HB61

189067-1

By Representative Beech

RFD: Boards, Agencies and Commissions

First Read: 09-JAN-18

PFD: 01/04/2018

189067-1:n:12/06/2017:KMS/th LSA2017-3668

SYNOPSIS: Under existing law, the Alabama State Board of Pharmacy is responsible for regulating the practice of pharmacy and the management and operation of pharmacies in the state.

This bill would require outsourcing facilities to annually register with the board by application for a permit.

A BILL

TO BE ENTITLED

AN ACT

To amend Sections 34-23-1 and 34-23-32, as last amended by Act 2017-422, 2017 Regular Session, relating to the Alabama State Board of Pharmacy; to require outsourcing facilities to annually register with the board by application for a permit.

BE IT ENACTED BY THE LEGISLATURE OF ALABAMA:

Section 1. Sections 34-23-1 and 34-23-32, as last amended by Act 2017-422, 2017 Regular Session, 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) BOARD or STATE BOARD. The Alabama State Board of Pharmacy.

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

"(7) 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.

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

"(12) 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) 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) 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.

"~~(14)~~ (15) 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.

"~~(15)~~ (16) 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.

"~~(16)~~ (17) PERSON. Any individual, partnership, corporation, association, trust, or other entity.

"~~(17)~~ (18) 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.

"~~(18)~~ (19) 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.

"~~(19)~~ (20) 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.

"~~(20)~~ (21) 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)~~ (22) PRECEPTOR. A person who is duly licensed to practice pharmacy in the state and meets the requirements as established by the board.

"~~(22)~~ (23) 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)~~ (24) 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.

"~~(24)~~ (25) PROFESSIONAL DEGREE. A degree in pharmacy requiring a minimum of five academic years.

"~~(25)~~ (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.

"~~(26)~~(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.

"~~(27)~~(28) 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.

"~~(28)~~(29) WHOLESALE DRUG DISTRIBUTORS. A person, other than a manufacturer, the colicensed 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.

"§34-23-32.

"(a) Commencing on August 1, 2017, every manufacturer, bottler, packager, repackager, third party logistic provider, wholesale drug distributor, private label distributor, outsourcing facility, or pharmacy business identified in the supply chain of drugs, medicines, chemicals, or poisons for medicinal purposes shall register annually with the board by application for a permit on a form furnished by the board and accompanied by a fee to be determined by the board as follows:

"(1) The fee shall not be less than five hundred dollars ($500) nor more than two thousand dollars ($2,000) for a new establishment.

"(2) The fee shall not be less than two hundred fifty dollars ($250) nor more than one thousand dollars ($1,000) for a renewal permit.

"(3) The fee shall not be less than five hundred dollars ($500) nor more than two thousand dollars ($2,000) for a permit due to transfer of ownership.

"(b) A holder of a permit shall employ a full-time licensed pharmacist whose principal duty shall be confined to

on-premise pharmaceutical operations. Wholesale drug distributors, who strictly limit their operation to distribution of drugs, medicines, chemicals, or poisons for medicinal purposes are exempt from the requirement to employ a full-time licensed pharmacist.

"(c) The professional practice of any physician licensed to practice medicine is exempt from the requirements of this section.

"(d) All permits issued under this section shall become due on October 31 and shall become null and void if not paid by December 31. Each application for the renewal of the permit shall be made annually on or before December 31. A penalty of one hundred dollars ($100) for each overdue month shall be assessed in addition to the permit fee for renewal of delinquent permits. For each application for a permit made and found to be satisfactory by the board, the secretary of the board shall issue to the applicant a permit for such ~~manufacturing or wholesale establishment~~ appropriate function, which permit shall be displayed in a conspicuous place.

"(e) All holders of a permit shall, before shipping any drug bearing the legend, "caution, federal law prohibits dispensing without prescription" or similar wording causing these drugs to be known as legend drugs to new customers, assure themselves that the recipient is either a duly licensed doctor of medicine, dentistry, or veterinary medicine or holds a registered pharmacy permit from the board by contacting the office of the board.

"(f) No manufacturer, manufacturer affiliate, bottler, packager, repackager, third party logistic provider, wholesale drug distributor, private label distributor, outsourcing facility, or pharmacy business identified in the supply chain of any legend drug or device shall ship, or cause to be shipped, into the state any legend drug or device without a valid permit issued by the board. The civil penalty for a violation of this subsection shall be four thousand dollars ($4,000) for each violation.

"(g) The holder of a permit to ship any legend drug or device into the state shall provide to the board a list of all trading partners, upon request of the board.

"(h) No holder of a permit shall ship any legend drug to any person or firm after receiving written notice from the board that the person or firm no longer holds a registered pharmacy permit. Any person violating this section shall be guilty of a misdemeanor."

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.