HB170

181894-4

By Representative Beech

RFD: Health

First Read: 09-FEB-17

ENGROSSED

A BILL

TO BE ENTITLED

AN ACT

Relating to the Alabama State Board of Pharmacy; to amend Sections 20-2-90, 20-2-190, 34-23-1, 34-23-3, 34-23-9, 34-23-30, 34-23-32, 34-23-32.1, 34-23-33, 34-23-70, 34-23-92, 34-23-131, 34-23-159, and 34-23-160, Code of Alabama 1975, to rename board drug inspectors as drug investigators; to clarify the status of a pharmacist as a health care provider; to list the qualifications a laboratory must satisfy for the board to use its product analysis data; to increase the maximum fee for certain new pharmacy permit, permit renewal, and permit transfer applications; to specify fee ranges the board may charge for certain out-of-state pharmacy permit and permit renewal applications; to increase the frequency of registration for certain drug supply chain entities from biennially to annually; to require packagers, third party logistic providers, private label distributors, and other pharmacy businesses identified in the drug supply chain to register annually; to increase the fee range for a permit due to transfer of ownership; to prohibit any entity identified within a drug supply chain from shipping a legend drug or device into the state without a valid permit and to provide a

civil penalty for each violation; to require each holder of a permit to ship a legend drug or device into the state, upon request of the board, to provide a list of all trading partners; to authorize the board to discipline any pharmacist who obtains registration from the board by fraudulent means; to provide further for the initial and renewal registration and continuing education requirements of pharmacy technicians; and to add Section 34-23-32.2 to the Code of Alabama 1975, to authorize the board to permit any manufacturer, manufacturer affiliate, bottler, packager, repackager, third party logistic provider, wholesale drug distributor, private label distributor, or pharmacy business identified in the supply chain of any drugs, legend drugs, medicines, chemicals, or poisons for medicinal purposes and to clarify adherence to requirements established by the FDA Guidelines in the Drug Quality and Security Act.

BE IT ENACTED BY THE LEGISLATURE OF ALABAMA:

Section 1. Sections 20-2-90, 20-2-190, 34-23-1, 34-23-3, 34-23-9, 34-23-30, 34-23-32, 34-23-32.1, 34-23-33, 34-23-70, 34-23-92, 34-23-131, 34-23-159, ~~34-23-160, and 34-23-162~~ and 34-23-160 of the Code of Alabama 1975, are amended to read as follows:

"§20-2-90.

"(a) The State Board of Pharmacy and its drug ~~inspectors~~ investigators shall enforce ~~all provisions of~~ this chapter. The agents and officers of this Alabama State Law Enforcement Agency, the drug and narcotic agents and

inspectors of the State Board of Health, the investigators of the State Board of Medical Examiners, the investigators of the Board of Dental Examiners, and all peace officers of the state and all prosecuting attorneys are also charged with the enforcement of this chapter. The agents and officers of the Alabama State Law Enforcement Agency, the drug ~~inspectors~~ investigators of the State Board of Pharmacy, the investigators of the State Board of Medical Examiners, the investigators of the Board of Dental Examiners, and the drug and narcotic agents and inspectors of the State Board of Health shall have the powers of peace officers in the performance of their duties to:

"(1) Make arrests without warrant for any offense under this chapter committed in their presence, or if they have probable cause to believe that the person to be arrested has committed or is committing a violation of this chapter which may constitute a felony.

"(2) Make seizures of property pursuant to this chapter.

"(3) Carry firearms in the performance of their official duties.

"(b) In addition to the requirements of subsection (a), drug ~~inspectors~~ investigators of the State Board of Pharmacy shall, beginning October 1, 1993, meet the minimum standards required of peace officers in this state.

"§20-2-190.

"(a) Any person who manufactures, sells, transfers, receives, or possesses a listed precursor chemical violates this article if the person:

"(1) Knowingly fails to comply with the reporting requirements of this article;

"(2) Knowingly makes a false statement in a report or record required by this article or the rules adopted thereunder;

"(3) Is required by this article to have a listed precursor chemical license or permit, and is a person as defined by this article, and knowingly or deliberately fails to obtain such a license or permit. An offense under this subsection shall constitute a Class C felony.

"(b) Notwithstanding the provisions of Section 20-2-188, a person who possesses, sells, transfers, or otherwise furnishes or attempts to solicit another or conspires to possess, sell, transfer, or otherwise furnish a listed precursor chemical or a product containing a precursor chemical or ephedrine or pseudoephedrine, their salts or optical isomers, or salts of optical isomers commits an offense if the person possesses, sells, transfers, or furnishes the substance with the knowledge or intent that the substance will be used in the unlawful manufacture of a controlled substance. An offense under this subsection shall constitute a Class B felony.

"(c)(1) It shall be unlawful for any person, business, or entity to knowingly sell any ephedrine or

pseudoephedrine, their salts or optical isomers, or salts of optical isomers unless sold from a pharmacy licensed by the Alabama Board of Pharmacy. Any ephedrine or pseudoephedrine, their salts or optical isomers, or salts of optical isomers sold within a pharmacy must be sold by an individual licensed as a pharmacist, a pharmacy technician licensed by the Alabama Board of Pharmacy, or by an employee of the pharmacy under the direct supervision and control of a licensed pharmacist.

"(2) Products whose sole active ingredient is ephedrine or pseudoephedrine in strength of 30 mg. or more per tablet cannot be offered for retail sale loose in bottles, but must be sold only in blister packages.

"(3) All packages of tablets containing ephedrine or pseudoephedrine shall be stored by a pharmacy by placing the products behind a counter, within the pharmacy where the public is not permitted.

"(4) No person shall deliver, sell, or purchase products sold over-the-counter that contain a combined total of more than 3.6 grams per calendar day or more than 7.5 grams per 30 days, of ephedrine base or pseudoephedrine base. It shall not be a defense under this subdivision if no money was exchanged during a transaction that would otherwise be unlawful under this subdivision.

"(5)a. Each pharmacy selling an over-the-counter product in compliance with paragraph b. of this subdivision shall require the purchaser of the product or products to be at least 18 years of age, to provide a valid, unsuspended

driver's license or nondriver identification card issued by this state, a valid, unsuspended driver's license or nondriver identification card issued by another state, a United States Uniformed Services Privilege and Identification Card, or a United States or foreign passport, and to sign a record of each transaction. A record of each transaction shall include the magnetic transfer or electronic entry of information data from the identification card into the system, as well as the type of identification card used, including the number, name, date of birth, and current, valid address of the purchaser, the date and time of the sale, the name of the product being sold, as well as the total quantity in grams, of ephedrine or pseudoephedrine being sold. The system required pursuant to this section shall be available to the state and to pharmacies accessing the system without cost. Effective January 1, 2011, provided a system is available to the state without cost to the state or pharmacies for accessing the system, before completing a sale of a product covered by this section, a pharmacy shall submit the required information to the electronic sales tracking system established under subdivision (1) of subsection (i). The seller shall not complete the sale if the system generates a stop sale alert except when the seller follows the procedure described under subsection (i) for overriding the stop sale alert when the seller has fear of bodily harm. Any seller who fails to comply with this subdivision shall be guilty of a Class A misdemeanor upon a first offense, and a Class C felony on a second or subsequent

offense, except that sellers who exercise the override feature described under subdivision (3) of subsection (i) when a stop sale alert is generated shall not be subject to misdemeanor or felony charges. Absent negligence, wantonness, recklessness, or deliberate misconduct, any retailer maintaining the electronic sales tracking system in accordance with this subdivision shall not be civilly liable as a result of any act or omission in carrying out the duties required by this subsection and shall be immune from liability to any third party unless the retailer has violated any provision of this subsection in relation to a claim brought for such violation. Any excessive or suspicious sales of such a product by any wholesaler, manufacturer, or repackager as defined in Section 34-23-1 shall be reported to the Alcohol Beverage Control Board and the Board of Pharmacy. Any person who fails to comply with this subdivision shall be guilty of a Class A misdemeanor upon a first offense, and a Class C felony upon a second or subsequent offense.

"b. If a pharmacy selling an over-the-counter product in compliance with subdivision (3) experiences mechanical or electronic failure of the electronic sales tracking system and is unable to comply with paragraph a. of this subdivision, the pharmacy shall maintain a written log or an alternative electronic recordkeeping mechanism that complies with all identification and documentation requirements of Act 2012-237, until the pharmacy is able to comply with paragraph a. of this subdivision.

"(6) This subsection does not apply to products dispensed pursuant to a legitimate prescription.

"(7) This subsection shall preempt all local ordinances or regulations governing the sale or purchase of products containing ephedrine or pseudoephedrine.

"(8) A pharmacist who is the general owner or operator of an establishment where ephedrine or pseudoephedrine products are available for sale shall not be penalized pursuant to this section for conduct of an employee if the retailer documents that an employee training program was conducted by or approved by the Alabama Drug Abuse Task Force (ADATF), pursuant to subsection (h). As provided in subsection (h), the Alabama Board of Pharmacy shall develop or approve all training programs for those pharmacy employees referenced in subdivision (1) and submit such programs to the ADATF for approval. The ADATF must review any training programs submitted by the Alabama Board of Pharmacy at its next subsequent called or scheduled public meeting and within 7 days, report its decision in writing to the Alabama Board of Pharmacy.

"(9) A violation of subdivision (1), (2), (3), or (4) shall constitute a Class A misdemeanor on a first offense and a Class C felony on subsequent offenses. The violations shall be punishable as provided by law.

"(d) Any person who resides within any state that requires a prescription for any purchase of ephedrine or pseudoephedrine, their salts or optical isomers, or salts of

optical isomers, or who presents a valid identification as provided in subdivision (5) of subsection (c) from any state that requires a prescription for any purchase of ephedrine or pseudoephedrine, their salts or optical isomers, or salts of optical isomers, may purchase those products only upon presentation of a valid prescription for the ephedrine or pseudoephedrine, their salts or optical isomers, or salts of optical isomers. The electronic system established in Act 2012-237 shall generate a stop sale and block any purchase in violation of this subsection, absent a valid lawful prescription.

"(e) Beginning October 1, 2005, any wholesaler, manufacturer, or repackager of drug products as defined in Section 34-23-1, other than a wholesaler, manufacturer, or repackager licensed by the Board of Pharmacy, shall obtain a registration annually from the Alcoholic Beverage Control Board which may promulgate and implement administrative rules for the registrations. Beginning October 1, 2010, any wholesaler, manufacturer, or repackager shall keep complete records of all sales and transactions involving a listed precursor chemical or a product containing a precursor chemical including the names of all parties involved in the transaction, the name of the products being sold, as well as the total quantity in grams, of the precursor chemical or product involved. Any wholesaler, manufacturer, or repackager selling a listed precursor chemical or product to an individual shall require the purchaser of the product or

products to be at least 18 years of age and to provide government-issued photographic identification of himself or herself. The records shall be maintained for at least 36 months and the records shall be available for inspection by any law enforcement officer or ~~inspector~~ investigator of the Board of Pharmacy during normal business hours. Failure to comply with subsection (d) and this subsection shall be a Class A misdemeanor for a first offense and a Class C felony for a second or subsequent offense.

"(f) Beginning October 1, 2005, every retailer of ephedrine or pseudoephedrine, or a product containing ephedrine or pseudoephedrine, is required to be registered with the Alcoholic Beverage Control Board to lawfully sell ephedrine or pseudoephedrine products to consumers.

"(g) In addition to any other penalty that may be provided, a sale of ephedrine or pseudoephedrine by a wholesaler, manufacturer, repackager, or retailer without a license as required by ~~subsection~~ subsections (e) and (f) is a Class A misdemeanor for a first offense and a Class C felony for a second or subsequent offense. In addition to any other penalty that may be provided, a sale of ephedrine or pseudoephedrine in violation of this section by a wholesaler, manufacturer, repackager, or retailer who is licensed as required by subsection (e) or (f) shall result in cancellation of the required registration and forfeiture of the right to sell the products for at least two years or longer as determined by the Alcoholic Beverage Control Board.

"(h)(1) The Alabama Drug Abuse Task Force (ADATF) is established and given the authority to do all of the following:

"a. Approve or develop drug awareness, enforcement, education, prevention, and training programs. The programs shall be designed to curb the abuse of all dangerous, illegal, or abused drugs, including but not limited to, methamphetamine precursors, other key, critical, common ingredients used to make methamphetamine, or other illegal or abused drugs in the State of Alabama. These programs may be targeted for, but not limited to, employees of establishments where ephedrine or pseudoephedrine products or other key or critical or common ingredients in the illegal manufacture of methamphetamine or other illegal or dangerous drugs are available for sale. Education, prevention, and training programs also may be targeted to law enforcement, prosecutors, the judiciary, students, or that may further serve to protect, educate, and inform the public. The programs may be administered by the Alcoholic Beverage Control Board in conjunction with its program to restrict access to tobacco products by minors pursuant to Chapter 11, Title 28. The programs may be further administered by any law enforcement drug abuse and violent crime task force, the Alabama Department of Education, a licensed private drug education or prevention entity approved by the ADATF, or any other governmental or quasi-governmental agency or entity partnering with the ADATF to serve the purposes of this article. The Alabama Department of Public

Health, ADATF, and the Alabama State Board of Education, shall enter into a memorandum of understanding to develop and implement the training, education, or prevention programs referenced in this section, and are authorized to expend any funds necessary to further the requirements and objectives of the ADATF and this subsection or any other legitimate drug abuse prevention or law enforcement purpose for the protection of the citizens of this state.

"b. Advise the ABC Board, the Alabama Board of Pharmacy, Alabama law enforcement, prosecutorial entities, or other governmental or quasi-governmental agency or entity partnering with the ADATF regarding its responsibilities prescribed in this article.

"c. Report to the Legislature by the 10th day of each legislative session, on the state of illegal drug abuse, trends in the use, distribution, and manufacture of illegal or synthetic drugs, and the use and misuse of related precursors in Alabama. The ADATF may only gather such information from legitimately verifiable sources or in a public forum. The report may include recommendations with regard to public policy, potential legislation, allocation of resources, or other recommendations which may aid in the curbing of drug abuse and drug crime or would best serve the safety and well being of the state. The report may include, but is not limited to, all of the following:

"1. Statistical data involving drug abuse, drug crime, or drug related crime.

"2. Efforts within the state involving education, prevention, and treatment of drug addiction.

"3. Critical needs of law enforcement.

"4. Organized crime efforts in the area of drug distribution, trafficking, manufacturing, or related criminal activity.

"5. Critical needs for prisons.

"6. Prosecution entities and the courts.

"7. Other critical threat assessments involving the safety of the State of Alabama.

"(2) The task force shall consist of the following members:

"a. The Attorney General, or his or her designee.

"b. The President of the Alabama State Board of Pharmacy, or his or her designee.

"c. A representative appointed by the District Attorney's Association.

"d. A member of a regional county drug task force as appointed by the District Attorney's Association.

"e. The ~~Director~~ Secretary of the ~~Department of Public Safety~~ Alabama State Law Enforcement Agency, or his or her designee.

"f. A representative appointed by the Chiefs of Police Association.

"g. A member of a regional county drug task force as appointed by the Chiefs of Police Association.

"h. A representative appointed by the Sheriff's Association.

"i. A representative appointed by the Narcotics Officers Association.

"j. A representative of the Alabama Association of Pharmacists.

"k. The Director ~~to~~ of the Alabama Department of Revenue, or his or her designee.

"l. A member or director of the Alabama Sentencing Commission.

"m. The Chair of the Alabama Assistant District Attorneys Association.

"n. The Director of the Alabama Department of Human Resources, or his or her designee.

"o. A representative of the Alabama Retail Association.

"p. A representative of the Alabama Administrative Office of Courts.

"q. The Commissioner of the Alabama Department of Corrections, or his or her designee.

"r. The State Superintendent of Education, or his or her designee.

"s. A representative of the Commission of Environmental Management.

"t. The Director of the Alabama Department of Forensic Sciences, or his or her designee.

"u. The State Health Officer, or his or her designee.

"~~v. The Director of the Alabama Department of Homeland Security, or his or her designee.~~

"~~w~~v. A representative of the mental illness and substance abuse services of the Alabama Department of Mental Health.

"~~x~~w. The Director of the Office of Prosecution Services, or his or her designee.

"~~y~~x. A representative of the State Bureau of Investigations.

"~~z~~y. A representative of the Board of Dental Examiners.

"~~aa~~z. A representative of the Alcoholic Beverage Control Board.

"(3) The membership shall select a chair on a bi-annual basis.

"(4) The membership of the task force shall be inclusive and reflect the racial, gender, geographic, urban/rural, and economic diversity of the state.

"(5) The chair of the task force shall be responsible for the conduct of the meetings and any correspondence or reports derived therefrom.

"(6) The chair of the task force shall call an organizational meeting of the task force within 60 days of July 1, 2010, and the task force shall report its meeting schedule and procedural rules to the Clerk of the House of

Representatives and the Secretary of the Senate within 10 days of the meeting. The task force shall instruct the State Bureau of Investigations regarding the creation of a drug abuse information system, as well as a drug offender tracking system pursuant to Section 20-2-190.2, to further the mission of the task force and assist law enforcement in the prevention of illegal drug activity. This system shall include, but not be limited to, data regarding illegal drug manufacture, trafficking, distribution, and usage trends across the state. This information shall be made available and be in a form and method which will enable the task force to have an accurate and detailed understanding of the nature of drug abuse and the geographical impact of the various abused drugs in Alabama.

"(7) The task force may expend any funds from any source, including, but not limited to, donations, grants, and appropriations of public funds received for purposes of this subsection.

"(8) No function or duties of the Drug Abuse Task Force shall be the responsibility or under the purview of the Governor of Alabama.

"(9) The task force shall not be obligated to fund the development of programs described in subdivision (1) unless the Legislature appropriates funding to the task force for this purpose.

"(10)a. A subcommittee shall be created within the task force to study the availability of ephedrine and ephedrine products. Members of the subcommittee shall include:

"1. The Attorney General.

"2. A member of the Legislature appointed by the Speaker of the House of Representatives.

"3. A member of the Legislature appointed by the President Pro Tempore of the Senate.

"4. A district attorney, or his or her designee, appointed by the Alabama District Attorneys Association, from a jurisdiction with a significant and statistically verifiable number of methamphetamine laboratory seizures.

"5. A sheriff appointed by the Alabama Sheriff's Association, from a jurisdiction with a significant and statistically verifiable number of methamphetamine laboratory seizures.

"6. A chief of police appointed by the Alabama Chiefs of Police Association, from a jurisdiction with a significant and statistically verifiable number of methamphetamine laboratory seizures.

"7. The Director of the Alabama Department of Forensic Sciences, or his or her designee.

"8. The ~~Chairman~~ Chair of the Alabama Drug Abuse Task Force.

"b. On the tenth day of the next regular session of the Legislature, the subcommittee of the task force shall report to the ADATF and the Legislature a full and detailed assessment of all efforts to limit or ultimately eliminate the availability of ephedrine or ephedrine products to persons with the intent to use them for manufacturing methamphetamine.

"c. The subcommittee of the task force shall evaluate and report the effectiveness of the electronic drug offender tracking system created in Section 20-2-190.2, as well as statutory provisions to track or block any illegal or inappropriate sales of ephedrine products. This evaluation and report shall include consideration of criminal statutes regarding the trafficking and manufacture of methamphetamine, industry efforts to prevent improper usage of ephedrine products, as well as other pertinent laws. Where possible, the task force shall also endeavor to project future capabilities to sustain or improve efforts to limit illegal access to ephedrine products for purposes of manufacturing methamphetamine.

"d. The subcommittee of the task force, in its effort to provide a complete and accurate report, may utilize, but is not limited to, the use of the following resources:

"1. Reports from any governmental or quasi-governmental entity.

"2. Statistical data or reports from State Bureau of Investigations, National Precursor Log Exchange, Alabama Fusion Center, Drug Enforcement Administration, or any entity that has membership on the task force.

"3. Other appropriate law enforcement, drug treatment, drug prevention, or medical entities that gather verifiable data regarding drug usage, abuse, or any drug crime or drug related crime.

"4. Relevant public hearings by the ADATF.

"5. Anecdotal information from named and legitimately verifiable sources.

"6. All data or information must be sourced and verifiable.

"e.1. Any report of the ADATF subcommittee to any governmental entity shall first be submitted to the Alabama Department of Public Health. The department shall evaluate the report. In its review, the department shall evaluate the quality and authenticity of the underlying sourced data. The department shall also determine if the data contained within the report is verifiable and if the ADATF or subcommittee of the task force followed generally accepted scientific or statistical methods in the compilation of the report.

"2. In making its determination, the department may consider, but is not limited to, evaluating any method, process, research, calculations, design, control, analysis, hypothesis, or program utilized in the report.

"3. In the event that the department determines that the proper methods were not followed, it shall notify the task force or subcommittee of the task force of any deficiencies in the report and allow the task force or subcommittee to revise the report to correct the deficiencies. Otherwise, the report shall contain a notation of the findings of any deficiencies by the department.

"(i)(1) The State Bureau of Investigations shall implement a real-time electronic sales tracking system to monitor the over-the-counter, nonprescription sale of products

in this state containing any detectable quantity of ephedrine or pseudoephedrine, their salts or optical isomers, or salts of optical isomers, provided that such system is available to the state without cost to the state or retailers for accessing the system. The electronic sales tracking system shall have the technological capability to receive ephedrine and pseudoephedrine sales data from retail establishments submitted pursuant to this subsection. The electronic sales tracking system shall be capable of bridging with existing and future operational systems used by retail at no cost to such retail establishment. The State Bureau of Investigations may enter into a public-private partnership, through a memorandum of understanding or similar arrangement, to make the system available to retailers and law enforcement in the state.

"(2) The information contained in this electronic sales tracking system shall be available to:

"a. Any law enforcement agency or entity as authorized by the State Bureau of Investigations;

"b. Pursuant to a subpoena.

"(3) This database established pursuant to this subsection shall be capable of generating a stop sale alert, which shall be a notification that completion of the sale would result in the seller or purchaser violating the quantity limits set forth in subdivision (4) of subsection (c). The system shall contain an override function for use by a dispenser of ephedrine or pseudoephedrine who has a reasonable

fear of imminent bodily harm. Each instance in which the override function is utilized shall be logged by the system.

"(j)(1) Upon conviction for any violation of Section 13A-12-260 or 20-2-190, or any violation of a controlled substance or illegal drug crime under Title 13A or this title and in addition to restitution and other costs that may be ordered pursuant to Section 15-18-67, the primary investigative law enforcement or prosecutorial entity shall be entitled, upon request of the district attorney and an order of the court, to recover restitution from any defendant for any legitimate cost incurred in the course of the investigation or prosecution.

"(2) Restitution may include, but shall not be limited to, any cost incurred by the primary investigative law enforcement entity of any hazardous material or environmental cleanup of substances related to the manufacture of a controlled substance.

"(3) Any real property owner that demonstrates to the court that he or she had no knowledge of, or had no reason to have knowledge of, any illegal manufacturing of controlled substances on his or her property by a defendant convicted of a violation of Section 13A-12-260 or 20-2-190, or any violation of a controlled substance or illegal drug crime under Title 13A or this title, through the district attorney, may request a court order requiring the defendant to pay to the real property owner all reasonable costs, if any, associated with any legitimate environmental cleanup or

remediation or repair of the real property where the defendant had committed a controlled substance crime.

"§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 their 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 ~~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) 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 ~~State Board of Pharmacy~~ 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, ~~compounds~~

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) 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) 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) PERSON. Any individual, partnership, corporation, association, trust, or other entity.

"(17) PHARMACIST. Any person licensed by the ~~Alabama State Board of Pharmacy~~ 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) 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) 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) 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) 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) 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) 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.

"~~(23)~~(24) PROFESSIONAL DEGREE. A degree in pharmacy requiring a minimum of five academic years.

"~~(24)~~(25) 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)~~(26) 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) 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.

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

"§34-23-3.

"Each state drug ~~inspector~~ investigator employed by the board following the passage of this chapter must furnish satisfactory proof to the board that he or she is a person of good moral character and that in the judgment of the members of the board he or she has sufficient knowledge of the laws pertaining to the practice of pharmacy and law enforcement to enable him or her to carry out his or her duties as an ~~inspector~~ investigator consistent with ~~the provisions of~~ this chapter. Each state drug ~~inspector~~ investigator employed by the board shall serve an apprenticeship of a minimum of six months working with and under the supervision of the Chief Drug ~~Inspector~~ Investigator or other ~~inspector~~ investigator designated by the board. Each such ~~inspector~~ investigator, before entering upon his or her duties, shall post with the ~~State Board of Pharmacy~~ board a bond in the amount of ~~$2,000~~ two thousand dollars ($2,000) conditioned upon the faithful performance of his or her duties. Each state drug ~~inspector~~ investigator shall have the power to inspect the medicines and drugs or drug products or domestic remedies which are manufactured, packaged, packed, made, sold, offered for sale, exposed for sale, or kept for sale in this state, and for this purpose shall have the right to enter and inspect during business hours any pharmacy or any other place in this state where medicines or drugs or drug products or proprietary

medicines are manufactured, packaged, packed, made, sold, offered for sale, or kept for sale, whether or not licensed by the ~~State Board of Pharmacy~~ board. Each state drug ~~inspector~~ investigator shall be subject to the same restrictions as other officers of the law in regard to search and seizure. They shall report to the board all violations of the laws relating to pharmacy and all rules and regulations of the board. As directed by the board, it shall be the duty of the state drug ~~inspectors~~ investigators to issue citations for violations of such laws, rules, or regulations or institute criminal proceedings against persons for such violations. When authorized by the board and where there are specific complaints, the state drug ~~inspector~~ investigator shall have the right to inspect all records, shipping tickets, or any other document pertaining to the transfer of drugs or drug preparations, from or to hospitals, pharmacists, wholesale establishments and manufacturers, or any other place or establishment where the preparations of drugs are kept or stored. They shall have the authority to inspect all prescription files, prescription record books, poison registers, exempt narcotic registers, and any other records pertaining to the filling and filing of prescriptions. It shall be the duty of the state drug ~~inspector~~ investigator to take possession of all revoked ~~and/or~~ licenses and permits or suspended licenses and permits, or both, when such licenses and permits are not surrendered voluntarily to the board by the person or pharmacist whose license or permit has been

revoked or suspended. Nothing in this chapter shall authorize or require the state drug ~~inspector~~ investigator or state drug ~~inspectors~~ investigators to inspect the offices of doctors of medicine who have duly qualified with the State Board of Medical Examiners.

"§34-23-9.

"No person shall compound or sell or offer for sale or cause to be compounded, sold, or offered for sale any medicine, drug, poison, chemical, or pharmaceutical preparation that is adulterated. Any one of the above-named substances shall be deemed to be adulterated if it is sold by a name recognized in the United States Pharmacopoeia or National Formulary and it differs from the standard of strength, quality, or purity as determined by the test laid down therein ~~unless the label so clearly states, or if its strength, quality, or purity shall fall below the professed standard of strength, quality, or purity under which it is sold. The board shall examine into any claimed adulteration by using the services of an analyst or chemist of recognized approved standing. Any person violating the provisions of this section shall be guilty of a misdemeanor~~. A product may be of a lesser strength only if the product is clearly labeled with the actual strength. The board may use product analysis data from any laboratory that satisfies all of the following qualifications:

"(1) Is registered by the Food and Drug Administration.

"(2) If the product is a legend controlled drug, is licensed by the Bureau of Narcotics and Dangerous Drugs.

"(3) Is ISO 17025 certified.

"§34-23-30.

"(a) Every pharmacy, hospital pharmacy, drugstore, pharmacy department, prescription department, prescription laboratory, dispensary, apothecary, or any other establishment with a title implying the sale, offering for sale, compounding, or dispensing of drugs in this state, or any person performing pharmacy services in this state, shall register biennially and receive a permit from the ~~Board of Pharmacy~~ board. Any person desiring to open, operate, maintain, or establish a pharmacy or perform pharmacy services in this state shall apply to the board for a permit at least 30 days prior to the opening of the business. No pharmacy or entity performing pharmacy services shall open for the transaction of business until it has been registered, inspected, and a permit issued by the board. The application for a permit shall be made on a form prescribed and furnished by the board which when properly executed shall indicate the ownership desiring such permit and the names and license numbers of all licensed pharmacists employed as well as the location of the pharmacy or entity where pharmacy services are performed and other information as the board may require. If more than one pharmacy or entity where pharmacy services are performed is operated by the same owner, a separate application for registration shall be made and a separate

permit issued for each such establishment. All permits issued under this section shall become due on October 31 and shall become null and void on December 31 of even-numbered years. Every application for a permit for a new pharmacy or entity where pharmacy services are performed shall be accompanied by a fee to be determined by the board, but the fee shall not be less than one hundred dollars ($100) nor more than two hundred dollars ($200) ~~three hundred dollars ($300)~~. Every application for a renewal permit shall be accompanied by a fee to be determined by the board, but the fee shall not be less than fifty dollars ($50) nor more than one hundred fifty dollars ($150) ~~two hundred fifty dollars ($250)~~. Every application for a permit due to transfer of ownership shall be accompanied by a fee to be determined by the board, but the fee shall not be less than one hundred fifty dollars ~~($50)~~ ($150) nor more than ~~one hundred fifty dollars ($150)~~ four hundred dollars ($400). Every application for a permit for an out-of-state pharmacy or entity where pharmacy services are performed shall be accompanied by a fee to be determined by the board, but the fee shall not be less than seven hundred fifty dollars ($750) nor more than two thousand dollars ($2,000). Every application for a renewal permit for an out-of-state pharmacy or entity where pharmacy services are performed shall be accompanied by a fee to be determined by the board, but the fee shall not be less than four hundred dollars ($400) nor more than seven hundred fifty dollars ($750). Each application for the renewal of a permit shall be made on or before October 31 of each

even-numbered year, at which time the previous permit shall become null and void on December 31 of even-numbered years. A penalty of twenty-five dollars ($25) for each overdue month shall be assessed in addition to the permit fee for renewal of delinquent permits. The secretary of the board shall issue a permit for each pharmacy or entity where pharmacy services are performed whose application is found to be satisfactory by the board. Permits issued under this section shall not be transferable. Any change in the control of ownership or licensed pharmacists shall be reported to the board in writing within 10 days of such occurrence. If the pharmacy or entity where pharmacy services are performed is owned by a corporation, the permit shall be issued in the name of the corporation. It shall be the duty of the owners of pharmacies or the owners of entities where pharmacy services are performed who are not licensed pharmacists to immediately notify the board upon the termination of employment of licensed pharmacists and to cause the surrender of permits as indicated. The further operation of the pharmacy or entity where pharmacy services are performed in the absence of licensed pharmacists is forbidden; provided, that the nonregistered owner shall have a period of 30 days within which to comply with this ~~provision~~ subsection. The next of kin of any deceased licensed pharmacist owner shall have a period of 30 days within which to comply with ~~the provisions of~~ this chapter, during which time no prescriptions shall be filled unless a licensed pharmacist is on duty. No mail order

pharmacy shall transact business in this state without a permit from the board.

"(b) Requirements for the grant of authority by the board to any person who offers or performs pharmacy services shall be by board rule.

"(c) Nothing contained in this section related to pharmacy services permits shall be interpreted to delegate to the board the authority to promulgate rules governing pharmacy benefit managers.

"~~(c)~~(d) Any person who violates this section shall be guilty of a misdemeanor.

"§34-23-32.

"(a) ~~Every~~ Commencing on the effective date of the act amending this subsection, every manufacturer, bottler, ~~packer~~ packager, repackager, third party logistic provider, ~~or~~ wholesale drug distributor, private label distributor, or pharmacy business identified in the supply chain of drugs, medicines, chemicals, or poisons for medicinal purposes shall register ~~biennially~~ 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 ~~two hundred fifty dollars ($250)~~ five hundred dollars ($500) nor more than ~~one thousand dollars ($1,000)~~ 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 ~~on~~ if not paid by December 31 ~~of even-numbered years~~. Each application for the renewal of the permit shall be made on or before December 31 ~~of even-numbered years~~. A penalty of ~~twenty-five dollars ($25)~~ 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, 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, 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.

"§34-23-32.1.

"Any requirements established by the FDA Guidelines, as required by the Federal Prescription Drug Marketing Act of 1987 (PDMA), as amended, specifically addressed in Sections 34-23-1 and 34-23-32, shall be adhered to by the affected parties.

"§34-23-33.

"(a) The board may revoke, suspend, place on probation, or require remediation for any licensed pharmacist or a holder of a pharmacy intern or extern certificate for a specified time as determined by the board and take the same or similar action against the permit to operate any pharmacy in this state, whenever the board finds by a preponderance of the evidence, or pursuant to a consent decree, that the pharmacist has been guilty of any of the following acts or offenses:

(1) Obtaining ~~the license to practice pharmacy or the permit to operate a pharmacy~~ a license, permit, or registration from the board by fraudulent means.

"(2) Violation of the laws regulating the sale or dispensing of narcotics, exempt narcotics, or drugs bearing the label "caution, federal law prohibits dispensing without prescription," or similar wording which causes the drugs to be classified as prescription legend drugs.

"(3) Conviction of a felony. A copy of the record of the conviction, certified by the clerk of the court entering the conviction, shall be conclusive evidence of the conviction.

"(4) Conviction of any crime or offense that reflects the inability of the practitioner to practice pharmacy with due regard for the health and safety of the patients.

"(5) Inability to practice pharmacy with reasonable skill and safety to patients by reason of illness, inebriation, misuse of drugs, narcotics, alcohol, chemicals, or any other substance, or as a result of any mental or physical condition.

"When the issue is whether or not a pharmacist is physically or mentally capable of practicing pharmacy with reasonable skill and safety to patients, then, upon a showing of probable cause to the board that the pharmacist is not capable of practicing pharmacy with reasonable skill and safety to patients, the board may require the pharmacist in question to submit to a psychological examination by a psychologist to determine psychological status or a physical examination by a physician, or both, to determine physical condition. The psychologist or physician, or both, shall be designated by the board. The expense of the examination shall be borne by the board. Where the pharmacist raises the issue of mental or physical competence or appeals a decision regarding his or her mental or physical competence, the pharmacist shall be permitted to obtain his or her own evaluation at the pharmacist's expense. If the objectivity or adequacy of the examination is suspect, the board may complete the examination by the designated practitioners at its own

expense. When mental or physical capacity to practice is at issue, every pharmacist licensed to practice pharmacy in the state shall be deemed to have given consent to submit to a mental or physical examination or to any combination of the examinations and to waive all objections to the admissibility of the examination, or to previously adjudicated evidence of mental incompetence.

"(6) Gross malpractice or repeated malpractice or gross negligence in the practice of pharmacy.

"(7) Violation of any provisions contained in this chapter.

"(8) Employing, assisting, or enabling in any manner any unlicensed person to practice pharmacy.

"(9) The suspension, revocation, or probation by another state of a license to practice pharmacy. A certified copy of the record of suspension, revocation, or probation of the state making such a suspension, revocation, or probation shall be conclusive evidence of the suspension, revocation, or probation.

"(10) Refusal to appear before the board after having been ordered to do so in writing by the executive officer or chair of the board.

"(11) Making any fraudulent or untrue statement to the board.

"(12) Violation of any rule or regulation of the board.

"(13) Violation of the code of professional conduct adopted by the board in the rules and regulations of the board.

"(b) The board shall have the authority to adopt rules imposing a non-disciplinary administrative penalty for designated violations of this chapter.

"§34-23-70.

"(a) Every pharmacy when opened for business shall be under the personal supervision of a duly licensed pharmacist who shall have personal supervision of not more than one pharmacy at the same time. During temporary absences of the licensed pharmacist, not to exceed three hours daily or more than one and one-half hours at any one time, nor more than one week for temporary illness, the prescription department shall be closed, and no prescriptions are to be filled. During the temporary absence of a pharmacist, a sign shall be placed on the prescription counter in a prominent location easily seen by the public stating, "Prescription Department Closed, No Pharmacist on Duty."

"(b) The permit issued to each pharmacist by the board and the licensure certificates issued to the licensed pharmacist employed by each pharmacy must be prominently and conspicuously displayed in the pharmacy. The name of the licensed pharmacist on duty must be conspicuously displayed in the prescription department in a place readily observable by the public.

"(c)(1) No licensed pharmacist or pharmacy operating within this state shall accept for refund purposes or otherwise any unused portion of any dispensed prescription.

"(2) The prohibition in subdivision (1) shall not apply to any unused or expired dispensed medication returned solely for the purpose of destruction in compliance with applicable law or rules of the board.

"(d) The sale of poisons is restricted to the immediate supervision of a licensed pharmacist, and such poison shall not be displayed in a pharmacy in such a manner that a customer may obtain possession of such poisons when standing in an area allocated for customer use. No sale of a poison shall be made or delivered to any minor under 12 years of age or to any person known to be of unsound mind or under the influence of alcohol.

"(e) No pharmacy shall authorize any person, firm, or business establishment to serve as a pick-up station or intermediary for the purpose of having prescriptions filled or delivered, whether for profit or gratuitously. Except with respect to controlled substances, the following federally qualified health care centers are expressly exempt from this subsection: Birmingham Health Care, Inc., Central Alabama Comprehensive Health, Inc., Health Services, Inc., Family Oriented Primary Health Care Clinic/Mobile County Health Department, Franklin Primary Health Center, Quality of Life Health Services, Inc., and Whatley Health Services, Inc. Each named federally qualified health center is authorized to fill

certain prescriptions at one location and deliver medications to clinics for patient pick-up subject to the review of the ~~Board of Pharmacy~~ board.

"(f) No prescription blank supplied by a pharmacy or pharmacist to a practitioner shall bear the imprint thereon of the name or address of any pharmacy or bear the name or address of any person registered under this chapter.

"(g)(1) No person shall fill or compound a prescription or drug order in an institution unless he or she is a duly licensed pharmacist or otherwise permitted to do so under ~~the provisions of~~ this chapter. The act of filling or compounding prescriptions or drug orders in an institution shall be as defined in the rules and regulations adopted by the ~~Board of Pharmacy~~ board.

"(2) However, such rules and regulations shall not apply to the reading, interpreting, and writing or verifying the writing of adequate directions as are necessary to assure patient's understanding of the prescriber's intentions by a duly qualified nurse practicing ~~her/his~~ his or her profession in a licensed hospital or similar institution.

"(h) Nothing in this chapter shall authorize the ~~Board of Pharmacy~~ board to promulgate or to enforce any rule or regulation which governs, regulates, or restricts the professional practice of a physician licensed to practice medicine in this state. No provision of this chapter, or any rule promulgated under the authority of this chapter, shall be

interpreted to amend, alter, or modify ~~the provisions of~~ Section 34-23-11.

"~~(h)~~(i) Only a licensed pharmacist or registered intern may accept an oral prescription of any nature. Upon so accepting such oral prescription, it must immediately be reduced to writing, and only a licensed pharmacist or an intern supervised by a licensed pharmacist may prepare a copy of a prescription or read a prescription to any person for purposes of providing reference concerning treatment of the person or animal for whom the prescription was written; and, when the copy is given, a notation shall be made upon the prescription that a copy has been given, the date given, and to whom given.

"~~(i)~~(j) If a prescription is refilled, a record of the date upon which the prescription is refilled must appear on the prescription or in a permanent prescription record book. On prescriptions which may be refilled, written or oral authorization must be received before refilling unless the number of refills is indicated on the original prescription. Those prescriptions marked "refill prn" or equivalent designation shall be refilled only in quantities commensurate with the dosage scheduled.

"~~(j)~~(k) Each prescription must be written in a manner so that it can be compounded by any registered pharmacist. The coding of any prescription is in violation of this chapter. No prescription shall be written in any characters, figures, or ciphers, other than in the English or

Latin language, generally in use among medical and pharmaceutical practitioners.

"~~(k)~~(l) A prescription file or files shall be kept by every pharmacy for a period of not less than two years in which the original of every prescription compounded or dispensed shall be filed in the order of compounding with number and date of dispensing placed on each prescription. Each pharmacy shall produce any prescription file whenever legally required to do so. Such prescription file shall at all times be open for inspection by the prescriber, the ~~Board of Pharmacy~~ board, or its ~~inspectors~~ investigators.

"~~(l)~~(m) All drugs or drug preparations bearing upon the package the words, "caution, federal law prohibits dispensing without prescription" or words to the same effect, otherwise known as ~~"~~legend drugs,~~"~~ shall be stored within the confines of the prescription department or the prescription department storage room of each pharmacy. Such drugs shall be sold or dispensed only on the prescription of a licensed practitioner authorized to prescribe such drugs and shall not be sold or dispensed as a refilled prescription except upon the express authorization of the prescriber. This shall not be construed to prohibit return to authorized suppliers or sale or transfer to others licensed to possess legend drugs.

"~~(m)~~(n) Any person who violates ~~any of the provisions of~~ this section shall be guilty of a misdemeanor.

"§34-23-92.

"The board shall exercise, subject to ~~the provisions of~~ this chapter, the following powers and duties:

"(1) To adopt rules concerning the records and reports to be kept and made by a pharmacy relating to the filling of prescriptions and the handling and preservation of drugs.

"(2) To fix standards and requirements for licenses and permits except as otherwise specified in this chapter.

"(3) To make rules and regulations regarding sanitation consistent with state health regulations.

"(4) To employ such chemists, agents, clerical help, and attorneys necessary for the proper administration of the duties of the board.

"(5) To employ a Chief Drug ~~Inspector~~ Investigator and such other drug ~~inspectors~~ investigators that it deems necessary to enforce ~~the provisions of~~ this chapter which are under the supervision of the board.

"(6) To adopt rules and regulations for the administration and enforcement of this chapter and not inconsistent herewith. Such rules and regulations shall be referenced to the section or sections of this chapter which set forth the legislative standard which it interprets or to which it applies. Every such rule and regulation shall be adopted in accordance with the Alabama Administrative Procedure Act. A copy of every rule and regulation containing a requirement of general application shall be electronically mailed to each registered pharmacist at least 10 days before

the effective date thereof. A printed copy of such rules and regulations shall be mailed to any registered pharmacist upon written request to the board.

"(7) To investigate violations of this chapter or any other law pertaining to the practice of pharmacy that may come to the knowledge of the board and institute or cause to be instituted before the board or in a proper court appropriate proceedings in connection therewith.

"(8) To issue subpoenas and compel the attendance of witnesses and the production of all necessary papers, books and records, documentary evidence and materials, or other evidence in matters pending before the board relating to the revocation, suspension, or probation of any license. Those persons issued subpoenas and compelled to attend hearings or meetings in matters pending before the ~~Board of Pharmacy~~ board shall be entitled to witness fees from ~~Board of Pharmacy~~ board funds. Claims for witness fees shall be made on accepted State of Alabama voucher forms as appropriate. Travel and mileage expenses shall be reimbursed to witnesses in the amounts officially authorized to the board and its personnel at the time the service to the ~~Board of Pharmacy~~ board is performed.

"(9) ~~The members of the board shall have the power and authority to~~ To administer oaths in connection with the duties of the board.

"(10) ~~The board shall~~ To make a written report annually of its receipts and disbursements to the Governor and to the State Pharmaceutical Association. Included in this

report shall be the names of all registrants licensed to practice under this chapter and a record of all permits issued during the period covered by the report.

"(11) ~~It shall be the duty of the board to~~ To enforce ~~the provisions of~~ the state barbiturate act, the state amphetamine act, the state narcotic law, and all other laws of the state which pertain to the practice of pharmacy, the examination of applicants, the licensing of pharmacists, the manufacture, packaging, repackaging, production, sale, or distribution of drugs, chemicals, and poisons, and all laws pertaining to standards for their strength and purity. The board may work in conjunction with other law enforcement agencies to enforce ~~the provisions of~~ any law pertaining to the practice of pharmacy. Nothing in this section shall be construed to deprive the State Board of Health of any powers or duties otherwise prescribed by law including the enforcement of the narcotic law.

"(12) ~~It shall be the duty of the board to~~ To investigate alleged violations of this chapter or any rule or regulation published by the board and conduct hearings to revoke, suspend, or probate any license or permit granted by the board under ~~the provisions of~~ this chapter and to invoke penalties not to exceed the sum of ~~$1,000~~ one thousand dollars ($1,000) for each ~~such violation(s)~~ violation and to institute any legal proceedings necessary to effect compliance with this chapter; provided, that any person, firm, or corporation

subjected to such penalty or legal proceedings may take an appeal in accordance with ~~the provisions of~~ Section 34-23-94.

"(13) On application of any person and payment of the cost therefor, the secretary of the board shall furnish, under its seal and signed by ~~him~~ the secretary, a certified copy of ~~his~~ the license or permit of the requestor, or a certified copy of a regulation or rule of the board. In any court or proceeding, such copy shall be prima facie evidence of the fact of the issuance of such permit or license and the adoption of such rule or regulation.

"(14) To acquire by gift, grant, purchase, condemnation, or otherwise, and to convey or hold title to, real property, together with all rights incidental thereto.

"§34-23-131.

"(a) A pharmacy technician shall not perform pharmacy functions or be present in the prescription department of a pharmacy unless he or she is under the direct supervision of a licensed pharmacist. A pharmacy technician shall not perform pharmacy functions or be present in the prescription department of a pharmacy unless he or she is registered by the board.

"(b) When supervision is required, a licensed pharmacist shall be jointly responsible and liable for the actions of a pharmacy technician.

"(c) A pharmacy technician shall register and pay a fee as determined by the board before performing any pharmacy functions. The board shall develop rules and regulations

relating to the registration of all pharmacy technicians. The registration of a pharmacy technician shall be renewable biennially in odd-numbered years upon payment of the required renewal fee. The registration of each pharmacy technician shall expire on December 31 of odd-numbered years. In order to continue to be licensed, each registered pharmacy technician shall pay a biennial renewal fee of not less than twenty dollars ($20), as determined by rule of the board, the fee being due on October 31 and delinquent after December 31 of odd-numbered years. The payment of the renewal fee shall entitle the pharmacy technician to renewal of his or her registration at the discretion of the board. If any pharmacy technician fails to pay the renewal fee as required by this subsection, he or she may be reinstated as a pharmacy technician only upon payment of a penalty of not less than ten dollars ($10) nor more than twenty dollars ($20), as determined by rule of the board, for each lapsed year and all lapsed fees for each lapsed year, provided the lapsed time of registration shall not exceed five years, in which case reinstatement may be had only upon satisfactory examination by the board.

"(d) In addition to any other registration requirements, a pharmacy technician shall complete three hours of continuing education annually, or six hours biennially, of which one hour per year shall be live presentation. The board may grant an extension to a pharmacy technician who fails to complete the required continuing education hours in the

allotted time. A pharmacy technician who fails to complete the annual continuing education requirements shall be subject to disciplinary action by the board.

"§34-23-159.

"A pharmacy may prepare a compounded drug product to be sold over the counter without a prescription order. The product shall not contain an ingredient which exceeds recommended strengths and doses for over the counter drugs. The finished product shall not be one for which a prescription is required. It shall be properly labeled with the product's name, directions for use, list of active ingredients, and any necessary warnings. A compounded product shall be sold directly to the ~~consumer~~ patient after professional interaction or consultation between the pharmacist and the ~~consumer~~ patient. The product may be prepared in advance in reasonable amounts in anticipation of estimated needs. The product shall be stored within the prescription department. The product may not be sold in bulk to other pharmacies or vendors for resale.

"§34-23-160.

"(a) A pharmacy may prepare a compounded drug product for a prescriber's office use. An order by a prescriber indicating the formula and quantity ordered shall be filed in the pharmacy. The product shall be administered in ~~the prescriber's office and shall not be dispensed to the consumerthe prescriber may not resell the product . A record~~ the prescriber's office and shall not be dispensed to the

~~consumer~~ patient. A record of the compounded drug product may be kept as a prescription record in the computer of the pharmacy. A label may be generated and a number assigned by the computer of the pharmacy for the compounded product. A record of the product's written procedure shall be on file in the pharmacy as provided in Section 34-23-156. A record of the product's sale to the prescriber shall remain on file at the pharmacy for not less than one year. The record shall contain the following information:

"(1) The name and address of the prescriber.

"(2) The date of sale.

"(3) A description and amount of the product sold.

"(b) The label on the compounded product shall include the following information:

"(1) The designated name and the strength of the finished product.

"(2) The quantity dispensed.

"(3) The date on which the product was compounded.

"(4) The beyond use date.

"(5) A lot or batch number.

"(6) Any other information the pharmacist deems necessary.

"(7) The name and address of the pharmacy.

"(c) The label ~~may not~~ shall include the phrase "For Office Use."

"§34-23-162.

~~"(a) The board shall promulgate such rules and regulations as are necessary for the implementation, administration, and enforcement of this article.~~

~~"(b) The board shall recognize and enforce the standards for sterile compounding, non-sterile compounding, and handling or compounding of hazardous products, and all other provisions of the United States Pharmacopoeia or National Formulary, as amended from time to time, relating to drug handling or compounding processes. Nothing in this section shall grant, or be construed to grant, any authority to the board over physicians or their agents or employees concerning sterile compounding, non-sterile compounding, and handling or compounding of hazardous products, and all other provisions of the United States Pharmacopeia-National Formulary, as amended from time to time, related to compounding processes."~~

Section 2. Section 34-23-32.2 is added to the Code of Alabama 1975, to read as follows:

§34-23-32.2.

Any requirements established by the FDA Guidelines in the Drug Quality and Security Act shall be adhered to by the affected parties. The board may permit any manufacturer, manufacturer affiliate, bottler, packager, repackager, third party logistic provider, wholesale drug distributor, private label distributor, or pharmacy business identified in the supply chain of any drugs, legend drugs, medicines, chemicals, or poisons for medicinal purposes. The board, by rule, shall

establish fees for permits issued under this section and fines for violations of this section. Proceeds received by the board from fees levied and fines collected pursuant to this section shall be used by the board to fund the costs of permitting, inspecting, and investigating any business permitted pursuant to this section.

Section 3. ~~All laws or parts of laws which conflict with this act are repealed. Specifically, Sections 34-23-152, 34-23-153, 34-23-154, 34-23-155, 34-23-156, and 34-23-157, Code of Alabama 1975, relating to the compounding of drugs, are repealed.~~

Section 4. 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.

House of Representatives

Read for the first time and referred to the House of Representatives committee on Health	.....	09-FEB-17
Read for the second time and placed on the calendar 2 amendments	.....	23-FEB-17
Read for the third time and passed as amended.....	.....	09-MAR-17

Yeas 97, Nays 0, Abstains 0

Jeff Woodard
Clerk