H. B. 2513

(By Delegates Morgan, Stephens, Givens, Hartman, Hatfield, Martin, Staggers, Swartzmiller, Cowles, C. Miller and Rowan)

[Introduced January 17, 2011; referred to the Committee on Government Organization 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, §30-5-12b, §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; to amend and reenact §30-5-1, §30-5-2, §30-5-3, §30-5-4, §30-5-5, §30-5-6, §30-5-7, §30-5-8, §30-5-9, §30-5-10, §30-5-11, §30-5-12, §30-5-13, §30-5-14, §30-5-15, §30-5-16, §30-5-17, §30-5-18, §30-5-19, §30-5-20, §30-5-21, §30-5-22, §30-5-23, §30-5-24, §30-5-26, §30-5-27, §30-5-28 and §30-5-30 of said code; and to amend said code by adding thereto five new sections, designated §30-5-25, §30-5-29, §30-5-31, §30-5-32 and §30-5-33, all relating to the practice of pharmacy; prohibiting the practice of pharmacy without a license; 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, certificate and registration requirements; creating a scope of practice; creating a temporary permit; establishing renewal requirements; providing for exemptions from licensure; providing requirements for the display of a license; setting forth grounds for disciplinary actions; allowing for specific disciplinary actions; providing procedures for investigation of complaints; providing for judicial review and appeals of decisions; setting forth hearing and notice requirements; providing for civil causes of action; providing criminal penalties; providing for privileged communication and providing that a single act is evidence of practice.

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§30-5-14a, §30-5-14b, §30-5-16a, §30-5-16b, §30-5-16c and §30-5-22a of the Code of West Virginia, 1931, as amended, be repealed; that §30-5-1, §30-5-2, §30-5-3, §30-5-4, §30-5-5, §30-5-6, §30-5-7, §30-5-8, §30-5-9, §30-5-10, §30-5-11, §30-5-12, §30-5-13, §30-5-14, §30-5-15, §30-5-16,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

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 pharmacy or practice or offer to assist in the practice of pharmacy in this state without a license or certification, issued under this article, or advertise or use any title or description tending to convey the impression that they are a pharmacist or pharmacy technician, unless such person has been licensed or certified under this article.

(b) A business entity may not render any service or engage in any activity which, if rendered or engaged in by an individual, would constitute the practice of pharmacy, except through a licensee.

(c) It is unlawful for the proprietor of a pharmacy or a ambulatory health care facility to permit any person not a licensed pharmacist to practice pharmacy.

(d) It is unlawful for a charitable clinic pharmacy to permit any person not a licensed practitioner to prescribe or dispense pharmaceuticals.

§30-5-2. Applicable law.

The practices authorized under this article and the Board of Pharmacy are subject to article one of this chapter, this article, and any rules promulgated hereunder.

§30-5-3. Definitions.

The following words and phrases have the following meanings:

(1) "Ambulatory health care facility" is defined in section one, article five-b, chapter sixteen of this code, that offers pharmaceutical 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) "Adulterated": A drug or device shall be deemed to be adulterated:

(A) If:

(i) It consists, in whole or in part, of any filthy, putrid, or decomposed substance; or

(ii) It has been produced, prepared, packed, or held under unsanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health; or if the methods used in, or the facilities or controls used for its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practices to ensure that the drug or device meets the requirements of this part as to safety and has the identity and

strength, and meets the quality and purity characteristics that it purports or is represented to possess; or

(iii) Its container is composed, in whole or in part, of any poisonous or deleterious substance that may render the contents injurious to health; or

(iv) It bears or contains, for purposes of coloring only, a color additive that is unsafe within the meaning of the Federal Food, Drug, and Cosmetic Act; or it is a color additive, the intended use of which is for purposes of coloring only, and is unsafe within the meaning of the act;

(B) If it purports to be or is represented as a drug, the name of which is recognized in an official compendium, and its strength differs from, or its quality or purity falls below, the standard set forth in the compendium. Such a determination as to strength, quality, or purity shall be made in accordance with the tests or methods of assay set forth in the compendium, or in the absence of or inadequacy of these tests or methods of assay, those prescribed under authority of the act. No drug defined in an official compendium shall be deemed to be adulterated under this paragraph because it differs from the standard of strength, quality, or purity therefore set forth in the compendium, if its difference in strength, quality, or purity from that standard is plainly stated on its label. Whenever a drug is recognized in both the United States Pharmacopeia (USP) and the Homeopathic Pharmacopoeia of the United States it shall be subject to the requirements of the USP

unless it is labeled and offered for sale as a homeopathic drug, in which case it shall be subject to the Homeopathic Pharmacopoeia of the United States and not those of the USP;

(C) If it is not subject to paragraph ii and its strength differs from, or its purity or quality falls below, that which it purports or is represented to possess; or

(D) If it is a drug and any substance has been mixed or packed therewith so as to reduce its quality or strength or substituted wholly or in part thereof.

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

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

(7) "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.

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

(9) "Charitable clinic pharmacy" means a clinic or facility organized as a not-for-profit corporation that offers pharmaceutical care and dispenses prescriptions free of charge to appropriately screened and qualified indigent patients.

(10) "Collaborative pharmacy practice" is that practice of

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

(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 any 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) "Compounding" means:

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

(i) As the result of a practitioner's prescription drug order or initiative based on the practitioner/patient/pharmacist

relationship in the course of professional practice for sale or dispensing; or

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

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

(15) "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 C.F.R. §160.103, 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; as authorized by the patient or required by court order.

(16) "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.

(17) "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."

(18) “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.

(19) "Dispense" or "dispensing" means the preparation and delivery of a drug or device in an appropriately labeled and suitable container to a patient or patient's representative or surrogate pursuant to a lawful order of a practitioner for subsequent administration to, or use by, a patient.

(20) “Distribute” or “distribution” means to sell, offer to sell, deliver, offer to deliver, broker, give away, or transfer a Drug, whether by passage of title, physical movement, or both. The term does not include:

(A) To dispense or administer;

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

(ii) A health care professional acting at the direction and under the supervision of a practitioner; or the pharmacy of a hospital or of another health care entity that is acting at the direction of such a practitioner and that received such sample in

accordance with the act and regulations to administer or dispense.

(21) "Drug" means:

(A) Articles recognized as drugs by the food and drug administration in the USP-DI, facts and comparisons, physician's desk reference or supplements thereto for use in the diagnosis, cure, mitigation, treatment or prevention of disease in human 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 and underuse and optimum therapeutic outcomes.

(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 shall be limited to:

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

(B) Collecting and reviewing patient histories;

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

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

(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 C.F.R. §160.103, either directly or through an electronic data intermediary. E-prescribing includes, but is not limited to, two-way transmissions between the point of care and the pharmacist. E-prescribing may also be referenced by the terms "electronic prescription" or "electronic order."

(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, ie, ambulance companies and firefighting organizations in the same state or same marketing or service area, or nearby licensed practitioners of prescription drugs for use in the treatment of acutely ill or injured persons; and provision of minimal emergency supplies of prescription drugs to nearby nursing homes for use in emergencies or during hours of the day when necessary prescription drugs cannot be obtained.

(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 chapter.

(31) “FDA” means 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 any person that provides diagnostic, medical, surgical, dental treatment, or rehabilitative care but does not include any retail pharmacy or wholesale distributor.

(34) “Health information” means any 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 information that is a subset of health information, including demographic information collected from an individual and is created

or received by a health care provider, health plan, employer, or health care clearinghouse; and relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual; and that identifies the individual; or with respect to which there is a reasonable basis to believe the information can be used to identify the individual.

(38) "Intracompany transaction" means any transaction between a division, subsidiary, parent, and/or affiliated or related company under the common ownership and control of a corporate 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 ten percent prescription drugs via the mail.

(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 or may not include a prescription drug order.

(46) “Medication therapy management” is a distinct service or group of services that optimize therapeutic outcomes for individual patients. Medication therapy management services are independent of, but can occur in conjunction with, the provision of a medication or a medical device. Medication therapy management encompasses a broad range of professional activities and 0responsibilities within the licensed pharmacist’s scope of practice. These services 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 other 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 may be allowed by law.

(47) "Misbranded": A drug or device shall be deemed to be misbranded if the label is false or misleading in any particular; or the label does not bear the name and address of the manufacturer, packer, or distributor and does not have an accurate statement of the quantities of the active ingredients in the case of a drug; or the label does not show an accurate monograph for

prescription drugs.

(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; or

(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; or

(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; or

(D) 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 form or electronic form, approved by the board, that records each wholesale distribution of any given prescription drug (excluding veterinary prescription drugs), which leaves the normal distribution channel.

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

(53) "Pharmaceutical care" is the provision of drug therapy and other pharmaceutical patient care services 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 as defined in the rules of the board.

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

(55) “Pharmacist care” is the provision 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, as defined in the rules of the board.

(56) "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 rules pertinent to the practice of pharmacy and the distribution of drugs and who is personally in full and actual charge of the pharmacy and personnel.

(57) "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.

(58) "Pharmacy" means any drugstore, apothecary or place within this state where drugs are dispensed and sold at retail or displayed for sale at retail and pharmaceutical care is provided and any place outside of this state where drugs are dispensed and pharmaceutical care is provided to residents of this state.

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

(60) "Pharmacy technician" means personnel registered with the board to practice certain tasks permitted by the board.

(61) "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.

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

(63) "Practitioner" means an individual authorized by a jurisdiction of the United States to prescribe and administer drugs in the course of professional practices, including allopathic and osteopathic physicians, dentists, physician assistants, optometrists, veterinarians, podiatrists and nurse practitioners as allowed by law.

(64) "Prescription drug" or "legend drug" means a drug which, under federal law, is required, prior to being dispensed or delivered, to be labeled with either of the following statements:

(A) “Rx Only”; or

(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" or is a drug which is required by any applicable federal or state law or rule to be dispensed pursuant only to a prescription drug order or is restricted to use by practitioners only.

(65) "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 licensed pharmacy.

(66)"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: chronic disease management; smoking cessation; maternal and child health; immunizations; family planning; self-care consulting; drug selection under protocol; treatment of common diseases and injuries; nutrition; and general health education and promotion.)

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

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

(69) “Repackager” means a person who repackages.

(70) "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.

(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 chapter.

(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, and 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 Section 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;

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

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

(J) The sale, transfer, merger, or consolidation of all or part of the business of a retail pharmacy or pharmacies from or with another retail pharmacy or pharmacies, whether accomplished as a purchase and sale of stock or business assets, in accordance with the board's 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, 2011, 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 pharmacy in this state; and,

(2) Two citizen members, who are not licensed under this article, and who do not perform any services related to the practice of the professions regulated under this article.

(d) 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.

(e) 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.

(f) Each member of the board must be a resident of this state during the appointment term.

(g) A vacancy on the board shall be filled by appointment by the Governor for the unexpired term of the member whose office is vacant.

(h) The Governor may remove any member from the board for neglect of duty, incompetency or official misconduct.

(i) 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.

(j) 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.

(k) 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.

(l) Each member of the board is entitled to receive compensation and expense reimbursement in accordance with article one of this chapter.

(m) A majority of the members of the board constitutes a quorum.

(n) 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.

(o) 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.

(p) The members of the board when acting in good faith and without malice shall enjoy immunity from individual civil liability while acting within the scope of their duties as board members.

§30-5-5. 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:

(1) Hold meetings;

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

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

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

(5) Establish the fees charged under this article;

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

(7) Prepare, conduct, administer and grade written, oral or written and oral examinations for a license, certificate and registration;

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

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

(11) Maintain an office, and hire, discharge, establish the job requirements and fix the compensation of employees and contract with persons necessary to enforce this article. Inspectors shall be licensed pharmacists;

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

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

(14) Determine disciplinary action and issue orders;

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

(16) Maintain an accurate registry of names and addresses of

all persons regulated by the board;

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

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

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

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

(21) 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 article three, chapter twenty-nine-a of this code, to implement this article, including:

(1) Standards and requirements for a license, permit, certificate 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, certificate 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 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 any outpatient, mail order or institutional pharmacy;

(17) Regulation of telepharmacy;

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

(19) Establish a formulary of generic type and brand name drug products which are determined by the board to demonstrate significant biological or therapeutic inequivalence and which, if substituted, would pose a threat to the health and safety of patients receiving prescription medication.

(20) Establish standards for substituted drug products;

(21) Establish the regulations for E-prescribing of controlled substances;

(22) Establish the proper use of the automated Data Processing System;

(23) Registration and control of the manufacture and distribution of controlled substances within this State.

(24) Regulation for pharmacies;

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

(26) The procedures for denying, suspending, revoking, reinstating or limiting the practice of a licensee, permittee, certificate holder or registrant;

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

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

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

(30) Any other rules necessary to implement this article.

(b) 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 article three, chapter twenty-nine-a of the code;

(c) The board with the advice of the Board of Medicine and the Board of Osteopathy shall propose rules for legislative approval in accordance with article three, chapter twenty-nine-a of this code to perform immunizations, such as Influenza, Pneumonia, Hepatitis A, Hepatitis B, Herpes Zoster and Tetanus on persons 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; and

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

(d) All of the board's rules in effect on July 1, 2011, 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 pharmacy under

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 approved by the board; and

(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) 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 practice for licensed pharmacist;

(a) The "Practice of pharmacy" means the provision of health care related to the interpretation, evaluation, and implementation of Medical Orders; the dispensing of prescription drug orders; participation in drug and device selection, drug administration, drug regimen review, drug or drug-related research, the provision of patient counseling, the provision of those acts or services

necessary to provide pharmacist care in all areas of patient care, including primary care and collaborative pharmacy practice and the responsibility for compounding and labeling of drugs and devices (except labeling by a manufacturer, repackager, or distributor of nonprescription drugs and commercially packaged legend drugs and devices), proper and safe storage of drugs and devices, maintenance of proper records, and proper counseling to the patient concerning the therapeutic value and proper use of drugs and devices. The practice of pharmacy also includes continually optimizing patient safety and quality of services through effective use of emerging technologies and competency-based training.

(b) A pharmacist licensed under this article and meeting the requirements as promulgated by legislative rule may administer immunizations.

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

(a) To be eligible for a certification as a pharmacy technician to assist in the practice pharmacy, 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 approved by the board; or

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

(6)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 related to the practice of pharmacy, which conviction remains unreversed.; and

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

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

§30-5-11. Scope practice for certified pharmacy technician;

(a) A certified pharmacy technician, under the supervision of the licensed pharmacist, may, but is not limited to, perform the following:

(1) Assist in the dispensing process;

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

(3) Compound;

(4) Process of medical coverage claims;

(5) Stock of medications; and

(6) Cashier.

(b) A certified 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 of new oral prescription drug orders.

(b) Indirect supervision of a certified pharmacy technician is permitted to allow a pharmacist to take a break of no more than thirty minutes. The pharmacist may leave the pharmacy area but may not leave the building during the break.

(c) 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.

(d) A pharmacy that permits indirect supervision of 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.

(e) The pharmacy shall establish protocols that require a certified 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 pharmacy 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 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 re-licensure; or

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

§30-5-13. 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 pharmacy in another state: *Provided,* That the applicant for licensure meets the requirements of the rules for reciprocity promulgated by the board in accordance with chapter twenty-nine-a of this code: *Provided, however,* That reciprocity is not authorized for pharmacists from another state where that state does not permit reciprocity to pharmacists licensed in West Virginia.

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

§30-5-14. Renewal requirements.

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

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

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

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

§30-5-15. Special volunteer pharmacist license; civil immunity for voluntary services rendered to indigents.

(a) There is established a special volunteer pharmacist license for pharmacists retired or retiring from the active practice of pharmaceutical care who wish to donate their expertise for the pharmaceutical 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 West Virginia Board to pharmacists licensed or otherwise eligible for licensure under this article and the legislative rules promulgated hereunder without the payment of an application fee, license fee or renewal fee, and the initial license shall be issued for the remainder of the licensing period, and renewed consistent with the boards other licensing requirements. The board shall develop application forms for the special license provided in this subsection which shall contain the pharmacist's acknowledgment that:

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

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

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

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

(b) Any pharmacist who renders any 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 pharmaceutical service 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 will provide voluntary uncompensated

pharmaceutical services under the control of the clinic to patients of the clinic before the rendering of any services by the pharmacist at the clinic: *Provided*, That any clinic entering into such written agreement is required to maintain liability coverage of not less than $1 million per occurrence.

(c) Notwithstanding 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 five of this article and in the legislative rules promulgated thereunder, except the fee requirements of subsection (b) of that section and of the legislative rules promulgated by the board relating to fees.

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

inactive status in lieu of having a complaint initiated or other action taken against his or her license, or who has been denied a pharmacist license.

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

§30-5-16. Pharmacist requirements to participate in a collaborative pharmacy practice agreement.

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

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

(2) Have at least $1 million of professional liability insurance coverage;

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

(A) Earned a Certification from the Board of Pharmaceutical Specialties, is a Certified Geriatric Practitioner, or has completed an American Society of Health System Pharmacists(ASHP)

accredited residency program, which includes two years of clinical experience approved by the boards;

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

(C) Successfully completed the course of study and holds the academic degree of Bachelor of Science in Pharmacy and has five years of clinical experience approved by the boards 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.

§30-5-17. 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 such 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.

All activities performed by the pharmacist in conjunction with the protocol shall be documented in the patient's medical record.

The pharmacists shall report at least every thirty days to the physician regarding the patient's drug therapy management. The collaborative pharmacy practice agreement and protocols shall be available for inspection by the West Virginia 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.

(c) Collaborative pharmacy agreements shall not include the management of controlled substances.

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

(e) Up to five pilot project sites in the community based pharmacy setting which meet the requirements established in rule shall be jointly selected by the Board, Board of Medicine and the Board of Osteopathy.

§30-5-18. Authorizations must be displayed.

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

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

§30-5-19. Responsibility for quality of drugs dispensed; exception; falsification of labels; deviation from prescription.

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

(b) Except as provided in section twenty three of this article, the following acts shall be prohibited: (1) The falsification of any label upon the immediate container, box and/or package containing a drug; (2) the substitution or the dispensing of a different drug in lieu of any drug prescribed in a prescription without the approval of the practitioner authorizing the original prescription: *Provided*, That this shall not be construed to interfere with the art of prescription compounding which does not alter the therapeutic properties of the prescription or appropriate generic substitute; and (3) the filling or refilling of any prescription for a greater quantity of any drug or drug product than that prescribed in the original prescription without a written or electronic order or an oral order reduced to writing, or the refilling of a prescription without the verbal, written or electronic consent of the practitioner authorizing the original

prescription.

§30-5-20. Generic drug products.

(a) A pharmacist who receives a prescription for a brand name drug or drug product shall substitute a less expensive equivalent generic name drug or drug product unless in the exercise of his or her professional judgment the pharmacist believes that the less expensive drug is not suitable for the particular patient: *Provided*, That no substitution may be made by the pharmacist where the prescribing practitioner indicates that, in his or her professional judgment, a specific brand name drug is medically necessary for a particular patient.

(b) A written prescription or electronic prescription order shall permit the pharmacist to substitute an equivalent generic name drug or drug product except where the prescribing practitioner has indicated in his or her own handwriting the words "Brand Medically Necessary." The following sentence shall be printed on the prescription form. "This prescription may be filled with a generically equivalent drug product unless the words 'Brand Medically Necessary' are written, in the practitioner's own handwriting, on this prescription form.": *Provided*, That "Brand Medically Necessary" may be indicated on the prescription order other than in the prescribing practitioner's own handwriting unless otherwise required by federal mandate.

(c) A verbal prescription order shall permit the pharmacist to substitute an equivalent generic name drug or drug product except

where the prescribing practitioner shall indicate to the pharmacist that the prescription is "Brand Necessary" or "Brand Medically Necessary." The pharmacist shall note the instructions on the file copy of the prescription or chart order form.

(d) No person may by trade rule, work rule, contract or in any other way prohibit, restrict, limit or attempt to prohibit, restrict or limit the making of a generic name substitution under this section. No employer or his or her agent may use coercion or other means to interfere with the professional judgment of the pharmacist in deciding which generic name drugs or drug products shall be stocked or substituted: *Provided*, That this section shall not be construed to permit the pharmacist to generally refuse to substitute less expensive therapeutically equivalent generic drugs for brand name drugs and that any pharmacist so refusing shall be subject to the penalties prescribed in this article.

(e) A pharmacist may substitute a drug pursuant to this section only where there will be a savings to the buyer. Where substitution is proper, pursuant to this section, or where the practitioner prescribes the drug by generic name, the pharmacist shall, consistent with his or her professional judgment, dispense the lowest retail cost-effective brand which is in stock.

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

manufacturer and generic name of the drug product selected.

(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 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) No pharmacist may 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 any drug shall, either personally or through his or her agent, assistant or employee, notify the person presenting the prescription of such substitution. The person presenting the prescription shall have the right to refuse the substitution. Upon request the pharmacist shall relate the retail price difference between the brand name and the drug substituted for it.

(m) Every pharmacy shall post in a prominent place that is in clear and unobstructed public view, at or near the place where prescriptions are dispensed, a sign which shall read: "West Virginia law requires pharmacists to substitute a less expensive generic-named therapeutically equivalent drug for a brand name drug, if available, unless you or your physician direct otherwise." The sign shall be printed with lettering of at least one and one-half inches in height with appropriate margins and spacing as prescribed by the board.

(n) Any person shall have the right to file a complaint with the board regarding any violation of this article. Such complaints shall be investigated by the board.

(o) Fifteen days after the board has notified, by registered mail, a person that such person is suspected of being in violation of this section, the board shall hold a hearing on the matter.

(p) A pharmacist complying with this section may not be liable in any way for the dispensing of a generic-named therapeutically equivalent drug, substituted under this section, unless the

generic-named therapeutically equivalent drug was incorrectly substituted.

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

(r) 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.

§30-5-21. Pharmacies to be registered.

(a) A pharmacy, 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 be registered with the board:

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

(1) Submit a written application to the board;

(2) Pay all applicable fees;

(3) Designate a Pharmacist-in-charge;

(4) Successfully complete an inspection by the board.

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

(e) Permits are not be 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 pharmacy and the operation of a pharmacy.

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

§30-5-22. 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. 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.

(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 such a change. This change in designation shall be filed with the

board within thirty days of the designation.

§30-5-23. Permits for mail-order houses.

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

(b) A mail-order house shall submit the application for the permit to the board. The application shall contain the following information:

(1) The owner of the mail-order house, 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; and

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

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

§30-5-24. Permit for manufacture and packaging of drugs, medicines, cosmetics; distribution of legend drugs.

(a) No drugs or shall be manufactured, made, produced, packed, packaged or prepared within the state, except under the personal supervision of a pharmacist or other person as may be approved by the board;

(b) No person shall manufacture, package or prepare a drug without obtaining a permit from the board.

(c) Any person, who offers for sale, sells, 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 separate place of manufacture, distribution, making, producing, packing, packaging or preparation.

§30-5-25. Filling of prescriptions more than one year after issuance.

No prescription order may 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.

§30-5-26. Partial filling of prescriptions.

(a) The partial filling of a prescription for a controlled substance listed in Schedule II is permissible if the pharmacist is unable to supply the full quantity called for in a written or emergency oral prescription and the pharmacist makes a notation of the quantity supplied on the face of the written prescription or on

the written record of the emergency oral prescription. The remaining portion of the prescription may be filled within seventy-two hours of the first partial filling: *Provided,* That if the remaining portion is not or cannot be filled within the seventy-two hour period, the pharmacist shall so notify the prescribing individual practitioner. No further quantity may be supplied beyond seventy-two hours without a new prescription.

(b) The partial filling of an electronic prescription for a controlled substance listed in Schedule II is permissible if the pharmacist is unable to supply the full quantity called for in an electronic prescription and the pharmacist makes a notation on the quantity supplied within the electronic record. The remaining portion of the prescription may be filled consistent with the limitations set forth in subsection (a) of this section.

§30-5-27. Partial filling of prescriptions for long-term care facility or terminally ill patients; requirements; records; violations.

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

be deemed to constitute a nursing home, personal care home or residential board and care home within the meaning of this article. This section does not apply to:

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

(2) State hospitals as defined in section six, article one, chapter twenty-seven of this code and state institutions as defined 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 shall be valid for a period of sixty days from the date of issue unless terminated within a shorter period by the discontinuance of the medication.

(d) A prescription for a Schedule II controlled substance written for a patient in a LTCF or for a terminally ill patient may

be filled in partial quantities, including, but not limited to, individual dosage units. The total quantity of Schedule II controlled substances dispensed in all partial filling shall not exceed the total quantity prescribed.

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

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

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

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

(1) The date of the partial filling;

(2) The quantity dispensed;

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

(4) The identification of the dispensing pharmacist.

(g) Information pertaining to current Schedule II

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

§30-5-28. Limitations of article.

(a) Nothing in this article shall be construed to prevent, restrict or in any manner interfere with the sale of nonnarcotic nonprescription drugs which may be lawfully sold without a prescription in accordance with the United States Food, Drug and Cosmetic Act or the laws of this state, nor shall any rule be adopted by the board which shall require the sale of nonprescription drugs by a licensed pharmacist or in a pharmacy or which shall prevent, restrict or otherwise interfere with the sale or distribution of such drugs by any retail merchant. The sale or distribution of nonprescription drugs shall not be deemed to be improperly engaging in the practice of pharmacy.

(b) Nothing in this article shall be construed to interfere with any legally qualified practitioner of medicine, dentistry or veterinary medicine, who is not the proprietor of the store for the

dispensing or retailing of drugs and who is not in the employ of such proprietor, in the compounding of his or her own prescriptions or to prevent him or her from supplying to his or her patients such medicines as he or she may deem proper, if such supply is not made as a sale.

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

§30-5-29. Actions to enjoin violations.

(a) If the board obtains information that any person has engaged in, is engaging in or is about to engage in any act which constitutes or will constitute a violation of 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 courts of this state 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 this section is final unless reversed, vacated or modified on appeal to the West Virginia Supreme Court of Appeals.

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

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

(b) After reviewing any information obtained through an investigation, the board shall determine if probable cause exists that the licensee, certificate holder, 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, certificate holder, registrant or permittee.

(d) Upon a finding that probable cause exists that the licensee, certificate holder, 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, certificate holder, registrant or permittee. Any hearing shall be held in accordance with this article, and shall require a violation to be proven by a preponderance of the evidence.

(e) Any member of the board or the executive director of the

board may issue subpoenas and subpoenas duces tecum to obtain testimony and documents to aid in the investigation of allegations against any person regulated by the article.

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

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

(1) Obtaining an 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 any 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 an authorization revoked or suspended, other disciplinary action taken, or an application for an 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 certificate holder from engaging in the practice of pharmacy or assisting in the practice of pharmacy, 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 pharmacy, drug samples, drug manufacturing, wholesale or retail drug or device distribution, or controlled substances;

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

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

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

(13) Failure to report to the board one's surrender of a license or authorization to practice pharmacy in another jurisdiction while under disciplinary investigation by any of those

authorities or bodies for conduct that would constitute grounds for action as defined in this section;

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

(15) Knowing or suspecting that a licensee or certificate holder is incapable of engaging in the practice of pharmacy or assisting in the practice of pharmacy, 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 such product for which the pharmacist or pharmacy received any form of financial remuneration, or 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 whereby in any way the public is denied, limited or influenced in selecting pharmaceutical service or counseling; or

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

(h) For the purposes of subsection (g) of this section, effective July 1, 2011, 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, certificate holder, 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, certificate holder, registrant, or permittee to pay the costs of the proceeding.

(j) The board may defer disciplinary action with regard to an impaired licensee or certificate holder who voluntarily signs an

agreement, in a form satisfactory to the board, agreeing not to practice pharmacy and to enter an approved treatment and monitoring program in accordance with the board's legislative rule. This subsection, provided that this section should not apply to a licensee or certificate holder who has been convicted of, pleads guilty to, or enters a plea of nolo contendere or a conviction relating to a controlled substance in any jurisdiction.

(l) Nothing shall be construed as barring criminal prosecutions for violations of this article.

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

§30-5-31. Procedures for hearing; right of appeal.

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

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

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

actions if the board so directs. The board may accept, reject or modify the decision of the administrative law judge.

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

(e) If, after a hearing, the board determines the licensee, certificate holder, registrant or permittee has violated 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.

§**30-5-32. Judicial review.**

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

§30-5-33. 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) Any person, who violates any 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 confined in jail not to exceed thirty days, or both fined and confined. Each and every day that the violation continues shall constitute a separate offense.

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. The bill defines terms. The bill provides for a board and its composition. The bill 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. Further, the bill sets forth grounds for disciplinary actions, allows for specific disciplinary actions, provides procedures for investigation of complaints. Additionally, the bill provides judicial review and appeals of decisions and sets forth hearing and notice requirements. The bill provides for civil causes of action and providing criminal penalties. The bill also provides for privileged communication and provides that a single act is evidence of practice.

This article has been completely rewritten; therefore, the entire article is underscored.