WEST VIRGINIA LEGISLATURE

2022 REGULAR SESSION

ENROLLED

Committee Substitute

for

House Bill 4324

BY DELEGATE ROHRBACH

[Passed March 8, 2022; in effect from passage.]

AN ACT to amend and reenact §30-5-4 and §30-5-19 of the Code of West Virginia, 1931, as amended, all relating to collaborative pharmacy practice; defining terms; setting forth requirements for different practice settings; prohibiting certain practices; removing board approval of specified items; updating the terms of collaborative practice agreements; providing for a practice notification; and providing for the procedure for the practice notification.

Be it enacted by the Legislature of West Virginia:

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

§30-5-4. Definitions.

As used in this article:

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

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

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

"Board" means the West Virginia Board of Pharmacy.

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

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

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

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

"Collaborative pharmacy practice agreement" is a written and signed agreement, which is a physician directed approach, that is entered into between an individual physician or physician group, or for a medical provider in training where the agreement is signed by the supervising physician or chairperson of the medical department where the medical provider in training is practicing, and an individual pharmacist or pharmacists that provides for collaborative pharmacy practice for the purpose of drug therapy management of a patient.

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

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

"Compounding" means:

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

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

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

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

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

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

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

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

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

(A) To dispense or administer;

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

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

(iii) Intracompany sales.

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

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

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

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

"Drug" means:

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

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

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

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

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

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

(i) Known allergies;

(ii) Rational therapy-contraindications;

(iii) Reasonable dose and route of administration; and

(iv) Reasonable directions for use.

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

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

(i) Drug-drug;

(ii) Drug-food;

(iii) Drug-disease; and

(iv) Adverse drug reactions.

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

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

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

(B) Collecting and reviewing patient histories;

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

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

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

(A) An electronic prescription order;

(B) A refill authorization request;

(C) A communication; or

(D) Other patient care information.

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

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

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

"Emergency medical reasons" include, but are not limited to, transfers of a prescription drug by one pharmacy to another pharmacy to alleviate a temporary shortage of a prescription drug; sales to nearby emergency medical services, i.e., ambulance companies and firefighting organizations in the same state or same marketing or service area, or nearby licensed

practitioners of prescription drugs for use in the treatment of acutely ill or injured persons; and provision of minimal emergency supplies of prescription drugs to nearby nursing homes for use in emergencies or during hours of the day when necessary prescription drugs cannot be obtained.

"Exclusive distributor" means an entity that:

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

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

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

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

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

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

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

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

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

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

"Individually identifiable health information" is information that is a subset of health information, including demographic information collected from an individual and is created or

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

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

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

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

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

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

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

"Manufacturing" means the production, preparation, propagation, or processing of a drug or device, either directly or indirectly, by extraction from substances of natural origin or independently by means of chemical or biological synthesis and includes any packaging or repackaging of the substance or substances or labeling or relabeling of its contents and the promotion and marketing of the drugs or devices. Manufacturing also includes the preparation

and promotion of commercially available products from bulk compounds for resale by pharmacies, practitioners, or other persons.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

"Pharmacist's scope of practice pursuant to the collaborative pharmacy practice agreement" means those duties and limitations of duties placed upon the pharmacist by the collaborating physician.

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

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

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

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

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

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

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

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

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

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

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

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

"Repackager" means a person who repackages.

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

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

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

(A) A patient has a medical complaint;

(B) A medical history has been taken;

(C) A face-to-face physical examination adequate to establish the medical complaint has been performed by the prescribing practitioner or in the instances of telemedicine through telemedicine practice approved by the appropriate practitioner board; and

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

"Wholesale distribution" and "wholesale distributions" mean distribution of prescription drugs, including directly or through the use of a third-party logistics provider or any other situation in which title, ownership, or control over the prescription drug remains with one person or entity

but the prescription drug is brought into this state by another person or entity on his, her, or its behalf, to persons other than a consumer or patient, but does not include:

(A) Intracompany sales, as defined in this section;

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

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

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

(E) The sale, purchase, or trade of a drug or an offer to sell, purchase or trade a drug for “emergency medical reasons” for purposes of this article includes transfers of prescription drugs by a retail pharmacy to another retail pharmacy to alleviate a temporary shortage, except that the gross dollar value of such transfers shall not exceed five percent of the total prescription drug sales revenue of either the transferor or transferee pharmacy during any 12 consecutive month period;

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

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

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

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

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

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

(a) A pharmacist engaging in collaborative pharmacy practice shall have on file at his or her place of practice the collaborative pharmacy practice agreement. The existence and subsequent termination of the agreement and any additional information the rules may require concerning the agreement, including the agreement itself, shall be made available to the appropriate licensing board for review upon request. The agreement may allow the pharmacist, within the pharmacist's scope of practice pursuant to the collaborative pharmacy practice agreement, to conduct drug therapy management activities approved by the collaborating physician. The collaborative pharmacy practice agreement shall be a voluntary process, which is a physician directed approach after informed consent of the patient and noted in the patient's medical record, that is entered into between an individual physician or physician group and an individual pharmacist or pharmacists. A pharmacist may not diagnose.

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

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

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

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

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

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

(c) All activities performed by the pharmacist in conjunction with the protocol shall be documented in the patient's medical record. The pharmacists shall report at least every 30 days to the physician regarding the patient's drug therapy management. The collaborative pharmacy practice agreement and protocols shall be available for inspection by the board, the West Virginia Board of Medicine, or the West Virginia Board of Osteopathic Medicine, depending on the licensing board of the participating physician. A copy of the protocol shall be filed in the patient's medical record.

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

(e) A collaborative pharmacy practice agreement, meeting the requirements herein established and in accordance with joint rules, shall be allowed in the hospital setting, the nursing home setting, the medical school setting and the hospital, community pharmacy setting and

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

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

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

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

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

.....
Chairman, House Committee

.....
Chairman, Senate Committee

Originating in the House.

In effect from passage.

.....
Clerk of the House of Delegates

.....
Clerk of the Senate

.....
Speaker of the House of Delegates

.....
President of the Senate

_____

The within ..... this the.....

day of ....., 2022.

.....
Governor