H. B. 2577

(By Delegates Perdue, Perry, Eldridge,
Lawrence and Staggers)

[Introduced February 20, 2013; referred to the Committee on Health and Human Resources then the Judiciary.]

A Bill 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 §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, §30-5-25, §30-5-26, §30-5-27, §30-5-28, §30-5-29 and §30-5-30 of said code; to amend said code by adding thereto four new sections, designated §30-5-31, §30-5-32, §30-5-33 and §30-5-34; and to amend and reenact §60A-10-3 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; setting forth the powers and duties of the board; clarifying rule-making authority; continuing a special revenue account; establishing license, registration and permit requirements; creating a scope of practice; creating a temporary permit; establishing renewal requirements; providing for exemptions from licensure; providing requirement to participate in collaborative pharmacy practice; providing requirement 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; 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 penalties; and updating 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, §30-5-12b, §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 §16-5A-9a 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, §30-5-25, §30-5-26, §30-5-27, §30-5-28, §30-5-29 and §30-5-30 of said code be amended and reenacted; that said code be amended by adding thereto four new sections, designated §30-5-31, §30-5-32, §30-5-33 and §30-5-34; and that §60A-10-3 of said code be amended and reenacted, all to read as follows:

CHAPTER 16. PUBLIC HEALTH.

ARTICLE 5A. CANCER CONTROL.

§16-5A-9a. Laetrile use; informed consent.

A hospital or other health care facility may not interfere with the physician-patient relationship by restricting or forbidding the intravenous use of amygdalin (laetrile) as certified in accordance with ~~section sixteen-a,~~ article five, chapter thirty of this code, as an adjunct to recognized, customary or accepted modes of therapy in the treatment of any malignancy for terminally ill cancer patients when it is prescribed or administered by a physician holding an unlimited license for the practice of medicine in the State of West Virginia and the patient has signed the

"written informed request" ~~therefor~~ as set forth in this section. ~~*Provided, That*~~ A parent or guardian may sign the "written informed request" on a minor's behalf.

~~In the event that~~ If no recognized, customary or accepted mode of therapy is available for the treatment of any malignancy for a terminally ill cancer patient, the physician may prescribe or administer intravenous amygdalin (laetrile), as certified in accordance with ~~section sixteen-a,~~ article five, chapter thirty of this code, as the sole mode of therapy providing ~~further that said patient~~ that the patient has executed the "written informed request" as set forth in this section.

~~Any~~ A physician, hospital or other health care facility participating in ~~any~~ an act permitted or required by this section is immune from ~~any~~ civil or criminal liability that otherwise might result by reason of such actions. A physician may not be subjected to disciplinary action by the State Board of Medicine of West Virginia for prescribing or administering intravenous amygdalin (laetrile), in compliance with the provisions of this section.

Nothing in this section ~~shall be construed as constituting~~ constitutes an endorsement of amygdalin (laetrile), as certified in accordance with ~~section sixteen-a,~~ article five, chapter thirty of this code, for the treatment of any malignancy, disease, illness or physical condition.

The "written informed request" referred to in this section

shall be on a form prepared by and obtained from the State Department of Health and shall be in substance as follows:

"WRITTEN INFORMED REQUEST" FOR PRESCRIPTION OF
INTRAVENOUS AMYGDALIN (LAETRILE) FOR
MEDICAL TREATMENT

Patient's name: _____

Address _____

Age _____ Sex _____

Name and address of prescribing physician:

_____

Nature of malignancy diagnosed for medical treatment by amygdalin (laetrile):

_____

_____

_____

My physician has explained to me:

(a) That the manufacture and distribution of amygdalin (laetrile) has not been approved by the Federal Food and Drug Administration.

(b) That neither the American Cancer Society, the American Medical Association nor the West Virginia State Medical Association recommends use of amygdalin (laetrile) in the treatment of any malignancy, disease, illness or physical condition.

(c) That there are alternative recognized treatments for the

malignancy, disease, illness or physical condition from which I suffer which he or she has offered to provide for me including:

(here describe) (state "none" if applicable) _____

_____

_____

(d) That I have the right to refuse or terminate the intravenous use of laetrile at any time.

I understand that physicians, hospitals or health care facilities are immune from civil and criminal liability for prescribing or administering amygdalin (laetrile) in compliance with state statutes.

That notwithstanding the foregoing, I hereby request prescription and use of intravenous amygdalin (laetrile) in the medical treatment of the malignancy from which I suffer.

_____

Patient or person signing for patient

Date of execution of request _____

ATTEST: _____

Prescribing physician

The prescribing physician shall forward a copy of the written informed request to the State Registrar of Vital Statistics within ten days of the execution of such request and shall retain a copy of the request in the patient's medical file.

ARTICLE 5. PHARMACISTS, PHARMACY TECHNICIANS, PHARMACY INTERNS

AND PHARMACIES.

§30-5-1. Unlawful acts.

(a) It is unlawful for any person to practice or offer to practice pharmacist care or practice or offer to assist in the practice of pharmacist care in this state without a license or registration, issued under the provisions of this article, or advertise or use any title or description tending to convey or give the impression that they are 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 a service or engage in an 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 not a licensed pharmacist to practice pharmacist care except that a charitable clinic pharmacy may permit a licensed practitioner to act in place of the pharmacist when no pharmacist is present in the charitable clinic.

§30-5-2. 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

hereunder.

§30-5-3. Definitions.

The following words and phrases have the following meaning:

(1) "Ambulatory health care facility" as defined in section one, article five-b, chapter sixteen of this code, that 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) "Brand name" means the proprietary or trade name selected by the manufacturer and placed upon a drug or drug product, its container, label or wrapping at the time of packaging.

(7) "Cash retail sales price" means the price paid by the consumer which is not affected by contractual governmental or private third-party payors.

(8) "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 and under common ownership and control.

(9) "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.

(10) "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.

(11) "Collaborative pharmacy practice agreement" is a written and signed agreement between a pharmacist, a physician and the individual patient, or the patient's authorized representative who has granted his or her informed consent, that provides for collaborative pharmacy practice for the purpose of drug therapy management of a patient, which has been approved by the board, the Board of Medicine in the case of an allopathic physician or the West Virginia Board of Osteopathy in the case of an osteopathic

physician.

(12) "Common carrier" means a person or entity who undertakes, whether directly or by any other arrangement, to transport property including prescription drugs for compensation.

(13) "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.

(14) "Confidential information" means information maintained by the pharmacist in the patient record or which is communicated to the patient as part of patient counseling or which is communicated by the patient to the pharmacist. This information is privileged and may be released only to the patient or to other members of the health care team and other pharmacists where, in the pharmacists' professional judgment, the release is necessary to the patient's health and well-being; to health plans, as that term is defined in 45 CFR §160.103 (2012), for payment; to other persons or governmental agencies authorized by law to receive the privileged information; as necessary for the limited purpose of peer review and utilization review; and, as authorized by the patient or required by court order.

(15) "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.

(16) "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."

(17) "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.

(18) "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.

(19) "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) Delivering or offering to deliver a drug by a common carrier in the usual course of business as a common carrier;

(C) Providing a drug sample to a patient by a practitioner licensed to prescribe such drug, by a health care professional acting at the direction and under the supervision of a practitioner

or by the pharmacy of a hospital or of another health care entity acting at the direction of a practitioner and that received the sample in accordance with the Prescription Drug Marketing Act and regulations to administer or dispense.

(20) "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 the 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.

(21) "Drug" means:

(A) Articles recognized as drugs by the United States Food and Drug Administration, or in any official compendium, or supplement thereto, designated by the board for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or other animals;

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

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

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

(A) Evaluation of the prescription drug orders and 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 patient records for proper use including overuse, underuse and optimum therapeutic outcomes; and

(E) All drug regimen review activities according to subdivision (22).

(23) "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 specifically set out in the collaborative pharmacy practice agreement between the pharmacist and physician.

(24) "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.

(25) "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 (2012), 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".

(26) "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.

(27) "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.

(28) "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 fire fighting 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.

(29) "Equivalent drug product" means a drug product which has the same established name, active ingredient(s), strength or concentration, dosage form and route of administration and which is formulated to contain the same amount of active ingredient(s) in the same dosage form and to meet the same compendial or other applicable standards (e.g, strength, quality, purity, and identity) and is approved by the United States Food and Drug Administration, but which may differ in characteristics, such as shape, scoring, configuration, packaging, excipients (including colors, flavors, and preservatives), and expiration time.

(30) "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.

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

(32) "Generic name" means the official title of a drug or drug combination for which a new drug application or an abbreviated new drug application has been approved by the FDA.

(33) "Health care entity" means a person that provides diagnostic, medical, community pharmacies, surgical, dental treatment, or rehabilitative care but does not include a retail pharmacy or wholesale distributor.

(34) "Health information" means information, whether oral or recorded in any 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.

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

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

(37) "Individually identifiable health information" is a subset of health information that identifies the individual or upon which there is a reasonable basis to believe the information can be used to identify the individual and includes demographic information collected from an individual and created or received by a health care provider, health plan, employer or health care clearinghouse that relates to:

(A) The past, present, or future physical or mental health or condition of an individual;

(B) The provision of health care to an individual; or

(C) The past, present or future payment for the provision of health care to an individual.

(38) "Intracompany transaction" means a 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.

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

(40) "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 legend drug or device.

(41) "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.

(42) "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.

(43) "Manufacturer" means a person engaged in the manufacture of drugs or devices.

(44) "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.

(45) "Medical order" means a lawful order of a practitioner that may include a prescription drug order.

(46) "Medication therapy management" is a distinct service or group of services that optimize therapeutic outcomes for individual patients and are independent of, but can occur in conjunction with, the provision of a medication or a medical device; encompasses a

broad range of professional activities and responsibilities within the licensed pharmacist's scope of practice; and, may include, but are not limited to, the following, according to the individual needs of the patient:

(A) Performing or obtaining necessary assessments of the patient's health status;

(B) Formulating a medication treatment plan;

(C) Selecting, initiating, modifying or administering medication therapy;

(D) Monitoring and evaluating the patient's response to 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 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 allowed by law.

(47) "Misbranded" means a drug or device that has a label which is false or misleading in any particular; 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.

(48) "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.

(49) "Normal distribution channel" means a chain of custody for a prescription drug that goes 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 rules.

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

(51) "Pedigree" means a statement or record in a written or electronic form, approved by the board, that records each wholesale distribution of a prescription drug (excluding veterinary prescription drugs), which leaves the normal distribution channel.

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

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

(54) "Pharmacist care" is the provision of health care by a pharmacist of medication therapy management services, 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 in section nine.

(55) "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 and actual charge of the pharmacy and personnel.

(56) "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 Board of Osteopathy.

(57) "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.

(58) "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.

(59) "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.

(60) "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 Osteopathy.

(61) "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.

(62) "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.

(63) "Prescription drug" or "legend drug" means a drug which is required by an applicable federal or state law or rule to be dispensed pursuant only to a prescription drug order, which is restricted to use by practitioners only or which, under federal law, is required to be labeled with one of the following statements prior to being dispensed and delivered:

(A) "Rx Only";

(B) "Caution: Federal law prohibits dispensing without prescription"; or

(C) "Caution: Federal law restricts this drug to use by, or on the order of, a licensed veterinarian".

(64) "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.

(65) "Primary care" is the first level of contact of individuals, the family and the community with the health care delivery system, bringing health care as close as possible to where people live and work and constitutes the first element of a continuing health care process. Areas of primary care where pharmacists provide pharmacist care include, but are not limited to, the following:

(A) Chronic disease management;

(B) Smoking cessation;

(C) Maternal and child health;

(D) Immunizations;

(E) Family planning;

(F) Self-care consulting;

(G) Drug selection under protocol;

(H) Treatment of common diseases and injuries;

(I) Nutrition; and

(J) General health education and promotion.

(66) "Product labeling" means all labels and other written, printed or graphic matter upon any article or any of its containers or wrappers or which accompany the article.

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

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

(69) "Substitute" means to dispense without the prescriber's express authorization, a therapeutically equivalent generic drug product in the place of the drug ordered or prescribed.

(70) "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, route of administration and strength.

(71) "Third-Party logistics provider" means an entity that:

(A) Provides or coordinates 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; and

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

(72) "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, the physical examination and the drug prescribed.

(73) "Wholesale distribution" means the distribution of prescription drugs or devices by wholesale distributors to persons other than consumers or patients and includes the transfer of prescription drugs by a pharmacy to another pharmacy if the value of the goods transferred exceeds five percent of total prescription drug sales revenue of either the transferor or transferee pharmacy during any consecutive twelve-month period. Wholesale distribution does not include:

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

(B) The sale, purchase or trade of a prescription drug or device or an offer to sell, purchase or trade a prescription drug or device for emergency medical reasons;

(C) Intracompany transactions unless in violation of own use provisions;

(D) The sale, purchase or trade of a prescription drug or device or an offer to sell, purchase or trade a prescription drug or device among hospitals, chain pharmacy warehouses, pharmacies or other health care entities that are under common control;

(E) The sale, purchase or trade of a prescription drug or device or the offer to sell, purchase or trade a prescription drug or device by a charitable organization described in 503(c)(3) of the Internal Revenue Code of 1954 to a nonprofit affiliate of the organization to the extent otherwise permitted by law;

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

(G) The sale, purchase or trade of blood and blood components intended for transfusion;

(H) The return of recalled, expired, damaged or otherwise nonsalable prescription drugs when conducted by a hospital, health care entity, pharmacy or charitable institution in accordance with the board's rules; or

(I) The sale, transfer, merger or consolidation of all or part of the business of a pharmacy or pharmacies from or with another pharmacy or pharmacies, whether accomplished as a purchase and sale of stock or business assets, in accordance with the board's legislative rules.

(74) "Wholesale distributor" means a person engaged in wholesale distribution of drugs, including, but not limited to, manufacturers' and distributors' warehouses, chain drug warehouses

and wholesale drug warehouses, independent wholesale drug trader and retail pharmacies that conduct wholesale distributions.

§30-5-4. 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 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, must 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 must 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 a 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 are immune from individual civil liability while acting within the scope of their duties as board members.

§30-5-5. 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:

(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 the fees charged under the provisions of this article;

(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;

(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) 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: *Provided,* That Inspectors shall be licensed pharmacists;

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

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

(m) Determine disciplinary action and issue orders;

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

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

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

(q) 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;

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

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

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

§30-5-6. 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;

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

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

(16) A ratio of pharmacy technicians to on-duty pharmacist operating in an 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) The procedures for denying, suspending, revoking, reinstating or limiting the practice of a licensee, permittee or registrant;

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

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

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

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

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

(31) Rules 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 Osteopathy 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 Osteopathy, 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 must be based on the standards established for such courses by the Centers for Disease Control and Prevention in the public health service of the United States Department of Health and Human Services;

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

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

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

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

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

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

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

(e) The board, the Board of Medicine and the Board of Osteopathy 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 on July 1, 2013, shall remain in effect until they are amended, modified, repealed or

replaced.

§30-5-7. 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.

§30-5-8. Qualifications for licensure as pharmacist;

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

(1) Submit a written application to the board;

(2) Be eighteen years of age or older;

(3) Pay all applicable fees;

(4) Graduate from a recognized 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 and has not been convicted of a felony involving controlled substances or violent crime;

(9) Has 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.

§30-5-9. Scope of 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 and 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 pharmacist care in all areas of patient care including collaborative pharmacy practice;

(8) Compound and label drugs and drug devices;

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

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

(11) Provide medication therapy management.

(b) A licensed pharmacist must:

(1) Maintain proper and safe storage of drugs and devices; and

(2) Maintain proper records.

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

§30-5-10. Registration of pharmacy technicians;

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

(1) Submit a written application to the board;

(2) Be at least eighteen years of age;

(3) Pay the applicable fees;

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

(5) 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;

(6) Effective July 1, 2013, have successfully passed an examination developed using nationally recognized and validated psychometric and pharmacy practice standards 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) 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 bears a rational nexus to the practice of pharmacist care, which conviction remains unreversed; and

(10) Has 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 July 1, 2013, shall for all purposes be considered registered under this article and may renew pursuant to the provisions of this article.

§30-5-11. Scope of practice for registered pharmacy technician.

(a) A registered pharmacy technician's activities, under the direct supervision of the licensed pharmacist, include, but are not limited to, performance of the following:

(1) Assist in the dispensing process;

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

(3) Compound medications; and

(4) Stock medications.

(b) A registered pharmacy technician may perform the following under indirect supervision:

(1) Process medical coverage claims; and

(2) Serve as 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.

§30-5-12. Pharmacist interns.

(a) To be eligible for a license to assist in the practice of

pharmacist care as a pharmacy intern, the applicant must be:

(1) Enrolled in a professional degree program of a school or college of pharmacy that has been approved by the board, is in good standing 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.

§30-5-13. Prohibiting the dispensing of prescription orders in absence of practitioner-patient relationship.

A pharmacist may not compound or dispense a prescription order when he or she has knowledge that the prescription was issued by a practitioner without establishing an ongoing practitioner-patient relationship. An online or telephonic evaluation by questionnaire is inadequate to establish an appropriate 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.

§30-5-14. 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 so long as the 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. Reciprocity is not authorized, however, 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.

§30-5-15. Renewal requirements.

(a) 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 a board authorization and shall charge a late fee for a 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 July 1, 2014, a previously registered pharmacist technician may renew his or her current registration without having successfully completed subdivision (6), subsection (a), section ten of this article. The previously registered pharmacist may continue to renew his or her registration under this provision.

§30-5-16. 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. 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 is 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) A pharmacist who renders a pharmaceutical service to indigent and needy patients of a clinic organized, in whole or in part, for the delivery of health care services without charge under a special volunteer 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's 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 must 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. A 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 pharmaceutical services 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 eight 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 requires the board to issue a

special volunteer pharmacist license to a pharmacist whose license is or has been subject to disciplinary action; to a pharmacist who has surrendered a license or caused a license to lapse, expire and become invalid in lieu of having a complaint initiated or other action taken against his or her license; to a pharmacist 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, to a pharmacist 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 a 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 a 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.

§30-5-17. 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) Have at least $1 million of professional liability insurance coverage;

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

(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 boards;

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

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

§30-5-18. 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 must be a voluntary process, which is a physician directed approach, that is entered into between an individual physician, an individual pharmacist and an individual patient or the patient's authorized representative who has given informed consent.

(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) 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 Osteopathy 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 permits a pharmacist to accept delegation of a physician's authority outside the limits included in the appropriate board's statute and rules.

§30-5-19. Board authorizations shall be displayed.

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

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

§30-5-20. Responsibility for quality of drugs dispensed; exception; falsification of labels; deviation from prescription.

(a) All persons, whether licensed pharmacists or not, are responsible for the quality of all drugs, chemicals and medicines they 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 is responsible.

(b) Except as provided in section twenty-one of this article, the following acts are 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 a drug prescribed in a prescription without the approval of the practitioner authorizing the original prescription: *Provided*, That this does not 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 a prescription for a greater quantity of a 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.

§30-5-21. Generic drug products.

(a) A pharmacist who receives a prescription for a brand name drug or drug product shall substitute the least expensive therapeutic equivalent generic drug or drug product based on the cash retail sales price of the respective products at the time it is dispensed unless otherwise required by a third party payor, the patient or in the exercise of his or her professional judgment the

pharmacist affirmatively indicates that the least expensive therapeutic equivalent drug is not suitable for the particular patient. No substitution may be made by the pharmacist where the prescribing practitioner indicates that, in his or her professional judgment, a specific brand name drug is medically necessary for a particular patient.

(b) A written prescription order may permit the pharmacist to substitute an equivalent generic name drug or drug product except where the prescribing practitioner has indicated, in his or her own handwriting, the words “Brand Necessary” or "Brand Medically Necessary". The following sentence shall be printed on the prescription form. "This prescription may be filled with a generically equivalent drug product unless the words ‘Brand Necessary’ or 'Brand Medically Necessary' are written, in the practitioner's own handwriting, indicated by the prescribing practitioner on this prescription form."

(c) A verbal prescription order permits the pharmacist to substitute an equivalent generic name drug or drug product except where the prescribing practitioner indicates to the pharmacist that the prescription is "Brand Necessary" or "Brand Medically Necessary". The pharmacist shall note the instructions on the file copy of the prescription or electronic chart.

(d) An electronic prescription order permits the pharmacist to

substitute an equivalent generic name drug or drug product except where the prescribing practitioner indicates to the pharmacist that the prescription is "Brand Necessary" or "Brand Medically Necessary". The pharmacist shall note the instructions on the file copy of the prescription or electronic chart.

(e) No person may, by trade rule, work rule, contract or in any other way, prohibit, restrict, limit or attempt to prohibit, restrict or limit the making of a generic name drug or other product substitution under the provisions of this section. No employer or his or her agent may use coercion or other means to interfere with the professional judgment of the pharmacist in deciding which generic name drugs or drug products may be stocked or substituted. This section does not permit the pharmacist to refuse to substitute less expensive therapeutically equivalent generic drugs for brand name drugs and a pharmacist who refuses is subject to the penalties prescribed in this article.

(f) A pharmacist may substitute a drug pursuant to the provisions of this section only if the drug is a lower cash retail sales price than the prescribed drug. Where substitution is proper or where the practitioner prescribes the drug by generic name, the pharmacist shall, consistent with his or her professional judgment, dispense an equivalent generic drug product with the lowest cash retail sales price available in the pharmacy at the time of

dispensing. All savings in the retail price of the prescription are passed on to the purchaser and shall be equal to the difference between the retail price of the brand name product and the customary and usual costs of the generic product substituted. In no event may such savings be less than the difference in acquisition cost of the brand name product prescribed and the acquisition cost of the substituted product.

(g) Each pharmacy shall maintain a record of a substitution of an equivalent generic name drug product for a prescribed brand name drug product on the file copy of a written, electronic or verbal prescription or chart order. The record shall include the manufacturer and generic name of the drug product selected.

(h) All drugs shall be labeled in accordance with the instructions of the practitioner.

(i) Unless the practitioner directs otherwise, the prescription label on all drugs dispensed by the pharmacist shall indicate the generic name using abbreviations, if necessary, and either the name of the manufacturer or packager, whichever is applicable, in the pharmacist's discretion. The same notation will be made on the original prescription retained by the pharmacist.

(j) A pharmacist may not dispense a product under the provisions of this section unless the manufacturer has shown that the drug has been manufactured with the following minimum good

manufacturing standards and practices by:

(1) Labeling products with the name of the original manufacturer and control number;

(2) Maintaining quality control standards equal to or greater than those of the FDA;

(3) Marking products with identification code or monogram; and

(4) Labeling products with an expiration date.

(k) A pharmacist may not substitute a generic named therapeutically equivalent drug product for a prescribed brand name drug product if the brand name drug product or the generic drug type is listed on the formulary established by the board pursuant to this article or is found to be in violation of the requirements of the FDA.

(l) A pharmacist who substitutes a drug shall, either personally or through his or her agent, assistant or employee, notify the person presenting the prescription of the substitution. The person presenting the prescription has the right to refuse the substitution. Upon request, the pharmacist shall relate the cash retail sales price difference between the brand name and the drug substituted for it.

(m) A pharmacist complying with the provisions of this section is not liable for the dispensing of a generic-named therapeutically equivalent drug substituted under the provisions of this section

unless the generic named therapeutically equivalent drug was incorrectly substituted.

(n) In no event, where the pharmacist substitutes a drug under the provisions of this section, may the prescribing physician be liable in an action for loss, damage, injury or death of a person occasioned by or arising from the use of the substitute drug unless the original drug was incorrectly prescribed.

(o) Failure of a practitioner to specify that a specific brand name is necessary for a particular patient does not constitute evidence of negligence unless the practitioner had reasonable cause to believe that the health of the patient required the use of a certain product and no other.

§30-5-22. 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 permits issued for each location.

(e) Permits are not transferable.

(f) Permits expire and shall be renewed annually.

(g) If a permit 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 must 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 without 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 in designation. This change 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 requires 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 a mail-order pharmacy which operates solely as a wholesale distributor.

§30-5-25. Permit for manufacture and packaging of drugs, medicines, distribution of legend 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, or offers for sale through the method of distribution any legend 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 a 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. The pharmacist shall make 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. 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, does not 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 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 are 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 a 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" is 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 the following information on the back of the prescription or on another appropriate record which is readily retrievable:

(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 the system has the capability to permit by display or printout, for each patient and each medication, all of the information required by this section and 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 does not 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. No legislative rule may be adopted by the board which requires the sale of nonprescription drugs by a licensed pharmacist or in a pharmacy or which prevents, restricts or otherwise interferes with the sale or distribution of the drugs by a retail merchant. The sale or distribution of nonprescription drugs does not constitute improperly engaging in the practice of pharmacist care.

(b) This article does not interfere with a 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 and does not 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 a person has engaged in, is engaging in or is about to engage in an 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 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. Hearing shall be held in accordance with the provisions of this article and requires 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 a 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, a 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 or other crime involving drugs, violent crime or moral turpitude or engaging in an act involving moral turpitude or gross immorality;

(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 the surrender of a license or authorization to practice pharmacist care in another jurisdiction while under disciplinary investigation by 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 arising 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 engaging in any conduct which obstructs an investigation being conducted by the board;

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

products; or, agreed to an action whereby the public is denied, limited or influenced in selecting pharmaceutical service or counseling in any way; or

(20) Violation of any of the terms or conditions of an 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 does not apply to a licensee or registrant who has been convicted of, pleads guilty to or enters a plea of nolo contendere relating to a controlled substance in any jurisdiction.

(k) No language or provision of this article bars criminal prosecution for violations of this article.

(l) 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 a peer review organization, is not liable to any person for making a report if the report is made without actual malice and with the reasonable belief that the 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. If the board directs, the proposed order shall contain proposed disciplinary actions. 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.

A 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 a ruling resulting from judicial review in accordance with article six, chapter twenty-nine-a of this code.

§30-5-34. Criminal proceedings; penalties.

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

of an appropriate law-enforcement official.

(b) A person who violates a provision of this article is guilty of a misdemeanor and, upon conviction, shall be fined not to exceed $50 for the first offense and, upon conviction of a second offense, shall be fined not less than $50 nor more than $500, or shall be confined in jail not to exceed thirty days, or both fined and confined. Each and every day that the violation continues constitutes a separate offense.

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~~ a drug product made subject to the requirements of this article by the provisions of section seven of this article.

(c) "Distributor" means ~~any~~ a 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~~ a 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~~ a person within this state who produces, compounds, packages or in any manner initially prepares for sale or use ~~any~~ a 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 ~~pharmacy and pharmaceutical~~ pharmacist care as defined in ~~subsection (t), section one-b,~~ section three, 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,~~ section three, article five, chapter thirty of this code.

(n) "Pharmacy" means ~~any~~ a drugstore, apothecary or place within this state where drugs are dispensed and sold at retail or display for sale at retail and ~~pharmaceutical~~ pharmacist care is provided outside of this state where drugs are dispensed and ~~pharmaceutical~~ 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~~ an 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~~ article 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~~ a 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.

NOTE: The purpose of this bill is to update and revise the law governing the practice of pharmacy. The bill prohibits the practice

of pharmacy without a license, defines terms, provides for a board and its composition, sets forth the powers and duties of the board and clarifies rule-making authority. The bill also continues a special revenue account. The bill establishes license, certificate and registration requirements and creates a scope of practice. Also, the bill provides for a temporary permit, establishes renewal requirements and provides for exemptions from licensure. The bill requires the display of a license, sets forth grounds for disciplinary actions, allows for specific disciplinary actions and provides procedures for investigation of complaints. Additionally, the bill provides judicial review and appeals of decisions and establishes hearing and notice requirements. The bill provides for civil causes of action and provides for criminal penalties. The bill also provides for privileged communication and provides that a single act is evidence of practice.

Strike-throughs indicate language that would be stricken from the present law and underscoring indicates new language that would be added.

§30-5-31, §30-5-32, §30-5-33 and §30-5-34 are new; therefore, they have been completely underscored.

§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, §30-5-25, §30-5-26, §30-5-27, §30-5-28, §30-5-29 and §30-5-30 have been completely rewritten; therefore, the entire article is underscored.

This bill has been recommended for passage during the 2013 Regular Session by the Joint Committee on Health.