WEST VIRGINIA LEGISLATURE

REGULAR SESSION, 1978

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ENROLLED

Committee Substitute for

HOUSE BILL No. 1108

(By Mr. S. Withrow & Mr. Caudle)

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PASSED March 11, 1978

In Effect ninety days from Passage

C 641

ENROLLED

COMMITTEE SUBSTITUTE

FOR

H. B. 1108

(By MRS. WITHROW and MR. CAUDLE)

(Originating in the House Committee on the Judiciary)

[Passed March 11, 1978; in effect ninety days from passage.]

AN ACT to amend and reenact sections twelve and twenty-two, article five, chapter thirty of the code of West Virginia, one thousand nine hundred thirty-one, as amended; and to further amend said article five by adding thereto a new section, designated section twelve-b, all relating to manufacturers' responsibility for drug products, definitions, selection of generic drug products, written and oral orders required for prescription changes, substitution of generic name drug products generally, prohibition against limiting the making of a generic substitution, requirements as to method of selecting less expensive drug product, passing on savings to purchaser, notification to purchaser of substitution, interference with professional judgment of pharmacists prohibited, display of informational sign required, record of drug product substitutions to be maintained by pharmacists, minimum manufacturing standards required, board of pharmacy's responsibilities for promulgating regulations and enforcement of the provisions of this article, prescribing penalties for violation thereof, prescribing penalties

for violation of article, and excepting board members from certain violations.

Be it enacted by the Legislature of West Virginia:

That sections twelve and twenty-two, 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 five be further amended by adding thereto a new section, designated section twelve-b, all to read as follows:

ARTICLE 5. PHARMACISTS, ASSISTANT PHARMACISTS AND DRUGSTORES.

§30-5-12. Responsibility for quality of drugs dispensed; exception; falsification of labels; deviation from prescription.

All persons, whether registered pharmacists or not shall be held responsible for the quality of all drugs, chemicals and medicines they may sell or dispense, with the exception of those sold in the original retail package of the manufacturer, in which event the manufacturer shall be held responsible.

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

§30-5-12b. Definitions, selection of generic drug products.

(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 essentially the same therapeutic efficacy and toxicity when administered to an individual.

(5) "Practitioner" means a physician, osteopath, dentist, veterinarian, podiatrist, optometrist or any other person duly licensed to practice and to prescribe drugs under the laws of this state.

(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 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. Every drug prescription order shall contain an instruction on whether or not an equivalent generic name drug or drug product may be substituted.

If a written prescription is involved, the prescription or chart order form shall have two signature lines at opposite ends on the bottom of the form. Under the signature line at the left side shall be clearly printed or written the words "Brand Necessary" or words of similar purport which clearly indicate the physicians' intent to prohibit substitution. Under the signature line at the right side shall be clearly printed the

words "Generic Equivalent Permitted." A written prescription order not in the form hereinabove prescribed shall be construed as permitting the pharmacist to substitute an equivalent generic name drug or drug product except where the prescribing practitioner has indicated in writing his intent that the pharmacist not substitute an equivalent generic name drug or drug product.

If an oral prescription order is involved, the prescribing practitioner or his agent shall indicate to the pharmacist whether or not an equivalent generic name drug or drug product may be substituted. The pharmacist shall note the instructions on the file copy of the prescription or chart order form.

(c) 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 subsection (b) of this section. No employer or his 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, article five, chapter thirty of this code.

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

(e) 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.

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

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

Unless the physician directs otherwise, the prescription label on all drugs dispensed by the pharmacist shall indicate the generic name using abbreviations if necessary and the name of the manufacturer. The same notation will be made on the original prescription retained by the pharmacist.

(g) 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.

(h) The West Virginia board of pharmacy shall establish by rule 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 article, and may be amended in ac-

cordance with the provisions of chapter twenty-nine-a of this code.

(i) 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 esstablished 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.

(j) Any pharmacist who substitutes any drug shall, either personally or through his agent, assistant or employee, notify the person presenting the prescription of such substitution. The person presenting the prescription shall have the right to refuse the substitution. Upon request the pharmacist shall relate the retail price difference between the brand name and the drug substituted for it.

(k) 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.

(l) The West Virginia board of pharmacy shall promulgate rules and regulations setting standards for substituted drug products, obtaining compliance with the provisions of this section and enforcing the provisions of this section. 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.

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 co-partnership 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 or drug store.

(m) 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.

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

Failure of a licensed physician to specify that a specific brand name is necessary for a particular patient shall not constitute evidence of negligence unless the physician had reasonable cause to believe that the health of the patient required the use of a certain product and no other.

(n) This section shall take effect on the first day of July, one thousand nine hundred seventy-eight.

§30-5-22. Offenses; penalties.

Any person who shall violate any of the provisions of section three of this article shall be guilty of a misdemeanor, and, upon conviction thereof, shall for each offense, be fined not exceeding two hundred dollars, or confined in the county jail not to exceed six months, or both fined and imprisoned, in the discretion of the court, and each day such violation shall continue shall be deemed a separate offense.

Any person who violates any of the provisions of section twelve shall be deemed guilty of a misdemeanor, and, upon conviction thereof, shall be punished by a fine of not less

than fifty nor more than one hundred fifty dollars for each such offense.

Any person, except for the board of pharmacy or member thereof acting within the scope of his responsibilities or duties as such member, who violates any of the provisions of section twelve-b shall be deemed guilty of a misdemeanor, and, upon conviction thereof, shall be punished by a fine of not less than fifty nor more than one thousand dollars for each such offense.

Any person, firm, partnership or corporation who shall violate any of the provisions of section fourteen shall be deemed guilty of a misdemeanor, and, upon conviction thereof, for the first offense shall be fined not to exceed one hundred dollars, or shall be imprisoned in the county jail not to exceed six months, or both such fine and imprisonment, in the discretion of the court, and each and every day that such violation continues shall constitute a separate offense.

Any person, firm, partnership or corporation who shall violate any of the provisions of section eighteen shall be deemed guilty of a misdemeanor, and, upon conviction thereof, shall be fined not to exceed fifty dollars for the first offense, and upon conviction of a second offense shall be fined not less than fifty nor more than five hundred dollars, or shall be imprisoned in the county jail not to exceed thirty days, or both such fine and imprisonment, in the discretion of the court, and each and every day that such violation continues shall constitute a separate offense.

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

James L. Davis
Chairman Senate Committee

Clarence C. Chrisley Jr
Chairman House Committee

Originated in the House.

Takes effect ninety days from passage.

J. C. Dillon, Jr.
Clerk of the Senate

C. A. Blankenship
Clerk of the House of Delegates

W. T. Brotherton Jr.
President of the Senate

Donald L. Kopp
Speaker House of Delegates

The within is approved this the 27
day of March, 1978.

John D. Rockefeller IV
Governor

C-641

RECEIVED
MAR 23 4 02 PM '78
OFFICE OF THE GOVERNOR

APPROVED AND SIGNED BY THE GOVERNOR

Date March 28, 1978

Time 9:10 A.M.

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OFFICE
SEC'Y. OF STATE