SB 722

WEST VIRGINIA LEGISLATURE

SEVENTY-EIGHTH LEGISLATURE

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ENROLLED

Senate Bill No. 722

(By Senators Prezioso and Unger)

[Passed March 8, 2008; in effect ninety days from passage.]

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AN ACT to amend and reenact §30-5-1b, §30-5-3, §30-5-14 and §30-5-21 of the Code of West Virginia, 1931, as amended, all relating to regulation by the Board of Pharmacy of ambulatory health care facilities and free clinics who dispense pharmaceuticals; and defining terms.

Be it enacted by the Legislature of West Virginia:

That §30-5-1b, §30-5-3, §30-5-14 and §30-5-21 of the Code of West Virginia, 1931, as amended, be amended and reenacted, 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) "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. The Board of Pharmacy shall promulgate rules regarding 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 the charitable clinic pharmacies shall be exempt from licensure by the board until rules are in effect for a charitable clinic pharmacy. A charitable clinic pharmacy may not be charged any applicable licensing fees and such clinics may receive donated drugs.

(4) "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.

(5) "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 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.

(6) "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.

(7) "Confidential information" means information maintained by the pharmacist in the patient record or

which is communicated to the patient as part of patient counseling or which is communicated by the patient to the pharmacist. This information is privileged and may be released only to the patient or to other members of the health care team and other pharmacists where, in the pharmacists' professional judgment, the release is necessary to the patient's health and well-being; to health plans, as that term is defined in 45 CFR §160.103, 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. Appropriate disclosure, as permitted by this section, may occur by the pharmacist either directly or through an electronic data intermediary, as defined in subdivision (14) of this section.

(8) "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.

(9) "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."

(10) "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.

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

(12) "Drug" means:

(A) Articles recognized as drugs 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.

(13) "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.

(14) "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.

(15) "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 pharmacist 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.

(16) "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".

(17) "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.

(18) "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.

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

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

(21) "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.

(22) "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.

(23) "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.

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

(25) "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.

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

(27) "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.

(28) "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.

(29) "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.

(30) "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.

(31) "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.

(32) "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 assistants, optometrists, veterinarians, podiatrists and nurse practitioners as allowed by law.

(33) "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.

(34) "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.

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

(36) "Prospective drug use review" means a review of the patient's 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.

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

(38) "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.

§30-5-3. When licensed pharmacist required; person not licensed pharmacist, pharmacy technician or licensed intern not to compound prescriptions or dispense poisons or narcotics; licensure of interns; prohibiting the dispensing of prescription orders in absence of practitioner-patient relationship.

(a) It is unlawful for any person not a pharmacist, or who does not employ a pharmacist, to conduct any pharmacy or store for the purpose of retailing, compounding or dispensing prescription drugs or prescription devices.

(b) It is unlawful for the proprietor of any store or pharmacy, any ambulatory health care facility, as that term is defined in section one, article five-b, chapter sixteen of this code, that offers pharmaceutical care, or a facility operated to provide health care or mental health care services free of charge or at a reduced rate

and that operates a charitable clinic pharmacy to permit any person not a pharmacist to compound or dispense prescriptions or prescription refills or to retail or dispense the poisons and narcotic drugs named in sections two, three and six, article eight, chapter sixteen of this code: *Provided,* That a licensed intern may compound and dispense prescriptions or prescription refills under the direct supervision of a pharmacist: *Provided, however,* That registered pharmacy technicians may assist in the preparation and dispensing of prescriptions or prescription refills, including, but not limited to, reconstitution of liquid medications, typing and affixing labels under the direct supervision of a licensed pharmacist.

(c) It is the duty of a pharmacist or employer who employs an intern to license the intern with the board within ninety days after employment. The board shall furnish proper forms for this purpose and shall issue a certificate to the intern upon licensure.

(d) The experience requirement for licensure as a pharmacist shall be computed from the date certified by the supervising pharmacist as the date of entering the internship. If the internship is not registered with the board of pharmacy, then the intern shall receive no credit for such experience when he or she makes application for examination for licensure as a pharmacist: *Provided,* That credit may be given for such unregistered experience if an appeal is made and evidence produced showing experience was obtained but not registered and that failure to register the internship experience was not the fault of the intern.

(e) An intern having served part or all of his or her

internship in a pharmacy in another state or foreign country shall be given credit for the same when the affidavit of his or her internship is signed by the pharmacist under whom he or she served, and it shows the dates and number of hours served in the internship and when the affidavit is attested by the secretary of the state board of pharmacy of the state or country where the internship was served.

(f) Up to one third of the experience requirement for licensure as a pharmacist may be fulfilled by an internship in a foreign country.

(g) No pharmacist may compound or dispense any prescription order when he or she has knowledge that the prescription was issued by a practitioner without establishing an ongoing practitioner-patient relationship. An online or telephonic evaluation by questionnaire is inadequate to establish an appropriate practitioner-patient relationship: *Provided,* That this prohibition does not apply:

(1) In a documented emergency;

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

(3) Where patient care is rendered in consultation with another practitioner who has an ongoing relationship with the patient and who has agreed to supervise the patient's treatment, including the use of any prescribed medications.

§30-5-14. Pharmacies to be registered; permit to operate; fees; pharmacist to conduct business.

(a) The Board of Pharmacy shall require and provide for the annual registration of every pharmacy doing business in this state, including an ambulatory health care facility, as that term is defined in section one, article five-b, chapter sixteen of this code, who offers pharmaceutical care, and a facility operated to provide health care or mental health care services free of charge or at a reduced rate and who operates charitable clinic pharmacy. Any person, firm, corporation or partnership desiring to operate, maintain, open or establish a pharmacy in this state shall apply to the Board of Pharmacy for a permit to do so. The application for such permit shall be made on a form prescribed and furnished by the Board of Pharmacy, which, when properly executed, shall indicate the owner, manager, trustee, lessee, receiver or other person or persons desiring such permit, as well as the location of such pharmacy, including street and number, and any other information as the Board of Pharmacy may require. If it is desired to operate, maintain, open or establish more than one pharmacy, separate application shall be made and separate permits or licenses shall be issued for each.

(b) Every initial application for a permit shall be accompanied by the required fee of one hundred fifty dollars. The fee for renewal of such permit or license shall be one hundred dollars annually.

(c) If an application is approved, the Secretary of the Board of Pharmacy shall issue to the applicant a permit or license for each pharmacy for which application is made. Permits or licenses issued under this section shall not be transferable and shall expire on the thirtieth day of June of each calendar year and if application for renewal of permit or license is not made on or before

that date, or a new one granted on or before the first day of August, following, the old permit or license shall lapse and become null and void and shall require an inspection of the pharmacy and a fee of one hundred fifty dollars plus one hundred fifty dollars for the inspection.

(d) Every place of business so registered shall employ a pharmacist in charge and operate in compliance with the general provisions governing the practice of pharmacy and the operation of a pharmacy.

(e) The provisions of this section shall have no application to the sale of nonprescription drugs which are not required to be dispensed pursuant to a practitioner's prescription.

§30-5-21. 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, as that term is defined in section one, article five-b, chapter sixteen of this code, that offers pharmaceutical care or a facility operated to provide health care or mental health care services free of charge or at a reduced rate that operates a charitable clinic pharmacy: *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.

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

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Chairman Senate Committee

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Chairman House Committee

Originated in the Senate.

In effect ninety days from passage.

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Clerk of the Senate

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Clerk of the House of Delegates

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President of the Senate

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Speaker House of Delegates

The within ..... this

the ..... Day of ....., 2008.

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Governor

PRESENTED TO THE
GOVERNOR

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