for an interchangeable biological product, a pharmacist must personally, or through his or her agent or employee inform the patient or the patient's agent that a less expensive interchangeable biological product is available for the brand prescribed; and ask the patient or the patient's agent to choose between the interchangeable biological product and the brand prescribed.

4.2. Exceptions. A pharmacy is not required to comply with the provisions of subsection 4.1. of this section:

4.2.1. in the case of the refill of a prescription for which the pharmacy previously complied with subsection 4.1. of this section with regard to the same patient or patient's agent; or

4.2.2. if the patient's physician or physician's agent advises the pharmacy that:

4.2.2.a. the physician has informed the patient or the patient's agent that a less expensive interchangeable biological product is available for the brand prescribed; and

4.2.2.b. the patient or the patient's agent has chosen either the brand prescribed or the less interchangeable biological product.

4.3. Notification by pharmacies delivering prescriptions by mail.

4.3.1. A pharmacy that supplies a prescription by mail is considered to have complied with the provision of subsection 4.1. of this section if the pharmacy includes on the prescription order form completed by the patient or the patient's agent language that clearly and conspicuously:

4.3.1.a. states that if a less expensive generically equivalent drug or interchangeable biological product is available for the brand prescribed, the patient or the patient's agent may choose between the generically equivalent drug or interchangeable biological product and the brand prescribed; and

4.3.1.b. allows the patient or the patient's agent to indicate the choice of the generically equivalent drug or interchangeable biological product or the brand prescribed.

4.3.2. If the patient or patient's agent fails to indicate otherwise to a pharmacy on the prescription order form under 4.1.a. of this subsection, the pharmacy may dispense an interchangeable biological product.

§15-17-5. Communication with prescriber.

5.1. Not later than the fifth business day after the date of dispensing a biological product, the dispensing pharmacist or the pharmacist's designee shall communicate to the prescribing practitioner the specific product provided to the patient, including the name of the product and the manufacturer or national drug code number.

5.2. The communication must be conveyed by making an entry into an interoperable electronic medical records system or through electronic prescribing technology or a pharmacy benefit management system or a pharmacy record, which may include information submitted for the payment of claims, that a pharmacist reasonably concludes is electronically accessible by the prescribing practitioner. Otherwise, the pharmacist or the pharmacist's designee shall communicate the biological product dispensed to the prescribing practitioner, using facsimile, telephone, electronic transmission, or other prevailing means, provided that communication is not required if:

5.2.1. there is no interchangeable biological product approved by the United States Food and Drug Administration for the product prescribed; or

5.2.2. a refill prescription is not changed from the product dispensed on the prior filling of the prescription.

§15-17-6. Records.

6.1. When a pharmacist dispenses an interchangeable biological product, the following information shall be noted on the original prescription or in the pharmacy's data processing system:

6.1.1. any substitution instructions communicated orally to the pharmacist by the practitioner or practitioner's agent; and

6.1.2. the name and strength of the actual drug product dispensed shall be noted on the original or hard-copy prescription drug order. The name shall be either:

6.1.2.a. the brand name and strength; or

6.1.2.b. the name of the interchangeable biological product, strength, and name of the manufacturer or distributor of such generic drug or interchangeable biological product. (The name of the manufacturer or distributor may be reduced to an abbreviation or initials, provided the abbreviation or initials are sufficient to identify the manufacturer or distributor. For combination drug products having no brand name, the principal active ingredients shall be indicated on the prescription.)

6.2. If a pharmacist refills a prescription drug order with a generically equivalent product or interchangeable biological product from a different manufacturer or distributor than previously dispensed, the pharmacist shall record on the prescription drug order the information required in subsection 6.1 of this section for the product dispensed on the refill.

6.3. If a pharmacy utilized patient medication records for recording prescription information, the information required in subsections 6.1. and 6.2. of this section shall be recorded on the patient medication records.

6.4. The National Drug Code (NDC) of a drug or any other code may be indicated on the prescription drug order at the discretion of the pharmacist, but such code shall not be used in place of subsections 6.1. and 6.2.

§15-17-7. Dispensing Responsibilities.

7.1. The determination of the drug product to be substituted as authorized by West Virginia Code of State Rules §15-17 et seq. is the professional responsibility of the pharmacist, and the pharmacist may not dispense any product that does not meet the requirements of the West Virginia Code of State Rules §15-17 et seq.

7.2. Pharmacists shall use as a basis for the determination of interchangeability as defined in West Virginia Code of State Rules §15-17 et seq., most recent edition or supplement of the United States Food and Drug Administration's references (e.g. the Purple Book).

7.3. Pharmacists shall use Lists of Licensed Biological Products with Reference Product Exclusivity and Biosimilarity or Interchangeability Evaluations (Purple Book) and current supplements published by the Federal Food and Drug Administration, within the limitations stipulated in that publication, to determine biosimilarity to or interchangeability with a reference biological product.

TITLE 15
LEGISLATIVE RULE
WEST VIRGINIA BOARD OF PHARMACY

SERIES 18
APPLICATION FOR WAIVER OF INITIAL LICENSING FEES
FOR CERTAIN INDIVIDUALS

§15-18-1. General.

1.1. Scope. -- This rule establishes procedures for waiving the initial licensing fee for low income individuals and military personnel and their spouses.

1.2. Authority. -- W. Va. Code §30-5-7 and §30-1-22.

1.3. Filing Date. – April 27, 2020.

1.4. Effective Date. – April 27, 2020.

1.5. Sunset Provision. -- This rule shall terminate and have no further force or effect on April 27, 2025.

§15-18-2. Definitions.

2.1. “Board” means the West Virginia Board of Pharmacy.

2.3. “Initial license” means an individual applying for a pharmacist intern, pharmacist, pharmacy technician, or pharmacy technician trainee license in West Virginia for the first time;

2.4 "Local labor market" means every county in West Virginia, and any county outside of West Virginia if any portion of that county is within fifty miles of the border of West Virginia, pursuant to W.Va. Code §21-1C-2;

2.5. “Low-income individual” means an individual in the local labor market as defined in §21-1C-2, whose household adjusted gross income is below 130 percent of the federal poverty line. This term also includes any person enrolled in a state or federal public assistance program including, but not limited to, the Temporary Assistance for Needy Families Program, Medicaid, or the Supplemental Nutrition Assistance Program;

2.6. “Military families” means any person who serves as an active member of the armed forces of the United States, the National Guard, or a reserve component as described in 38 U. S. C. §101, honorably discharged veterans of those forces, and their spouses. This term also includes surviving spouses of deceased service members who have not remarried; and

§15-18-3. Application for Waiver of Initial Licensure Fees.

3.1. An applicant seeking a low income or military family waiver of the initial licensing fee shall apply for licensure to the board and provide the required documentation.

3.2. The Board shall provide the application form and instructions on what documentation is necessary to submit with the license application requesting the low income or military family initial licensing fee waiver.

3.3. An applicant shall submit all required documentation to the board and upon the submission of a complete application, the board shall review the application and issue a decision within 30 days of receipt of the completed application.

3.4. The board may issue a license to an applicant who meets the requirements of W. Va. Code §30-5-1 *et seq*., the rules promulgated by the board, and the board shall waive the initial licensing fee for an applicant that meets the requirement of "low-income individuals" or "military families" as defined in W.Va. Code §30-1-22.

§15-18-4. Required Documentation for Waiver of Initial Licensure Fees.

4.1. Individuals requesting a waiver of initial licensure fees for low income or military service personnel and their spouses, shall submit with the application for licensure the initial licensure waiver forms provided by the board and the appropriate documentation as specified in this section.

4.2. To establish low income eligibility for the initial licensing fee waiver, an applicant shall submit to the board evidence that the adjusted gross income of the household of the applicant is at or below 130% of the federal poverty level by submitting documentation of eligibility for:

4.2.1. Temporary Assistance for Needy Families Program;

4.2.2. Medicaid;

4.2.3. Supplemental Nutrition Assistance Program; or

4.2.4. A Federal Tax Return.

4.3. To establish military family eligibility for the initial licensing fee waiver, an applicant shall submit to the board proof of qualifying military service and proof of eligibility as a qualifying spouse or widow, as follows:

4.3.1. A service members DD-214 form;

4.3.2. A service members NGB-22 form;

4.3.3. A service members DD-1300 form; or

4.3.4. A copy of their current military orders; and

4.3.5. A copy of the marriage certificate with the qualifying service member and, where applicable, the death certificate of the service member if the widow is applying for the military family waiver.

4.4. Honorably discharged applicants shall submit a completed application, and a DD-214 form or an NGB-22 form showing the applicant has been an honorably discharged from military service.

TITLE 15
LEGISLATIVE RULE
WEST VIRGINIA BOARD OF PHARMACY

SERIES 19
INSPECTIONS

§15-19-1. General.

1.1. Scope. -- Inspection process for the West Virginia Board of Pharmacy.

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

1.3. Filing date -- May 2, 2023

1.4. Effective date -- May 2, 2023

1.5. Sunset Provision -- This rule will terminate and have no further force or effect on August 1, 2027.

§15-19-2. Definitions. The following words and phrases as used in this Rule mean:

2.1. “Board” means the West Virginia Board of Pharmacy.

2.2. "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.

2.3. “Controlled Substance Permit” means the permit require to be obtained by the Board, unless otherwise exempt, for every person who manufactures, distributes, including reverse distributing, or dispenses any controlled substances or who proposes to engage in the manufacture, distribution or dispensing of any controlled substance within this state.

2.4. “Inspection” means the process by which the Board verifies certain information of Board licenses.

2.5. “Inspector” means a person employed by the Board to perform inspections.

2.6. “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.

2.7. “Non-compliance report” means a report created noting a deficiency discovered during an inspection.

2.8. “Non-sterile compounding” means the process of combining, admixing, diluting, pooling, reconstituting other than as provided in the manufacturer’s labeling, or otherwise altering a drug or bulk drug substance to create a non-sterile preparation.

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

2.10. "Outpatient pharmacy" means any pharmacy, apothecary, or place within this state where drugs are

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

2.11. “Unscheduled inspection” means an unannounced inspection.

2.12. “Sterile compounding” means compounding or mixing prescription orders for sterile solutions or suspensions to be administered parenterally, enterally, by irrigation or ophthalmic drops.

2.13. “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.

§15-19-3. Inspector Qualifications.

3.1. In order to qualify for the position of inspector, a candidate must be a WV licensed pharmacist and have at least ten (10) years of pharmacy practice experience.

3.2. Upon being hired, each inspector shall complete a training program in accordance with the Board’s training manual, complete the National Investigator and Inspector Training Basic Course, and complete the National Association of Boards of Pharmacy Certification for Inspecting Sterile Compounding Facilities.

§15-19-4. Regions.

4.1 The Board shall establish regions within the state. Each region shall have approximately the same amount of licensed facilities requiring inspection pursuant to W. Va. Code §30-5-1 *et seq.*

4.2. Each inspector shall be assigned a region.

§15-19-5. Scheduling of Inspections.

5.1. Inspections shall be conducted within ninety days of the regularly scheduled inspection frequency, unless circumstances make compliance with this timeframe unattainable.

5.2. Inspectors shall schedule Inspections by notifying the facility to be inspected at least one week in advance of the inspection.

5.3. Unscheduled inspections shall be conducted by each Inspector on an annual basis for an amount of inspections not to exceed 10% of the facilities within the Inspector’s region.

§15-19-6. Conducting Inspections.

6.1. At a minimum, the methods established by the Board for conducting inspections shall include the following:

6.1.1. presentation of credentials;

6.1.2. copies of the inspection forms to be used;

6.1.3. details on the use of electronic inspection forms;

6.1.4. a listing of documents to be reviewed; and

6.1.5. listing of staff that may be interviewed.

6.2. Completed hard copy inspections shall be submitted to the Board office within 90 days.

6.3. Completed hard copy inspections shall be recorded in the Board database.

6.4. Inspections completed on the electronic inspection form shall be automatically entered into the Board database.

6.5. Copies of the completed inspection form shall be provided to the facility inspected.

6.6. Non-compliance reports shall be completed and entered into the Board database.

6.7. Completed inspections shall be reviewed by the Chief Compliance Officer within ninety days. This review shall be documented in the Board database.

6.8. Non-compliance reports shall be logged in a manner which allows for the systematic monitoring of facility's actions toward correcting areas of significant deficiencies.

6.9. Facilities not meeting the expected corrections within the timeframe established by the inspector may be referred to the Complaint Committee of the Board.

6.10. All records, documents, communications, and images shall be maintained in the Board database for a period of five years.

§15-19-7. Inspection Forms.

7.1. The Board shall create inspection forms for each type of facility inspected. The inspection forms shall contain citations to relevant laws and appropriate Board of Pharmacy Rules.

7.2. The inspection forms used by the Board shall be made available to the public on the Board's website www.wvbop.com.

§15-19-8. Inspection Frequency.

8.1. The following facility types shall be inspected annually:

8.1.1. outpatient pharmacies;

8.1.2. institutional pharmacies;

8.1.3. charitable clinic pharmacies;

8.1.4. nuclear pharmacies;

8.1.5. sterile compounding facilities;

8.1.6. non-sterile compounding facilities.

8.2. Facilities that only hold a controlled substance permit and no other Board permit or license shall be inspected biennially.

TITLE 15
LEGISLATIVE RULE
WEST VIRGINIA BOARD OF PHARMACY

SERIES 20
DONATED DRUG REPOSITORY PROGRAM

§15-20-1 General

1.1. Scope. – To establish requirements and process for donated drug repository programs

1.2. Authority – W. Va. Code §60B-1-8

1.3. Filing Date --- May 2, 2023

1.4. Effective Date --- May 2, 2023

1.5. Sunset Date – This rule shall terminate and have no further force or effect on August 1, 2028.

§15-20-2 Definitions

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

2.1.1. “Board” means the West Virginia Board of Pharmacy.

2.1.2. “Controlled substance” means a drug, substance, or immediate precursor in Schedules I through V of §60A-2-1 *et seq.* of this code, and Schedules I through V of 21 CFR Part 1308.

2.1.3. “Donor” means any person, including an individual member of the public, or any entity legally authorized to possess drugs with a license or permit in good standing in the state in which it is located, including, but not limited to, a wholesaler or distributor, third party logistic provider, pharmacy, dispenser, clinic, surgical or health center, detention and rehabilitation center, laboratory, medical or pharmacy school, prescriber or other health care professional, or healthcare facility. Donor also means government agencies and entities that are federally authorized to possess drugs including, but not limited to, drug manufacturers, repackagers, relabelers, outsourcing facilities, Veteran Affairs hospitals, and prisons.

2.1.4. “Drugs” means both prescription and nonprescription (“over-the-counter”) drugs.

2.1.5. “Donated drug repository program" means a program authorized to accept prescription and non-prescription drugs donated or given for the purpose of being dispensed or personally furnished to individuals who are residents of this state and meets eligibility standards

2.1.6. “Eligible patient” means an indigent person. However, if the recipient’s supply of donated drugs exceeds the need for donated drugs by indigent patients, then any other person in need of a particular drug can be an eligible patient.

2.1.7. “Eligible recipient” means a pharmacy, wholesaler, reverse distributor, hospital, federally qualified health center, nonprofit clinic, healthcare facility, an entity participating in a drug donation or repository program pursuant to another state’s law, or a private office of a healthcare professional that has been authorized by the West Virginia Board of Pharmacy.

2.1.8. “Healthcare facility” means a facility licensed by the State of West Virginia as a:

(1) Nursing home;

(2) Personal care home;

(3) Assisted living community;

(4) Residential care facility for the elderly;

(5) Hospice;

(6) Hospital;

(7) Home health agency; or

(8) A similar entity licensed in the state in which it is located.

2.1.9. “Health care professional” means a person who is licensed by the State of West Virginia to practice as a:

(1) Physician;

(2) Registered nurse or licensed practical nurse;

(3) Physician assistant;

(4) Dentist or dental hygienist;

(5) Optometrist; or

(6) Pharmacist.

2.1.10. “Indigent patient” means a patient whose income is at or below the income eligibility requirements of the West Virginia Medicaid program, or who is uninsured, underinsured, or enrolled in a public assistance health benefits program.

2.1.11. “Program” means the donated drug repository program established by rule pursuant to §60B-1-8 of this code.

2.1.12. “Responsible individual” means a person permitted by law to have legal possession of prescription drugs.

2.1.13. “Transaction date” means the date on which ownership of the drugs is transferred between two participants of the program as established by contract or other arrangement. If no such contract or arrangement exists, the transaction date shall be the date the drug was accepted into inventory by the recipient.

§15-20-3 Waivers

3.1. A donor or eligible recipient may request a waiver from the board with regard to any rule related to this program by demonstrating the waiver is in the interest of public health and safety.

3.2. The donor or eligible recipient seeking the waiver will receive correspondence from the board with the decision.

§15-20-4 Authorization process for eligible recipients

4.1. To be eligible for participation in the program, a pharmacy, wholesaler, reverse distributor, hospital, federally qualified health center, nonprofit clinic, healthcare facility, an entity participating in a drug donation or repository program pursuant to another state's law, or private office of a healthcare professional shall be in compliance with all applicable federal and state laws, including laws applicable to the storage and distribution of drugs and all the appropriate licensure standards, and shall hold active, state-issued licenses or registrations in good standing.

4.2. An eligible recipient may establish a donated drug repository program at an authorized address.

4.3. The eligible recipient shall provide written notification to the Board of participation in the program on the form provided on the Board of Pharmacy website at www.wvbop.com.

4.4. Each eligible recipient shall make a separate notification to the board for each drug repository program address.

4.5. Each donated drug repository program must designate a responsible individual.

4.6. Each donated drug repository program notification shall be accompanied by a notification fee of $50 annually.

4.7. The notification shall serve for participation in the program for a period of one year, unless revoked by the Board. The eligible recipient may renew its authority via renotification annually by June 30.

4.8. Withdrawal from participation. A donated drug repository program may withdraw from the Program at any time by providing written notice to the Board on a form provided and available on the Board's website.

4.9. Failure to comply with any provision of §60B-1-1 *et seq.* or statutes governing prescription drugs may result in revocation of authority to participate in the program. Revocation shall be provided as a written notice including the specific requirements that were violated and corrective actions necessary to reinstate its authority to participate in the program.

§15-20-5 Eligible Drugs

5.1. Any individual who is 18 years of age or older may donate legally obtained prescription drugs or supplies to a drug repository program if the drugs meet the requirements of this rule, as determined by the pharmacist or responsible healthcare provider of the drug repository program. The 18 year or older parent or guardian of a minor may donate the minor's legally obtained drugs or supplies if all requirements are met.

5.1.1. The donor shall remove or redact any patient names and prescription numbers on donated drugs or otherwise maintain patient confidentiality by executing a confidentiality agreement with the eligible recipient.

5.2. No drugs that require storage temperatures other than normal room temperature as specified by the manufacturer or United States Pharmacopeia shall be donated or accepted as part of the donated drug repository program due to the increased potential for adulteration. Drugs donated directedly from a drug manufacturer, wholesaler, third party logistics provider, or pharmacy are excluded from this provision and may be donated.

5.3 Controlled substances shall not be donated or accepted.

5.4 Drugs subject to a federal Food and Drug Administration managed risk evaluation and mitigation strategy pursuant to 21 U.S.C. §355-1 if inventory transfer is prohibited may not be donated or accepted.

5.5 Drugs may be dispensed by a donated drug repository program only if all of the following are met:

5.5.1 The drug is in unopened, tamper-evident packaging as defined by the United States Pharmacopeia General Chapter 659, Packaging and Storage Requirements, including but not limited to unopened, unit-dose and multiple dose packaging. A drug in a single-unit dose or blister pack with the outside packaging opened may be dispensed if the single unit-dose packaging is undisturbed and meets the labeling requirements of 15 CSR 1-20.2.1;

5.5.2 The drug has been stored according to manufacturer's or USP storage conditions;

5.5.3 The packaging contains the expiration date;

5.5.4 The drug has an expiration date that is more than six months after the date that the drug was donated. However, a donated prescription drug bearing an expiration date that is six months or less after the date the prescription drug was donated may be accepted and dispensed if the drug is in high demand and can be dispensed for use prior to the drug's expiration date;

5.5.5 The drug does not have any physical signs of tampering or adulteration, and there is no reason the believe that the drug is adulterated;

5.5.6 The packaging does not have any physical signs of tampering, misbranding, deterioration, compromised integrity, or adulteration; and

5.6 A drop box may not be used to deliver or accept donations.

§15-20-6 Storage and handling of donated drugs by eligible recipients

6.1 A licensed pharmacist or the responsible healthcare professional for the donated drug repository program shall inspect the donated drugs prior to dispensing to determine, to the extent reasonable possible in their professional judgement, that the drugs are not adulterated or misbranded, are safe and suitable for dispensing.

6.2 The eligible recipient shall store and maintain donated drugs in a secure and temperature-controlled environment that meets the drug manufacturers' recommendations and United States Pharmacopeia Standards.

6.3 If a recall notification is received, the donated drug repository program shall identify all recalled prescription product in the facility, dispose of all recalled drug as directed in the recall, and document the disposal in the records for the donated drug repository program. If a recalled drug has been dispensed, the donated drug repository program shall immediately notify the recipient of the recalled drug pursuant to established drug recall procedures.

§15-20-7 Eligible Patients

7.1 An individual must meet the following criteria to be eligible to receive medication from a donated drug repository:

7.1.1 Income is at or below the income eligibility requirements of the West Virginia Medicaid Program;

7.1.2 Uninsured;

7.1.3 Underinsured; or

7.1.4 Enrolled in a public assistance health benefits program.

7.2 If a donated drug repository program's supply of donated drugs exceeds the need for donated drugs by indigent patients, then any other person in need of a particular drug can be an eligible patient.

§15-20-8 Dispensing of donated drugs

8.1. Donated drugs may only be dispensed to eligible patients pursuant to a valid prescription order.

8.2. A donated drug repository program shall dispense donated prescription drugs in compliance with federal and state laws and regulations for dispensing prescription drugs, including but not limited to all requirements relating to packaging, labeling, record keeping, drug utilization review, and patient counseling. The eligible patient will be counseled and sign an acknowledgement that the drug was donated.

8.3. Donated drugs may not be resold and shall be considered nonsalable. However, reimbursement for any handling fee does not constitute reselling. A donated drug repository program may charge the eligible recipient a handling fee not to exceed the reasonable costs of participating in the program including, but not limited to, the current and anticipated costs of educating eligible donors, providing technical support to participating donors, shipping and handling, labor, storage, licensing, utilities, advertising, technology, supplies, and equipment.

8.4. The fees charged, and costs listed in 15 CSR 20-8.3 shall be included in the audit information made available to the Board.

8.5. Nothing in the preceding paragraph limits an eligible recipient from charging fees, including, but not limited to, a usual and customary charge, to donors, eligible recipients, health plans, pharmacy benefit managers, and other entities.

§15-20-9 Required Records

9.1. Prior to accepting a donation into inventory, a donated drug repository program that dispenses donated drugs or supplies to an eligible patient shall maintain a written or electronic inventory of each donated drug or supply that shall include the following information:

9.1.1. The transaction date;
9.1.2. The name, strength, and quantity of each accepted drug; and
9.1.3. The name, address, and phone number of the eligible donor providing each drug or supply.

9.2. A donated drug repository program shall keep all donated drugs physically or electronically separated from other inventory. Donated inventory may be used to replenish purchased inventory with the same drug name and strength that was previously dispensed or administered to an eligible person. Replenishment shall follow applicable provisions of the federal 340B Drug Pricing Program. Replenishment may not be done using drugs donated by the public.

9.3. In addition to all records required for dispensing a prescription drug or supply under W. Va. Code 30-5 and rules, a donated drug repository program shall note, either on the face of a written prescription or in the electronic record of a prescription, that a donated drug was dispensed to the patient if the site dispenses both donated and non-donated drugs.

9.4. All records must be made available for audit by the Board within five business days.

9.5. All records must be kept for six years.

9.6. Prior to the first donation from a new donor, an eligible recipient shall collect an attestation signed electronically or physically by the person making the donation or that person's authorized representative, verifying and recording information required by W. Va. Code §60B-1-5(c).

§15-20-10 Exemption from disciplinary action, civil liability or criminal prosecution

10.1. Unless an action or omission constitutes willful or wanton misconduct, the following persons or entities shall not be subject to criminal or civil prosecution, criminal or civil liability from injury, death, or loss to person or property, or other criminal or civil action, or disciplinary actions by licensing, professional, or regulatory agencies:

10.1.1. A person who donates or gives drugs to an eligible recipient, including a drug wholesaler, drug manufacturer, reverse distributor, pharmacy, third-party logistics provider, government entity, hospital or health care entity;

10.1.2. An eligible recipient;

10.1.3. A healthcare professional who prescribes or dispenses a donated drug;

10.1.4. The Board of Pharmacy;

10.1.5. An intermediary that helps administer the program by facilitating the donation or transfer of drugs to eligible recipients;

10.1.6. A repackager or manufacturer of a donated drug; and

10.1.7. Any employee, volunteer, trainee, or other staff of individuals and entities listed in (1) through (6)

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 Osteopathic Medicine for legislative approval pertaining to a pharmacist's scope of practice pursuant to collaborative pharmacy practice and collaborative pharmacy practice agreements, content of collaborative pharmacy agreements, responsibilities of a pharmacist and physician with respect to collaborative pharmacy agreements, the content, process and fee for filing collaborative pharmacy practice notifications, and the termination of collaborative pharmacy practice agreements by the parties or the boards.

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

1.3. Filing date. -- May 10, 2023

1.4. Effective date. -- June 1, 2023

1.5. Sunset Provision – This rule shall terminate and have no further force or effect upon August 1, 2028.

§11-8-2. Definitions.

For purposes of this rule, the following definitions apply:

2.1. "Boards" means the West Virginia Board of Pharmacy, the West Virginia Board of Medicine, and the West Virginia Board of Osteopathic Medicine.

2.2. "Collaborating pharmacist" means a pharmacist licensed in West Virginia who has been verified by the Board of Pharmacy to engage in collaborative pharmacy practice:

With one or more collaborating physicians:

Pursuant to a collaborative pharmacy practice agreement developed in accord with this rule; and

For which a complete and valid practice notification is filed with the boards.

2.3. "Collaborating physician" means a doctor of medicine or osteopathic medicine fully and actively licensed to practice clinical medicine, without restriction, in West Virginia by the Board of Medicine or the Board of Osteopathic Medicine who collaborates with pharmacists:

Pursuant to a collaborative pharmacy practice agreement developed in accord with this rule; and

For which a complete and valid practice notification is filed with the boards.

A physician in training may also collaborate with pharmacists pursuant to an active collaborative pharmacy agreement if the trainee's supervising physician or medical department chair executes the collaborative pharmacy practice agreement and the physician in training collaborates under the supervision of the physician who executed the agreement.

2.4. "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.

2.5. “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, or for a medical provider in training where the agreement is signed by the supervising physician or chairperson of the medical department where the medical provider in training is practicing, and an individual pharmacist or pharmacists that provides for collaborative pharmacy practice for the purpose of drug therapy management of a patient.

2.6. “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.

2.7. “Controlled substances” means drugs that are classified by federal or state law in Schedules I, II, III, IV or V, as defined in W. Va. Code Chapter 60A, Article 2.

2.8. “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:

2.8.1. Implementing, modifying, and managing drug therapy according to the terms of the collaborative pharmacy practice agreement;

2.8.2. Collecting and reviewing patient histories;

2.8.3. Performing patient evaluations that are mutually agreed upon in the collaborative agreement; and

2.8.4. 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.

2.9. “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 W. Va. Code § 30-5-10.

2.10. “*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.

2.11. “Practice notification” means a written notice to the appropriate licensing board that an individual physician or physician group or a medical provider in training where the agreement is signed by the supervising physician or chairperson of the medical department where the medical provider in training is practicing, and an individual pharmacist or pharmacists will practice in collaboration.

2.12. “Website” means the set of related web pages operated by or on behalf of the boards located at the domain names of wvbop.com, wvbom.wv.gov, and wvbdosteo.org or at any successor domain name published by the boards.

§11-8-3. Requirements for Collaborative Pharmacy Practice.

3.1. Pharmacists and physicians may engage in collaborative pharmacy practice in accordance with the provisions of this rule.

3.2. Collaborative pharmacy practice may only occur:

3.2.1. Pursuant to a collaborative pharmacy practice agreement developed in accord with this rule; and

3.2.2. Once a complete and valid practice notification is filed with the boards.

3.3. A physician's eligibility to serve as a collaborating physician may be verified through information available on the websites of the Board of Medicine and Board of Osteopathic Medicine. Physicians who are eligible to collaborate with pharmacists shall ensure that pharmacy collaboration remains within:

3.3.1. The medical specialty and scope of the physician's practice; and

3.3.2. The education, training and experience of the collaborating pharmacist.

3.4. The Board of Pharmacy shall verify a pharmacist's eligibility to enter into collaborative pharmacy practice agreements upon receipt of an eligibility verification request which is accompanied by satisfactory documentation that the pharmacist:

3.4.1. Has an unrestricted and current license to practice as a pharmacist in West Virginia;

3.4.2. Has at least one million dollars of professional liability insurance coverage; and

3.4.3. Meets one of the following eligibility criteria:

3.4.3.a. The pharmacist earned a Certification from the Board of Pharmaceutical Specialties, or has completed an American Society of Health System Pharmacists (ASHP) accredited residency program, and two years of experienced verified by the Board of Pharmacy;

3.4.3.b. The pharmacist successfully completed the course of study and holds an academic degree of Doctor of Pharmacy and has three years of clinical experience verified by the Board of Pharmacy and has completed an Accreditation Council for Pharmacy Education (ACPE) approved certificate program in the area of practice covered by the collaborative pharmacy practice agreement; or

3.4.3.c. The pharmacist successfully completed the course of study and holds the academic degree Bachelor of Science in Pharmacy and has five years clinical experience verified by the Board of Pharmacy 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.

3.5. Eligible pharmacists and physicians may enter into collaborative pharmacy practice agreements in any practice setting. Collaborative pharmacy practice agreements must contain all required elements set forth in section 4 of this rule.

3.6. Prior to commencing practice pursuant to a collaborative pharmacy practice agreement, the parties shall file a complete practice notification with the Board of Pharmacy.

3.7. A practice notification shall be submitted on a form approved by the boards and shall be accompanied by a $50 fee payable to the Board of Pharmacy. The practice notification form shall be published on the boards' websites.

3.8. A practice notification shall include:

3.8.1. The full name, license number, licensing board, preferred mailing address, telephone number, and

email address of the pharmacist(s) and physician(s) who are entering into a collaborative pharmacy practice agreement;

3.8.2. The name and address of each location where the pharmacist will engage in collaborative pharmacy practice pursuant to the agreement;

3.8.3. The proposed effective date of the collaborative pharmacy practice agreement;

3.8.4. Certification by the collaborating pharmacist and collaborating physician that:

3.8.4.a. The pharmacist has been verified as eligible for collaborative pharmacy practice by the Board of Pharmacy;

3.8.4.b. The physician is eligible to serve as a collaborating physician;

3.8.4.c. A collaborative pharmacy practice agreement has been agreed upon and executed by the pharmacist and physician which is consistent with the physician's scope of practice, the pharmacist's education, training and experience, and includes, at a minimum, the protocols required by section 4 of this rule;

3.8.4.d. The collaborating pharmacist will maintain a copy of the collaborative pharmacy practice agreement at his or her place of practice and the parties will provide a copy to any of the boards, upon request;

3.8.4.e. Collaborative pharmacy practice shall only occur after informed consent of the patient, which must be noted in the patient medical record; and

3.8.4.f. The parties acknowledge that the collaborative pharmacy practice agreement does not include the management of controlled substances.

3.9. A complete practice notification is effective upon filing, remains valid until the collaborative pharmacy practice agreement terminates, and is not subject to renewal or renewal fees.

3.10. The boards shall acknowledge receipt of all practice notifications. If a practice notification is incomplete or appears to be invalid, the Board of Pharmacy shall contact the collaborating pharmacist about any issue of validity and any information needed to complete the practice notification. The Board of Pharmacy may request the assistance of the Board of Medicine or the Board of Osteopathic Medicine to evaluate or respond to any issues of practice notification completeness or validity.

3.11. Within five business days of receiving a complete, valid practice notification, the Board of Pharmacy shall confirm receipt to the collaborating pharmacist and provide a copy of the practice notification to the collaborating physician's licensing board. Within five days of receipt of the practice notification from the Board of Pharmacy, the Board of Medicine or Board of Osteopathic Medicine shall notify the collaborating physician.

3.12. The boards shall maintain a current list of all practice notifications for collaborative pharmacy practice agreements.

§11-8-4. Collaborative Pharmacy Practice Agreements.

4.1. Collaborative pharmacy practice agreements are voluntarily implemented by practitioners who seek to serve patients with active pharmacist participation in drug therapy management and other related protocols.

4.2. Collaborative pharmacy practice is a collaborative, physician-directed approach which may be utilized after informed consent is received from the patient and recorded in the patient medical record.

4.3. A collaborative pharmacy practice agreement shall establish the pharmacist's scope of practice for purposes of the agreement.

4.4. A pharmacist may not diagnose patients.

4.5. Collaborative pharmacy practice agreements shall be in writing. All pharmacists and physicians who are parties to the agreement shall sign the agreement, and copies of the agreement shall be made available to all individuals collaborating thereunder.

4.6. Collaborating pharmacists shall maintain a copy of the collaborative practice agreement at their place of practice.

4.7. Collaborative practice agreements shall incorporate protocols containing detailed direction concerning the services that collaborating pharmacists may perform for patients and the role of collaborating physicians. The protocols shall, at a minimum, include:

4.7.1. The specific drug or drugs to be managed by the collaborating pharmacist, and the terms and conditions under which drug therapy may be implemented, modified, or discontinued, including:

4.7.1.a. The protocols may authorize implementation or modification of drug dosages based on symptoms or laboratory or patient evaluations defined in the protocol;

4.7.1.b. The protocol shall include information specific to the drugs authorized by the collaborating physician;

4.7.1.c. In instances where drug therapy is discontinued, the pharmacist shall notify the treating physician of the discontinuance within seventy-two hours unless the protocol incorporates a shorter time period for notice;

4.7.1.d. Specific protocols for patients identified by the collaborating physician as having complex medical conditions or comorbidities, one or more of which are under treatment by another medical provider or specialist;

4.7.1.e. The protocol may not authorize the pharmacist to change a controlled substance or to initiate a drug not included in the established protocol.

4.7.2. The conditions and events upon which the pharmacist is required to notify 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 patient's medical record within one week of the evaluation and/or drug management change. If there are no drug therapy changes the information shall be provided to the physician within 30 days unless the protocol incorporates a shorter time period for such notice;

4.7.3. The laboratory tests that may be ordered in accordance with drug therapy management, including:

4.7.3.a. Authorization of the collaborating pharmacist to obtain or to conduct specific laboratory tests related to the drug therapy management;

4.7.3.b. The collaborating pharmacist may only obtain the laboratory tests specified in the collaborative pharmacy practice agreement;

4.7.3.c. Laboratories utilized by the pharmacist may be in a pharmacy or pharmacy center; and

4.7.3.d. 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;

4.7.4. The mutually agreed upon patient evaluations the pharmacist may conduct;

4.7.5. The protocol may authorize the pharmacist to monitor specific patient activities;

4.7.6. Procedures for documenting patient informed consent in the patient's medical record;

4.7.7. A provision for the collaborative drug therapy management protocol to be reviewed, updated, and re-executed or discontinued at least every two years;

4.7.8. A description of the method the pharmacist shall use to document the pharmacist's decisions or recommendations for the physician;

4.7.9. Procedures for record keeping, record sharing, and long-term record storage.

4.7.10. Procedures to follow in emergency situations.

4.7.11. 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. Pharmacist visits may not be substituted for physician visits.

4.8. A copy of the protocols set forth in the collaborative pharmacy practice agreement shall be filed in the patient's medical record.

4.9. A collaborating pharmacist may not delegate drug therapy management to anyone other than another collaborating pharmacist that has signed the applicable protocol.

4.10 A collaborating physician may not delegate collaborative drug therapy management to any unlicensed person or licensed person other than another physician, a collaborating physician assistant or a collaborating pharmacist.

§11-8-5. Termination of Collaborative Pharmacy Practice Agreements.

5.1. A collaborative pharmacy practice agreement automatically terminates if either the collaborating pharmacist(s) or collaborating physician(s) are no longer eligible to collaborate. If multiple practitioners are parties to the agreement, it shall not automatically terminate as long as there is at least one collaborating pharmacist and physician remaining.

5.2. A collaborative pharmacy practice agreement may be terminated at any time by any of the parties to the agreement.

5.3. A collaborating pharmacist shall notify the Board of Pharmacy in writing within ten days of the termination of an active collaborative pharmacy practice agreement.

5.4. The Board of Pharmacy shall notify the collaborating physician's licensing board within five days of receiving notice of termination of a collaborative pharmacy practice agreement.

5.5. A patient may, at any time, revoke consent for collaborative pharmacy practice. Immediately upon withdrawal of patient consent, collaborative pharmacy practice with respect to the non-consenting patient shall cease. Collaboration may continue pursuant to the collaborative pharmacy practice agreement with respect to other patients.

§11-8-6. Ethics.

6.1. There shall be no advertising of any collaborative pharmacy practice by either the physician or the pharmacist.

6.2. No physician may be employed by any pharmacist or pharmacy for the purpose of collaborative pharmacy practice.

6.3. No pharmacist or pharmacy shall make any direct or indirect referral to any physician or medical clinic for the purpose of collaborative pharmacy practice.

6.4. 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.

6.5. Pharmacists and physicians who collaborate shall not allow an employment arrangement to:

6.5.1. Interfere with sound clinical judgment;

6.5.2. Diminish or influence the practitioners' ethical obligation to patients; or

6.5.3. Exert undue influence on, or interfere with the robustness of, the collaborative relationship.

§11-8-7. Reporting and Discipline.

7.1. Any 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.

7.2. 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 agreement.

7.3. 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. The licensure denial, complaint and disciplinary process and procedures and appeal rights set forth in each boards' practice act and rules shall apply to their respective licensees in connection with allegations of professional misconduct in connection with pharmacist-physician collaboration.

7.4. In their discretion, the boards may refer and receive information from one another concerning:

7.4.1. Mutual registrants and/or respective licensees;

7.4.2. Information developed during the complaint and investigation process of one board which implicates or otherwise relates to applicants, registrants and/or licensees of another board;

7.4.3. Any complaints received or discovered by one board which relate to mutual applicants, registrants and/or licensees or applicants, registrants and/or licensees of the other board.

7.5. It is dishonorable, unethical or unprofessional conduct for a pharmacist or a physician to engage in collaborative pharmacy practice without first entering into a written agreement which comports with the requirements of this rule and filing a complete practice notification with the boards through the process described in section 3 of this rule.

§30-4 Scope of Practice of a Dentist

The practice of dentistry includes the following:

(1) Coordinate dental services to meet the oral health needs of the patient;

(2) Examine, evaluate and diagnose diseases, disorders and conditions of the oral cavity, maxillofacial area and adjacent and associated structures;

(3) Treat diseases, disorders and conditions of the oral cavity, maxillofacial area and the adjacent and associated structures;

(4) Provide services to prevent diseases, disorders and conditions of the oral cavity, maxillofacial area and the adjacent and associated structures;

(5) Fabricate, repair or alter a dental prosthesis;

(6) Administer anesthesia in accordance with the provisions of article four-a of this chapter;

(7) Prescribe drugs necessary for the practice of dentistry;

(8) Execute and sign a death certificate when it is required in the practice of dentistry;

(9) Employ and supervise dental auxiliary personnel;

(10) Authorize delegated procedures to be performed by dental auxiliary personnel; and

(11) Perform any other work included in the curriculum of an approved dental school, college or dental department of a university.

Prescriptive Authority for APRN and Physician Assistant

§30-7-15a. Prescriptive authority for prescription drugs. APRN

(a) An advanced practice registered nurse may not prescribe a Schedule I controlled substance as provided in **§60A-2-204** *et seq.* of this code.

(b) An advanced practice registered nurse may prescribe up to a three-day supply of a Schedule II narcotic as provided in **§60A-2-206** *et seq.* of this code.

(c) There are no other limitations on the prescribing authority of an advanced practice registered nurse, except as provided in **§16-54-1** *et seq.* of this code.

§30-3E-3. Rulemaking. Prescriptive authority for physician assistants

(1) A physician assistant may not prescribe a Schedule I controlled substance as provided in §60A-2-204 of this code.

(2) A physician assistant may prescribe up to a three-day supply of a Schedule II narcotic as provided in §60A-2-206 of this code.

(3) There are no other limitations on the prescribing authority of a physician assistant, except as provided in §16-54-1 *et seq*. of this code.

Board of Optometry Prescribing Scope of Practice

§30-8-14. Prescriptive authority.

(a) A licensee may prescribe: (1) Topical pharmaceutical agents; (2) oral pharmaceutical agents that are included in the drug formulary established by the board pursuant to section six of this article or new drugs or new drug indications added by a decision of the board; and (3) contact lenses that contain and deliver pharmaceutical agents that have been approved by the Food and Drug Administration as a drug.

(b) An applicant must:

(1) Submit a completed application;

(2) Pay the appropriate fee;

(3) Show proof of current liability insurance coverage;

(4) Complete the board required training;

(5) Pass an examination; and

(6) Complete any other criteria the board may establish by rule.

TITLE 14
LEGISLATIVE RULE
WEST VIRGINIA BOARD OF OPTOMETRY

SERIES 2
ORAL PHARMACEUTICAL CERTIFICATE

§14-2-1. General.

1.1. Scope. -- This legislative rule establishes the requirements, procedures and standards for the certification and re-certification of licensees to obtain an oral pharmaceutical certificate.

1.2. Authority. -- W. Va. Code §30-8-6, §30-8-9, and §30-8-14.

1.3. Filing Date. -- August 12, 2011.

1.4. Effective Date. -- August 19, 2011.

§14-2-2. Requirements For Oral Pharmaceutical Certificate.

2.1. To be permitted to prescribe oral drugs under the provisions of W. Va. Code §§30-8-9 and 30-8-14, a licensee shall apply to the Board for certification. To qualify for certification, a licensee:

2.1.a. Shall satisfactorily complete a course in clinical pharmacology as applied to optometry. This course shall have particular emphasis on the administration of oral pharmaceutical agents for the diagnosis and treatment of visual defects or abnormal conditions of the human eye and its appendages. In addition, the course shall include instruction on the clinical use of Schedule III, IV, and V agents. This course shall consist of a minimum of thirty (30) hours in clinical systemic pharmacology. The course shall be taught by:

2.1.a.1. a school or college of optometry or a medical school, accredited by a regional or professional accreditation organization which is recognized or approved by the council on postsecondary accreditation or by the United States Department of Education;

2.1.a.2. a federally sponsored health education center; or

2.1.a.3. other non-profit continuing education agencies in cooperation with appropriate optometry or medical school faculty. All courses of instruction shall be approved by the Board; and

2.1.b. Shall pass an examination relating to the treatment and management of ocular disease, which is prepared, administered, and graded by the National Board of Examiners in Optometry or other nationally recognized optometric organization as approved by the Board.

§14-2-3. Certificate Application.

3.1. The licensee shall complete the prescribed oral pharmaceutical certificate application form.

3.2. The licensee shall submit a certificate of successful completion by the licensee for the course listed in section 2 of this rule. The Board or its designee shall verify successful completion of the course directly with the provider.

3.3. The licensee shall submit the passing score report for the examination listed in 2.1.b. of this rule. The Board or its designee shall verify passage of the examination directly with the provider.

3.4. The licensee shall submit a copy of a liability insurance certificate in an amount of not less than one million dollars ($1,000,000) per occurrence and three million ($3,000,000) aggregate coverage.

3.5. The licensee shall submit the fee listed in the Board's rule, Schedule of Fees, W. Va. Code of State Rules, §14CSR5.

§14-2-4. Certification.

4.1. Upon the licensee's successful completion of the requirements and application listed in sections 2 and 3 and approval by the Board or its designee a certificate may be issued.

4.2. Upon issuance of the certificate, the licensee's license number shall be changed. The license number will be followed by a dash and "OD" for oral prescriptive authority.

§14-2-5. Re-certification.

5.1. The certificate holder applying for re-certification shall have available for the Board, satisfactory evidence that he or she has acquired the continuing education hours required under the W. Va. Code of State Rules, §14CSR10 and this rule, to renew his or her annual license. Of those required hours, an optometrist certified under the provisions of this rule shall furnish to the Board satisfactory evidence that at least six (6) hours of the required hours were acquired in educational optometric programs in ocular pathology or therapeutic pharmacological agents.

5.2. The certificate holder shall submit a copy of a liability insurance certificate in an amount of not less than one million dollars ($1,000,000) per occurrence and three million ($3,000,000) aggregate coverage.

5.3. The certificate holder shall submit the fee listed in the W. Va. Code of State Rules, §14CSR5, Schedule of Fees.

5.4. It is the responsibility of each licensee to furnish proof of current liability insurance coverage to the Board upon application for certification and re-certification.

§14-2-6. Insurance.

6.1. All licensees certified under this rule shall carry liability insurance coverage in an amount of not less than one million dollars ($1,000,000) per occurrence and three million dollars ($3,000,000) aggregate coverage. No licensee shall practice under the provisions of this rule unless and until he or she has submitted to the board evidence of the liability insurance coverage in an amount not less than one million dollars ($1,000,000) per occurrence and three million dollars ($3,000,000) aggregate coverage.

§14-2-7. Drug Formulary.

7.1. Licensees certified under the provisions of this rule may prescribe the drugs set forth in W. Va. Code §§30-8-9, 30-8-14 and this section.

7.2. W. Va. Code §30-8-6 authorizes the Board to develop a formulary of categories of oral drugs to be considered rational to the diagnosis and treatment of visual defects or abnormal conditions of the human eye and its appendages from Schedules III, IV and V, excluding Schedule I and Schedule II of the Uniform Controlled Substances Act. The categories include:

7.2.a. Oral Antibiotics;

7.2.b. Oral Nonsteroidal Anti-inflamatory Drugs;

7.2.c. Oral Carbonic Anhydrase Inhibitors;

7.2.d. Antihistamines;

7.2.e. Oral Corticosteroids, may be prescribed for a duration of no more than six days;

7.2.f. Analgesics, provided that no oral narcotic analgesic may be prescribed for a duration of more than three days; and

7.2.g. Nutritional Supplements.

7.2.h. New drugs or new drug indications from Schedules III, IV and V, excluding Schedule I and Schedule II of the Uniform Controlled Substances Act which, regardless of their listed classification, have been shown to be effective in the examination, diagnosis or treatment of diseases and conditions of the human eye and its appendages may be approved by the Board according to the provisions of W. Va. Code §§30-8-9 and 30-8-14.

7.2.i. A list of approved new drugs and new drug indications proven to be effective in the examination, diagnosis or treatment of diseases and conditions of the human eye and its appendages will be maintained by the Board for public inspection.

7.2.j. The approval of Schedule I and Schedule II drugs is prohibited.

§14-2-8. New Drug Approval.

8.1. The addition of new drugs or drug indications by the Board as cited in subsection 7.2 of this rule may be based on any of the following criteria:

8.1.a. A new or existing drug has been approved by the Food and Drug Administration for the treatment of the eye or its appendages.

8.1.b. A new drug or new drug indication has gained accepted use in the eye care field. Such acceptance may be indicated by its inclusion in the curriculum of an optometry school accredited by the Accreditation Council on Optometric Education or its successor approved by the U.S. Department of Education or approved post-graduate continuing education, through peer-reviewed, evidence-based research and professional journal articles, or by inclusion in established standards of practice and care published by professional organizations.

§14-2-9. Education and Training on the Use of New Drugs and New Drug Indications.

9.1. Additional education and training may be required by the Board as it deems appropriate when it adds new drugs or new drug indications.

9.2. This training may be provided through an optometry school accredited by the Accreditation Council on Optometric Education or its successor recognized by the U.S. Department of Education or approved post-graduate training.

9.3. A list of Board required training for new drugs or new drug indications will be maintained by the Board for public inspection.

§14-2-10. Restrictions.

10.1. A certificate holder may not establish a pharmacy in an optometric office or sell oral pharmaceutical agents prescribed in treatment unless there is a licensed pharmacist on staff and present when the prescriptions are filled.

10.1.a. The certificate holder may also pass on to the patient a charge for any medications provided to initiate treatment which reflects only the actual amount paid by the optometrist for the agents. In no event shall an optometrist increase the cost of the pharmaceutical agent beyond the wholesale cost of that medication.

10.2. The certificate holder practicing under the authority of this rule shall be held to the same standards of care as that of other health care practitioners providing similar services.

§16-4F Expanded Partner Therapy

§16-4F-1 Definitions

As used in this article, unless the context otherwise indicates, the following terms have the following meanings:

(1) "Department" means the Department of Health.

(2) "Expedited partner therapy" means prescribing, dispensing, furnishing or otherwise providing prescription antibiotic drugs to the sexual partner or partners of a person clinically diagnosed as infected with a sexually transmitted disease without physical examination of the partner or partners.

(3) "Health care professional" means:

(A) An allopathic physician licensed pursuant to article three, chapter thirty of this code;

(B) An osteopathic physician licensed pursuant to article fourteen, chapter thirty of this code;

(C) A physician assistant licensed pursuant to §30-3E-4 of this code;

(D) An advanced practice registered nurse authorized with prescriptive authority pursuant to §03-7-15a of this code; or

(E) A pharmacist licensed pursuant to article five, chapter thirty of this code.

(4) "Sexually transmitted disease" means a disease that may be treated by expedited partner therapy as determined by rule of the department.

§16-4F-2 Expedited Partner Therapy

(a) Notwithstanding any other provision of law to the contrary, a health care professional who makes a clinical diagnosis of a sexually transmitted disease may provide expedited partner therapy for the treatment of the sexually transmitted disease if, in the judgment of the health care professional, the sexual partner is unlikely or unable to present for comprehensive health care, including evaluation, testing and treatment for sexually transmitted diseases. Expedited partner therapy is limited to a sexual partner who may have been exposed to a sexually transmitted disease within the previous sixty days and who is able to be contacted by the patient.

(b) Any health care professional who provides expedited partner therapy shall comply with all necessary provisions of article four of this chapter.

(c) A health care professional who provides expedited partner therapy shall provide counseling for the patient, including advice that all women and symptomatic persons, and in particular women with symptoms suggestive of pelvic inflammatory disease, are encouraged to seek medical attention. The health care professional shall also provide in written or electronic format materials provided by the department to be given by the patient to his or her sexual partner.

§16-4F-3 Informational materials

(a) The department shall provide information and technical assistance as appropriate to health care professionals who provide expedited partner therapy. The department shall develop and disseminate in electronic and other formats the following written materials:

(1) Informational materials for sexual partners, as described in subsection (c), section two of this article;

(2) Informational materials for persons who are repeatedly diagnosed with sexually transmitted diseases; and

(3) Guidance for health care professionals on the safe and effective provision of expedited partner therapy.

(b) The department may offer educational programs about expedited partner therapy for health care professionals.

§16-4F-4 Limitation of liability

(a) A health care professional who provides expedited partner therapy in good faith without fee or compensation under this article and provides counseling and written materials as required in subsection (c), section two of this article is not subject to civil or professional liability in connection with the provision of the therapy, counseling and materials, except in the case of gross negligence or willful and wanton misconduct. A health care professional is not subject to civil or professional liability for choosing not to provide expedited partner therapy.

(b) A pharmacist or pharmacy is not subject to civil or professional liability for choosing not to fill a prescription that would cause that pharmacist or pharmacy to violate any provision of article five, chapter thirty of this code.

§16-4F-5 Rulemaking

The secretary shall propose rules for legislative approval in accordance with article three, chapter twenty-nine-a of this code to designate certain diseases as sexually transmitted diseases which may be treated by expedited partner therapy. The department shall consider the recommendations and classifications of the federal Department of Health and Human Services, Centers for Disease Control and Prevention and other nationally recognized medical authorities in making these designations.

§16B-13 Medication Assisted Treatment Program Licensing Act

§16B-13-1. Purpose.

The purpose of this act is to establish licensing and registration requirements for facilities and physicians that treat patients with substance use disorders to ensure that patients may be lawfully treated by the use of medication and drug screens, in combination with counseling and behavioral therapies, to provide a holistic approach to the treatment of substance use disorders and comply with oversight requirements developed by the Inspector General. The Legislature recognizes the problem of substance use disorders in West Virginia and the need for quality, safe treatment of substance use disorders to adequately protect the people of West Virginia.

§16B-13-2. Definitions.

"Addiction" means a primary, chronic disease of brain reward, motivation, memory, and related circuitry. Dysfunction in these circuits leads to characteristic biological, psychological, social, and spiritual manifestations which is reflected in an individual pathologically pursuing reward or relief by substance use, or both, and other behaviors. Addiction is characterized by inability to consistently abstain; impairment in behavioral control; craving; diminished recognition of significant problems with one's behaviors; interpersonal problems with one's behaviors and interpersonal relationships; a dysfunctional emotional response; and as addiction is currently defined by the American Society of Addiction Medicine.

"Administrator" means an individual designated by the governing body to be responsible for the day-to-day operation of the opioid treatment programs.

"Advanced alcohol and drug abuse counselor" means an alcohol and drug abuse counselor who is certified by the West Virginia Certification Board for Addiction and Prevention Professionals who demonstrates a high degree of competence in the addiction counseling field.

"Alcohol and drug abuse counselor" means a counselor certified by the West Virginia Certification Board for Addiction and Prevention Professionals for specialized work with patients who have substance use problems.

"Biopsychosocial" means relating to, or concerned with, biological, psychological, and social aspects in contrast to the strictly biomedical aspects of disease.

"Center for Substance Abuse Treatment" means the center under the Substance Abuse and Mental Health Services Administration that promotes community-based substance abuse treatment and recovery services for individuals and families in the community and provides national leadership to improve access, reduce barriers, and promote high quality, effective treatment and recovery services.

"Controlled Substances Monitoring Program Database" means the database maintained by the West Virginia Board of Pharmacy pursuant to §60A-9-3 of this code that monitors and tracks certain prescriptions written or dispensed by dispensers and prescribers in West Virginia.

"Director" means the Director of the Office of Health Facility Licensure and Certification, or his or her designee.

"Dispense" means the preparation and delivery of a medication-assisted treatment medication in an appropriately labeled and suitable container to a patient by a medication-assisted treatment program or pharmacist.

"Governing body" means the person or persons identified as being legally responsible for the operation of the opioid treatment program. A governing body may be a board, a single entity or owner, or a partnership. The governing body must comply with the requirements prescribed in rules promulgated pursuant to this article.

"Inspector General" means the Inspector General of the Office of Inspector General as described in §16B-2-1 of this code, or his or her designee.

"Medical director" means a physician licensed within the State of West Virginia who assumes responsibility for administering all medical services performed by the medication-assisted treatment program, either by performing them directly or by delegating specific responsibility to authorized program physicians and health care professionals functioning under the medical director's direct supervision and functioning within their scope of practice.

"Medication-assisted treatment" means the use of medications and drug screens, in combination with counseling and behavioral therapies, to provide a holistic approach to the treatment of substance use disorders.

"Medication-assisted treatment program" means all publicly and privately owned opioid treatment programs and office-based, medication-assisted treatment programs, which prescribe medication-assisted treatment medications and treat substance use disorders, as those terms are defined in this article.

"Medication-assisted treatment medication" means any medication that is approved by the United States Food and Drug Administration under Section 505 of the Federal Food, Drug and Cosmetic Act, 21 U. S. C. § 355, for use in the treatment of substance use disorders that is an opioid agonist or partial opioid agonist and is listed on the Schedule of Controlled Substances in §60A-2-2201 *et seq*. of this code.

"Office-based, medication-assisted treatment" means all publicly or privately owned clinics, facilities, offices, or programs that provide medication-assisted treatment to individuals with substance use disorders through the prescription, administration, or dispensing of a medication-assisted treatment medication in the form of a partial opioid agonist.

"Office of Health Facility Licensure and Certification" means the West Virginia Office of Health Facility Licensure and Certification within the Office of Inspector General.

"Opioid agonist" means substances that bind to and activate the opiate receptors resulting in analgesia and pain regulation, respiratory depression, and a wide variety of behavioral changes. As used in this article, the term "opioid agonist" does not include partial agonist medications used as an alternative to opioid agonists in the treatment of opioid addiction.

"Opioid treatment program" means all publicly- or privately-owned medication-assisted treatment programs in clinics, facilities, offices, or programs that provide medication-assisted treatment to individuals with substance use disorders through on-site administration or dispensing of a medication-assisted treatment medication in the form of an opioid agonist or partial opioid agonist.

"Owner" means any person, partnership, association, or corporation listed as the owner of a medication-assisted treatment program on the licensing or registration forms required by this article.

"Partial opioid agonist" means a Federal Drug Administration approved medication that is used as an alternative to opioid agonists for the treatment of substance use disorders and that binds to and activates opiate receptors, but not to the same degree as full agonists.

"Physician" means an individual licensed in this state to practice allopathic medicine or surgery by the West Virginia Board of Medicine or osteopathic medicine or surgery by the West Virginia Board of Osteopathic Medicine and that meets the requirements of this article.

"Prescriber" means a person authorized in this state, working within their scope of practice, to give direction, either orally or in writing, for the preparation and administration of a remedy to be used in the treatment of substance use disorders.

"Program sponsor" means the person named in the application for the certification and licensure of an opioid treatment program who is responsible for the administrative operation of the opioid treatment program and who assumes responsibility for all of its employees, including any practitioners, agents, or other persons providing medical, rehabilitative, or counseling services at the program.

"State opioid treatment authority" means the agency or individual designated by the Governor to exercise the responsibility and authority of the state for governing the treatment of substance use disorders, including, but not limited to, the treatment of opiate addiction with opioid drugs.

"State oversight agency" means the agency or office of state government identified by the Inspector General to provide regulatory oversight of medication-assisted treatment programs on behalf of the State of West Virginia.

"Substance" means the following:

(1) Alcohol;

(2) Controlled substances defined by §60A-2-204, §60A-2-206, §60A-2-208, and §60A-2-210 of this code; or

(3) Any chemical, gas, drug, or medication consumed which causes clinically and functionally significant impairment, such as health problems, disability, and failure to meet major responsibilities at work, school, or home.

"Substance Abuse and Mental Health Services Administration" means the agency under the United States Department of Health and Human Services responsible for the accreditation and certification of medication-assisted treatment programs and that provides leadership, resources, programs, policies, information, data, contracts, and grants for the purpose of reducing the impact of substance abuse and mental or behavioral illness.

"Substance use disorder" means patterns of symptoms resulting from use of a substance that the individual continues to take, despite experiencing problems as a result; or as defined in the most recent edition of the American Psychiatric Association’s Diagnostic and Statistical Manual of Mental Disorders.

"Telehealth" means the mode of delivering health care services and public health via information and communication technologies to facilitate the diagnosis, consultation, treatment education, care management, and self-management of a patient’s health care while the patient is at the originating site and the health care provider is at a distant site.

"Variance" means written permission granted by the Inspector General, or designee, to a medication-assisted treatment program that a requirement of this article or rules promulgated pursuant to this article may be accomplished in a manner different from the manner set forth in this article or associated rules.

"Waiver" means a formal, time-limited agreement between the designated oversight agency and the medication-assisted treatment program that suspends a rule, policy, or standard for a specific situation so long as the health and safety of patients is better served in the situation by suspension of the rule, policy, or standard than by enforcement.

§16B-13-3. Opioid treatment programs to obtain license; application; fees and inspections.

(a) No person, partnership, association, or corporation may operate an opioid treatment program without first obtaining a license from the director in accordance with the provisions of this article and the rules lawfully promulgated pursuant to this article.

(b) Any person, partnership, association, or corporation desiring a license to operate an opioid treatment program in this state shall file with the Office of Health Facility Licensure and Certification an application in such form and with such information as the director shall prescribe and furnish accompanied by an application fee.

(c) The Director of the Office of Health Facility Licensure and Certification or his or her designee shall inspect each facility and review all documentation submitted with the application. The director shall then approve or deny the application for a license. The director shall issue a license if the facility is in compliance with the provisions of this article and with the rules lawfully promulgated pursuant to this article.

(d) A license shall be issued in one of three categories:

(1) An initial 12 month license shall be issued to an opioid treatment program establishing a new program or service for which there is insufficient consumer participation to demonstrate substantial compliance with this article and with all rules promulgated pursuant to this article;

(2) A provisional license shall be issued when an opioid treatment program seeks a renewal license, or is an existing program as of the effective date of this article and is seeking an initial license, and the opioid treatment program is not in substantial compliance with this article and with all rules promulgated pursuant to this article, but does not pose a significant risk to the rights, health and safety of a consumer. It shall expire not more than six months from the date of issuance, and may not be consecutively reissued; or

(3) A renewal license shall be issued when an opioid treatment program is in substantial compliance with this article and with all rules promulgated pursuant to this article. A renewal license shall expire not more than one year from the date of issuance.

(e) At least 60 days prior to the license expiration date, an application for renewal shall be submitted by the opioid treatment program to the director on forms furnished by the director. A license shall be renewed if the director determines that the applicant is in compliance with this article and with all rules promulgated pursuant to this article. A license issued to one program location pursuant to this article is not transferrable or assignable. Any change of ownership of a licensed medication-assisted treatment program requires submission of a new application. The medication-assisted treatment program shall notify the director of any change in ownership within 10 days of the change and must submit a new application within the time frame prescribed by the director.

(f) Any person, partnership, association, or corporation that seeks to obtain or renew a license for an opioid treatment program in this state must submit to the director the following documentation:

(1) Full operating name of the program as advertised;

(2) Legal name of the program as registered with the West Virginia Secretary of State;

(3) Physical address of the program;

(4) Preferred mailing address for the program;

(5) Email address to be used as the primary contact for the program;

(6) Federal Employer Identification Number assigned to the program;

(7) All business licenses issued to the program by this state, the State Tax Department, the Secretary of State and all other applicable business entities;

(8) Brief description of all services provided by the program;

(9) Hours of operation;

(10) Legal Registered Owner Name – name of the person registered as the legal owner of the program. If more than one legal owner (i.e., partnership, corporation, etc.) list each legal owner separately, indicating the percentage of ownership;

(11) Medical director's full name, medical license number, Drug Enforcement Administration registration number, and a list of all current certifications;

(12) For each employee of the program, provide the following:

(A) Employee's role and occupation within the program;

(B) Full legal name;

(C) Medical license, if applicable;

(D) Drug Enforcement Administration registration number, if applicable;

(E) Drug Enforcement Administration identification number to prescribe buprenorphine for addiction, if applicable; and

(F) Number of hours per week worked at program;

(13) Name and location address of all programs owned or operated by the applicant;

(14) Notarized signature of applicant;

(15) Check or money order for licensing fee and inspection fee;

(16) Verification of education and training for all physicians, counselors and social workers practicing at or used by referral by the program such as fellowships, additional education, accreditations, board certifications and other certifications;

(17) Board of Pharmacy Controlled Substance Prescriber Report for each prescriber practicing at the program for the three months preceding the date of application; and

(18) If applicable, a copy of a valid Certificate of Need or a letter of exemption from the West Virginia Health Care Authority.

(g) Upon satisfaction that an applicant has met all of the requirements of this article, the director shall issue a license to operate an opioid treatment program. An entity that obtains this license may possess, have custody, or control of, and dispense drugs indicated and approved by the United States Food and Drug Administration for the treatment of substance use disorders.

(h) The opioid treatment program shall display the current license in a prominent location where services are provided and in clear view of all patients.

(i) The director or his or her designee shall inspect on a periodic basis all opioid treatment programs that are subject to this article and all rules adopted pursuant to this article to ensure continued compliance.

§16B-13-4. Office-based, medication-assisted treatment programs to obtain registration; application; fees and inspections.

(a) No person, partnership, association, or corporation may operate an office-based, medication-assisted treatment program without first obtaining a registration from the director in accordance with the provisions of this article and the rules lawfully promulgated pursuant to this article.

(b) Any person, partnership, association, or corporation desiring a registration to operate an office-based, medication-assisted treatment program in this state shall file with the Office of Health Facility Licensure and Certification an application in such form and with such information as the director shall prescribe and furnish accompanied by an application fee.

(c) The Director of the Office of Health Facility Licensure and Certification or his or her designee shall inspect and review all documentation submitted with the application. The director shall approve or deny the application for registration. The director shall issue a registration if the facility is in compliance with the provisions of this article and with the rules lawfully promulgated pursuant to this article.

(d) A registration shall be issued in one of three categories:

(1) An initial 12-month registration shall be issued to an office-based, medication-assisted treatment program establishing a new program or service for which there is insufficient consumer participation to demonstrate substantial compliance with this article and with all rules promulgated pursuant to this article;

(2) A provisional registration shall be issued when an office-based, medication-assisted treatment program seeks a renewal registration, or is an existing program as of the effective date of this article and is seeking an initial registration, and the office-based, medication-assisted treatment program is not in substantial compliance with this article and with all rules promulgated pursuant to this article, but does not pose a significant risk to the rights, health, and safety of a consumer. It shall expire not more than six months from the date of issuance, and may not be consecutively reissued; or

(3) A renewal registration shall be issued when an office-based, medication-assisted treatment program is in substantial compliance with this article and with all rules promulgated pursuant to this article. A renewal registration shall expire not more than one year from the date of issuance.

(e) At least 60 days prior to the registration expiration date, an application for renewal shall be submitted by the office-based, medication-assisted treatment program to the director on forms furnished by the director. A registration shall be renewed if the director determines that the applicant is in compliance with this article and with all rules promulgated pursuant to this article. A registration issued to one program location pursuant to this article is not transferrable or assignable. Any change of ownership of a registered office-based, medication-assisted treatment program requires submission of a new application. The office-based, medication-assisted treatment program shall notify the director of any change in ownership within 10 days of the change and must submit a new application within the time frame prescribed by the director.

(f) Any person, partnership, association, or corporation seeking to obtain or renew a registration for an office-based, medication-assisted treatment program in this state must submit to the director the following documentation:

(1) Full operating name of the program as advertised;

(2) Legal name of the program as registered with the West Virginia Secretary of State;

(3) Physical address of the program;

(4) Preferred mailing address for the program;

(5) Email address to be used as the primary contact for the program;

(6) Federal Employer Identification Number assigned to the program;

(7) All business licenses issued to the program by this state, the state Tax Department, the Secretary of State, and all other applicable business entities;

(8) Brief description of all services provided by the program;

(9) Hours of operation;

(10) Legal Registered Owner Name – name of the person registered as the legal owner of the program. If more than one legal owner (i.e., partnership, corporation, etc.) list each legal owner separately, indicating the percentage of ownership;

(11) Medical director’s full name, medical license number, Drug Enforcement Administration registration number, and a listing of all current certifications;

(12) For each physician, counselor, or social worker of the program, provide the following:

(A) Employee's role and occupation within the program;

(B) Full legal name;

(C) Medical license, if applicable;

(D) Drug Enforcement Administration registration number, if applicable;

(E) Drug Enforcement Administration identification number to prescribe buprenorphine for addiction, if applicable; and

(F) Number of hours worked at program per week;

(13) Name and location address of all programs owned or operated by the applicant;

(14) Notarized signature of applicant;

(15) Check or money order for registration fee;

(16) Verification of education and training for all physicians, counselors, and social workers practicing at or used by referral by the program such as fellowships, additional education, accreditations, board certifications, and other certifications; and

(17) Board of Pharmacy Controlled Substance Prescriber Report for each prescriber practicing at the program for the three months preceding the date of application.

(g) Upon satisfaction that an applicant has met all of the requirements of this article, the director shall issue a registration to operate an office-based, medication-assisted treatment program. An entity that obtains this registration may possess, have custody or control of, and dispense drugs indicated and approved by the United States Food and Drug Administration for the treatment of substance use disorders.

(h) The office-based, medication-assisted treatment program shall display the current registration in a prominent location where services are provided and in clear view of all patients.

(i) The director or his or her designee shall perform complaint and verification inspections on all office-based, medication-assisted treatment programs that are subject to this article and all rules adopted pursuant to this article to ensure continued compliance.

(j) Any person, partnership, association, or corporation operating an office-based, medication-assisted treatment program shall be permitted to continue operation until the effective date of the new rules promulgated pursuant to this article. At that time a person, partnership, association, or corporation shall file for registration within six months pursuant to the licensing procedures and requirements of this section and the new rules promulgated hereunder. The existing procedures of the person, partnership, association, or corporation shall remain effective until receipt of the registration.

(k) A person, partnership, association, or corporation providing office-based, medication-assisted treatment to no more than 30 patients of their practice or program is exempt from the registration requirement contained in §16-5Y-4(a) of this code: *Provided*, That it:

(1) Attests to the Office of Health Facility Licensure and Certification on a form prescribed by the director that the person, partnership, association, or corporation requires counselling and drug screens, has implemented diversion control measures, has completed medical education training on addiction treatment encompassing all forms of medication-assisted treatment, will provide patient numbers upon request, and will provide any other information required by the director related to patient health and safety; and

(2) Is prohibited from establishing an office-based, medication-assisted treatment at any other location or facility after the submission of an attestation submitted pursuant to §16-5Y-4(k)(2) of this code. This subdivision includes any person, partnership, association, or corporation that has an ownership interest in a partnership, association, or corporation or other corporate entity providing office-based, medication-assisted treatment.

(l) A licensed behavioral health center, pursuant to Behavioral Health Center Licensure, 64 CSR 11, providing office-based medication-assisted treatment is exempt from the registration requirement contained in §16-5Y-4(a) of this code: *Provided*, That it:

(1) Attests to the Office of Health Facility Licensure and Certification on a form prescribed by the director that the person, partnership, association, or corporation requires counseling and drugs screens, has implemented diversion control measures, will provide patient numbers upon request, and will provide any other information required by the director related to patient health and safety; and

(2) Must notify the Office of Health Facility Licensure and Certification prior to establishing or terminating an office-based medication-assisted treatment program at any other licensed behavioral health center location after the submission of an attestation submitted pursuant to §16-5Y-4(l)(1) of this code.

§16B-13-5. Operational requirements.

(a) The medication-assisted treatment program shall be licensed and registered in this state with the director, the Secretary of State, the State Tax Department, and all other applicable business or licensing entities.

(b) The program sponsor need not be a licensed physician but shall employ a licensed physician for the position of medical director, when required by the rules promulgated pursuant to this article.

(c) Each medication-assisted treatment program shall designate a medical director. If the medication-assisted treatment program is accredited by a Substance Abuse and Mental Health Services Administration approved accrediting body that meets nationally accepted standards for providing medication-assisted treatment, including the Commission on Accreditation of Rehabilitation Facilities or the Joint Commission on Accreditation of Healthcare Organizations, then the program may designate a medical director to oversee all facilities associated with the accredited medication-assisted treatment program. The medical director shall be responsible for the operation of the medication-assisted treatment program, as further specified in the rules promulgated pursuant to this article. He or she may delegate the day-to-day operation of a medication-assisted treatment program as provided in rules promulgated pursuant to this article. Within 10 days after termination of a medical director, the medication-assisted treatment program shall notify the director of the identity of another medical director for that program. Failure to have a medical director practicing at the program may be the basis for a suspension or revocation of the program license. The medical director shall:

(1) Have a full, active, and unencumbered license to practice allopathic medicine or surgery from the West Virginia Board of Medicine or to practice osteopathic medicine or surgery from the West Virginia Board of Osteopathic Medicine in this state and be in good standing and not under any probationary restrictions;

(2) Meet both of the following training requirements:

(A) If the physician prescribes a partial opioid agonist, he or she shall complete the requirements for the Drug Addiction Treatment Act of 2000; and

(B) Complete other programs and continuing education requirements as further described in the rules promulgated pursuant to this article;

(3) Practice at the licensed or registered medication-assisted treatment program a sufficient number of hours, based upon the type of medication-assisted treatment license or registration issued pursuant to this article, to ensure regulatory compliance, and carry out those duties specifically assigned to the medical director as further described in the rules promulgated pursuant to this article;

(4) Be responsible for monitoring and ensuring compliance with all requirements related to the licensing and operation of the medication-assisted treatment program;

(5) Supervise, control, and direct the activities of each individual working or operating at the medication-assisted treatment program, including any employee, volunteer, or individual under contract, who provides medication-assisted treatment at the program or is associated with the provision of that treatment. The supervision, control, and direction shall be provided in accordance with rules promulgated by the Inspector General; and

(6) Complete other requirements prescribed by the Inspector General by rule.

(d) Each medication-assisted treatment program shall designate counseling staff, either employees, or those used on a referral-basis by the program, which meet the requirements of this article and the rules promulgated pursuant to this article. The individual members of the counseling staff shall have one or more of the following qualifications:

(1) Be a licensed psychiatrist;

(2) Certification as an alcohol and drug counselor;

(3) Certification as an advanced alcohol and drug counselor;

(4) Be a counselor, psychologist, marriage and family therapist, or social worker with a master's level education with a specialty or specific training in treatment for substance use disorders, as further described in the rules promulgated pursuant to this article;

(5) Under the direct supervision of an advanced alcohol and drug counselor, be a counselor with a bachelor's degree in social work or another relevant human services field: *Provided*, That the individual practicing with a bachelor's degree under supervision applies for certification as an alcohol and drug counselor within three years of the date of employment as a counselor;

(6) Be a counselor with a graduate degree actively working toward licensure or certification in the individual's chosen field under supervision of a licensed or certified professional in that field and/or advanced alcohol and drug counselor;

(7) Be a psych-mental health nurse practitioner or a psych-mental health clinical nurse specialist; or

(8) Be a psychiatry CAQ-certified physician assistant.

(e) The medication-assisted treatment program shall be eligible for, and not prohibited from, enrollment with West Virginia Medicaid and other private insurance. Prior to directly billing a patient for any medication-assisted treatment, a medication-assisted treatment program must receive either a rejection of prior authorization, rejection of a submitted claim, or a written denial from a patient's insurer or West Virginia Medicaid denying coverage for such treatment: *Provided*, That the director, in consultation with the Inspector General, may grant a variance from this requirement pursuant to §16B-13-6 of this code. The program shall also document whether a patient has no insurance. At the option of the medication-assisted treatment program, treatment may commence prior to billing.

(f) The medication-assisted treatment program shall apply for and receive approval as required from the United States Drug Enforcement Administration, Center for Substance Abuse Treatment, or an organization designated by Substance Abuse and Mental Health and Mental Health Administration.

(g) All persons employed by the medication-assisted treatment program shall comply with the requirements for the operation of a medication-assisted treatment program established within this article or by any rule adopted pursuant to this article.

(h) All employees of an opioid treatment program shall furnish fingerprints for a state and federal criminal records check by the Criminal Identification Bureau of the West Virginia State Police and the Federal Bureau of Investigation. The fingerprints shall be accompanied by a signed authorization for the release of information and retention of the fingerprints by the Criminal Identification Bureau and the Federal Bureau of Investigation. The opioid treatment program shall be subject to the provisions of §16B-15-1 *et seq*. of this code and subsequent rules promulgated thereunder.

(i) The medication-assisted treatment program shall not be owned by, nor shall it employ or associate with, any physician or prescriber:

(1) Whose Drug Enforcement Administration number is not currently full, active, and unencumbered;

(2) Whose application for a license to prescribe, dispense, or administer a controlled substance has been denied by and is not full, active, and unencumbered in any jurisdiction; or

(3) Whose license is anything other than a full, active, and unencumbered license to practice allopathic medicine or surgery by the West Virginia Board of Medicine or osteopathic medicine or surgery by the West Virginia Board of Osteopathic Medicine in this state, and who is in good standing and not under any probationary restrictions.

(j) A person may not dispense any medication-assisted treatment medication, including a controlled substance as defined by §60A-1-101 of this code, on the premises of a licensed medication-assisted treatment program, unless he or she is a physician or pharmacist licensed in this state and employed by the medication-assisted treatment program unless the medication-assisted treatment program is a federally certified narcotic treatment program. Prior to dispensing or prescribing medication-assisted treatment medications, the treating physician must access the Controlled Substances Monitoring Program Database to ensure the patient is not seeking medication-assisted treatment medications that are controlled substances from multiple sources and to assess potential adverse drug interactions, or both. Prior to dispensing or prescribing medication-assisted treatment medications, the treating physician shall also ensure that the medication-assisted treatment medication utilized is related to an appropriate diagnosis of a substance use disorder and approved for such usage. The physician shall also review the Controlled Substances Monitoring Program Database no less than quarterly and at each patient's physical examination. The results obtained from the Controlled Substances Monitoring Program Database shall be maintained with the patient's medical records.

(k) A medication-assisted treatment program responsible for medication administration shall comply with:

(1) The West Virginia Board of Pharmacy regulations;

(2) The West Virginia Board of Examiners for Registered Professional Nurses regulations;

(3) All applicable federal laws and regulations relating to controlled substances; and

(4) Any requirements as specified in the rules promulgated pursuant to this article.

(l) Each medication-assisted treatment program location shall be licensed separately, regardless of whether the program is operated under the same business name or management as another program.

(m) The medication-assisted treatment program shall develop and implement patient protocols, treatment plans, or treatment strategies and profiles, which shall include, but not be limited by, the following guidelines:

(1) When a physician diagnoses an individual as having a substance use disorder, the physician may treat the substance use disorder by managing it with medication in doses not exceeding those approved by the United States Food and Drug Administration as indicated for the treatment of substance use disorders and not greater than those amounts described in the rules promulgated pursuant to this article. The treating physician and treating counselor's diagnoses and treatment decisions shall be made according to accepted and prevailing standards for medical care;

(2) The medication-assisted treatment program shall maintain a record of all of the following:

(A) Medical history and physical examination of the individual;

(B) The diagnosis of substance use disorder of the individual;

(C) The plan of treatment proposed, the patient's response to the treatment, and any modification to the plan of treatment;

(D) The dates on which any medications were prescribed, dispensed, or administered, the name and address of the individual for whom the medications were prescribed, dispensed, or administered, and the amounts and dosage forms for any medications prescribed, dispensed, or administered;

(E) A copy of the report made by the physician or counselor to whom referral for evaluation was made, if applicable; and

(F) A copy of the coordination of care agreement, which is to be signed by the patient, treating physician, and treating counselor. If a change of treating physician or treating counselor takes place, a new agreement must be signed. The coordination of care agreement must be updated or reviewed at least annually. If the coordination of care agreement is reviewed, but not updated, this review must be documented in the patient's record. The coordination of care agreement will be provided in a form prescribed and made available by the director;

(3) Medication-assisted treatment programs shall report information, data, statistics, and other information as directed in this code, and the rules promulgated pursuant to this article to required agencies and other authorities;

(4) A prescriber authorized to prescribe a medication-assisted treatment medication who practices at a medication-assisted treatment program is responsible for maintaining the control and security of his or her prescription blanks and any other method used for prescribing a medication-assisted treatment medication. The prescriber shall comply with all state and federal requirements for tamper-resistant prescription paper. In addition to any other requirements imposed by statute or rule, the prescriber shall notify the director and appropriate law-enforcement agencies in writing within 24 hours following any theft or loss of a prescription blank or breach of any other method of prescribing a medication-assisted treatment medication; and

(5) The medication-assisted treatment program shall have a drug testing program to ensure a patient is in compliance with the treatment strategy.

(n) Medication-assisted treatment programs shall only prescribe, dispense, or administer liquid methadone to patients pursuant to the restrictions and requirements of the rules promulgated pursuant to this article.

(o) The medication-assisted treatment program shall immediately notify the director, or his or her designee, in writing of any changes to its operations that affect the medication-assisted treatment program's continued compliance with the certification and licensure requirements.

(p) If a physician treats a patient with more than 16 milligrams per day of buprenorphine then clear medical notes shall be placed in the patient's medical file indicating the clinical reason or reasons for the higher level of dosage.

(q) If a physician is not the patient's obstetrical or gynecological provider, the physician shall consult with the patient's obstetrical or gynecological provider to the extent possible to determine whether the prescription is appropriate for the patient.

(r) A practitioner providing medication-assisted treatment may perform certain aspects of telehealth if permitted under his or her scope of practice.

(s) The physician shall follow the recommended manufacturer's tapering schedule for the medication-assisted treatment medication. If the schedule is not followed, the physician shall document in the patient's medical record and the clinical reason why the schedule was not followed. The director may investigate a medication-assisted treatment program if a high percentage of its patients are not following the recommended tapering schedule.

§16B-13-6. Restrictions; variances and waivers.

(a) A medication-assisted treatment program shall not be located, operated, managed or owned at the same location where a chronic pain management clinic licensed and defined in §16B-7-1 *et seq*. of this code is located.

(b) Medication-assisted treatment programs shall not have procedures for offering a bounty, monetary, equipment, or merchandise reward, or free services for individuals in exchange for recruitment of new patients into the facility.

(c) Medication-assisted treatment programs shall not be located within one-half mile of a public or private licensed day care center or public or private K-12 school.

Existing medication-assisted treatment programs, including both opioid treatment programs and office based medication-assisted treatment programs that are located within one-half mile of a public or private licensed day care center or public or private K-12 school, shall be granted a variance, provided that the facility demonstrates adequate patient population controls and that it may otherwise meet the requirements of this article and the rules promulgated pursuant to this article.

(d) The director, in consultation with the Inspector General, may grant a waiver or a variance from any licensure or registration standard, or portion thereof, for the period during which the license or registration is in effect.

(1) Requests for waivers or variances of licensure or registration standards shall be in writing to the director and shall include:

(A) The specific section of this article or rules promulgated pursuant to this article for which a waiver or variance is sought;

(B) The rationale for requesting the waiver or variance;

(C) Documentation by the medication-assisted treatment program's medical director to the director that describes how the program will maintain the quality of services and patient safety if the wavier or variance is granted; and

(D) The consequences of not receiving approval of the requested wavier or variance.

(2) The director, in consultation with the Inspector General, shall issue a written statement to the medication-assisted treatment program granting or denying a request for a waiver or variance of program licensure or registration standards.

(3) The medication-assisted treatment program shall maintain a file copy of all requests for waivers or variances and the approval or denial of the requests for the period during which the license or registration is in effect.

(4) The Office of Health Facility Licensure and Certification shall inspect each medication-assisted treatment program prior to a waiver or variance being granted, including a review of patient records, to ensure and verify that any waiver or variance request meets the spirit and purpose of this article and the rules promulgated pursuant to this article. The Office of Health Facility Licensure and Certification may verify, by unannounced inspection, that the medication-assisted treatment program is in compliance with any waiver or variance granted by the director, in consultation with the Inspector General, for the duration of such waiver or variance.

§16B-13-7. Inspection; inspection warrant.

(a) The Office of Health Facility Licensure and Certification shall inspect each opioid treatment program annually, including a review of the patient records, to ensure that the program complies with this article and the applicable rules. A pharmacist, employed or contracted by the director, licensed in this state, and a law-enforcement officer may be present at each inspection.

(b) The Office of Health Facility Licensure and Certification shall perform unannounced complaint and verification inspections at office based medication-assisted treatment programs, including a review of the patient records, to ensure that the program complies with this article and the applicable rules. A pharmacist, employed or contracted by the Inspector General, licensed in this state and a law-enforcement officer may be present at each inspection.

(c) During an onsite inspection, the inspectors shall make a reasonable attempt to discuss each violation with the medical director or other owners of the medication-assisted treatment program before issuing a formal written notification.

(d) Any action taken to correct a violation shall be documented in writing by the medical director or other owners of the medication-assisted treatment program and may be verified by follow-up visits by the Office of Health Facility Licensure and Certification.

(e) Notwithstanding the existence or pursuit of any other remedy, the Inspector General may, in the manner provided by law, maintain an action in the name of the state for an inspection warrant against any person, partnership, association, or corporation to allow any inspection or seizure of records in order to complete any inspection allowed by this article or the rules promulgated pursuant to this article, or to meet any other purpose of this article or the rules promulgated pursuant to this article.

(f) When possible, inspections for annual certification and licensure by the medication-assisted treatment programs will be done consecutively or concurrently. However, this provision does not limit the ability to conduct unannounced inspections pursuant to a complaint.

§16B-13-8. License and registration limitation; denial; suspension; revocation.

(a) The director, in consultation with the Inspector General, may, by order, impose a ban on the admission of patients or reduce the patient capacity of the medication-assisted treatment program, or any combination thereof, when he or she finds upon inspection of the medication-assisted treatment program that the licensee or registrant is not providing adequate care under the medication-assisted treatment program's existing patient quota, and that a reduction in quota or imposition of a ban on admissions, or any combination thereof, would place the licensee or registrant in a position to render adequate care. Any notice to a licensee or registrant of reduction in quota or ban on new admissions shall include the terms of the order, the reasons therefor and the date set for compliance.

(b) The director, in consultation with the Inspector General, shall deny, suspend, or revoke a license or registration issued pursuant to this article if the provisions of this article or of the rules promulgated pursuant to this article are violated. The director, in consultation with the Inspector General, may revoke a program's license or registration and prohibit all physicians and licensed disciplines associated with that medication-assisted treatment program from practicing at the program location based upon an annual, periodic, complaint, verification or other inspection and evaluation.

(c) Before any such license or registration is denied, suspended, or revoked, however, written notice shall be given to the licensee or registrant, stating the grounds for such denial, suspension, or revocation.

(d) An applicant, licensee or registrant has 10 working days after receipt of the director's order denying, suspending, or revoking a license or registration to request a formal hearing contesting such denial, suspension, or revocation of a license or registration under this article. If a formal hearing is requested, the applicant, licensee or registrant and the director shall proceed in accordance with the provisions of §29A-5-1 *et seq*. of this code.

(e) If a license or registration is denied or revoked as herein provided, a new application for license or registration shall be considered by the director, in consultation with the Inspector General, if, when and after the conditions upon which the denial or revocation was based have been corrected and evidence of this fact has been furnished. A new license or registration shall then be granted after proper inspection, if applicable, has been made and all provisions of this article and rules promulgated pursuant to this article have been satisfied.

(f) Any applicant, licensee or registrant who is dissatisfied with the decision of the director as a result of the hearing provided in this section may, within 30 days after receiving notice of the decision, petition the circuit court of Kanawha County, in term or in vacation, for judicial review of the decision.

(g) The West Virginia Intermediate Court of Appeals may affirm, modify or reverse the decision of the Board of Review and either the applicant, licensee or registrant, or the director may appeal from the court's decision to the Supreme Court of Appeals.

(h) If the license or registration of a medication-assisted treatment program is denied, suspended, or revoked, the medical director of the program, any owner of the program or owner or lessor of the medication-assisted treatment program property shall cease to operate the clinic, facility, office, or program as a medication-assisted treatment program as of the effective date of the denial, suspension, or revocation. The owner or lessor of the medication-assisted treatment program property is responsible for removing all signs and symbols identifying the premises as a medication-assisted treatment program within 30 days. Any administrative appeal of such denial, suspension or revocation shall not stay the denial, suspension, or revocation.

(i) Upon the effective date of the denial, suspension or revocation, the medical director of the medication-assisted treatment program shall advise the director and the Board of Pharmacy of the disposition of all medications located on the premises. The disposition is subject to the supervision and approval of the director. Medications that are purchased or held by a medication-assisted treatment program that is not licensed may be deemed adulterated.

(j) If the license or registration of a medication-assisted treatment program is suspended or revoked, any person named in the licensing or registration documents of the program, including persons owning or operating the medication-assisted treatment program, may not, as an individual or as part of a group, apply to operate another medication-assisted treatment program for up to five years after the date of suspension or revocation. The director, in consultation with the Inspector General, may grant a variance pursuant to §16B-13-6 of this code to the prohibition of this subsection.

(k) The period of suspension for the license or registration of a medication-assisted treatment program shall be prescribed by the director, in consultation with the Inspector General, but may not exceed one year.

§16B-13-9. Violations; penalties; injunction.

(a) Any person, partnership, association, or corporation which establishes, conducts, manages, or operates a medication-assisted treatment program without first obtaining a license or registration as herein provided, or who violates any provisions of this article or any rule lawfully promulgated pursuant to this article, shall be assessed a civil penalty by the director, in consultation with the Inspector General, in accordance with this subsection. Each day of continuing violation after conviction shall be considered a separate violation:

(1) If a medication-assisted treatment program or any owner or medical director is found to be in violation of any provision of this article, unless otherwise noted herein, the director, in consultation with the Inspector General, may limit, suspend or revoke the program's license or registration;

(2) If the program's medical director knowingly and intentionally misrepresents actions taken to correct a violation, the director, in consultation with the Inspector General, may impose a civil money penalty not to exceed $10,000 and, in the case of any owner-operator medication-assisted treatment program, limit or revoke a medication-assisted treatment program's license or registration;

(3) If any owner or medical director of a medication-assisted treatment program concurrently operates an unlicensed or unregistered medication-assisted treatment program, the director, in consultation with the Inspector General, may impose a civil money penalty upon the owner or medical director, or both, not to exceed $5,000 per day;

(4) If the owner of a medication-assisted treatment program that requires a license or registration under this article fails to apply for a new license or registration for the program upon a change of ownership and operates the program under new ownership, the director, in consultation with the Inspector General, may impose a civil money penalty upon the owner, not to exceed $5,000; or

(5) If a physician operates, owns or manages an unlicensed or unregistered medication-assisted treatment program that is required to be licensed or registered pursuant to this article; knowingly prescribes or dispenses or causes to be prescribed or dispensed, a medication-assisted treatment medication through misrepresentation or fraud; procures, or attempts to procure, a license or registration for a medication-assisted treatment program for any other person by making or causing to be made any false representation, the director, in consultation with the Inspector General, may assess a civil money penalty of not more than $20,000. The penalty may be in addition to or in lieu of any other action that may be taken by the director, in consultation with the Inspector General, or any other board, court or entity.

(b) Notwithstanding the existence or pursuit of any other remedy, the Inspector General may, in the manner provided by law, maintain an action in the name of the state for an injunction against any person, partnership, association or corporation to restrain or prevent the establishment, conduct, management or operation of any medication-assisted treatment program or violation of any provision of this article or any rule lawfully promulgated thereunder without first obtaining a license or registration in the manner herein provided.

(c) In determining whether a penalty is to be imposed and in fixing the amount of the penalty, the director, in consultation with the Inspector General, shall consider the following factors:

(1) The gravity of the violation, including the probability that death or serious physical or emotional harm to a patient has resulted, or could have resulted, from the medication-assisted treatment program's actions or the actions of the medical director or any practicing physician, the severity of the action or potential harm, and the extent to which the provisions of the applicable laws or rules were violated;

(2) What actions, if any, the owner or medical director took to correct the violations;

(3) Whether there were any previous violations at the medication-assisted treatment program; and

(4) The financial benefits that the medication-assisted treatment program derived from committing or continuing to commit the violation.

(d) Upon finding that a physician has violated the provisions of this article or rules adopted pursuant to this article, the director shall provide notice of the violation to the applicable licensing board.

§16B-13-10. Advertisement disclosure.

Any advertisement made by or on behalf of a medication-assisted treatment program through public media, such as a telephone directory, medical directory, newspaper or other periodical, outdoor advertising, radio or television, or through written or recorded communication, concerning the treatment of substance use disorders, as defined in section two of this article, shall include the name of, at a minimum, the medical director responsible for the content of the advertisement.

§16B-13-11. State Opioid Treatment Authority.

(a) Prior to establishing, operating, maintaining, or advertising a medication-assisted treatment program within this state, a medication-assisted treatment program shall be approved by the state opioid treatment authority for operation of a medication-assisted treatment program in this state.

(b) The state opioid treatment authority shall act as the state's coordinator for the development and monitoring of medication-assisted treatment programs and it shall serve as a liaison with the appropriate federal agencies.

(c) The designated state oversight agency is responsible for licensing, monitoring, and investigating complaints and grievances regarding medication-assisted treatment programs.

(d) The powers and duties of the state opioid treatment authority include, but are not limited to, the following:

(1) Facilitate the development and implementation of rules, regulations, standards and best practice guidelines to ensure the quality of services delivered by medication-assisted treatment programs;

(2) Act as a liaison between relevant state and federal agencies;

(3) Be available for consultation regarding medication-assisted treatment guidelines, rules, regulations and recovery models for individualized treatment plans of care developed by the federal government and other nationally recognized authorities;

(4) Ensure delivery of technical assistance and informational materials to medication-assisted treatment programs as needed;

(5) Perform both scheduled and unscheduled site visits to medication-assisted treatment programs in cooperation with the identified state oversight agency when necessary and appropriate;

(6) Consult with the federal government regarding approval or disapproval of requests for exceptions to federal regulations, where appropriate;

(7) Review and approve exceptions to federal and state dosage policies and procedures;

(8) Receive and refer patient appeals and grievances to the designated state oversight agency when appropriate; and

(9) Work cooperatively with other relevant state agencies to determine the services needed and the location of a proposed medication-assisted treatment program.

§16B-13-12. Moratorium; certificate of need.

There is a moratorium on the licensure of new opioid treatment programs which do not have a certificate of need as of the effective date of the enactment of this section during the 2016 regular session of the Legislature

which shall continue until the Legislature determines that there is a necessity for additional opioid treatment programs in West Virginia.

§16B-13-13. Rules; minimum standards for medication-assisted treatment programs.

(a) The Inspector General shall promulgate rules in accordance with the provisions of §29A-1-1 *et seq*. of this code for the licensure of medication-assisted treatment programs to ensure adequate care, treatment, health, safety, welfare, and comfort of patients at these facilities. These rules shall include, at a minimum:

(1) The process to be followed by applicants seeking a license;

(2) The qualifications and supervision of licensed and nonlicensed personnel at medication-assisted treatment programs and training requirements for all facility health care practitioners who are not regulated by another board;

(3) The provision and coordination of patient care, including the development of a written plan of care and patient contract;

(4) The management, operation, staffing and equipping of the medication-assisted treatment program;

(5) The clinical, medical, patient and business records kept by the medication-assisted treatment program;

(6) The procedures for inspections and for review of utilization and quality of patient care;

(7) The standards and procedures for the general operation of a medication-assisted treatment program, including facility operations, physical operations, infection control requirements, health and safety requirements and quality assurance;

(8) Identification of drugs that may be used to treat substance use disorders that identify a facility as a medication-assisted treatment program;

(9) Any other criteria that identify a facility as a medication-assisted treatment program;

(10) The standards and procedures to be followed by an owner in providing supervision, direction and control of individuals employed by or associated with a medication-assisted treatment program;

(11) Data collection and reporting requirements;

(12) Criteria and requirements related to specific medication-assisted treatment medications; and

(13) Such other standards or requirements as the Inspector General determines are appropriate.

(b) The Legislature finds that an emergency exists and, therefore, the Inspector General shall file an emergency rule to implement the provisions of this section pursuant to the provisions of §29A-3-15 of this code.

§16-46 Access to Opioid Antagonist Act

§16-46-1. Purpose and findings.

(a) The purpose of this article is to prevent deaths in circumstances involving individuals who have overdosed on opiates.

(b) The Legislature finds that permitting licensed health care providers to prescribe opioid antagonists to initial responders as well as individuals at risk of experiencing an overdose, their relatives, friends or caregivers may prevent accidental deaths as a result of opiate-related overdoses.

§16-46-2. Definitions.

As used in this article:

(1) "Initial responder" means emergency medical service personnel, as defined in subdivision (g), section three, article four-c of this chapter, including, but not limited to, a member of the West Virginia State Police, a sheriff, a deputy sheriff, a municipal police officer, a volunteer or paid firefighter and any other person acting under color of law who responds to emergencies.

(2) "Licensed health care provider" means a person, partnership, corporation, professional limited liability company, health care facility or institution licensed by or certified in this state to provide health care or professional health care services. This includes, but is not limited to, medical physicians, allopathic and osteopathic physicians, pharmacists, physician assistants or osteopathic physician assistants who hold a certificate to prescribe drugs, advanced nurse practitioners who hold a certificate to prescribe drugs, hospitals, emergency service agencies and others as allowed by law to prescribed drugs.

(3) "Opiates" or "opioid drugs" means drugs that are members of the natural and synthetic opium family, including, but not limited to, heroin, morphine, codeine, methadone, oxycodone, hydrocodone, fentanyl and hydromorphone.

(4) "Opioid antagonist" means a federal Food and Drug Administration-approved drug for the treatment of an opiate-related overdose, such as naloxone hydrochloride or other substance, that, when administered, negates or neutralizes, in whole or in part, the pharmalogical effects of an opioid in the body.

(5) "Opioid overdose prevention and treatment training program" or "program" means any program operated or approved by the Office of Emergency Medical Services as set forth in rules promulgated pursuant to this article.

(6) "Overdose" means an acute condition, including, but not limited to, life-threatening physical illness, coma, mania, hysteria or death, which is the result of the consumption or use of opioid drugs.

(7) "Standing order" means a written document containing rules, policies, procedures, regulations and orders for the conduct of patient care, including the condition being treated, the action to be taken and the dosage and route of administration for the drug prescribed.

§16-46-3. Licensed health care providers may prescribe opioid antagonists to initial responders and certain individuals; required educational materials; limited liability.

(a) The following individuals may prescribe an opioid antagonist in the manner prescribed by this subsection:

(1) A licensed health care provider acting in good faith and exercising good reasonable care may directly or by standing order prescribe an opioid antagonist to:

(A) A person at risk of experiencing an opioid-related overdose; or

(B) A family member, friend, or other person in a position to assist a person at risk of experiencing an opioid-related overdose.

(2) A licensed health care provider acting in good faith and exercising reasonable care may directly or by standing order prescribe an opioid antagonist to any governmental or non-governmental organization, including a local health department, a law enforcement agency, or an organization that promotes scientifically proven ways of mitigating health risks associated with substance use disorders and other high risk behaviors, for the purpose of distributing, through its agents, the opioid antagonist, to:

(A) A person at risk of experiencing an opioid-related overdose or

(B) A family member, friend, or other person in a position to assist a person at risk of experiencing an opioid-related overdose.

(b) A pharmacist may dispense an opioid antagonist to a person or organization pursuant to a prescription issued in accordance with subsection (a) of this section.

(c)(1) A governmental or non-governmental organization, including a local health department, a law enforcement agency, or organization that promotes scientifically proven ways to mitigate health risks associated with substance use disorders and other high-risk behaviors may, through its trained agents, distribute an opioid antagonist obtained pursuant to a prescription issued in accordance with this section to:

(A) A person at risk of experiencing an opioid-related overdose or

(B) A family member, friend, or other person in a position to assist a person at risk of experiencing an opioid-related overdose.

(2) An organization, through its trained agents, shall include with any distribution of an opioid antagonist pursuant to this subsection required education including opioid-related overdose prevention and treatment programs and instruction on how to administer the opioid antagonist.

(d) A person who receives an opioid antagonist that was prescribed pursuant to subsection (a) or distributed pursuant to subsection (c) may administer an opioid antagonist to another person if:

(1) The person has a good faith belief that the other person is experiencing a drug-related overdose; and

(2) The person exercises reasonable care in administering the drug to another person.

(e) A person and organization acting in good faith under the provisions of this section are immune from civil or criminal liability.

(f) A person and organization may possess an opioid antagonist, regardless of whether the person or organization holds a prescription for the opioid antagonist.

§16-46-3a. Pharmacist or pharmacy intern may dispense, pursuant to a protocol, opioid antagonists without a prescription; patient counseling required; required educational materials.

(a) Pursuant to the protocol developed under subsection (f) of this section, a pharmacist or pharmacy intern under the supervision of a pharmacist may dispense an opioid antagonist without a prescription.

(b) A pharmacist or pharmacy intern who dispenses an opioid antagonist without a prescription under this section shall provide patient counseling to the individual for whom the opioid antagonist is dispensed regarding, but not limited to, the following topics: (1) The proper administration of the opioid antagonist; (2) the importance of contacting emergency services as soon as practicable either before or after administering the opioid antagonist; and (3) the risks associated with failure to contact emergency services following administration of an opioid antagonist. The patient counseling described in this section is mandatory and the person receiving the opioid antagonist may not opt out.

(c) A pharmacist shall document the dispensing of an opioid antagonist without a prescription as set forth in the protocol developed under subsection (f) of this section and the reporting requirements set forth in subsection (a), section four, article nine, chapter sixty-a of this code.

(d) All pharmacists or pharmacy interns who dispense an opioid antagonist under this section shall provide educational materials to any person receiving such an opioid antagonist on opiate-related overdose prevention and treatment programs, as well as materials on administering the opioid antagonist.

(e) This section does not affect the authority of a pharmacist or pharmacy intern to fill or refill a prescription for an opioid antagonist.

(f) To implement the provisions of this section, the Board of Pharmacy shall, after consulting with the Bureau for Public Health: (1) Develop a protocol under which pharmacists or pharmacy interns may dispense an opioid antagonist without a prescription; (2) specify educational materials which shall be provided to the individual receiving the opioid antagonist; and (3) develop a form, template or the like to be used by pharmacists and pharmacy interns when dispensing the opioid antagonists without a prescription. The protocol developed by the board may be updated or revised as necessary.

§16-46-4. Possession and administration of an opioid antagonist by initial responders; limited liability.

(a) Local and state governmental agencies that employ initial responders must provide opioid antagonist rescue kits to their initial responders, require initial responders to successfully complete the training required by §16-46-6(b) of this code, and require the initial responders to carry the opioid antagonist rescue kits in accordance with agency procedures so as to optimize the initial responders' capacity to timely assist in the prevention of opioid overdoses: Provided, That a local or state governmental agency has designated sufficient funding or supplies of opioid antagonist rescue kits.

(b) In the absence of gross negligence or willful misconduct, nothing in this section shall be construed to impose civil or criminal liability on a local or state governmental agency or an initial responder acting in good faith in the administration or provision of an opioid antagonist in cases where an individual appears to be experiencing an opioid overdose.

(c) As used in this section, an "opioid antagonist rescue kit" means a kit containing:

(1) Two doses of an opioid antagonist in either a generic form or in a form approved by the United States Federal Food and Drug Administration; and

(2) Overdose education materials that conform to Office of Emergency Medical Services or federal Substance Abuse and Mental Health Services Administration guidelines for opioid overdose education that explain the signs and causes of an opioid overdose and instruct when and how to administer in accordance with medical best practices:

(A) Life-saving rescue techniques; and

(B) An opioid antagonist.

§16-46-5. Licensed health care providers limited liability related to opioid antagonist prescriptions.

(a) A licensed health care provider who is permitted by law to prescribe drugs, including opioid antagonists, may, if acting in good faith, prescribe and subsequently dispense or distribute an opioid antagonist without being subject to civil liability or criminal prosecution unless prescribing the opioid antagonist was the result of the licensed health care providers gross negligence or willful misconduct.

(b) For purposes of this chapter and chapter sixty-a of this code, any prescription written, as described in section three of this article, shall be presumed as being issued for a legitimate medical purpose in the usual course of professional practice unless the presumption is rebutted by a preponderance of the evidence.

(c) Any person who possesses an opioid antagonist and administers it to a person whom they believe to be suffering from an opioid-related overdose and who is acting in good faith is not, as a result of his or her actions or omissions, subject to criminal prosecution arising from the possession of an opioid antagonist or subject to any civil liability with respect to the administration of or failure to administer the opioid antagonist unless the act or failure to act was the result of gross negligence or willful misconduct.

(d) Any person who administers an opioid antagonist to a person whom they believe to be suffering from an opioid-related overdose is required to seek additional medical treatment at a medical facility for that person immediately following the administration of the opioid antagonist to avoid further complications as a result of suspected opioid-related overdose.

(e) Any pharmacist or pharmacy intern who dispenses or refuses to dispense an opioid antagonist under the provisions of this article who is acting in good faith and subject to the requirements of section three-a of this article is not, as a result of his or her actions or omissions, subject to civil liability or criminal prosecution unless dispensing the opioid antagonist was the result of the pharmacist or pharmacy interns gross negligence or willful misconduct.

§16-46-6. Data collection and reporting requirements; training.

(a) Beginning March 1, 2016, and annually after that the following reports shall be compiled:

(1) The Office of Emergency Medical Services shall collect data regarding each administration of an opioid antagonist by an initial responder. The Office of Emergency Medical Services shall report this information to the Legislative Oversight Commission on Health and Human Resources Accountability, Joint Committee on Health and the West Virginia Bureau for Behavioral Health and Health Facilities. The data collected and reported shall include:

(A) The number of training programs operating in an Office of Emergency Medical Services-designated training center;

(B) The number of individuals who received training to administer an opioid antagonist;

(C) The number of individuals who received an opioid antagonist administered by an initial responder;

(2) The distribution of an opioid antagonist by a governmental or non-governmental entity, granting institution, medical provider, or pharmacy whose software cannot automatically report to the West Virginia Controlled Substance Monitoring Program database must report to the West Virginia Office of Drug Control Policy on a monthly basis. Report must be generated and submitted by the 10th day of each month for the opioid antagonists dispensed or distributed in the previous month. The following information must be reported:

(A) The name and address of the entity dispensing or distributing the opioid antagonist;

(B) The name and national drug code for each formulation of opioid antagonist dispensed or distributed;

(C) The total quantity of each formulation of opioid antagonist dispensed or distributed.

(3) The West Virginia Board of Pharmacy shall query the West Virginia Controlled Substances Monitoring Program database to compile all data related to the dispensing of opioid antagonists and combine that data with any additional data maintained by the Board of Pharmacy related to prescriptions for and distribution of opioid antagonists. The aggregate data shall be reported to the West Virginia Office of Drug Control Policy by the 10th day of each month. By February 1 and annually thereafter, the West Virginia Office of Drug Control Policy shall provide a report of this information, excluding any personally identifiable information, to the Legislative Oversight Commission on Health and Human Resources Accountability, Joint Committee on Health and the West Virginia Bureau for Behavioral Health and Health Facilities.

(b) To implement the provisions of this article, including establishing the standards for certification and approval of opioid overdose prevention and treatment training programs and protocols regarding a refusal to transport, the Office of Emergency Medical Services may promulgate emergency rules pursuant to the provisions of section fifteen, article three, chapter twenty-nine-a of this code and shall propose rules for legislative approval in accordance with the provisions of said article.

§16-46-7. Statewide standing orders for opioid antagonist.

(a) The state health officer may prescribe on a statewide basis an opioid antagonist by one or more standing orders to eligible recipients.

(b) A standing order must specify, at a minimum:

(1) The opioid antagonist formulations and means of administration that are approved for dispensing;

(2) The eligible recipients to whom the opioid antagonist may be dispensed;

(3) Any training that is required for an eligible recipient to whom the opioid antagonist is dispensed;

(4) The circumstances under which an eligible recipient may distribute or administer the opioid antagonist; and

(5) The timeline for renewing and updating the standing order.

§16-50 Epinephrine Auto-injector Availability and Use

§16-50-1. Definitions.

As used in this article the term:

(1) "Administer" means to directly apply an epinephrine auto-injector to the body of an individual.

(2) "Authorized entity" means an entity or organization where allergens capable of causing a severe allergic reaction may be present.

(3) "Authorized health care practitioner" means an allopathic physician licensed to practice pursuant to the provisions of article three, chapter thirty of this code and an osteopathic physician licensed to practice pursuant to the provisions of article fourteen, chapter thirty of this code.

(4) "Department" means the Department of Health.

(5) "Epinephrine auto-injector" means a single-use device used for the automatic injection of a premeasured dose of epinephrine into the human body.

(6) "Self-administration" means an individual's discretionary administration of an epinephrine auto-injector on herself or himself.

§16-50-2. Authority.

The department may:

(1) Propose legislative rules for legislative approval in accordance with the provisions of article three, chapter twenty-nine-a of this code, necessary to administer this article; and

(2) Conduct and approve education training programs.

§16-50-3. Educational training programs.

Educational training programs shall be conducted by a nationally recognized organization experienced in training laypersons in emergency health treatment or an entity or individual approved by the department. The curriculum shall include at a minimum:

(1) Recognition of the symptoms of allergic reactions to food, insect stings and other allergens; and

(2) The proper administration of a subcutaneous injection of epinephrine auto-injector.

§16-50-4. Prescriptive authority for epinephrine auto-injectors; emergency administration.

(a) An authorized health care practitioner may prescribe an epinephrine injector to an authorized entity. A pharmacist may dispense an epinephrine auto-injectors pursuant to a prescription issued in the name of an authorized entity.

(b) An authorized entity may acquire and stock a supply of epinephrine auto-injectors pursuant to a prescription issued in accordance with this section. The epinephrine auto-injectors shall be stored in accordance with the epinephrine auto-injector's instructions. An authorized entity shall designate employees or agents who are trained pursuant to section three of this article to be responsible for the storage, maintenance and general oversight of epinephrine auto-injectors.

(c) An individual trained pursuant to section three of this article may, on the premises of or in connection with the authorized entity, use epinephrine auto-injectors to:

(1) Provide an epinephrine auto-injector to a person who the trained individual in good faith believes is experiencing a severe allergic reaction for that person's immediate self-administration, regardless of whether the person has a prescription for an epinephrine auto-injector or has previously been diagnosed with an allergy; or

(2) Administer an epinephrine auto-injector to a person who the trained individual in good faith believes is experiencing a severe allergic reaction, regardless of whether the person has a prescription for an epinephrine auto-injector or has previously been diagnosed with an allergy.

§16-50-5. Not practice of medicine; limits on liability.

(a) The administration of an epinephrine auto-injector in accordance with this article is not the practice of medicine.

(b) An authorized health care practitioner who prescribes epinephrine auto-injectors to an authorized entity; an authorized entity that possesses and makes available epinephrine auto-injectors; and, an entity or person that conducts the training under section three of this article are not liable for civil damages that result from the administration or self-administration of an epinephrine auto-injector, the failure to administer an epinephrine auto-injector, or any other act or omission committed, in good faith, pursuant to this article.

(c) An individual employed by an authorized entity who administers or provides an epinephrine auto-injection to a person as provided in this article is immune from liability for any civil action arising out of an act or omission resulting from the administration of the epinephrine auto-injection unless the act or omission was the result of the individual's gross negligence or willful misconduct.

§16-54 Opioid Reduction Act

§16-54-1. Definitions.

As used in this section:

"Acute pain" means a time limited pain caused by a specific disease or injury.

"Chronic pain" means a noncancer, nonend of life pain lasting more than three months or longer than the duration of normal tissue healing.

"Health care practitioner" or "practitioner" means:

(1) A physician authorized pursuant to the provisions of §30-3-1 et seq. and §30-14-1 et seq. of this code;

(2) A podiatrist licensed pursuant to the provisions of §30-3-1 et seq. of this code;

(3) A physician assistant with prescriptive authority as set forth in §30-3E-3 of this code;

(4) An advanced practice registered nurse with prescriptive authority as set forth in §30-7-15a of this code;

(5) A dentist licensed pursuant to the provisions of §30-4-1 et seq. of this code;

(6) An optometrist licensed pursuant to the provisions of §30-8-1 et seq. of this code;

(7) A physical therapist licensed pursuant to the provisions of §30-20-1 et seq. of this code;

(8) An occupational therapist licensed pursuant to the provisions of §30-28-1 et seq. of this code;

(9) An osteopathic physician licensed pursuant to the provisions of §30-14-1 et seq. of this code; and

(10) A chiropractor licensed pursuant to the provisions of §30-16-1 et seq. of this code.

"Insurance provider" means an entity that is regulated under the provisions of §33-15-1 et seq., §33-16-1 et seq., §33-24-1 et seq., §33-25-1 et seq. and §33-25A-1 et seq. of this code.

"Office" means the Office of Drug Control Policy.

"Pain clinic" means the same as that term is defined in §16-5H-2 of this code.

"Pain specialist" means a practitioner who is board certified in pain management or a related field.

"Prescribe" means the advisement of a physician or other licensed practitioner to a patient for a course of treatment. It can include but is not limited to medication, services, supplies, equipment, procedures, diagnostic tests, or screening as permitted by the physician or other licensed practitioner’s scope of practice.

"Referral" means the recommendation by a person to another person for the purpose of initiating care by a health care practitioner.

"Schedule II opioid drug" means an opioid drug listed in §60A-2-206 of this code.

"Surgical procedure" means a medical procedure involving an incision with instruments performed to repair damage or arrest disease in a living body.

§16-54-2. Voluntary nonopioid advanced directive form.

(a) The office shall establish a voluntary nonopioid advanced directive form. The form shall be available on the office's web site. The form shall indicate to a health care practitioner that an individual may not be administered or offered a prescription or medication order for an opioid. The advance directive shall be filed in the individual's medical record in either a health care facility or a private office of a practitioner, or both, and shall be transferred with the person from one practitioner to another or from one health care facility to another.

(b) An individual may revoke the voluntary nonopioid advanced directive form for any reason and may do so by written or oral means.

(c) A practitioner without actual knowledge of an advance directive as set forth in §16-54-2(a) of this code and who prescribes an opioid in a medical emergency situation is not civilly or criminally liable for failing to act in accordance with the directives unless the act or omission was the result of a practitioner's gross negligence or willful misconduct. For purposes of this section, a "medical emergency situation" shall mean an acute injury or illness that poses an immediate risk to a person's life or long-term health.

§16-54-3. Opioid prescription notifications.

Prior to issuing a prescription for a Schedule II opioid drug, a practitioner shall:

(1) Advise the patient regarding the quantity of the Schedule II opioid drug and a patient's option to fill the prescription in a lesser quantity; and

(2) Inform the patient of the risks associated with the Schedule II opioid drug prescribed.

§16-54-4. Opioid prescription limitations.

(a) When issuing a prescription for a Schedule II opioid drug to an adult patient seeking treatment in an emergency room for outpatient use, a health care practitioner may not issue a prescription for more than a four-day supply: Provided, That a prescription for a Schedule II opioid drug issued to an adult patient in an emergency room for outpatient use is not considered to be an initial Schedule II opioid prescription.

(b) When issuing a prescription for a Schedule II opioid drug to an adult patient seeking treatment in an urgent care facility setting for outpatient use, a health care practitioner may not issue a prescription for more than a four-day supply: Provided, That an additional dosing for up to no more than a seven-day supply may be permitted, but only if the medical rationale for more than a four-day supply is documented in the medical record.

(c) A health care practitioner may not issue an initial Schedule II opioid drug prescription to a minor for more than a three-day supply and shall discuss with the parent or guardian of the minor the risks associated with Schedule II opioid drug use and the reasons why the prescription is necessary.

(d) A dentist or an optometrist may not issue a Schedule II opioid drug prescription for more than a three-day supply.

(e) A practitioner, other than a dentist or an optometrist, may not issue an initial Schedule II opioid drug prescription for more than a seven-day supply. The prescription shall be for the lowest effective dose which in the medical judgement of the practitioner would be the best course of treatment for this patient and his or her condition.

(f) Prior to issuing an initial Schedule II opioid drug prescription, a practitioner shall:

(1) Take and document the results of a thorough medical history, including the patient's experience with nonopioid medication, nonpharmacological pain management approaches, and substance abuse history;

(2) Conduct, as appropriate, and document the results of a physical examination. The physical exam should be relevant to the specific diagnosis and course of treatment, and should assess whether the course of treatment would be safe and effective for the patient.

(3) Develop a treatment plan, with particular attention focused on determining the cause of the patient's pain; and

(4) Access relevant prescription monitoring information under the Controlled Substances Monitoring Program Database.

(g) Notwithstanding any provision of this code or legislative rule to the contrary, no medication listed as a Schedule II opioid drug as set forth in §60A-2-206 of this code, may be prescribed by a practitioner for greater than a 30-day supply: Provided, That two additional prescriptions, each for a 30-day period for a total of a 90-day supply, may be prescribed if the practitioner accesses the West Virginia Controlled Substances Monitoring Program Database as set forth in §60A-9-1 et seq. of this code: Provided, however, That the limitations in this section do not apply to cancer patients, patients receiving hospice care from a licensed hospice provider, patients receiving palliative care, a patient who is a resident of a long-term care facility, or a patient receiving medications that are being prescribed for use in the treatment of substance abuse or opioid dependence.

(h) A practitioner is required to conduct and document the results of a physical examination every 90 days for any patient for whom he or she continues to treat with any Schedule II opioid drug as set forth in §60A-2-206 of this code. The physical examination should be relevant to the specific diagnosis and course of treatment, and should assess whether continuing the course of treatment would be safe and effective for the patient.

(i) A veterinarian licensed pursuant to the provisions of §30-10-1 et seq. of this code may not issue an initial Schedule II opioid drug prescription for more than a seven-day supply. The prescription shall be for the lowest effective dose which in the medical judgment of the veterinarian would be the best course of treatment for the patient and his or her condition.

(j) In conjunction with the issuance of the third prescription for a Schedule II opioid drug, the patient shall execute a narcotics contract with the prescribing practitioner. The contract shall be made a part of the patient's medical record. The narcotics contract is required to provide at a minimum that:

(1) The patient agrees only to obtain scheduled medications from this particular prescribing practitioner;

(2) The patient agrees he or she will only fill those prescriptions at a single pharmacy which includes a pharmacy with more than one location;

(3) The patient agrees to notify the prescribing practitioner within 72 hours of any emergency where he or she is prescribed scheduled medication;

(4) If the patient fails to honor the provisions of the narcotics contract, the prescribing practitioner may either terminate the provider-patient relationship or continue to treat the patient without prescribing a Schedule II opioid drug for the patient. Should the practitioner decide to terminate the relationship, he or she is required to do so pursuant to the provisions of this code and any rules promulgated hereunder. Termination of the relationship for the patient's failure to honor the provisions of the contract is not subject to any disciplinary action by the practitioner's licensing board; and

(5) If another physician is approved to prescribe to the patient.

(k) A pharmacist is not responsible for enforcing the provisions of this section and the Board of Pharmacy may not discipline a licensee if he or she fills a prescription in violation of the provisions of this section.

§16-54-5. Subsequent prescriptions; limitations.

(a) After issuing the initial Schedule II opioid drug prescription as set forth in §16-54-4 of this code, the practitioner, after consultation with the patient, may issue a subsequent prescription for a Schedule II opioid drug to the patient if:

(1) The subsequent prescription would not be deemed an initial prescription pursuant to §16-54-4 of this code;

(2) The practitioner determines the prescription is necessary and appropriate to the patient's treatment needs and documents the rationale for the issuance of the subsequent prescription; and

(3) The practitioner determines that issuance of the subsequent prescription does not present an undue risk of abuse, addiction, or diversion and documents that determination.

(b) Prior to issuing the subsequent Schedule II opioid drug prescription of the course of treatment, a practitioner shall discuss with the patient, or the patient's parent or guardian if the patient is under 18 years of age, the risks associated with the Schedule II opioid drugs being prescribed. This discussion shall include:

(1) The risks of addiction and overdose associated with Schedule II opioid drugs and the dangers of taking Schedule II opioid drugs with alcohol, benzodiazepines, and other central nervous system depressants;

(2) The reasons why the prescription is necessary;

(3) Alternative treatments that may be available; and

(4) Risks associated with the use of the Schedule II opioid drug being prescribed, specifically that Schedule II opioid drugs are highly addictive, even when taken as prescribed, that there is a risk of developing a physical or psychological dependence on the Schedule II opioid drug, and that the risks of taking more opioids than prescribed, or mixing sedatives, benzodiazepines, or alcohol with opioids, can result in fatal respiratory depression.

(c) The discussion as set forth in §16-54-5(b) of this code shall be included in a notation in the patient's medical record.

§16-54-6. Ongoing treatment; referral to pain clinic or pain specialist.

(a) At the time of the issuance of the third prescription for a Schedule II opioid drug the practitioner shall consider referring the patient to a pain clinic or a pain specialist. The practitioner shall discuss the benefits of seeking treatment through a pain clinic or a pain specialist and provide him or her with an understanding of any risks associated by choosing not to pursue that as an option.

(b) If the patient declines to seek treatment from a pain clinic or a pain specialist and opts to remain a patient of the practitioner, and the practitioner continues to prescribe a Schedule II opioid drug as provided in this code, the practitioner shall:

(1) Note in the patient's medical records that the patient knowingly declined treatment from a pain clinic or pain specialist;

(2) Review, at a minimum of every three months, the course of treatment, any new information about the etiology of the pain, and the patient's progress toward treatment objectives and document the results of that review;

(3) Assess the patient prior to every renewal to determine whether the patient is experiencing problems associated with physical and psychological dependence and document the results of that assessment; and

(4) Periodically make reasonable efforts, unless clinically contraindicated, to either stop the use of the controlled substance, decrease the dosage, try other drugs or treatment modalities in an effort to reduce the potential for abuse or the development of physical or psychological dependence, and document with specificity the efforts undertaken.

§16-54-7. Exceptions.

(a) This article does not apply to a patient who is currently in active treatment for cancer, receiving hospice care from a licensed hospice provider or palliative care provider, or is a resident of a long-term care facility.

(b) This article does not apply to a patient being prescribed, or ordered, any medication in an inpatient setting at a hospital.

(c) Notwithstanding the limitations on the prescribing of a Schedule II opioid drug contained in §16-54-4 of this code, a practitioner may prescribe an initial seven-day supply of a Schedule II opioid drug to a post-surgery patient immediately following a surgical procedure. Based upon the medical judgment of the practitioner, a subsequent prescription may be prescribed by the practitioner pursuant to the provisions of this code. Nothing in this section authorizes a practitioner to prescribe any medication which he or she is not permitted to prescribe pursuant to their practice act.

(d) A practitioner who acquires a patient after January 1, 2018, who is currently being prescribed a Schedule II opioid drug from another practitioner is required to access the Controlled Substances Monitoring Program Database as set forth in §60A-9-1 et seq. of this code. The practitioner shall otherwise treat the patient as set forth in this code.

(e) This article does not apply to an existing practitioner-patient relationship established before January 1, 2018, where there is an established and current opioid treatment plan which is reflected in the patient's medical records.

§16-54-8. Treatment of pain.

(a) When a patient seeks treatment, a health care practitioner shall refer or prescribe to the patient any of the following treatment alternatives, as is appropriate based on the practitioner's clinical judgment and the availability of the treatment, before starting a patient on a Schedule II opioid drug: physical therapy, occupational therapy, acupuncture, massage therapy, osteopathic manipulation, chronic pain management program, and chiropractic services, as defined in §30-16-3 of this code.

(b) Nothing in this section should be construed to require that all of the treatment alternatives set forth in §16-54-8(a) of this code are required to be exhausted prior to the patient's receiving a prescription for a Schedule II opioid drug.

(c) At a minimum, an insurance provider who offers an insurance product in this state, the Bureau for Medical Services, and the Public Employees Insurance Agency shall provide coverage for 20 visits per event of physical therapy, occupational therapy, osteopathic manipulation, a chronic pain management program, and chiropractic services, as defined in §30-16-3 of this code, when ordered or prescribed by a health care practitioner.

(d) A person may seek physical therapy, occupational therapy, osteopathic manipulation, a chronic pain management program, and chiropractic services, as defined in §30-16-3 of this code, prior to seeking treatment from any other health care practitioner. The licensed health care practitioner providing services pursuant to this section may prescribe within their scope of practice as defined in §16-54-1 of this code. A health care practitioner referral although permitted is not required as a condition of coverage by the Bureau for Medical Services the Public Employees Insurance Agency, and any insurance provider who offers an insurance product in this state. Any deductible, coinsurance, or copay required for any of these services may not be greater than the deductible, coinsurance, or copay required for a primary care visit.

(e) Nothing in this section precludes a practitioner from simultaneously prescribing a Schedule II opioid drug and prescribing or recommending any of the procedures set forth in §16-54-8(a) of this code.

§16-54-9. Discipline.

A violation of this article is grounds for disciplinary action by the board that regulates the health care practitioner who commits the violation.

Tobacco Therapy Access Act

§16-56-1. Definitions.

As used in this article:

"Dispense" means the same as that term is defined in §30-5-4 of this code.

"Patient counseling" means the same as that term is defined in §30-5-4 of this code.

"Pharmacist" means the same as that term is defined in §30-5-4 of this code.

"Pharmacy intern" means the same as that term is defined in §30-5-4 of this code.

"Physician" means the same as that term is defined in §30-3E-1 of this code.

"Tobacco cessation therapy" means a tobacco cessation noncontrolled prescription medication, over-the-counter medication or other professional service, that is approved by the United States Food and Drug Administration for treating tobacco use including all of the of various dosage forms.

§16-56-2. Voluntary participation.

This article does not create a duty or standard of care for a person to prescribe or dispense tobacco cessation therapy.

§16-56-3. Authorization to dispense.

A pharmacist licensed under §30-5-1 et seq. of this code may initiate and dispense a noncontrolled prescription medication, over-the-counter medication, or other professional service to a patient who is 18 years old or older; pursuant to a standing prescription drug order made in accordance with §16-56-4 of this code without any other prescription drug order from a person licensed to prescribe a tobacco cessation therapy; and in accordance with the dispensing guidelines in §16-56-6 of this code.

§16-56-4. Standing prescription drug orders for tobacco cessation therapy.

(a) The Commissioner of the Bureau for Public Health or designee shall prescribe on a statewide basis a tobacco cessation therapy by one or more standing orders permitting pharmacists to initiate the dispensing of noncontrolled prescription medications, over-the-counter medications, or other professional services to eligible individuals:

(b) A standing order must specify, at a minimum:

(1) Use of the Tobacco Cessation Therapy Protocol, that has been approved by the Commissioner of the Bureau for Public Health in collaboration with the Board of Pharmacy and the Board of Medicine;

(2) The eligible individuals to whom the tobacco cessation therapy may be dispensed;

(3) The timeline for renewing and updating the standing order.

§16-56-5. Pharmacist education and training required.

The Board of Pharmacy shall approve a training program or programs to be eligible to participate in the utilization of the standing prescription drug order for tobacco cessation therapy by a pharmacist.

Documentation shall be provided to the Board of Pharmacy upon request.

§16-56-6. Guidelines for dispensing a tobacco cessation therapy.

(a) A pharmacist who dispenses a tobacco cessation therapy under this article shall follow the Tobacco Cessation Therapy Protocol, that has been approved by the Commissioner of the Bureau for Public Health in collaboration with the Board of Pharmacy and the Board of Medicine, before dispensing the tobacco cessation therapy. The protocol shall include the:

(1) Criteria for identifying individuals eligible to receive the tobacco cessation therapy or other professional services under the protocol, and referral to an appropriate prescriber if the patient is high-risk or therapy is contraindicated;

(2) Medications authorized by the protocol;

(3) Procedures for initiation and monitoring of therapies, including a care plan based on clinical guidelines;

(4) Education requirements to be provided to the person receiving the medications and follow-up care;

(5) Documentation procedures in the pharmacy system; and

(6) Notification of the individual’s primary care provider, if provided, within two business days.

(b) If when following the protocol it is indicated that it is unsafe to dispense a tobacco cessation therapy to a patient, the pharmacist:

(A) May not dispense a tobacco cessation therapy to the patient; and

(B) Shall refer the patient to their primary care provider.

(c) The Board of Pharmacy regulates a pharmacist who dispenses a tobacco cessation noncontrolled prescription medication, over-the-counter medication, or other professional service.

FAMILY PLANNING ACCESS ACT

§16-58-1. Definitions.

As used in this article:

"Dispense" means the same as that term is defined in §30-5-4 of this code.

"Patient counseling" means the same as that term is defined in §30-5-4 of this code.

"Pharmacist" means the same as that term is defined in §30-5-4 of this code.

"Self-administered hormonal contraceptive" means a self-administered hormonal contraceptive that is approved by the United States Food and Drug Administration to prevent pregnancy and does not include the class of emergency contraceptives commonly known as the "morning after pill" or "Plan B".

§16-58-2. Voluntary participation.

This article does not create a duty or standard of care for a person to prescribe or dispense a self-administered hormonal contraceptive.

§16-58-3. Authorization to dispense self-administered hormonal contraceptives.

(a) A pharmacist licensed under §30-5-1 et seq. of this code may dispense a self-administered hormonal contraceptive: (1) pursuant to a standing prescription drug order made in accordance with §16-57-4 of this code without any other prescription drug order from a person licensed to prescribe a self-administered hormonal contraceptive; (2) in accordance with the dispensing guidelines in §16-57-6 of this code; and (3) to a patient who is 18 years old or older.

(b) All state and federal laws governing insurance coverage of contraceptive drugs, devices, products, and services shall apply to self-administered contraceptives dispensed by a pharmacist under a standing order pursuant to this section.

§16-58-4. Standing prescription drug orders for a self-administered hormonal contraceptive.

The state health officer may prescribe on a statewide basis a self-administered hormonal contraceptive by one or more standing orders in accordance with a protocol consistent with the United States Medical Eligibility Criteria for Contraceptive Use (MEC) Centers for Disease Control and Prevention, that requires:

(1) Use of the self-screening risk assessment questionnaire described below;

(2) Written and oral education;

(3) The timeline for renewing and updating the standing order;

(4) Who is eligible to utilize the standing order;

(5) The pharmacist to make and retain a record of each person to whom the self-administered hormonal contraceptive is dispensed, including:

(A) The name of the person;

(B) The drug dispensed; and

(C) Other relevant information.

§16-58-5. Pharmacist education and training required.

(a) The Board of Pharmacy, in collaboration with the Bureau for Public Health, shall approve a training program or programs to be eligible to participate in the utilization of the standing prescription drug order for self-administered hormonal contraceptives by a pharmacist.

(b) Documentation of training shall be provided to the Board of Pharmacy upon request.

§16-58-6. Guidelines for dispensing a self-administered hormonal contraceptive.

(a) A pharmacist who dispenses a self-administered hormonal contraceptive under this article:

(1) Shall obtain a completed self-screening risk assessment questionnaire that has been approved by the state health officer in collaboration with the Board of Pharmacy, the Board of Osteopathic Medicine, and the Board of Medicine from the patient before dispensing the self-administered hormonal contraceptive;

(2) Shall notify the patient's primary care provider, if provided;

(3) If when dispensing within the guidelines it is unsafe to dispense a self-administered hormonal contraceptive to a patient then the pharmacist:

(A) May not dispense a self-administered hormonal contraceptive to the patient; and

(B) Shall refer the patient to a health care practitioner or local health department;

(4) May not continue to dispense a self-administered hormonal contraceptive to the patient for more than 12 months after the date of the initial prescription without evidence that the patient has consulted with a health care practitioner during the preceding 12 months; and

(5) Shall provide the patient with:

(A) Written and verbal information regarding:

(i) The importance of seeing the patient's health care practitioner to obtain recommended tests and screening; and

(ii) The effectiveness and availability of long-acting reversible contraceptives and other effective contraceptives as an alternative to self-administered hormonal contraceptives; and

(B) A copy of the record of the encounter with the patient that includes:

(i) The patient's completed self-assessment tool; and

(ii) A description of the contraceptives dispensed, or the basis for not dispensing a contraceptive.

(b) If a pharmacist dispenses a self-administered hormonal contraceptive to a patient, the pharmacist shall, at a minimum, provide the patient counseling regarding:

(1) The appropriate administration and storage of the self-administered hormonal contraceptive;

(2) Potential side effects and risks of the self-administered hormonal contraceptive;

(3) The need for backup contraception;

(4) When to seek emergency medical attention;

(5) The risk of contracting a sexually transmitted infection or disease, and ways to reduce the risk of contraction; and

(6) Any additional counseling outlined in the protocol as prescribed in §16-57-4 of this code.

(c) The Board of Pharmacy regulates a pharmacist who dispenses a self-administered hormonal contraceptive under this article.