# WEST VIRGINIA LEGISLATURE

FIRST REGULAR SESSION, 2001

# ENROLLED

## COMMITTEE SUBSTITUTE
## FOR
## House Bill No. 3052

(By Delegates Border and Perdue)

Passed April 14, 2001

In Effect Ninety Days from Passage

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COMMITTEE SUBSTITUTE

FOR

# H. B. 3052

(BY DELEGATES BORDER AND PERDUE)

[Passed April ~~14~~ 13, 2001; in effect ninety days from passage.]

AN ACT to amend and reenact sections one-b, three and twelve-b, article five, chapter thirty of the code of West Virginia, one thousand nine hundred thirty-one, as amended; and to further amend said article by adding thereto two new sections, designated sections five-b and sixteen-a, relating generally to pharmacies; codifying procedure to dispense prescribed substances more than one year after issuance of the prescription by internet pharmacies; providing for indirect supervision of registered pharmacy technicians during pharmacist's break; providing for maximum break period in which a registered pharmacy technician may be indirectly supervised; limiting the physical area a pharmacist may take a break; providing for certain functions a registered pharmacy technician may perform while being indirectly supervised; requiring certain communication vehicles be implemented between a registered pharmacy technician and a pharmacist while on break; providing for certain protocols to be established by

individual pharmacies in the event of an emergency while a pharmacist is on break; redefining practitioner as it affects pharmacists; deleting obsolete definition; and prohibiting the dispensing of prescription orders in absence of practitioner-patient relationship.

*Be it enacted by the Legislature of West Virginia:*

That sections one-b, three and twelve-b, article five, chapter thirty of the code of West Virginia, one thousand nine hundred thirty-one, as amended, be amended and reenacted; and that said article be further amended by adding thereto two new sections, designated sections five-b and sixteen-a, 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, shall have the following meanings, unless the context otherwise requires:

(a) "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.

(b) "Board of pharmacy" or "board" means the West Virginia state board of pharmacy.

(c) "Compounding" means:

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

(A) 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

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

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

(d) "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 pharmacist's 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.

(e) "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.

(f) "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."

(g) "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.

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

(i) "Drug" means:

(1) 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;

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

(3) Articles intended for use as a component of any articles specified in subsection (1) or (2) of this section.

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

(1) Evaluation of the prescription drug orders and patient records for:

(A) Known allergies;

(B) Rational therapy-contraindications;

(C) Reasonable dose and route of administration; and

(D) Reasonable directions for use.

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

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

(A) Drug-drug;

(B) Drug-food;

(C) Drug-disease; and

(D) Adverse drug reactions.

(4) Evaluation of the prescription drug orders and patient records for proper use, including over use and under use and optimum therapeutic outcomes.

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

(1) 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

(2) 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

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

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

(l) "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.

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

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

(o) "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(s) 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.

(p) "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.

(q) "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.

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

(s) "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.

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

(u) "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.

(v) "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.

(w) "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.

(x) "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.

(y) "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.

(z) "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:

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

(2) "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.

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

(bb) "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.

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

(dd) "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 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.

**§30-5-5b. Indirect supervision of registered pharmacy technicians during pharmacist's break.**

(a) Indirect supervision of registered pharmacy technicians within a pharmacy may be permitted to allow pharmacists 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.

(b) When a pharmacist is on break, pharmacy technicians may continue to prepare prescriptions for the pharmacist's verification. No prescription may 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.

(c) A pharmacy that permits indirect supervision of registered pharmacy technicians 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.

(d) The pharmacy shall establish protocols that require a registered pharmacy technician to interrupt the pharmacist's break if an emergency arises.

**§30-5-12b. Definitions; selection of generic drug products; exceptions; records; labels; manufacturing standards; rules; notice of substitution; complaints; notice and hearing; immunity.**

(a) As used in this section:

(1) "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.

(2) "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 United States food and drug administration and is in effect.

(3) "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.

(4) "Equivalent" means drugs or drug products which are the same amounts of identical active ingredients and same dosage form and which will provide the same therapeutic efficacy and toxicity when administered to an individual and is approved by the United States food and drug administration.

(b) 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.

(c) A written 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.

(d) 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.

(e) No person may by trade rule, work rule, contract or in any other way prohibit, restrict, limit or attempt to prohibit, restrict or limit the making of a generic name substitution under the provisions of this section. No employer or his or her agent may use coercion or other means to interfere with the professional judgment of the pharmacist in deciding which generic name drugs or drug products 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 section twenty-two of this article.

(f) A pharmacist may substitute a drug pursuant to the provisions of 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) All savings in the retail price of the prescription shall be passed on to the purchaser; these savings shall be equal to the difference between the retail price of the brand name product and the customary and usual price of the generic product substituted therefor: *Provided,* That in no event shall such savings be less than the difference in acquisition cost of the brand name product prescribed and the acquisition cost of the substituted product.

(h) 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 or verbal prescription or chart order. Such record shall include the manufacturer and generic name of the drug product selected.

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

(j) 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.

(k) A pharmacist may not dispense a product under the provisions of this section unless the manufacturer has shown that the drug has been manufactured with the following minimum good manufacturing standards and practices by:

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

(2) Maintaining quality control standards equal to or greater than those of the United States food and drug administration;

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

(4) Labeling products with an expiration date.

(l) The West Virginia board of pharmacy shall promulgate rules in accordance with the provisions of chapter twenty-nine-a of this code which 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. The formulary shall be promulgated by the board within ninety days of the date of passage of this section and may be amended in accordance with the provisions of chapter twenty-nine-a of this code.

(m) No pharmacist shall 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 West Virginia board of pharmacy pursuant to this article or is found to be in violation of the requirements of the United States food and drug administration.

(n) Any 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 substitu-

tion. 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.

(o) 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 West Virginia board of pharmacy.

(p) The West Virginia board of pharmacy shall promulgate rules in accordance with the provisions of chapter twenty-nine-a of this code setting standards for substituted drug products, obtaining compliance with the provisions of this section and enforcing the provisions of this section.

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

(r) Fifteen days after the board has notified, by registered mail, a person, firm, corporation or copartnership that such person, firm, corporation or copartnership is suspected of being in violation of a provision of this section, the board shall hold a hearing on the matter. If, as a result of the hearing, the board determines that a person, firm, corporation or copartnership is violating any of the provisions of this section, it may, in addition to any penalties prescribed by section twenty-two of this article, suspend or revoke the permit of any person, firm, corporation or copartnership to operate a pharmacy.

(s) No pharmacist complying with the provisions of this section shall be liable in any way for the dispensing of a generic named therapeutically equivalent drug, substituted under the provisions of this section, unless the generic named therapeutically equivalent drug was incorrectly substituted.

(t) In no event where the pharmacist substitutes a drug under the provisions of 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.

(u) Failure of a practitioner to specify that a specific brand name is necessary for a particular patient shall 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.

**§30-5-16a. 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.

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 1st day of May, 2001.

*Governor*

PRESENTED TO THE
GOVERNOR
Date 5/1/01
Time 2:35 pm