HB 2577

WEST VIRGINIA LEGISLATURE

FIRST REGULAR SESSION, 2013

ENROLLED

COMMITTEE SUBSTITUTE
FOR

House Bill No. 2577

(By Delegate(s) Perdue, Perry,
Eldridge, Lawrence and Staggers)

Passed April 13, 2013

In effect July 1, 2013.

ENROLLED

COMMITTEE SUBSTITUTE

FOR

H. B. 2577

(BY DELEGATE(S) PERDUE, PERRY, ELDRIDGE,
LAWRENCE AND STAGGERS)

[Passed April 13, 2013; in effect July 1, 2013.]

AN ACT to repeal §30-5-1a, §30-5-1b, §30-5-2a, §30-5-3a, §30-5-5a, §30-5-5b, §30-5-6a, §30-5-7a, §30-5-7b, §30-5-7c, §30-5-9a, §30-5-10a, §30-5-12c, §30-5-14a, §30-5-14b, §30-5-16a, §30-5-16b, §30-5-16c and §30-5-22a of the Code of West Virginia, 1931, as amended; to amend and reenact §29-29-3 of said code; to amend and reenact §30-5-1, §30-5-2, §30-5-3, §30-5-4, §30-5-5, §30-5-6, §30-5-7, §30-5-8, §30-5-9, §30-5-10, §30-5-11, §30-5-12, §30-5-13, §30-5-14, §30-5-15, §30-5-16, §30-5-17, §30-5-18, §30-5-19, §30-5-20, §30-5-21, §30-5-22, §30-5-23, §30-5-24, §30-5-26, §30-5-27, §30-5-28 and §30-5-30 of said code; to amend said code by adding thereto six new sections, designated §30-5-25, §30-5-29, §30-5-31, §30-5-32, §30-5-33 and §30-5-34; to amend and reenact §60A-8-7 of said code; to amend and reenact §60A-10-3 of said code; and to amend and reenact §60A-10-5 of

said code, all relating to pharmacy practice; prohibiting the practice of pharmacist care without a license; permitting a licensed practitioner to dispense in certain settings; providing other applicable sections; providing definitions; providing for board composition and qualifications; setting forth the powers and duties of the board; clarifying rule-making authority; continuing a special revenue account; establishing license, registration and permit requirements; establishing qualifications for licensure as a pharmacist and registration as a pharmacy technician; creating a scope of practice for pharmacists and pharmacy technicians; establishing requirements for a pharmacy intern to assist in practice of pharmacy care; creating a temporary permit; prohibiting the dispensing of prescription orders in absence of a practitioner-patient relationship; providing for reciprocal licensure; establishing renewal requirements; providing for exemptions from licensure; creating a special volunteer license; providing requirement to participate in collaborative pharmacy practice; providing for collaborative pharmacy practice agreements; providing requirements for dispensing generic drugs; requiring and authorizing registration of pharmacies; establishing for permit for mail-order pharmacies and the manufacturing of drugs; providing requirements of filling prescriptions; providing requirements for the display of a board authorization; establishing requirements for pharmacist-in-charge; setting forth limitations of the article; permitting the board to file an injunction; setting forth grounds for disciplinary actions; allowing for specific disciplinary actions; providing procedures for investigation of complaints; providing duty to warn; providing for judicial review and appeals of decisions; setting forth hearing and notice requirements; providing for civil causes of action; providing criminal offenses are to be reported to law enforcement; and updating internal references.

Be it enacted by the Legislature of West Virginia:

That §30-5-1a, §30-5-1b, §30-5-2a, §30-5-3a, §30-5-5a, §30-5-5b, §30-5-6a, §30-5-7a, §30-5-7b, §30-5-7c, §30-5-9a, §30-5-10a, §30-5-12c, §30-5-14a, §30-5-14b, §30-5-16a, §30-5-16b, §30-5-16c

and §30-5-22a of the Code of West Virginia, 1931, as amended, be repealed; that §29-29-3 of said code be amended and reenacted; that §30-5-1, §30-5-2, §30-5-3, §30-5-4, §30-5-5, §30-5-6, §30-5-7, §30-5-8, §30-5-9, §30-5-10, §30-5-11, §30-5-12, §30-5-13, §30-5-14, §30-5-15, §30-5-16, §30-5-17, §30-5-18, §30-5-19, §30-5-20, §30-5-21, §30-5-22, §30-5-23, §30-5-24, §30-5-26, §30-5-27, §30-5-28 and §30-5-30 of said code be amended and reenacted; that said code be amended by adding thereto six new sections, designated §30-5-25, §30-5-29, §30-5-31, §30-5-32, §30-5-33 and §30-5-34; that §60A-8-7 of said code be amended and reenacted; that §60A-10-3 of said code be amended and reenacted; and that §60A-10-5 of said code be amended and reenacted, all to read as follows:

CHAPTER 29. MISCELLANEOUS BOARDS AND OFFICERS.

ARTICLE 29. VOLUNTEER FOR NONPROFIT YOUTH ORGANIZATIONS ACT.

§29-29-3. Definitions.

As used in this article:

(a) "Applicant" means any emergency medical service applicant, law-enforcement applicant or medical services applicant, that is registered as a volunteer of the nonprofit organization, making application for a nonprofit volunteer permit under the provisions of this article.

(b) "Appropriate licensing agency" means the board, department, division or other agency in each jurisdiction charged with the licensing, certification or permitting of persons performing services of the nature and kind described or duties provided for in this article.

(c) "Emergency medical service applicant" means a person authorized to provide emergency medical services in West Virginia, or in another state who but for this article would be

required to obtain a certification from the Commissioner of the Bureau for Public Health pursuant to article eight, chapter sixteen of this code to perform emergency medical services in this state.

(d) "Law-enforcement applicant" means a person authorized to work as a law-enforcement officer in West Virginia, or in another state who but for this article would be required to obtain authorization pursuant to article twenty-nine, chapter thirty of this code to work as a law-enforcement officer in this state: *Provided,* That any person authorized to work as a law-enforcement officer in another state shall have completed a training program approved by the governing authority of a political subdivision in order to work as a law-enforcement officer in that state.

(e) "Medical services applicant" means a person authorized to provide medical services in West Virginia, or in another state who but for this article would be required to obtain authorization to practice in this state, and who is a:

(1) Practitioner of medicine, surgery or podiatry as defined in article three, chapter thirty of this code;

(2) Physician assistant as defined in section three, article three, chapter thirty of this code;

(3) Chiropractor as defined in section three, article sixteen, chapter thirty of this code;

(4) Dentist or dental assistant as defined in article four, chapter thirty of this code;

(5) Nurse as defined in article seven or seven-a, chapter thirty of this code;

(6) Nurse practitioner as defined in section one, article four-b, chapter nine of this code;

(7) Occupational therapist as defined in section three, article twenty-eight, chapter thirty of this code;

(8) Practitioner of optometry as defined in section three, article eight, chapter thirty of this code;

(9) Osteopathic physician or surgeon as defined in article fourteen, chapter thirty of this code;

(10) Osteopathic physician assistant as defined in article fourteen-a, chapter thirty of this code;

(11) Pharmacist as defined in article five, chapter thirty of this code;

(12) Physical therapist as defined in article twenty, chapter thirty of this code;

(13) Professional counselor as defined in section three, article thirty-one, chapter thirty of this code;

(14) Practitioner of psychology or school psychologist as defined in section two, article twenty-one, chapter thirty of this code;

(15) Radiologic technologist, nuclear medicine technologist or practitioner of medical imaging and radiation therapy technology as defined in section four, article twenty-three, chapter thirty of this code; and

(16) Social worker licensed by the state Board of Social Work Examiners pursuant to article thirty, chapter thirty of this code.

(f) "Nonprofit volunteer permit" or "permit" means a permit issued to an applicant pursuant to the provisions of this article.

(g) "Nonprofit volunteer permittee" or "permittee" means a person holding a nonprofit volunteer permit issued under the provisions of this article.

(h) "Nonprofit youth organization" or "organization" means any nonprofit organization, including any subsidiary, affiliated or other related entity within its corporate or business structure, that has been chartered by the United States Congress to help train young people to do things for themselves and others, and that has established an area of at least six thousand contiguous acres within West Virginia in which to provide adventure or recreational activities for these young people and others.

(i) "Nonprofit volunteer organization medical director" means an individual licensed in West Virginia as a practitioner of medicine or surgery pursuant to article three, chapter thirty of this code, or an individual licensed in West Virginia as an osteopathic physician or surgeon pursuant to article fourteen, chapter thirty of this code, that has been designated by the nonprofit volunteer organization to serve as the medical director for an event or program offered by the organization.

CHAPTER 30. PROFESSIONS AND OCCUPATIONS.

ARTICLE 5. PHARMACISTS, PHARMACY TECHNICIANS, PHARMACY INTERNS AND PHARMACIES.

§30-5-1. Short title.

This article shall be known as and may be cited as the "The Larry W. Border Pharmacy Practice Act".

§30-5-2. 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.

§30-5-3. 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.

§30-5-4. Definitions.

As used in this article:

(1) "Ambulatory health care facility" includes any facility defined in section one, article five-b, chapter sixteen of this code, that also has a pharmacy, offers pharmacist care, or is otherwise engaged in the practice of pharmacist care.

(2) "Active Ingredients" means chemicals, substances, or other components of articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of diseases in humans or animals or for use as nutritional supplements.

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

(4) "Board" means the West Virginia Board of Pharmacy.

(5) "Board authorization" means a license, registration or permit issued under this article.

(6) "Chain Pharmacy Warehouse" means a permanent physical location for drugs and/or devices that acts as a central warehouse and performs intracompany sales and transfers of prescription drugs or devices to chain pharmacies, which are members of the same affiliated group, under common ownership and control.

(7) "Charitable clinic pharmacy" means a clinic or facility organized as a not-for-profit corporation that has a pharmacy, offers pharmacist care, or is otherwise engaged in the practice of pharmacist care and dispenses its prescriptions free of charge to appropriately screened and qualified indigent patients.

(8) "Collaborative pharmacy practice" is that practice of pharmacist care where one or more pharmacists have jointly agreed, on a voluntary basis, to work in conjunction with one or more physicians under written protocol where the pharmacist or pharmacists may perform certain patient care functions authorized by the physician or physicians under certain specified conditions and limitations.

(9) "Collaborative pharmacy practice agreement" is a written and signed agreement, which is a physician directed approach, that is entered into between an individual physician or physician group, an individual pharmacist or pharmacists and an individual patient or the patient's authorized representative who has given informed consent that provides for collaborative pharmacy practice for the purpose of drug therapy management of a patient, which has been approved by the board, the Board of Medicine in the case of an allopathic physician or the West Virginia Board of Osteopathic Medicine in the case of an osteopathic physician.

(10) "Common Carrier" means any person or entity who undertakes, whether directly or by any other arrangement, to

transport property including prescription drugs for compensation.

(11) "Component" means any active ingredient or added substance intended for use in the compounding of a drug product, including those that may not appear in such product.

(12) "Compounding" means:

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

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

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

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

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

(14) "Device" means an instrument, apparatus, implement or machine, contrivance, implant or other similar or related article, including any component part or accessory, which is required under federal law to bear the label, "Caution: Federal or state law requires dispensing by or on the order of a physician".

(15) "Digital Signature" means an electronic signature based upon cryptographic methods of originator authentication, and computed by using a set of rules and a set of parameters so that the identity of the signer and the integrity of the data can be verified.

(16) "Dispense" or "dispensing" means the interpretation, evaluation, and implementation of a prescription drug order, including the preparation, verification and delivery of a drug or device to a patient or patient's agent in a suitable container appropriately labeled for subsequent administration to, or use by, a patient.

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

(A) To dispense or administer;

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

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

(iii) Intracompany sales.

(18) "Drop shipment" means the sale of a prescription drug to a wholesale distributor by the manufacturer of the prescription drug or by that manufacturer's colicensed product partner, that manufacturer's third party logistics provider, that manufacturer's exclusive distributor, or by an authorized distributor of record that purchased the product directly from the manufacturer or from one of these entities whereby:

(A) The wholesale distributor takes title to but not physical possession of such prescription drug;

(B) The wholesale distributor invoices the pharmacy, pharmacy warehouse, or other person authorized by law to dispense or administer such drug; and

(C) The pharmacy, pharmacy warehouse or other person authorized by law to dispense or administer such drug receives delivery of the prescription drug directly from the manufacturer or from that manufacturer's colicensed product partner, that manufacturer's third party logistics provider, that manufacturer's exclusive distributor, or from an authorized distributor of record that purchased the product directly from the manufacturer or from one of these entities.

(19) "Drug" means:

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

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

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

(D) Articles intended for use as a component of any articles specified in paragraph (A), (B) or (C) of this subdivision.

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

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

(i) Known allergies;

(ii) Rational therapy-contraindications;

(iii) Reasonable dose and route of administration; and

(iv) Reasonable directions for use.

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

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

(i) Drug-drug;

(ii) Drug-food;

(iii) Drug-disease; and

(iv) Adverse drug reactions.

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

(21) "Drug therapy management" means the review of drug therapy regimens of patients by a pharmacist for the purpose of evaluating and rendering advice to a physician regarding adjustment of the regimen in accordance with the collaborative pharmacy practice agreement. Decisions involving drug therapy management shall be made in the best interest of the patient. Drug therapy management is limited to:

(A) Implementing, modifying and managing drug therapy according to the terms of the collaborative pharmacy practice agreement;

(B) Collecting and reviewing patient histories;

(C) Obtaining and checking vital signs, including pulse, temperature, blood pressure and respiration;

(D) Ordering screening laboratory tests that are dose related and specific to the patient's medication or are protocol driven and are also specifically set out in the collaborative pharmacy practice agreement between the pharmacist and physician.

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

(A) An electronic prescription order;

(B) A refill authorization request;

(C) A communication; or

(D) Other patient care information.

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

(24) "Electronic Signature" means an electronic sound, symbol, or process attached to or logically associated with a record and executed or adopted by a person with the intent to sign the record.

(25) "Electronic transmission" means transmission of information in electronic form or the transmission of the exact visual image of a document by way of electronic equipment.

(26) "Emergency medical reasons" include, but are not limited to, transfers of a prescription drug by one pharmacy to another pharmacy to alleviate a temporary shortage of a prescription drug; sales to nearby emergency medical services, i.e., ambulance companies and firefighting organizations in the same state or same marketing or service area, or nearby licensed practitioners of prescription drugs for use in the treatment of acutely ill or injured persons; and provision of minimal emergency supplies of prescription drugs to nearby nursing homes for use in emergencies or during hours of the day when necessary prescription drugs cannot be obtained.

(27) "Exclusive distributor" means an entity that:

(A) Contracts with a manufacturer to provide or coordinate warehousing, wholesale distribution, or other services on behalf of a manufacturer and who takes title to that manufacturer's prescription drug, but who does not have general responsibility to direct the sale or disposition of the manufacturer's prescription drug; and

(B) Is licensed as a wholesale distributor under this article.

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

(29) "Health care entity" means a person that provides diagnostic, medical, pharmacist care, surgical, dental treatment, or rehabilitative care but does not include a wholesale distributor.

(30) "Health information" means any information, whether oral or recorded in a form or medium, that:

(A) Is created or received by a health care provider, health plan, public health authority, employer, life insurer, school or university, or health care clearinghouse, and

(B) Relates to the past, present, or future physical or mental health or condition of an individual; or the past, present, or future payment for the provision of health care to an individual.

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

(32) "Immediate container" means a container and does not include package liners.

(33) "Individually identifiable health information" is information that is a subset of health information, including demographic information collected from an individual and is created or received by a health care provider, health plan, employer, or health care clearinghouse; and relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual; and that identifies the individual; or with respect to which there is a reasonable basis to believe the information can be used to identify the individual.

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

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

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

(37) "Long-Term care facility" means a nursing home, retirement care, mental care, or other facility or institution that provides extended health care to resident patients.

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

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

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

(41) "Medical order" means a lawful order of a practitioner that may or may not include a prescription drug order.

(42) "Medication therapy management" is a distinct service or group of services that optimize medication therapeutic outcomes for individual patients. Medication therapy management services are independent of, but can occur in conjunction with, the provision of a medication or a medical device. Medication therapy management encompasses a broad range of professional activities and responsibilities within the licensed pharmacist's scope of practice.

These services may include the following, according to the individual needs of the patient:

(A) Performing or obtaining necessary assessments of the patient's health status pertinent to medication therapy management;

(B) Optimize medication use, performing medication therapy, and formulating recommendations for patient medication care plans;

(C) Developing therapeutic recommendations, to resolve medication related problems;

(D) Monitoring and evaluating the patient's response to medication therapy, including safety and effectiveness;

(E) Performing a comprehensive medication review to identify, resolve, and prevent medication-related problems, including adverse drug events;

(F) Documenting the care delivered and communicating essential information to the patient's primary care providers;

(G) Providing verbal education and training designed to enhance patient understanding and appropriate use of his or her medications;

(H) Providing information, support services and resources designed to enhance patient adherence with his or her medication therapeutic regimens;

(I) Coordinating and integrating medication therapy management services within the broader health care management services being provided to the patient; and

(J) Such other patient care services as may be allowed by law.

(43) "Misbranded" means a drug or device that has a label that is false or misleading in any particular; or the label does not bear the name and address of the manufacturer, packer, or distributor and does not have an accurate statement of the quantities of the active ingredients in the case of a drug; or the label does not show an accurate monograph for prescription drugs.

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

(45) "Normal distribution channel" means a chain of custody for a prescription drug that goes directly or by drop shipment, from a manufacturer of the prescription drug, the manufacturer's third-party logistics provider, or the manufacturer's exclusive distributor to:

(A) A wholesale distributor to a pharmacy to a patient or other designated persons authorized by law to dispense or administer such prescription drug to a patient;

(B) A wholesale distributor to a chain pharmacy warehouse to that chain pharmacy warehouse's intracompany pharmacy to a patient or other designated persons authorized by law to dispense or administer such prescription drug to a patient;

(C) A chain pharmacy warehouse to that chain pharmacy warehouse's intracompany pharmacy to a patient or other designated persons authorized by law to dispense or administer such prescription drug to a patient;

(D) A pharmacy or to other designated persons authorized by law to dispense or administer such prescription drug to a patient; or

(E) As prescribed by the board's legislative rules.

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

(47) "Pedigree" means a statement or record in a written form or electronic form, approved by the board, that records

each wholesale distribution of any given prescription drug (excluding veterinary prescription drugs), which leaves the normal distribution channel.

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

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

(50) "Pharmacist Care" means the provision by a pharmacist of patient care activities, with or without the dispensing of drugs or devices, intended to achieve outcomes related to the cure or prevention of a disease, elimination or reduction of a patient's symptoms, or arresting or slowing of a disease process and as provided for in section ten.

(51) "Pharmacist-in-charge" means a pharmacist currently licensed in this state who accepts responsibility for the operation of a pharmacy in conformance with all laws and legislative rules pertinent to the practice of pharmacist care and the distribution of drugs and who is personally in full charge of the pharmacy and pharmacy personnel.

(52) "Pharmacist's scope of practice pursuant to the collaborative pharmacy practice agreement" means those duties and limitations of duties placed upon the pharmacist by the collaborating physician, as jointly approved by the board and the Board of Medicine or the West Virginia Board of Osteopathic Medicine.

(53) "Pharmacy" means any place within this state where drugs are dispensed and pharmacist care is provided and any place outside of this state where drugs are dispensed and pharmacist care is provided to residents of this state.

(54) "Pharmacy Intern" or "Intern" means an individual who is currently licensed to engage in the practice of pharmacist care while under the supervision of a pharmacist.

(55) "Pharmacy related primary care" means the pharmacist's activities in patient education, health promotion, selection and use of over the counter drugs and appliances and referral or assistance with the prevention and treatment of health related issues and diseases.

(56) "Pharmacy Technician" means a person registered with the board to practice certain tasks related to the practice of pharmacist care as permitted by the board.

(57) "Physician" means an individual currently licensed, in good standing and without restrictions, as an allopathic physician by the West Virginia Board of Medicine or an osteopathic physician by the West Virginia Board of Osteopathic Medicine.

(58) "Practice of telepharmacy" means the provision of pharmacist care by properly licensed pharmacists located within United States jurisdictions through the use of telecommunications or other technologies to patients or their agents at a different location that are located within United States jurisdictions.

(59) "Practitioner" means an individual authorized by a jurisdiction of the United States to prescribe drugs in the course of professional practices, as allowed by law.

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

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

(62) "Product Labeling" means all labels and other written, printed, or graphic matter upon any article or any of its containers or wrappers, or accompanying such article.

(63) "Repackage" means changing the container, wrapper, quantity, or product labeling of a drug or device to further the distribution of the drug or device.

(64) "Repackager" means a person who repackages.

(65) "Therapeutic equivalence" mean drug products classified as therapeutically equivalent can be substituted with the full expectation that the substituted product will produce the same clinical effect and safety profile as the prescribed product which contain the same active ingredient(s); dosage form and route of administration; and strength.

(66) "Third-party logistics provider" means a person who contracts with a prescription drug manufacturer to provide or coordinate warehousing, distribution or other services on behalf of a manufacturer, but does not take title to the prescription drug or have general responsibility to direct the prescription drug's sale or disposition. A third-party logistics provider shall be licensed as a wholesale distributor under this article and, in order to be considered part of the normal distribution channel, shall also be an authorized distributor of record.

(67) "Valid patient-practitioner relationship" means the following have been established:

(A) A patient has a medical complaint;

(B) A medical history has been taken;

(C) A face-to-face physical examination adequate to establish the medical complaint has been performed by the prescribing practitioner or in the instances of telemedicine

through telemedicine practice approved by the appropriate practitioner board; and

(D) Some logical connection exists between the medical complaint, the medical history, and the physical examination and the drug prescribed.

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

(A) Intracompany sales, as defined in subdivision thirty-four of this subsection;

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

(C) The sale, purchase or trade of a drug or an offer to sell, purchase or trade a drug by a charitable organization described in section 501(c)(3) of the United States Internal Revenue Code of 1986 to a nonprofit affiliate of the organization to the extent otherwise permitted by law;

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

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

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

(G) The distribution of drug samples by manufacturers' representatives or distributors' representatives, if the distribution is permitted under federal law [21 U. S. C. 353(d)];

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

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

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

hire carrier or person or entity hired solely to transport prescription drugs.

§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.

§30-5-6. Powers and duties of the board.

The board has all the powers and duties set forth in this article, by rule, in article one of this chapter and elsewhere in law, including the power to:

(a) Hold meetings;

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

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

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

(e) Establish a fee schedule;

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

(g) Prepare, conduct, administer and grade written, oral or written and oral examinations for a license and registration and establish what constitutes passage of the examination;

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

(i) Maintain records of the examinations the board or a third party administers, including the number of persons taking the examination and the pass and fail rate;

(j) Regulate mail order pharmacies;

(k) Maintain an office, and hire, discharge, establish the job requirements and fix the compensation of employees and

contract with persons necessary to enforce the provisions of this article. Inspectors shall be licensed pharmacists;

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

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

(n) Determine disciplinary action and issue orders;

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

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

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

(r) Propose rules in accordance with the provisions of article three, chapter twenty-nine-a of this code to implement the provisions of this article;

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

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

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

§30-5-7. Rule-making authority.

(a) The board shall propose rules for legislative approval, in accordance with the provisions of article three, chapter twenty-nine-a of this code, to implement the provisions of this article, and articles two, three, eight, nine and ten of chapter sixty-A including:

(1) Standards and requirements for a license, permit and registration;

(2) Educational and experience requirements;

(3) Procedures for examinations and reexaminations;

(4) Requirements for third parties to prepare, administer or prepare and administer examinations and reexaminations;

(5) The passing grade on the examination;

(6) Procedures for the issuance and renewal of a license, permit and registration;

(7) A fee schedule;

(8) Continuing education requirements;

(9) Set standards for professional conduct;

(10) Establish equipment and facility standards for pharmacies;

(11) Approve courses and standards for training pharmacist technicians;

(12) Regulation of charitable clinic pharmacies;

(13) Regulation of mail order pharmacies: *Provided*, That until the board establishes requirements that provide further conditions for pharmacists whom consult with or who provide pharmacist care to patients regarding prescriptions dispensed in this state by a mail order pharmacy, the pharmacist in charge of the out-of-state mail order pharmacy shall be licensed in West Virginia and any other pharmacist providing pharmacist care from the mail order pharmacy shall be licensed in the state where the pharmacy is located.

(14) Agreements with organizations to form pharmacist recovery networks;

(15) Create an alcohol or chemical dependency treatment program;

(16) Establish a ratio of pharmacy technicians to on-duty pharmacist operating in any outpatient, mail order or institutional pharmacy;

(17) Regulation of telepharmacy;

(18) The minimum standards for a charitable clinic pharmacy and rules regarding the applicable definition of a pharmacist-in-charge, who may be a volunteer, at charitable clinic pharmacies: *Provided*, That a charitable clinic pharmacy may not be charged any applicable licensing fees and such clinics may receive donated drugs.

(19) Establish standards for substituted drug products;

(20) Establish the regulations for E-prescribing;

(21) Establish the proper use of the automated data processing system;

(22) Registration and control of the manufacture and distribution of controlled substances within this state.

(23) Regulation of pharmacies;

(24) Sanitation and equipment requirements for wholesalers, distributers and pharmacies.

(25) Procedures for denying, suspending, revoking, reinstating or limiting the practice of a licensee, permittee or registrant;

(26) Regulations on prescription paper as provided in section five, article five-w, chapter sixteen;

(27) Regulations on controlled substances as provided in article two, chapter sixty-a;

(28) Regulations on manufacturing, distributing, or dispensing any controlled substance as provided in article three, chapter sixty-a;

(29) Regulations on wholesale drug distribution as provided in article eight, chapter sixty-a;

(30) Regulations on controlled substances monitoring as provided in article nine, chapter sixty-a;

(31) Regulations on Methamphetamine Laboratory Eradication Act as provided in article ten, chapter sixty-a; and

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

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

(c) The board, the Board of Medicine and the Board of Osteopathic Medicine shall jointly agree and propose rules concerning collaborative pharmacy practice for legislative approval in accordance with the provisions of article three, chapter twenty-nine-a of the code;

(d) The board with the advice of the Board of Medicine and the Board of Osteopathic Medicine shall propose rules for legislative approval in accordance with the provisions of article three, chapter twenty-nine-a of this code to perform influenza and pneumonia immunizations, on a person of eighteen years of age or older. These rules shall provide, at a minimum, for the following:

(1) Establishment of a course, or provide a list of approved courses, in immunization administration. The courses shall be

based on the standards established for such courses by the Centers for Disease Control and Prevention in the public health service of the United States Department of Health and Human Services;

(2) Definitive treatment guidelines which shall include, but not be limited to, appropriate observation for an adverse reaction of an individual following an immunization;

(3) Prior to administration of immunizations, a pharmacist shall have completed a board approved immunization administration course and completed an American Red Cross or American Heart Association basic life-support training, and maintain certification in the same.

(4) Continuing education requirements for this area of practice;

(5) Reporting requirements for pharmacists administering immunizations to report to the primary care physician or other licensed health care provider as identified by the person receiving the immunization;

(6) Reporting requirements for pharmacists administering immunizations to report to the West Virginia Statewide Immunization Information (WVSII);

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

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

(e) The board, the Board of Medicine and the Board of Osteopathic Medicine shall propose joint rules for legislative

approval in accordance with the provisions of article three, chapter twenty-nine-a of this code to permit licensed pharmacists to administer other immunizations such as Hepatitis A, Hepatitis B, Herpes Zoster and Tetanus. These rules shall provide, at a minimum, the same provisions contained in subsection (d)(1) through (d)(8) of this section.

(f) All of the board's rules in effect and not in conflict with these provisions, shall remain in effect until they are amended or rescinded.

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

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

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

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

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

(1) Submit a written application to the board;

(2) Be eighteen years of age or older;

(3) Pay all applicable fees;

(4) Graduate from an accredited school of pharmacy;

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

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

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

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

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

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

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

§30-5-10. 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.

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

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

(1) Submit a written application to the board;

(2) Pay the applicable fees;

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

(4) Have:

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

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

(5) Effective July 1, 2014, have successfully passed an examination developed using nationally recognized and validated psychometric and pharmacy practice standards approved by the board;

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

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

(9) Not have been convicted of a misdemeanor or felony in any jurisdiction if the offense for which he or she was convicted bearing a rational nexus to the practice of pharmacist care, which conviction remains unreversed; and

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

(b) A person whose license to practice pharmacist care has been denied, revoked, suspended, or restricted for disciplinary purposes in any jurisdiction is not eligible to be registered as a pharmacy technician.

(c) A person registered to assist in the practice pharmacist care issued by the board prior to June 30, 2014, shall for all purposes be considered registered under this article and may renew pursuant to the provisions of this article.

§30-5-12. Scope practice for registered pharmacy technician.

(a) A registered pharmacy technician shall, under the direct supervision of the licensed pharmacist, perform at a minimum the following:

(1) Assist in the dispensing process;

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

(3) Compound; and

(4) Stock medications.

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

(1) Process medical coverage claims; and

(2) Cashier.

(c) A registered pharmacy technician may not perform the following:

(1) Drug regimen review;

(2) Clinical conflict resolution;

(3) Contact a prescriber concerning prescription drug order clarification or therapy modification;

(4) Patient counseling;

(5) Dispense process validation;

(6) Prescription transfer; and

(7) Receive new oral prescription drug orders.

(d) Indirect supervision of a registered pharmacy technician is permitted to allow a pharmacist to take one break of no more than thirty minutes during any contiguous eight-hour period. The pharmacist may leave the pharmacy area but may not leave the building during the break. When a pharmacist is on break, a pharmacy technician may continue to prepare prescriptions for the pharmacist's verification. A prescription may not be delivered until the pharmacist has verified the accuracy of the prescription, and counseling, if required, has been provided to or refused by the patient.

(e) A pharmacy that permits indirect supervision of a pharmacy technician during a pharmacist's break shall have either an interactive voice response system or a voice mail system installed on the pharmacy phone line in order to receive new prescription orders and refill authorizations during the break.

(f) The pharmacy shall establish protocols that require a registered pharmacy technician to interrupt the pharmacist's break if an emergency arises.

§30-5-13. Pharmacist interns.

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

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

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

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

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

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

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

(1) In a documented emergency;

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

(3) Where patient care is rendered in consultation with another practitioner who has an ongoing relationship with the

patient and who has agreed to supervise the patient's treatment, including the use of any prescribed medications.

§30-5-15. 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.

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

(a) There is a special volunteer pharmacist license for pharmacists retired or retiring from the active practice of pharmacist care who wish to donate their expertise for the pharmacist care and treatment of indigent and needy patients in the clinic setting of clinics organized, in whole or in part, for the delivery of health care services without charge. The special volunteer pharmacist license shall be issued by the board to pharmacists licensed or otherwise eligible for licensure under this article and the legislative rules promulgated hereunder without the payment of an application fee, license fee or renewal fee, and the initial license shall be issued for the remainder of the licensing period, and renewed consistent with the boards other licensing requirements. The board shall develop application forms for the special license provided in this subsection which shall contain the pharmacist's acknowledgment that:

(1) The pharmacist's practice under the special volunteer pharmacist license shall be exclusively devoted to providing pharmacist care to needy and indigent persons in West Virginia;

(2) The pharmacist may not receive any payment or compensation, either direct or indirect, or have the expectation of any payment or compensation, for any pharmacist care rendered under the special volunteer pharmacist license;

(3) The pharmacist will supply any supporting documentation that the board may reasonably require; and

(4) The pharmacist agrees to continue to participate in continuing professional education as required by the board for the special volunteer pharmacist license.

(b) Any pharmacist who renders any pharmacist care to indigent and needy patients of a clinic organized, in whole or in part, for the delivery of health care services without charge under a special volunteer pharmacist license authorized under subsection (a) of this section without payment or compensation or the expectation or promise of payment or compensation is immune from liability for any civil action arising out of any act or omission resulting from the rendering of the pharmacist care at the clinic unless the act or omission was the result of the pharmacist's gross negligence or willful misconduct. In order for the immunity under this subsection to apply, there shall be a written agreement between the pharmacist and the clinic pursuant to which the pharmacist provides voluntary uncompensated pharmacist care under the control of the clinic to patients of the clinic before the rendering of any services by the pharmacist at the clinic: *Provided,* That any clinic entering into such written agreement is required to maintain liability coverage of not less than $1 million per occurrence.

(c) Notwithstanding the provisions of subsection (b) of this section, a clinic organized, in whole or in part, for the delivery of health care services without charge is not relieved from imputed liability for the negligent acts of a pharmacist rendering voluntary pharmacist care at or for the clinic under a special volunteer pharmacist license authorized under subsection (a) of this section.

(d) For purposes of this section, "otherwise eligible for licensure" means the satisfaction of all the requirements for licensure as listed in section nine of this article and in the legislative rules promulgated thereunder, except the fee requirements of that section and of the legislative rules promulgated by the board relating to fees.

(e) Nothing in this section may be construed as requiring the board to issue a special volunteer pharmacist license to any pharmacist whose license is or has been subject to any disciplinary action or to any pharmacist who has surrendered a license or caused such license to lapse, expire and become invalid in lieu of having a complaint initiated or other action taken against his or her license, or who has elected to place a pharmacist license in inactive status in lieu of having a complaint initiated or other action taken against his or her license, or who has been denied a pharmacist license.

(f) Any policy or contract of liability insurance providing coverage for liability sold, issued or delivered in this state to any pharmacist covered under the provisions of this article shall be read so as to contain a provision or endorsement whereby the company issuing such policy waives or agrees not to assert as a defense on behalf of the policyholder or any beneficiary thereof, to any claim covered by the terms of such policy within the policy limits, the immunity from liability of the insured by reason of the care and treatment of needy and indigent patients by a pharmacist who holds a special volunteer pharmacist license.

§30-5-18. Pharmacist requirements to participate in a collaborative pharmacy practice agreement.

For a pharmacist to participate in a collaborative pharmacy practice agreement, the pharmacist shall:

(a) Have an unrestricted and current license to practice as a pharmacist in West Virginia;

(b) Personally have or have employer coverage of at least $1 million of professional liability insurance coverage;

(c) Meet one of the following qualifications, at a minimum:

(1) Earned a Certification from the Board of Pharmaceutical Specialties, is a Certified Geriatric Practitioner, or has completed

an American Society of Health System Pharmacists(ASHP) accredited residency program, which includes two years of clinical experience approved by the board; or

(2) Successfully completed the course of study and holds the academic degree of Doctor of Pharmacy and has three years of clinical experience approved by the board and has completed an Accreditation Council for Pharmacy Education (ACPE) approved practice based continuing pharmacy education activity in the area of practice covered by the collaborative pharmacy practice agreement; or

(3) Successfully completed the course of study and hold the academic degree of Bachelor of Science in Pharmacy and has five years of clinical experience approved by the board and has completed two ACPE approved practice based continuing pharmacy education activity with at least one program in the area of practice covered by a collaborative pharmacy practice agreement.

§30-5-19. Collaborative pharmacy practice agreement.

(a) A pharmacist engaging in collaborative pharmacy practice shall have on file at his or her place of practice the collaborative pharmacy practice agreement. The existence and subsequent termination of the agreement and any additional information the rules may require concerning the agreement, including the agreement itself, shall be made available to the appropriate licensing board for review upon request. The agreement may allow the pharmacist, within the pharmacist's scope of practice pursuant to the collaborative pharmacy practice agreement, to conduct drug therapy management activities approved by the collaborating physician. The collaborative pharmacy practice agreement shall be a voluntary process, which is a physician directed approach, that is entered into between an individual physician or physician group, an individual pharmacist or pharmacists and an individual patient or the

patient's authorized representative who has given informed consent as per subsection (c).

(b) A collaborative pharmacy practice agreement may authorize a pharmacist to provide drug therapy management. In instances where drug therapy is discontinued, the pharmacist shall notify the treating physician of the discontinuance in the time frame and in the manner established by joint legislative rules. Each protocol developed, pursuant to the collaborative pharmacy practice agreement, shall contain detailed direction concerning the services that the pharmacists may perform for that patient. The protocol shall include, but need not be limited to:

(1) The specific drug or drugs to be managed by the pharmacist;

(2) The terms and conditions under which drug therapy may be implemented, modified or discontinued;

(3) The conditions and events upon which the pharmacist is required to notify the physician; and

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

(c) All activities performed by the pharmacist in conjunction with the protocol shall be documented in the patient's medical record. The pharmacists shall report at least every thirty days to the physician regarding the patient's drug therapy management. The collaborative pharmacy practice agreement and protocols shall be available for inspection by the board, the West Virginia Board of Medicine, or the West Virginia Board of Osteopathic Medicine, depending on the licensing board of the participating physician. A copy of the protocol shall be filed in the patient's medical record.

(d) Collaborative pharmacy agreements may not include the management of controlled substances.

(e) A collaborative pharmacy practice agreement, meeting the requirements herein established and in accordance with joint rules, shall be allowed in the hospital setting, the nursing home setting, the medical school setting and the hospital, community-based pharmacy setting and ambulatory care clinics. The pharmacist shall be employed by or under contract to provide services to the hospital, pharmacy, nursing home or medical school, or hold a faculty appointment with one of the schools of pharmacy or medicine in this state.

(f) Nothing pertaining to collaborative pharmacy practice shall be interpreted to permit a pharmacist to accept delegation of a physician's authority outside the limits included in the appropriate board's statute and rules.

§30-5-20. Board authorizations shall be displayed.

(a) The board shall prescribe the form for an board authorization, and may issue a duplicate upon payment of a fee.

(b) Any person regulated by the article shall conspicuously display his or her board authorization at his or her principal business location.

§30-5-21. Responsibility for quality of drugs dispensed; exception; falsification of labels; deviation from prescription.

(a) All persons, whether licensed pharmacists or not, shall be responsible for the quality of all drugs, chemicals and medicines they may sell or dispense, with the exception of those sold in or dispensed unchanged from the original retail package of the manufacturer, in which event the manufacturer shall be responsible.

(b) Except as provided in section twelve-b of this article, the following acts shall be prohibited:

(1) The falsification of any label upon the immediate container, box and/or package containing a drug;

(2) The substitution or the dispensing of a different drug in lieu of any drug prescribed in a prescription without the approval of the practitioner authorizing the original prescription: *Provided*, That this may not be construed to interfere with the art of prescription compounding which does not alter the therapeutic properties of the prescription or appropriate generic substitute;

(3) The filling or refilling of any prescription for a greater quantity of any drug or drug product than that prescribed in the original prescription without a written or electronic order or an oral order reduced to writing, or the refilling of a prescription without the verbal, written or electronic consent of the practitioner authorizing the original prescription.

§30-5-22. Pharmacies to be registered.

(a) A pharmacy, an ambulatory health care facility, and a charitable clinic pharmacy shall register with the board.

(b) A person desiring to operate, maintain, open or establish a pharmacy shall register with the board.

(c) To be eligible for a registration to operate, maintain, open or establish a pharmacy the applicant shall:

(1) Submit a written application to the board;

(2) Pay all applicable fees;

(3) Designate a pharmacist-in-charge; and

(4) Successfully complete an inspection by the board.

(d) A separate application shall be made and separate registration issued for each location.

(e) Registration are not transferable.

(f) Registration expire and shall be renewed annually.

(g) If a registration expires, the pharmacy shall be reinspected and an inspection fee is required.

(h) A registrant shall employ a pharmacist-in-charge and operate in compliance with the legislative rules governing the practice of pharmacist care and the operation of a pharmacy.

(i) The provisions of this section do not apply to the sale of nonprescription drugs which are not required to be dispensed pursuant to a practitioner's prescription.

§30-5-23. Pharmacist-in-charge.

(a) A pharmacy shall be under the direction and supervision of a licensed pharmacist who shall be designated by the owner of the pharmacy as the pharmacist-in-charge: *Provided*, That the Board may permit by rule for a charitable clinic pharmacy to be supervised by a committee of pharmacists-in-charge who accept as a group the responsibilities of the required pharmacist-in-charge. This designation shall be filed with the board within thirty days of the designation.

(b) The pharmacist-in-charge is responsible for the pharmacy's compliance with state and federal pharmacy laws and regulations and for maintaining records and inventory.

(c) A pharmacist-in-charge may not hold such designated position at more than one pharmacy, whether within or outside the State of West Virginia: *Provided*, That the Board may permit by rule that he or she may volunteer as the pharmacist-in-charge at a charitable clinic pharmacy while serving as a pharmacist-in-charge in another pharmacy.

(d) An interim pharmacist-in-charge may be designated for a period not to exceed sixty days. The request for an interim pharmacist-in-charge shall detail the circumstances which warrant the change. This change in designation shall be filed with the board within thirty days of the designation.

§30-5-24. Permits for mail-order pharmacy.

(a) A mail-order pharmacy which dispenses drugs shall register with the board.

(b) A mail-order pharmacy shall submit an application for a permit to the board. The application shall require the following information:

(1) The owner of the mail-order pharmacy, whether an individual, a partnership, or a corporation.

(2) The names and titles of all individual owners, partners or corporate officers.

(3) The pharmacy manager.

(4) The pharmacist-in-charge.

(5) The complete address, telephone number and fax number of the mail-order pharmacy.

(c) This section does not apply to any mail-order pharmacy which operates solely as a wholesale distributor.

§30-5-25. Permit for manufacture and packaging of drugs, medicines, distribution of prescription drugs.

(a) Drugs may not be manufactured, made, produced, packed, packaged or prepared within the state, except under the personal supervision of a pharmacist or other qualified person as may be approved by the board;

(b) A person may not manufacture, package or prepare a drug without obtaining a permit from the board.

(c) A person, who offers for sale, sells, offers for sale through the method of distribution any prescription drugs is subject to this article.

(d) The application for a permit shall be made on a form to be prescribed and furnished by the board and shall be accompanied by an application fee.

(e) The board shall promulgate rules on permit requirements and sanitation requirements.

(f) Separate applications shall be made and separate permits issued for each place of manufacture, distribution, making, producing, packing, packaging or preparation.

§30-5-26. Filling of prescriptions more than one year after issuance.

A prescription order may not be dispensed after twelve months from the date of issuance by the practitioner. A pharmacist may fill the prescription after twelve months if the prescriber confirms to the pharmacist that he or she still wants the prescription filled and the pharmacist documents upon the prescription that the confirmation was obtained.

§30-5-27. Partial filling of prescriptions.

(a) The partial filling of a prescription is permissible for any prescription if the pharmacist is unable to supply, or the patient requests less than the full quantity called for in a written, electronic, or oral prescription, provided the pharmacist makes a notation of the quantity supplied on either the written prescription or in the electronic record.

(b) The partial filling of a prescription for a controlled substance listed in Schedule II is permissible if the pharmacist is unable to supply or the patient requests less than the full quantity called for in the prescription. The remaining portion of the prescription may be filled within seventy-two hours of the first partial filling: *Provided*, That if the remaining portion is not or cannot be filled within the seventy-two hour period, the pharmacist shall notify the prescribing individual practitioner.

Further quantity may not be supplied beyond seventy-two hours without a new prescription.

§30-5-28. Partial filling of prescriptions for long-term care facility or terminally ill patients; requirements; records; violations.

(a) As used in this section, "long-term care facility" or "LTCF" means any nursing home, personal care home, or residential board and care home as defined in section two, article five-c, chapter sixteen of this code which provides extended health care to resident patients: *Provided,* That the care or treatment in a household, whether for compensation or not, of any person related by blood or marriage, within the degree of consanguinity of second cousin to the head of the household, or his or her spouse, may not be deemed to constitute a nursing home, personal care home or residential board and care home within the meaning of this article. This section does not apply to:

(1) Hospitals, as defined under section one, article five-b, chapter sixteen of this code or to extended care facilities operated in conjunction with a hospital;

(2) State institutions as defined in section six, article one, chapter twenty-seven or in section three, article one, chapter twenty-five, all of this code;

(3) Nursing homes operated by the federal government;

(4) Facilities owned or operated by the state government;

(5) Institutions operated for the treatment and care of alcoholic patients;

(6) Offices of physicians; or

(7) Hotels, boarding homes or other similar places that furnish to their guests only a room and board.

(b) As used in this section, "terminally ill" means that an individual has a medical prognosis that his or her life expectancy is six months or less.

(c) Schedule II prescriptions for patients in a LTCF and for terminally ill patients shall be valid for a period of sixty days from the date of issue unless terminated within a shorter period by the discontinuance of the medication.

(d) A prescription for a Schedule II controlled substance written for a patient in a LTCF or for a terminally ill patient may be filled in partial quantities, including, but not limited to, individual dosage units. The total quantity of Schedule II controlled substances dispensed in all partial filling may not exceed the total quantity prescribed.

(1) If there is any question whether a patient may be classified as having a terminal illness, the pharmacist shall contact the prescribing practitioner prior to partially filling the prescription.

(2) Both the pharmacist and the prescribing practitioner have a corresponding responsibility to assure that the controlled substance is for a terminally ill patient.

(e) The pharmacist shall record on the prescription that the patient is "terminally ill" or a "LTCF patient". A prescription that is partially filled and does not contain the notation "terminally ill" or "LTCF patient" shall be deemed to have been filled in violation of section three hundred eight, article three, chapter sixty-a of this code.

(f) For each partial filling, the dispensing pharmacist shall record on the back of the prescription, or on another appropriate record which is readily retrievable, the following information:

(1) The date of the partial filling;

(2) The quantity dispensed;

(3) The remaining quantity authorized to be dispensed; and

(4) The identification of the dispensing pharmacist.

(g) Information pertaining to current Schedule II prescriptions for terminally ill and LTCF patients may be maintained in a computerized system if such a system has the capability to permit either by display or printout, for each patient and each medication, all of the information required by this section as well as the patient's name and address, the name of each medication, original prescription number, date of issue, and prescribing practitioner information. The system shall also allow immediate updating of the prescription record each time a partial filling of the prescription is performed and immediate retrieval of all information required under this section.

§30-5-29. Limitations of article.

(a) This article may not be construed to prevent, restrict or in any manner interfere with the sale of nonnarcotic nonprescription drugs which may be lawfully sold without a prescription in accordance with the United States Food, Drug and Cosmetic Act or the laws of this state, nor may any legislative rule be adopted by the board which shall require the sale of nonprescription drugs by a licensed pharmacist or in a pharmacy or which shall prevent, restrict or otherwise interfere with the sale or distribution of such drugs by any retail merchant. The sale or distribution of nonprescription drugs may not be deemed to be improperly engaging in the practice of pharmacist care.

(b) This article may not be construed to interfere with any legally qualified practitioner of medicine, dentistry or veterinary medicine, who is not the proprietor of the store for the dispensing or retailing of drugs and who is not in the employ of such proprietor, in the compounding of his or her own

prescriptions or to prevent him or her from supplying to his or her patients such medicines as he or she may deem proper, if such supply is not made as a sale.

(c) The exception provided in subsection (b) of this section does not apply to an ambulatory health care facility: *Provided,* That a legally licensed and qualified practitioner of medicine or dentistry may supply medicines to patients that he or she treats in a free clinic and that he or she deems appropriate.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(6) Aiding or abetting unlicensed practice;

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

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

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

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

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

(12) Failure to report to the board any adverse action taken by another licensing jurisdiction, government agency, law-

enforcement agency, or court for conduct that would constitute grounds for action as defined in this section;

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

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

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

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

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

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

(19) Agreeing to participate in a prescription drug product conversion program promoted or offered by a manufacturer, wholesaler or distributor of such product for which the pharmacist or pharmacy received any form of financial remuneration, or agreed to participate in a prescription drug program in which the pharmacist or pharmacy is promoted or offered as the exclusive provider of prescription drug products

or whereby in any way the public is denied, limited or influenced in selecting pharmacist care or counseling;

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

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

(1) Reprimand;

(2) Probation;

(3) Restrictions;

(4) Suspension;

(5) Revocation;

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

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

(8) Practicing under supervision or other restriction; or

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

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

(j) The board may defer disciplinary action with regard to an impaired licensee or registrant who voluntarily signs an agreement, in a form satisfactory to the board, agreeing not to practice pharmacist care and to enter an approved treatment and

monitoring program in accordance with the board's legislative rule. This subsection, provided that this section should not apply to a licensee or registrant who has been convicted of, pleads guilty to, or enters a plea of nolo contendere or a conviction relating to a controlled substance in any jurisdiction.

(k) A person authorized to practice under this article, who reports or otherwise provides evidence of the negligence, impairment or incompetence of another member of this profession to the board or to any peer review organization, is not liable to any person for making such a report if such report is made without actual malice and in the reasonable belief that such report is warranted by the facts known to him or her at the time.

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

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

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

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

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

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

§30-5-33. Judicial review.

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

§30-5-34. Criminal offenses.

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

ARTICLE 8. WHOLESALE DRUG DISTRIBUTION LICENSING ACT OF 1991.

§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.

CHAPTER 60A. UNIFORM CONTROLLED SUBSTANCES ACT.

ARTICLE 10. METHAMPHETAMINE LABORATORY ERADICATION ACT.

§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-10-5. 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.

That Joint Committee on Enrolled Bills hereby certifies that the foregoing bill is correctly enrolled.

Chairman, House Committee

Member ~~Chairman~~, Senate Committee

Originating in the House.

In effect July 1, 2013.

Clerk of the House of Delegates

Clerk of the Senate

Speaker of the House of Delegates

President of the Senate

The within is approved this the 3rd day of May, 2013.

Governor

PRESENTED TO THE GOVERNOR

APR 2 9 2013

Time 2:10 pm