HB354

198530-2

By Representative Johnson

RFD: Health

First Read: 04-APR-19

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SYNOPSIS: This bill would authorize a licensed pharmacist to dispense a substitute interchangeable biological product for certain biological products under certain conditions.

A BILL

TO BE ENTITLED

AN ACT

To amend Section 34-23-1, Code of Alabama 1975, relating to the Alabama State Board of Pharmacy; to define biological products and interchangeable biological products; to add Section 34-23-8.1 to the Code of Alabama 1975, to authorize licensed pharmacists to dispense substitutes for certain biological products under certain conditions; to provide for certain notice provisions; and to further provide that this act is intended and shall be construed to apply only to biological drug products.

BE IT ENACTED BY THE LEGISLATURE OF ALABAMA:

Section 1. Section 1. Section 34-23-1 of the Code of Alabama 1975, as last amended by Act 2018-107, 2018 Regular Session, is 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. Has the same meaning as the term as 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 his or her 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 for which the federal Food and Drug Administration has made either a determination of licensure based on standards for interchangeability pursuant to 42 U.S.C. §262(k)(4), or a determination of therapeutic equivalence based on the latest edition of or supplement to the federal Food and Drug Administration's publication Approved Drug Products with Therapeutic Equivalence Evaluations (Orange Book).

"~~(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 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 board to a person authorizing him or her to engage in the practice of pharmacy in this state.

"~~(11)~~ (13) MANUFACTURER. A person or entity, except a pharmacy, who prepares, derives, produces, researches, tests, labels, 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) OUTSOURCING FACILITY. A facility at one geographic location or address that is engaged in the compounding of sterile drugs, which has elected to register with the federal Food and Drug Administration as an outsourcing facility and complies with the requirements of Section 503B(d)(4)(A) of the Federal Food, Drug, and Cosmetic Act.

"~~(15)~~ (17) 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 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.

"~~(16)~~ (18) PERMIT. The grant of authority by the 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.

"~~(17)~~ (19) PERSON. Any individual, partnership, corporation, association, trust, or other entity.

"~~(18)~~ (20) PHARMACIST. Any person licensed by the board to practice the profession of pharmacy as a health care provider in the State of Alabama and whose license is in good standing.

"~~(19)~~ (21) PHARMACY. A place licensed by the 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.

"~~(20)~~ (22) 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.

"a. 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.

"b. 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.

"c. 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.

"~~(21)~~(23) 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.

"~~(22)~~(24) PRECEPTOR. A person who is duly licensed to practice pharmacy in the state and meets the requirements as established by the board.

"~~(23)~~(25) 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.

"~~(24)~~(26) PRIVATE LABEL DISTRIBUTOR. A firm that does not participate in the manufacture or processing of a drug but instead markets and distributes under its own trade name, and labels a drug product made by someone else. A private label distributor is responsible for the products it introduces into interstate commerce and for compliance with

Federal Food, Drug, and Cosmetic Act requirements and Current Good Manufacturing Practices regulations.

"~~(25)~~ (27) PROFESSIONAL DEGREE. A degree in pharmacy requiring a minimum of five academic years.

"~~(26)~~ (28) 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.

"~~(27)~~ (29) 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.

"~~(28)~~ (30) THIRD-PARTY LOGISTICS PROVIDER. An entity that provides or coordinates warehousing or other logistics services of a product in interstate commerce on behalf of a manufacturer, wholesale distributor, or dispenser of a product, that does not take ownership of the product, nor have responsibility to direct the sale or disposition of the product.

"~~(29)~~ (31) WHOLESALE DRUG DISTRIBUTORS. A person, other than a manufacturer, the co-licensed partner of a manufacturer, a third-party logistics provider, or repackager, 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 all of the following:

"a. Intracompany sales.

"b. Manufacturer and distributor sales representatives who distribute drug samples.

"c. Charitable organizations distributing to nonprofit affiliates of that organization.

"d. Certain purchases by hospitals or other health care entities that are members of a group purchasing organization.

"e. The distributors of blood and blood components."

Section 2. Section 34-23-8.1 is added to the Code of Alabama 1975, to read as follows:

34-23-8.1

(a) No person shall dispense or cause to be dispensed a different biological or brand of biological product in lieu of that ordered or prescribed without the express permission in each case of the person ordering or prescribing the drug, except as provided in this section.

(b) A licensed pharmacist in this state shall be permitted to select for the brand name 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 interchangeable biological product in all cases where the practitioner expressly authorizes the selection in accordance with subsection (d).

(c) A licensed pharmacist located in this state shall be permitted to select for the brand name 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 interchangeable biological product, in all cases where the out-of-state licensed physician or other practitioner does not expressly prohibit a substitution.

(d)(1) Every written prescription for a biological product 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.

(2) An oral or electronic prescription from the practitioner for a biological product shall instruct the pharmacist whether or not a less expensive 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.

(e) The State Board of Pharmacy may not adopt any rule affecting the subject matter of this section.

(f) When a pharmacist dispenses an interchangeable biological product for the prescribed biological product, the pharmacist, or his or her designee, shall inform the patient or patient's designee prior to dispensing the interchangeable biological product.

(g)(1) Within 72 hours, a pharmacist who dispenses a different biological product than that ordered or prescribed shall inform the prescribing physician that a different biological product was substituted for the biological product prescribed and provide the name and manufacturer of the biological product dispensed. The notice to the prescribing physician or other practitioner shall be by the exact means used by the prescribing physician or other practitioner. However, if this is not available, notice may be accomplished by any of the following:

a. Electronic message sent to the electronic prescribing system used by the prescribing physician or other practitioner to transmit the prescription to the pharmacy.

b. Telephone.

c. Facsimile.

(2) In any instance where the prescribing practitioner indicates on the face of the prescription "to communicate using telephone or facsimile," the pharmacist shall utilize that method of communication.

(h) 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 authorized in this section.

(i) Notice to the prescribing physician is not required if a refill prescription is not changed from the product dispensed on the immediately prior filling of the prescription.

(j) Unless otherwise indicated by the practitioner, the prescription label on the dispensing container shall indicate the actual biological product dispensed, either the brand name, or if none, the name of the biosimilar biologic product as referred to by the federal Food and Drug Administration's Lists of Licensed Biological Products With Reference Product Exclusivity and Biosimilarity of Interchangeability Evaluations (Purple Book), and the name of the manufacturer or a reasonable abbreviation of the name of the manufacturer.

(k) The board may maintain a link on its website to the current list of all biological products that the federal Food and Drug Administration has licensed and meets the standards for "interchangeability" pursuant to 42 U.S.C. §262(k).

(l) Any person who violates this section shall be punished by a fine of up to one thousand dollars ($1,000).

(m) This section is intended and shall be construed to apply only to biological drug products.

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.