HB82

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By Representative Johnson (R)

RFD: Health

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SYNOPSIS: Under existing law, the Alabama State Board of Pharmacy regulates the manner in which a licensed pharmacist may dispense a different drug or brand of drug than that ordered or prescribed without the express permission of the person ordering or the prescriber.

This bill would authorize licensed pharmacists to dispense a substitute biological product for certain biological products that have been identified as interchangeable or therapeutically equivalent by the federal Food and Drug Administration.

A BILL

TO BE ENTITLED

AN ACT

To amend Sections 34-23-1 and 34-23-8, Code of Alabama 1975, relating to the Alabama State Board of Pharmacy and the dispensing of substitute drugs or brands of drugs by

licensed pharmacists; to authorize licensed pharmacists to dispense substitutes for certain biological products identified as interchangeable or therapeutically equivalent by the federal Food and Drug Administration.

BE IT ENACTED BY THE LEGISLATURE OF ALABAMA:

Section 1. Sections 34-23-1 and 34-23-8 of the Code of Alabama 1975, are amended to read as follows:

"§34-23-1.

"For the purpose of this chapter, the following words and phrases shall have the following meanings:

"(1) ASSOCIATION. The Alabama Pharmacy Association.

"(2) BIOLOGICAL PRODUCT. The same meaning as the term is defined in 42 U.S.C. §262.

"~~(2)~~(3) BOARD or STATE BOARD. The Alabama State Board of Pharmacy.

"~~(3)~~(4) CHEMICAL. Any substance of a medicinal nature, whether simple or compound, obtained through the process of the science and art of chemistry, whether of organic or inorganic origin.

"~~(4)~~(5) DISPENSE. To sell, distribute, administer, leave with, give away, dispose of, deliver, or supply a drug or medicine to the ultimate user or their agent.

"~~(5)~~(6) DRUGS. All medicinal substances, preparations, and devices recognized by the United States Pharmacopoeia and National Formulary, or any revision thereof, and all substances and preparations intended for external and internal use in the cure, diagnosis, mitigation, treatment, or

prevention of disease in man or animal and all substances and preparations other than food intended to affect the structure or any function of the body of man or animal.

"~~(6)~~(7) EXTERN. A candidate for licensure as a pharmacist during the time prior to graduation from an accredited college of pharmacy.

"~~(7)~~(8) HOSPITAL. An institution for the care and treatment of the sick and injured, licensed by the Alabama State Board of Health and authorized to be entrusted with the custody of drugs and medicines, the professional use of drugs and medicines being under the direct supervision of a medical practitioner or pharmacist.

"(9) INTERCHANGEABLE BIOLOGICAL PRODUCT. A biological product that the federal Food and Drug Administration has licensed and:

"a. Determined meets the standards for "interchangeability" pursuant to 42 U.S.C. §262(k)(4); or

"b. Determined is therapeutically equivalent as set forth in the latest edition of or supplement to the federal Food and Drug Administration Approved Drug Products with Therapeutic Equivalence Evaluations.

"~~(8)~~(10) INTERN. An individual who is currently licensed by this state to engage in the practice of pharmacy while under the personal supervision of a pharmacist and is satisfactorily progressing toward meeting the requirements for licensure as a pharmacist; or a graduate of an approved college of pharmacy who is currently licensed by the ~~State~~

~~Board of Pharmacy~~ board for the purpose of obtaining practical experience as a requirement for licensure as a pharmacist; or a qualified applicant awaiting examination for licensure.

"~~(9)~~ (11) LEGEND DRUG. Any drug, medicine, chemical, or poison bearing on the label the words, "caution, federal law prohibits dispensing without prescription," or similar wording indicating that such drug, medicine, chemical, or poison may be sold or dispensed only upon the prescription of a licensed medical practitioner.

"~~(10)~~ (12) LICENSE. The grant of authority by the ~~State Board of Pharmacy~~ board to a person authorizing him or her to engage in the practice of pharmacy in this state.

"~~(11)~~ (13) MANUFACTURER. A person, except a pharmacy, who prepares, derives, produces, compounds, or packages any drug, medicine, chemical, or poison.

"~~(12)~~ (14) MEDICAL PRACTITIONER. Any physician, dentist, or veterinarian, or any other person authorized by law to treat, use, or prescribe medicine and drugs for sick and injured human beings or animals in this state.

"~~(13)~~ (15) MEDICINE. Any drug or combination of drugs that has the property of curing, diagnosing, preventing, treating, or mitigating diseases or that which may be used for those purposes.

"~~(14)~~ (16) PATENT OR PROPRIETARY MEDICINES. Completely compounded nonprescription packaged drugs, medicines, and nonbulk chemicals which are sold, offered, promoted, or advertised by the manufacturer or primary

distributor under a trademark, trade name, or other trade symbol, and the labeling of which conforms to the requirements of the ~~Federal~~ federal Food, Drug, and Cosmetic Act; provided, that this definition shall not include:

"a. Drugs which are only advertised and promoted professionally to licensed physicians, dentists, or veterinarians by manufacturers or primary distributors.

"b. A narcotic or drug containing a narcotic.

"c. A drug the label of which bears substantially either the statements "caution--federal law prohibits dispensing without prescription" or "warning--may be habit-forming".

"d. A drug intended for injection.

"~~(15)~~(17) PERMIT. The grant of authority by the ~~State Board of Pharmacy~~ board to any person, firm, or corporation authorizing the operation of a pharmacy, wholesale drug distributor, repackager, bottler, manufacturer, or packer of drugs, medicines, chemicals, or poisons for medicinal purposes. Nonresident wholesale drug distributors registered with the appropriate agency, in the state in which they are domiciled, and operating in compliance with Prescription Drug Marketing Act standards, shall be allowed to do business in this state. No permit shall be required of any physician licensed to practice medicine for any act or conduct related to or connected with his or her professional practice.

"~~(16)~~(18) PERSON. Any individual, partnership, corporation, association, trust, or other entity.

"~~(17)~~ (19) PHARMACIST. Any person licensed by the ~~Alabama State Board of Pharmacy~~ board to practice the profession of pharmacy in the State of Alabama and whose license is in good standing.

"~~(18)~~ (20) PHARMACY. A place licensed by the ~~Alabama State Board of Pharmacy~~ board in which prescriptions, drugs, medicines, medical devices, chemicals, and poisons are sold, offered for sale, compounded, or dispensed, and shall include all places whose title may imply the sale, offering for sale, compounding, or dispensing of prescriptions, drugs, medicines, chemicals, or poisons.

"~~(19)~~ (21) PHARMACY SERVICES PERMIT. Certain services performed by a pharmacy, as defined by board rule, and specifically excluding, the receipt or inventory of drugs, medicines, chemicals, poisons, or medical devices. This subdivision, and any rule promulgated by the board pursuant to this subdivision, may not be interpreted to expand the practice of pharmacy as the practice of pharmacy and permits are limited by this section and Sections 34-23-11 and 34-23-70, or to restrict the practice of medicine as defined in Section 34-24-50.

"a. This subdivision, and any rule promulgated by the board pursuant to this subdivision, is subject to the restrictions contained in subsection (b) of Section 34-23-30.

"b. This subdivision shall not be interpreted to allow the board to promulgate any rule that would authorize a pharmacist to sell, offer for sale, or dispense any

prescription drug except pursuant to the terms of a valid prescription issued by a licensed practitioner authorized to prescribe such drug.

"~~(20)~~ (22) POISON. Any substance other than agricultural products and pesticides which when applied to, introduced into, or developed within the body in relatively small quantities by its inherent chemical action uniformly produces serious bodily injury, disease, or death.

"~~(21)~~ (23) PRECEPTOR. A person who is duly licensed to practice pharmacy in the state and meets the requirements as established by the ~~State Board of Pharmacy~~ board.

"~~(22)~~ (24) PRESCRIPTION. Any order for drug or medical supplies, written or signed or transmitted by word of mouth, telephone, telegraph, closed circuit television, or other means of communication by a legally competent practitioner, licensed by law to prescribe and administer such drugs and medical supplies intended to be filled, compounded, or dispensed by a pharmacist.

"~~(23)~~ (25) PROFESSIONAL DEGREE. A degree in pharmacy requiring a minimum of five academic years.

"~~(24)~~ (26) REPACKAGER. A person who purchases or acquires from a manufacturer or distributor, a drug, medicine, chemical, or poison for the purpose of bottling, labeling, or otherwise repackaging for sale or distribution. This definition shall not apply to a physician licensed to practice medicine who as a part of his or her professional practice

dispenses, administers, sells, or otherwise distributes any drug to a patient.

"~~(25)~~ (27) SALE. Barter, exchange, or gift, or offer of barter, exchange, or gift, and shall include each transaction made by any person, whether a principal, proprietor, agent, servant, or employee.

"~~(26)~~ (28) WHOLESALE DRUG DISTRIBUTORS. A person engaged in the business of distributing drugs and medicines for resale to pharmacies, hospitals, practitioners, government agencies, or other lawful outlets permitted to sell drugs or medicines. The sale, purchase, or trade of a drug by a retail pharmacy to another retail pharmacy or practitioner, for relief of temporary shortages, is exempt from this definition. Also exempt from this definition ~~shall be~~ are all of the following:

"~~(a) intracompany~~ a. Intracompany sales~~,~~.

"~~(b) manufacturer~~ b. Manufacturer and distributor sales representatives who distribute drug samples~~,~~.

"~~(c) charitable~~ c. Charitable organizations distributing to nonprofit affiliates of that organization~~,~~.

"~~(d) certain~~ d. Certain purchases by hospitals or other health care entities that are members of a group purchasing organization~~, and~~.

"~~(e) the~~ e. The distributors of blood and blood components.

"§34-23-8.

"No person shall dispense or cause to be dispensed a different ~~drug~~ biological product or brand of drug in lieu of that ordered or prescribed without the express permission in each case of the person ordering or prescribing such drug or biological product, except as provided below:

"(1) A licensed pharmacist in this state shall be permitted to select for the brand name drug prescribed or the specific biological product prescribed by a licensed physician or other practitioner who is located in this state and authorized by law to write prescriptions, hereinafter referred to as ~~"~~practitioner,~~"~~ a less expensive pharmaceutically and therapeutically equivalent drug product containing the same active ingredient or ingredients, and of the same dosage form strength as the drug prescribed, or a biological product that is interchangeable with the biological product prescribed, in all cases where the practitioner expressly authorizes such selection in accordance with subdivision ~~(4) of this section~~ (6).

"(2) A licensed pharmacist located in this state shall be permitted to select for the brand name drug prescribed or the specific biological product prescribed by a practitioner who is located in another state or licensing jurisdiction and who is authorized by the laws of that state or jurisdiction to write prescriptions, a less expensive pharmaceutically and therapeutically equivalent drug product containing the same active ingredient or ingredients, and of the same dosage form strength as the drug prescribed, or

biological product that is interchangeable with the biological product prescribed, in all cases where the out-of-state licensed physician or other practitioner does not expressly prohibit a substitution.

"(3) A pharmacist who selects an interchangeable biological product shall inform the patient of the selection made, which may be satisfied pursuant to the procedure specified in subdivision (4).

"~~(3)~~ (4) A pharmacist shall record on the prescription form the name and manufacturer or distributor of any drug product, or the name and manufacturer of any biological product, dispensed as herein authorized.

"(5)a. Within five business days after the dispensing of a biological product, the dispensing pharmacist, or a designee of the pharmacist, shall make an entry of the specific biological product provided to the patient, including the name of the biological product and the name of the manufacturer of the biological product. The communication shall be conveyed by making an entry that is electronically accessible to the prescriber through one of the following means:

"1. An interoperable electronic medical records system.

"2. An electronic prescribing technology.

"3. A pharmacy benefit management system.

"4. A pharmacy record.

"b. Entry into an electronic records system, as described in this subdivision, is presumed to provide notice to the prescribing practitioner. Otherwise, the pharmacist shall communicate the biological product dispensed to the prescriber using facsimile, telephone, electronic transmission, or other prevailing means, provided that communication is not required in either of the following circumstances:

"1. There is no federal Food and Drug Administration approved interchangeable biological product for the product prescribed.

"2. A refill prescription is not changed from the product dispensed on the immediately prior filling of the prescription.

"~~(4)~~(6)a. Every written prescription issued in this state by a licensed practitioner shall contain two signature lines. Under one signature line shall be printed clearly the words "dispense as written." Under the other signature line shall be printed clearly the words "product selection permitted." The practitioner shall communicate instructions to the pharmacist by signing on the appropriate line. The ~~State Board of Pharmacy~~ board shall not promulgate any rule or regulation affecting the subject matter of this subdivision.

"b. An oral prescription from the practitioner shall instruct the pharmacist whether or not a less expensive pharmaceutically and therapeutically equivalent drug or interchangeable biological product may be dispensed. The

pharmacist shall note instructions on the file copy of the prescription and retain the prescription form for the period specified by law.

"~~(5)~~ (7) Unless otherwise indicated by the practitioner, the prescription label on the dispensing container shall indicate the actual drug or biological product dispensed, either the brand name, or if none, the generic name, and the name of the manufacturer or a reasonable abbreviation of the name of the manufacturer.

"~~(6)~~ (8) This shall not be interpreted to exclude the use of a formulary or drug list as adopted and approved by a medical staff in a licensed hospital with drugs provided thereunder by procedures established for use within that licensed hospital.

"(9) The board shall maintain a link on its website to the current list of all biological products that the federal Food and Drug Administration has determined to be an interchangeable biological product.

"~~(7)~~ (10) Any person who violates ~~the provisions of~~ this section shall be punished by a fine of up to ~~$1,000~~ one thousand dollars ($1,000)."

Section 2. This act shall become effective on the first day of the third month following its passage and approval by the Governor, or its otherwise becoming law.