WEST VIRGINIA LEGISLATURE

FIRST REGULAR SESSION, 2005

ENROLLED

COMMITTEE SUBSTITUTE FOR House Bill No. 2371

(By Delegates Perdue, Amores and Anderson)

Passed April 9, 2005

In Effect Ninety Days from Passage

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COMMITTEE SUBSTITUTE

FOR

H. B. 2371

(BY DELEGATES PERDUE, AMORES AND ANDERSON)

[Passed April 9, 2005; in effect ninety days from passage.]

AN ACT to amend and reenact §30-5-1b of the Code of West Virginia,1931, as amended, and to amend said code by adding thereto four new sections, designated §30-5-26, §30-5-27, §30-5-28, and §30-5-29, all relating to requirements for collaborative pharmacy practice agreements between physicians and pharmacists, establishing locations, sunset provisions, and granting rule-making authority.

Be it enacted by the Legislature of West Virginia:

That §30-5-1b of the Code of West Virginia, 1931, as amended, be amended and reenacted; and that said code be amended by adding thereto four new sections, designated §30-5-26, §30-5-27, §30-5-28, and §30-5-29, all to read as follows:

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

§30-5-1b. Definitions.

The following words and phrases, as used in this article, have the following meanings, unless the context otherwise requires:

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

(2) "Board of pharmacy" or "board" means the West Virginia State Board of Pharmacy.

(3) "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.

(4) "Collaborative pharmacy practice agreement" is a written and signed agreement between a pharmacist, a physician, and the individual patient or the patients' 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 of Pharmacy, 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.

(5) "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.

(6) "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 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.

(7) "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.

(8) "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."

(9) "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.

(10) "Distribute" means the delivery of a drug or device other than by administering or dispensing.

(11) "Drug" means:

(A) Articles recognized as drugs in the USP-DI, facts and comparisons, physicians 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 paragraphs (A) or (B) of this subdivision.

(12) "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 over use and under use and optimum therapeutic outcomes.

(13) "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;

(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.

(14) "Intern" means an individual who is:

(A) Currently registered by this state to engage in the practice of pharmacy while under the supervision of a licensed pharmacist and is satisfactorily progressing toward meeting the requirements for licensure as a pharmacist; or

(B) A graduate of an approved college of pharmacy or a graduate who has established educational equivalency by obtaining a foreign pharmacy graduate examination committee (FPGEC) certificate, who is currently licensed by the board for the purpose of obtaining practical experience as a requirement for licensure as a pharmacist; or

(C) A qualified applicant awaiting examination for licensure; or

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

(15) "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. Any label shall include all information required by federal law or regulation and state law or rule.

(16) "Mail-order pharmacy" means a pharmacy, regardless of its location, which dispenses greater than ten percent prescription drugs via the mail.

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

(18) "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.

(19) "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.

(20) "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.

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

(22) "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.

(23) "Pharmacist" or "registered pharmacist" means an individual currently licensed by this state to engage in the practice of pharmacy and pharmaceutical care.

(24) "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.

(25) "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 of Pharmacy and the Board of Medicine or the Board of Osteopathy.

(26) "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.

(27) "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.

(28) "Pharmacy technician" means registered supportive personnel who work under the direct supervision of a pharmacist who have passed an approved training program as described in this article.

(29) "Practitioner" means an individual currently licensed, registered or otherwise authorized by any state, territory or district of the United States to prescribe and administer drugs in the course of professional practices, including allopathic and osteopathic physicians, dentists, physician's assistants, optometrists, veterinarians, podiatrists and nurse practitioners as allowed by law.

(30) "Preceptor" means an individual who is currently licensed as a pharmacist by the board, meets the qualifications

as a preceptor under the rules of the Board and participates in the instructional training of pharmacy interns.

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

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

(32) "Prescription drug order" means a lawful order of a practitioner for a drug or device for a specific patient.

(33) "Prospective drug use review" means a review of the patients' drug therapy and prescription drug order, as defined in the rules of the board, prior to dispensing the drug as part of a drug regimen review.

(34) "USP-DI" means the United States pharmacopeia-dispensing information.

(35) "Wholesale distributor" means any 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.

§30-5-26. Pharmacist requirements to participate in a collaborative pharmacy practice agreement.

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

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

(b) Have at least one million dollars of professional liability insurance coverage;

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

(1)Earned a Certification from the Board of Pharmaceutical Specialties, is a Certified Geriatric Practitioner, or has completed an American Society of Health System Pharmacists(ASHP) accredited residency program, which includes two years of clinical experience approved by the Boards;

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

(3) Successfully completed the course of study and holds the academic degree of Bachelor of Science in Pharmacy 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.

§30-5-27. 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 of Pharmacy, 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 of Pharmacy, Board of Medicine and the Board of Osteopathy.

(f) For the purpose of proposing a legislative rule to clarify and define a collaborative pharmacy practice relationship, the Boards responsible for promulgating the rule shall establish an advisory committee to assist them in the development and implementation of the pharmacy collaborative practice act. The advisory committee shall be made up of fourteen members. These members shall include one representative appointed by the West Virginia State Medical Association; one representative appointed by the West Virginia Academy of Family Physicians; one representative appointed by the West Virginia Society of Osteopathic Medicine; one representative appointed by the West Virginia School of Medicine; one representative appointed by the Marshall University School of Medicine; one representative appointed by the West Virginia School of Osteopathic Medicine; two representatives appointed by the West Virginia Pharmacy Association, one of whom shall

represent chain pharmacies and one of whom shall represent independent pharmacies; two representatives appointed by the West Virginia Society of Health System Pharmacists, one of whom shall represent long term care settings and one of whom shall represent hospital pharmacists; one representative appointed by the West Virginia School of Pharmacy; one representative appointed by the University of Charleston School of Pharmacy; one representative appointed by the West Virginia Hospital Association; and one representative appointed by the West Virginia Health Care Association. A representative of each board with rule-making authority shall serve as an ex officio member of the advisory committee.

§30-5-28. Rule-making authority.

The Board of Pharmacy, the Board of Medicine and the Board of Osteopathy shall jointly agree and propose rules for legislative approval in accordance with the provisions of article three, chapter twenty-nine-a of the code.

§30-5-29. Collaborative pharmacy practice continuation.

Pursuant to the provisions of article ten, [§§4-10-1 et seq.] chapter four of this code, pharmacy collaborative agreements in community settings shall continue to exist until the first day of July, two thousand eight, unless sooner terminated, continued or reestablished pursuant to that article.

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

Chairman Senate Committee

Chairman House Committee

Originating in the House.

In effect ninety days from passage.

Clerk of the Senate

Clerk of the House of Delegates

President of the Senate

Speaker of the House of Delegates

The within is approved this the 2nd day of May, 2005.

Governor

PRESENTED TO THE
GOVERNOR

APR 26 2005

Time 4:30 pm