

1 HB499
2 199443-1
3 By Representative Johnson
4 RFD: Health
5 First Read: 23-APR-19

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

12
13 A BILL
14 TO BE ENTITLED
15 AN ACT
16

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

26 BE IT ENACTED BY THE LEGISLATURE OF ALABAMA:

1 Section 1. Section 1. Section 34-23-1 of the Code of
2 Alabama 1975, as last amended by Act 2018-107, 2018 Regular
3 Session, is amended to read as follows:

4 "§34-23-1.

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

7 "(1) ASSOCIATION. The Alabama Pharmacy Association.

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

10 "~~(2)~~ (3) BOARD or STATE BOARD. The Alabama State
11 Board of Pharmacy.

12 "~~(3)~~ (4) CHEMICAL. Any substance of a medicinal
13 nature, whether simple or compound, obtained through the
14 process of the science and art of chemistry, whether of
15 organic or inorganic origin.

16 "~~(4)~~ (5) DISPENSE. To sell, distribute, administer,
17 leave with, give away, dispose of, deliver, or supply a drug
18 or medicine to the ultimate user or his or her agent.

19 "~~(5)~~ (6) DRUGS. All medicinal substances,
20 preparations, and devices recognized by the United States
21 Pharmacopoeia and National Formulary, or any revision thereof,
22 and all substances and preparations intended for external and
23 internal use in the cure, diagnosis, mitigation, treatment, or
24 prevention of disease in man or animal and all substances and
25 preparations other than food intended to affect the structure
26 or any function of the body of man or animal.

1 "~~(6)~~(7) EXTERN. A candidate for licensure as a
2 pharmacist during the time prior to graduation from an
3 accredited college of pharmacy.

4 "~~(7)~~(8) HOSPITAL. An institution for the care and
5 treatment of the sick and injured, licensed by the Alabama
6 State Board of Health and authorized to be entrusted with the
7 custody of drugs and medicines, the professional use of drugs
8 and medicines being under the direct supervision of a medical
9 practitioner or pharmacist.

10 "(9) INTERCHANGEABLE BIOLOGICAL PRODUCT. A
11 biological product for which the federal Food and Drug
12 Administration has made either a determination of licensure
13 based on standards for interchangeability pursuant to 42
14 U.S.C. §262(k) (4), or a determination of therapeutic
15 equivalence based on the latest edition of or supplement to
16 the federal Food and Drug Administration's publication
17 Approved Drug Products with Therapeutic Equivalence
18 Evaluations (Orange Book).

19 "~~(8)~~(10) INTERN. An individual who is currently
20 licensed by this state to engage in the practice of pharmacy
21 while under the personal supervision of a pharmacist and is
22 satisfactorily progressing toward meeting the requirements for
23 licensure as a pharmacist; or a graduate of an approved
24 college of pharmacy who is currently licensed by the board for
25 the purpose of obtaining practical experience as a requirement
26 for licensure as a pharmacist; or a qualified applicant
27 awaiting examination for licensure.

1 "~~(9)~~(11) LEGEND DRUG. Any drug, medicine, chemical,
2 or poison bearing on the label the words, "caution, federal
3 law prohibits dispensing without prescription," or similar
4 wording indicating that such drug, medicine, chemical, or
5 poison may be sold or dispensed only upon the prescription of
6 a licensed medical practitioner.

7 "~~(10)~~(12) LICENSE. The grant of authority by the
8 board to a person authorizing him or her to engage in the
9 practice of pharmacy in this state.

10 "~~(11)~~(13) MANUFACTURER. A person or entity, except a
11 pharmacy, who prepares, derives, produces, researches, tests,
12 labels, or packages any drug, medicine, chemical, or poison.

13 "~~(12)~~(14) MEDICAL PRACTITIONER. Any physician,
14 dentist, or veterinarian, or any other person authorized by
15 law to treat, use, or prescribe medicine and drugs for sick
16 and injured human beings or animals in this state.

17 "~~(13)~~(15) MEDICINE. Any drug or combination of drugs
18 that has the property of curing, diagnosing, preventing,
19 treating, or mitigating diseases or that which may be used for
20 those purposes.

21 "~~(14)~~(16) OUTSOURCING FACILITY. A facility at one
22 geographic location or address that is engaged in the
23 compounding of sterile drugs, which has elected to register
24 with the federal Food and Drug Administration as an
25 outsourcing facility and complies with the requirements of
26 Section 503B(d) (4) (A) of the Federal Food, Drug, and Cosmetic
27 Act.

1 "~~(15)~~(17) PATENT OR PROPRIETARY MEDICINES.

2 Completely compounded nonprescription packaged drugs,
3 medicines, and nonbulk chemicals which are sold, offered,
4 promoted, or advertised by the manufacturer or primary
5 distributor under a trademark, trade name, or other trade
6 symbol, and the labeling of which conforms to the requirements
7 of the Federal Food, Drug, and Cosmetic Act; provided, that
8 this definition shall not include:

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

12 "b. A narcotic or drug containing a narcotic.

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

17 "d. A drug intended for injection.

18 "~~(16)~~(18) PERMIT. The grant of authority by the
19 board to any person, firm, or corporation authorizing the
20 operation of a pharmacy, wholesale drug distributor,
21 repackager, bottler, manufacturer, or packer of drugs,
22 medicines, chemicals, or poisons for medicinal purposes.
23 Nonresident wholesale drug distributors registered with the
24 appropriate agency, in the state in which they are domiciled,
25 and operating in compliance with Prescription Drug Marketing
26 Act standards, shall be allowed to do business in this state.
27 No permit shall be required of any physician licensed to

1 practice medicine for any act or conduct related to or
2 connected with his or her professional practice.

3 "~~(17)~~ (19) PERSON. Any individual, partnership,
4 corporation, association, trust, or other entity.

5 "~~(18)~~ (20) PHARMACIST. Any person licensed by the
6 board to practice the profession of pharmacy as a health care
7 provider in the State of Alabama and whose license is in good
8 standing.

9 "~~(19)~~ (21) PHARMACY. A place licensed by the board in
10 which prescriptions, drugs, medicines, medical devices,
11 chemicals, and poisons are sold, offered for sale, compounded,
12 or dispensed, and shall include all places whose title may
13 imply the sale, offering for sale, compounding, or dispensing
14 of prescriptions, drugs, medicines, chemicals, or poisons.

15 "~~(20)~~ (22) PHARMACY SERVICES PERMIT. Certain services
16 performed by a pharmacy, as defined by board rule, and
17 specifically excluding, the receipt or inventory of drugs,
18 medicines, chemicals, poisons, or medical devices.

19 "a. This subdivision, and any rule promulgated by
20 the board pursuant to this subdivision, may not be interpreted
21 to expand the practice of pharmacy as the practice of pharmacy
22 and permits are limited by this section and Sections 34-23-11
23 and 34-23-70, or to restrict the practice of medicine as
24 defined in Section 34-24-50.

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

1 "c. This subdivision shall not be interpreted to
2 allow the board to promulgate any rule that would authorize a
3 pharmacist to sell, offer for sale, or dispense any
4 prescription drug except pursuant to the terms of a valid
5 prescription issued by a licensed practitioner authorized to
6 prescribe such drug.

7 "~~(21)~~ (23) POISON. Any substance other than
8 agricultural products and pesticides which when applied to,
9 introduced into, or developed within the body in relatively
10 small quantities by its inherent chemical action uniformly
11 produces serious bodily injury, disease, or death.

12 "~~(22)~~ (24) PRECEPTOR. A person who is duly licensed
13 to practice pharmacy in the state and meets the requirements
14 as established by the board.

15 "~~(23)~~ (25) PRESCRIPTION. Any order for drug or
16 medical supplies, written or signed or transmitted by word of
17 mouth, telephone, telegraph, closed circuit television, or
18 other means of communication by a legally competent
19 practitioner, licensed by law to prescribe and administer such
20 drugs and medical supplies intended to be filled, compounded,
21 or dispensed by a pharmacist.

22 "~~(24)~~ (26) PRIVATE LABEL DISTRIBUTOR. A firm that
23 does not participate in the manufacture or processing of a
24 drug but instead markets and distributes under its own trade
25 name, and labels a drug product made by someone else. A
26 private label distributor is responsible for the products it
27 introduces into interstate commerce and for compliance with

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

3 "~~(25)~~ (27) PROFESSIONAL DEGREE. A degree in pharmacy
4 requiring a minimum of five academic years.

5 "~~(26)~~ (28) REPACKAGER. A person who purchases or
6 acquires from a manufacturer or distributor, a drug, medicine,
7 chemical, or poison for the purpose of bottling, labeling, or
8 otherwise repackaging for sale or distribution. This
9 definition shall not apply to a physician licensed to practice
10 medicine who as a part of his or her professional practice
11 dispenses, administers, sells, or otherwise distributes any
12 drug to a patient.

13 "~~(27)~~ (29) SALE. Barter, exchange, or gift, or offer
14 of barter, exchange, or gift, and shall include each
15 transaction made by any person, whether a principal,
16 proprietor, agent, servant, or employee.

17 "~~(28)~~ (30) THIRD-PARTY LOGISTICS PROVIDER. An entity
18 that provides or coordinates warehousing or other logistics
19 services of a product in interstate commerce on behalf of a
20 manufacturer, wholesale distributor, or dispenser of a
21 product, that does not take ownership of the product, nor have
22 responsibility to direct the sale or disposition of the
23 product.

24 "~~(29)~~ (31) WHOLESALE DRUG DISTRIBUTORS. A person,
25 other than a manufacturer, the co-licensed partner of a
26 manufacturer, a third-party logistics provider, or repackager,
27 engaged in the business of distributing drugs and medicines

1 for resale to pharmacies, hospitals, practitioners, government
2 agencies, or other lawful outlets permitted to sell drugs or
3 medicines. The sale, purchase, or trade of a drug by a retail
4 pharmacy to another retail pharmacy or practitioner, for
5 relief of temporary shortages, is exempt from this definition.
6 Also exempt from this definition shall be all of the
7 following:

8 "a. Intracompany sales.

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

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

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

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

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

19 34-23-8.1

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

25 (b) A licensed pharmacist in this state shall be
26 permitted to select for the brand name biological product
27 prescribed by a licensed physician or other practitioner who

1 is located in this state and authorized by law to write
2 prescriptions, hereinafter referred to as "practitioner," a
3 less expensive interchangeable biological product in all cases
4 where the practitioner expressly authorizes the selection in
5 accordance with subsection (d).

6 (c) A licensed pharmacist located in this state
7 shall be permitted to select for the brand name biological
8 product prescribed by a practitioner who is located in another
9 state or licensing jurisdiction and who is authorized by the
10 laws of that state or jurisdiction to write prescriptions, a
11 less expensive interchangeable biological product, in all
12 cases where the out-of-state licensed physician or other
13 practitioner does not expressly prohibit a substitution.

14 (d) (1) Every written prescription for a biological
15 product issued in this state by a licensed practitioner shall
16 contain two signature lines. Under one signature line shall be
17 printed clearly the words "dispense as written." Under the
18 other signature line shall be printed clearly the words
19 "product selection permitted." The practitioner shall
20 communicate instructions to the pharmacist by signing on the
21 appropriate line.

22 (2) An oral or electronic prescription from the
23 practitioner for a biological product shall instruct the
24 pharmacist whether or not a less expensive interchangeable
25 biological product may be dispensed. The pharmacist shall note
26 instructions on the file copy of the prescription and retain
27 the prescription form for the period specified by law.

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

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

8 (g) (1) Within 24 hours, a pharmacist who dispenses a
9 different biological product than that ordered or prescribed
10 shall inform the prescribing physician that a different
11 biological product was substituted for the biological product
12 prescribed and provide the name and manufacturer of the
13 biological product dispensed. The notice to the prescribing
14 physician or other practitioner shall be by the exact means
15 used by the prescribing physician or other practitioner.
16 However, if this is not available, notice may be accomplished
17 by any of the following:

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

21 b. Telephone.

22 c. Facsimile.

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

1 (h) A pharmacist shall record on the prescription
2 form the name and manufacturer or distributor of any drug
3 product, or the name and manufacturer of any biological
4 product, dispensed as authorized in this section.

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

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

19 (k) The board may maintain a link on its website to
20 the current list of all biological products that the federal
21 Food and Drug Administration has licensed and meets the
22 standards for "interchangeability" pursuant to 42 U.S.C.
23 §262(k).

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

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

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