No: 1292

WEST VIRGINIA LEGISLATURE

REGULAR SESSION, 1984

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ENROLLED

Com. Sub. for
HOUSE BILL No. 1292

(By ~~Mr.~~ Del. Miller & Del. Leary)

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Passed February 28, 1984

In Effect Ninety Days From Passage

ENROLLED

COMMITTEE SUBSTITUTE

FOR

H. B. 1292

(By DELEGATE MILLER and DELEGATE LEARY)

[Passed February 28, 1984; in effect ninety days from passage.]

AN ACT to amend and reenact section sixteen, article three, chapter thirty of the code of West Virginia, one thousand nine hundred thirty-one, as amended; and to amend and reenact sections one and twelve-b, article five of said chapter, all relating to permitting certain authorized Type A physician assistants to prescribe drugs at the direction of a supervising physician under specific circumstances; directing the establishment of regulations by the board of medicine limiting the drugs which may be so prescribed; definitions enabling pharmacists to dispense drugs approved by the board of medicine when ordered by an authorized Type A physician assistant at the direction of his or her supervising physician.

Be it enacted by the Legislature of West Virginia:

That section sixteen, article three, chapter thirty of the code of West Virginia, one thousand nine hundred thirty-one, as amended, be amended and reenacted; and that sections one and twelve-b, article five of said chapter be amended and reenacted, all to read as follows:

ARTICLE 3. WEST VIRGINIA MEDICAL PRACTICE ACT.

§30-3-16. Physician assistants; definitions; board of medicine rules and regulations; annual report; certification; temporary certification; recertification; reciprocity; job description required; revocation or suspension of certification; responsibilities of supervising physician; legal responsibility for physician assistants; identification; limitations on employment and duties; fees; unlawful use of title of "physician assistant"; unlawful representation of physician assistant as a physician; criminal penalties.

(a) As used in this section:

(1) "Type A physician assistant" means an assistant to a primary care physician who is a graduate of an approved program of instruction in primary health care, has passed the national certification examination and is qualified to perform direct patient care services under the supervision of the primary care physician;

(2) "Type B physician assistant" means an assistant to a physician who is a graduate of an approved program of instruction in a recognized nonprimary care clinical specialty or is a graduate of an approved program of instruction in primary health care and has either received additional postgraduate training in a recognized nonprimary care clinical specialty or has received additional training from a physician adequate to qualify him or her to perform patient services in that specialty as defined by the supervising physician;

(3) "Supervising physician" means a doctor of medicine or podiatry permanently licensed in this state who assumes legal and supervisory responsibility for the work or training of any physician assistant under his or her supervision;

(4) "Approved program" means an educational program for physician assistants approved and accredited by the committee on allied health education and accreditation on behalf of the American Medical Association; and

(5) "Health care facility" means any licensed hospital,

nursing home, extended care facility, state health or mental institution, clinic or physician's office.

(b) The board shall promulgate rules and regulations governing the extent to which physician assistants may function in this state. Such regulations shall provide that the physician assistant is limited to the performance of those services for which he or she is trained and that he or she performs only under the supervision and control of a physician permanently licensed in this state, but such supervision and control does not require the personal presence of the supervising physician at the place or places where services are rendered if the physician assistant's normal place of employment is on the premises of the supervising physician. The supervising physician may send the physician assistant off the premises to perform duties under his or her direction, but a separate place of work for the physician assistant shall not be established. In promulgating such rules and regulations, the board shall allow the physician assistant to perform those procedures and examinations and in the case of certain authorized Type A physician assistants to prescribe at the direction of his or her supervising physician in accordance with subsection (1) of this section those categories of drugs submitted to it in the job description required by subsection (i) of this section. The board shall compile and publish an annual report that includes a list of currently certified physician assistants and their employers and location in the state; a list of approved programs; the number of graduates of such approved programs each year; and the number of physician assistants from other states practicing in this state.

(c) The board shall certify as a Type A physician assistant any person who files an application and furnishes satisfactory evidence to it that he or she has met the following standards:

(1) He or she is a graduate of an approved program of instruction in primary health care;

(2) He or she has passed the examination for a primary care physician assistant administered by the National Board of Medical Examiners on behalf of the National Commission on Certification of Physician Assistants; and

(3) He or she is of good moral character.

(d) The board may certify as a Type B physician assistant any person who files an application and furnishes satisfactory evidence to it that he or she has met the following standards:

(1) He or she is of good moral character;

(2) He or she is a graduate of an approved program of instruction in a recognized nonprimary care clinical specialty or is a graduate of an approved program of instruction in primary health care and has either received additional post-graduate training in a recognized nonprimary care clinical specialty or has received additional training from a physician adequate to qualify him or her to perform patient services in that specialty as defined by the supervising physician; or

(3) He or she has been previously certified by the board as a Type B physician assistant prior to the first day of July, one thousand nine hundred eighty-three.

Certification of an assistant to a physician practicing the specialty of ophthalmology is not permitted or required under this section.

(e) When any graduate of an approved program submits an application to the board, accompanied by a job description in conformity with subsection (i) of this section, for a Type A physician assistant certificate, the board shall issue to such applicant a temporary certificate allowing such applicant to function as a Type A physician assistant for the period of one year. Said temporary certificate may be renewed for one additional year upon the request of the supervising physician. A Type A physician assistant who has not been certified as such by the National Board of Medical Examiners on behalf of the National Commission on Certification of Physician Assistants will be restricted to work under the direct supervision of the supervising physician.

(f) When any person who meets the qualifications for a Type B physician assistant as defined in this section and who submits an application accompanied by a job description

for a Type B physician assistant certificate, the board may certify such applicant as a Type B physician assistant for a period of four months. Upon expiration of the four-month temporary certification, the board may certify the applicant as a Type B physician assistant. The Type B physician assistant will be restricted to work under the direct supervision of the supervising physician until he or she has passed either the examination for surgical assistants or the examination for primary care physician assistants administered by the National Board of Medical Examiners on behalf of the National Commission on Certification of Physician Assistants.

(g) Certification of a Type B physician assistant is subject to review and recertification after every three-year period following the first certification. Recertification requires a report from the supervising physician of a Type B physician assistant which must include a performance evaluation, a summary of experience or continuing medical education and any proposed change in job description.

(h) The board may certify as a physician assistant in this state without examination any person who has been certified or licensed by examination in another state of the United States which has requirements substantially equivalent to the requirements of this section.

(i) Any physician applying to the board to supervise either a Type A or Type B physician assistant shall provide a job description that sets forth the range of medical services to be provided by such assistant. Before a physician assistant can be employed or otherwise use his or her skills, the supervising physician must obtain approval of the job description from the board. The board may revoke or suspend any certification of an assistant to a physician for cause, after giving such person an opportunity to be heard in the manner provided by sections eight and nine, article one of this chapter.

(j) The supervising physician is responsible for observing, directing and evaluating the work, records and practices of each physician assistant performing under his or her supervision. He or she shall notify the board in writing of any termination of his or her supervisory relationship with a phy-

sician assistant within ten days of the termination. The legal responsibility for any physician assistant remains with the supervising physician at all times, including occasions when the assistant under his or her direction and supervision, aids in the care and treatment of a patient in a health care facility. A health care facility is not legally responsible for the actions or omissions of the physician assistant unless the physician assistant is an employee of the facility.

(k) When functioning as a physician assistant, the physician assistant shall wear a name tag that identifies him or her and specifies his or her type of classification and the name of his or her supervising physician. A two and one-half by three and one-half inch card of identification shall be furnished by the board upon certification of the physician assistant and shall specify the type of classification.

(l) A Type A physician assistant providing primary care outpatient services in a medically underserved area or other area of need, both as defined by the board, may write or sign prescriptions or transmit prescriptions by word of mouth, telephone or other means of communication at the direction of his or her supervising physician. The board shall promulgate rules and regulations governing the eligibility and extent to which such a Type A physician assistant may prescribe at the direction of the supervising physician. The regulations shall provide for a state formulary classifying pharmacologic categories of drugs which may be prescribed by such a Type A physician assistant. In classifying such pharmacologic categories, those categories of drugs which shall be excluded shall include, but not limited to, Schedules I and II of the Uniformed Controlled Substances Act, anticoagulants, antineoplastics, antipsychotics, radiopharmaceuticals, general anesthetics and radiographic contrast materials. Drugs listed under schedule III shall be limited to a forty-eight hour supply without refill. The regulations shall provide that all pharmacological categories of drugs to be prescribed by a Type A physician assistant shall be listed in each job description submitted to the board as required in subsection (i) of this section. The regulations shall provide the maximum dosage a Type A physician assistant may prescribe. The regulation shall also

provide that to be eligible for such prescription privileges, a Type A physician assistant shall have performed patient care services for a minimum of two years immediately preceding the submission to the board of the job description containing prescription privileges and shall have successfully completed an accredited course of instruction in clinical pharmacology approved by the board. The regulations shall also provide that to maintain prescription privileges, a physician assistant shall continue to maintain national certification as a physician assistant, and in meeting such national certification requirements shall complete a minimum of ten hours of continuing education in rational drug therapy in each certification period. Nothing in this subsection shall be construed to permit a Type A physician assistant to independently prescribe or dispense drugs.

(m) A supervising physician shall not supervise at any one time more than two physician assistants.

A physician assistant shall not sign any prescription, except in the case of an authorized Type A physician assistant at the direction of his or her supervising physician in accordance with the provisions of subsection (l) of this section. A physician assistant shall not perform any service that his or her supervising physician is not qualified to perform. A physician assistant shall not perform any service that is not included in his job description and approved by the board as provided for in this section.

The provisions of this section do not authorize any physician assistant to perform any specific function or duty delegated by this code to those persons licensed as chiropractors, dentists, dental hygienists, optometrists or pharmacists or certified as nurse anesthetists.

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(n) Each job description submitted by a licensed supervising physician shall be accompanied by a fee of fifty dollars. A fee of five dollars shall be charged for the annual renewal of the certificate.

(o) It is unlawful for any person who is not certified by the board as a physician assistant to use the title of "physician assistant" or to represent to any other person that he or she

is a physician assistant. Any person who violates the provisions of this subsection is guilty of a misdemeanor, and, upon conviction thereof, shall be fined not more than two thousand dollars.

(p) It is unlawful for any physician assistant to represent to any person that he or she is a physician, surgeon or podiatrist. Any person who violates the provisions of this subsection is guilty of a felony, and, upon conviction thereof, shall be imprisoned in the penitentiary for not less than one nor more than two years, or be fined not more than two thousand dollars, or both fined and imprisoned.

ARTICLE 5. PHARMACISTS, ASSISTANT PHARMACISTS AND DRUGSTORES.

§30-5-1. Definitions.

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

(1) The term "drug" means (a) articles in the official United States Pharmacopoeia, or official National Formulary, or any other supplement to either of them, which are intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in man or other animals, and (b) all other articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals, and (c) articles, other than food, intended to affect the structure or any function of the body of man or other animals and (d) articles intended for use as a component of any articles specified in clause (a), (b) or (c).

(2) The term "poisonous drug" means any drug likely to be destructive to adult human life in quantities of five grains or less.

(3) The term "deleterious drug" means any drug likely to be destructive to adult human life in quantities of sixty grains or less.

(4) The term "habit-forming drug" means any drug which

has been or may be designated as habit forming under the regulations promulgated in accordance with section 502 (d) of the Federal Food, Drug and Cosmetic Act of June twenty-fifth, one thousand nine hundred thirty-eight.

(5) The term "pharmacy" or "drugstore" or "apothecary" shall be held to mean and include every store or shop or other place (a) where drugs are dispensed or sold at retail or displayed for sale at retail; or (b) where physicians' prescriptions are compounded; or (c) which has upon it or displayed within it, or affixed to or used in connection with it, a sign bearing the word or words "pharmacy," "pharmacists," "apothecary," "drugstore," "drugs," "druggists," "medicine," "medicine store," "drug sundries," "remedies" or any word or words of similar or like import; or (d) any store or shop or other place, with respect to which any of the above words are used in any advertisement.

(6) The term "prescription" shall be held to mean an order for drugs or medicines or combinations or mixtures thereof, written or signed by a duly licensed physician, an authorized Type A physician assistant at the direction of his or her supervising physician in accordance with the provisions of section sixteen, article three of this chapter, dentist, optometrist, as authorized by section two, article eight of this chapter, veterinarian or other medical practitioner licensed to write prescriptions intended for the treatment or prevention of disease of man or animals. Any prescription written or signed by an authorized Type A physician assistant shall be imprinted with the name of his or her supervising physician, the name of the physician assistant, and a list of drugs approved under the Type A physician assistant's job description, in accordance with the provisions of section sixteen, article three of this chapter. The term "prescription" shall also include orders for drugs or medicines or combinations or mixtures thereof transmitted to the pharmacist by word of mouth, telephone or other means of communication by a duly licensed physician, an authorized Type A physician assistant, dentist, optometrist, veterinarian or other medical practitioner licensed to write prescriptions intended for treatment or prevention of disease

of man or animals, and such prescriptions received by word of mouth, telephone or other means of communication shall be recorded in writing by the pharmacist and the record so made by the pharmacist shall constitute the original prescription to be filed by the pharmacist. A pharmacist receiving a prescription by word of mouth, telephone or other means of communication from an authorized Type A physician assistant shall require a copy of the list of drugs approved under the job description of such Type A physician assistant prior to accepting such orders. All such descriptions shall be preserved on file for a period of five years, subject to inspection by the proper officer of the law. The above shall apply except for narcotic prescriptions, when all narcotic laws and regulations must be compiled with.

(7) The term "cosmetic," which shall be held to include "dentifrice" and "toilet article," means (a) articles intended to be rubbed, poured, sprinkled or sprayed on, introduced into, or otherwise applied to the human body, or any part thereof for cleansing, beautifying, promoting attractiveness or altering the appearance, and (b) articles intended for use as a component of any such articles, except that such term shall not include soap.

§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, an authorized Type A physician assistant at the direction of his or her supervising physician in accordance with the provisions of section sixteen, article three of this chapter, 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 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. 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 practitioners' 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 or her 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 or her 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 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, 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 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.

(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 practitioner 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 section, and may be amended in accordance 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 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.

(j) 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 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 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 or drugstore.

(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 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.

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.

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

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

James L. Davis
Chairman Senate Committee

Leonard Anello
Chairman House Committee

Originating in the House.

Takes effect ninety days from passage.

Todd C. Wells
Clerk of the Senate

Donald L. Kopp
Clerk of the House of Delegates

Warren R. McGraw
President of the Senate

Chas M. Lee, Jr.
Speaker House of Delegates

The within is approved this the 7 day of March, 1984.

John D. Rockefeller IV
Governor

C-641