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**CUMULATIVE SUPPLEMENT
INCLUDING ACT OF 2013 LEGISLATURE**



**TITLE 34 CHAPTER 23
PRACTICE OF PHARMACY ACT 205
LEGISLATURE 1966**

**ALABAMA STATE BOARD OF
PHARMACY**

PHARMACISTS AND PHARMACIES

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ARTICLE 1.

GENERAL PROVISIONS.

§ 34-23-1. Definitions.

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

(11) **MANUFACTURER.** A person, except a pharmacist, who prepares, derives, produces, compounds, 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 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 to practice the

profession of pharmacy in the State of Alabama and whose license is in good standing.

(18) **PHARMACY.** A place licensed by the Alabama State Board of Pharmacy 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. 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.

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.

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.

(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) **PROFESSIONAL DEGREE.** A degree in pharmacy requiring a minimum of five academic years.

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

(26) **WHOLESALE DRUG DISTRIBUTORS.** A person engaged in the business of distributing drugs and medicines for resale to pharmacies, hospitals, practitioners, government agencies, or other lawful outlets permitted to sell drugs or medicines. The sale, purchase, or trade of a drug by a retail pharmacy to another retail pharmacy or practitioner, for relief of temporary shortages, is exempt from this definition. Also exempt from this definition shall be (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, and (e) the distributors of blood and blood components. (Acts 1966, Ex. Sess., No. 205, p. 231, § 2; Acts 1991, No. 91-475, pg. 860, § 1; Acts 98-643, p. 1414, §1; Act No. 2012-213, p. 381, §1.)

§ 34-23-2. Objects and purposes of chapter.

The practice of pharmacy and the management and operation of pharmacies are hereby declared to affect the public health, safety and welfare of the people of Alabama, and thereby subject to regulation and control in the public interest. It is further declared to be a matter of public interest and concern that only qualified persons compound or dispense prescription drugs and medicines, and that pharmacies be managed in such a manner as to protect the public, and all provisions of this chapter shall be liberally construed to carry out these objects and purposes. (Acts 1966, Ex. Sess., No. 205, p 231, § 1.)

§ 34-23-3. State drug inspectors.

Each state drug inspector employed by the board following the passage of this chapter must furnish satisfactory proof to the board that he is a person of good moral character and that in the judgment of the members of the board he has sufficient knowledge of the laws pertaining to the practice of pharmacy and law enforcement to enable him to carry out his duties as an inspector consistent with the provisions of this chapter. Each state drug inspector 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 or other inspector designated by the board.

Each such inspector, before entering upon his duties, shall post with the state board of pharmacy a bond in the amount of \$2,000.00 conditioned upon the faithful performance of his duties. Each state drug inspector 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.

Each state drug inspector 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 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 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 said 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 to take possession of all revoked and/or suspended licenses and permits 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 or state drug inspectors to inspect the offices of doctors of medicine who have duly qualified with the state board of medical examiners. (Acts 1966, Ex. Sess., No. 205, p. 231, § 7.)

§ 34-23-4. Licensure limited to graduates from approved schools and colleges.

The Board of Pharmacy shall consider for licensure graduates from only those schools and colleges of pharmacy which are approved by the board. (Acts 1966, Ex. Sess., No. 205, p. 231, § 8; Act 2006-296; p. 607; §1.)

§ 34-23-5. Pharmacists exempt from jury duty.

Repealed by Acts 1989, No. 89-235, p. 303, §6, effective April 6, 1989.

§ 34-23-6. Bankruptcy sales, auction sales, etc., of drugs and medicines.

In the event of any sale in bankruptcy, at public auction or any other sale except in the normal course of business, the seller shall give written notice of such sale to the board at least one week prior to the day of sale, and a complete and accurate report must be made in writing to the board by the proposed seller within 10 days after such sale showing the names and addresses of the parties to whom any narcotics, exempt narcotics or dangerous drugs have been sold together with an itemized inventory thereof. This section shall not apply to the bona fide sale of a pharmacy as a business when the board has been notified of such proposed sale. (Acts 1966, Ex. Sess., No 205, p. 231, § 30.)

§ 34-23-7. Illegal possession of prescription drugs.

Any person found in possession of a drug or medicine limited by law to dispensation by a prescription, unless such drug or medicine was lawfully dispensed, shall be guilty of a misdemeanor and, upon conviction,

shall be fined not more than \$1,000.00 and, in addition thereto, may be imprisoned in the county jail for hard labor for not more than one year. This section shall not apply to a licensed pharmacy, licensed pharmacist, wholesaler, manufacturer or his representative acting within the line and scope of his employment, physician, veterinarian, dentist or nurse acting under the direction of a physician, nor to a common carrier or messenger when transporting such drug or medicine in the same unbroken package in which the drug or medicine was delivered to him for transportation. (Acts 1966, Ex. Sess., No. 205, p. 231, § 31.)

§ 34-23-8. Substitution of drugs or brands of drugs.

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

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

(2) A licensed pharmacist located in this state shall be permitted to select for the brand name drug product prescribed by a practitioner who is located in another state or licensing jurisdiction and who is authorized by the laws of that state or jurisdiction to write prescriptions, a less expensive pharmaceutically and therapeutically equivalent drug product containing the same active ingredient or ingredients, and of the same dosage form strength, in all cases where the out-of-state licensed physician or other practitioner does not expressly prohibit a substitution.

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

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

An oral prescription from the practitioner shall instruct the pharmacist whether or not a less expensive pharmaceutically and therapeutically equivalent drug product may be dispensed. The pharmacist shall note instructions on the file copy of the prescription and retain the prescription form for the period specified by law.

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

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

(7) Any person who violates the provisions of this section shall be punished by a fine of up to \$1,000. (Acts 1966, Ex. Sess., No. 205, p. 231, § 18; Acts 1979, No. 79-429, p.676, §1; Act 2002-58, p. 144, §1.)

§ 34-23-9. Purity of drugs dispensed.

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. (Acts 1966, Ex. Sess., No. 205, p. 231, § 17.)

§ 34-23-10. Notification by pharmacists of change of employment.

Each pharmacist licensed by the board shall notify the board in writing within 10 days on change of employment. The notice shall contain his name, license number, the name of the pharmacy where formerly employed and the name of the pharmacy where currently employed. (Acts 1966, Ex. Sess., No. 205, p. 231, § 12.)

§ 34-23-11. Physicians, dentists, registered nurses, etc., exempt from chapter.

(a) Nothing contained in this chapter shall prevent any licensed practitioner of the healing arts from personally compounding, dispensing, administering, or supplying to his or her patient drugs and medicines for their use. This chapter shall not apply to the manufacture or sale at wholesale or retail of patent or proprietary medicines as purchased from a manufacturer or wholesaler, or to the manufacture or sale at wholesale or retail of packaged, bottled, or nonbulk chemicals, medicines, medical and dental supplies, cosmetics, and dietary foods when identified by and sold under a trademark, trade name, or other trade symbol, privately owned or registered in the United States Patent Office, sold or offered to be sold to the general public, if the article meets the requirements of the federal Food, Drug, and Cosmetic Act other than prescription legend drugs.

(b) A registered nurse in the employment of the State Health Department or a county health department may, in the provision of health care services, dispense legend drugs as provided in this section under the standing orders or direct supervision of a physician licensed to practice medicine in this state and pursuant to procedures established by the Board of Pharmacy and implemented by a pharmacist licensed to practice pharmacy in this state. The nurse may dispense the legend drugs for the treatment of tuberculosis, sexually transmitted diseases, family planning, hypertension, and other programs if approved by the State Board of Pharmacy. The dispensing of the drugs shall meet all labeling, packaging, recordkeeping, and counseling requirements of a prescription. The Board of Pharmacy shall have the responsibility to inspect the site where the dispensing occurs. The authority granted to a registered nurse pursuant to this subsection shall not apply to controlled substances as defined in Chapter 2 of Title 20. (Acts 1966, Ex. Sess., No. 205, p. 231, § 32; Acts 1997, No. 97-643, p. 1176, §1.)

§ 34-23-12. Injunctions against violations of chapter.

When it shall appear to the board that any person who is not licensed under the provisions of this chapter is violating any of the provisions of this chapter, the board may in its own name bring an action in the circuit court for an injunction, and said court of this state may enjoin any person from violating the provisions of this chapter regardless of whether proceedings have been or may be instituted. (Acts 1966, Ex. Sess., No. 205, p. 231, § 23.)

§ 34-23-13. Penalty for practicing pharmacy without a license; compounding or dispensing prescriptions by unauthorized persons; violations of chapter or rules and regulations of board.

Any person who shall practice pharmacy in this state without having first obtained from the board a license, or who permits prescriptions to be compounded and/or dispensed by unauthorized persons; or who violates any of the provisions of this chapter; or who willfully violates any published rule or regulation of the board; or who does any act described in this chapter as unlawful, the penalty for which is not herein specifically provided, shall be guilty of a misdemeanor and, upon conviction, shall be punished by fine of not more than \$1,000.00 for each offense, to be fixed by the court trying said case, and in addition thereto may be, in the discretion of the court trying said case, sentenced to hard labor for the county for a period not to exceed 12 months. (Acts 1966, Ex. Sess., No 205, p. 231, § 10.)

ARTICLE 2.

LICENSES AND PERMITS

Division 1. General Provisions.

§ 34-23-30. Pharmacy permits generally.

(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. 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). 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). 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 fifty dollars (\$50) nor more than one hundred fifty dollars (\$150). 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. 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. 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) Any person who violates this section shall be guilty of a misdemeanor. (Acts 1966, Ex. Sess., No. 205, p. 231 § 14; Acts 1985, No. 85-702, p. 1151, § 1; Acts 2004-450, p. 801, §1, Act 2012-213, p.381, §1.)

§ 34-23-31. Permits for mail-order houses.

Every mail-order house which dispenses drugs or medicines through the United States mail or otherwise from any point in the state of Alabama to any point outside of the state of Alabama, and every such business which dispenses drugs or medicines through the United States mail or otherwise from any point outside the state of Alabama to any point within the state of Alabama shall obtain a permit from the state board of pharmacy as a condition precedent to being qualified and authorized to transact such business in the state of Alabama. (Acts 1966, Ex. Sess., No. 205, p. 231, § 29.)

§ 34-23-32. Manufacturer, bottler, packer, repackager, or wholesale distributor of drugs.

(a) Every manufacturer, bottler, packer, repackager, or wholesale drug distributor, of drugs, medicines, chemicals, or poisons for medicinal purposes shall register biennially 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) nor more than one thousand dollars (\$1,000) 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 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) 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. 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. (Acts 1966, Ex. Sess., No. 205, p. 231, § 24; Acts 1985, No. 85-702, p. 1151, § 1; Acts 1991, No. 91-475, p. 860, § 1; Acts 2004-450, p. 801, §1.)

§ 34-23-32.1 FDA requirements to be adhered to by affected parties.

Any requirements established by the FDA Guidelines, as required by the Federal Prescription Drug Marketing Act of 1987 (PDMA), specifically addressed in Section 34-23-1 and 34-23-32, shall be adhered to by the affected parties. (Acts 1991, No. 91-475, p. 860, § 2.)

§ 34-23-33. Revocation, suspension, etc., of license or certificate; non-disciplinary administrative penalty.

(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 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. (Acts 1966, Ex. Sess., No. 205, p. 231, § 20; Acts 1989, No. 89-235, p. 303, § 3; Acts 1990, No. 90-550, p. 856, §1; Acts 1995, No. 95-585, p. 1243, § 1.; Act 2009-576, p. 1688, §1.)

§ 34-23-34. Revocation or suspension of licenses to practice pharmacy and pharmacy permits – Statement of charges and notice of hearing.

No action to revoke or suspend the license of any pharmacist or the permit to operate any pharmacy in this state shall be taken until the licensee or holder of such permit has been furnished a statement in writing of the charges against him together with a notice of the time and place of hearing. The statement of charges and notice shall be served upon such a person at least 30 days before the date fixed for said hearing, either personally or by registered or certified mail sent to his last known post-office address. The burden of proof be on the board. (Acts 1966, Ex. Sess., No. 205, p. 231, § 21.)

Division 2.

Pharmacists' Licenses

§ 34-23-50. Required.

(a) It shall be unlawful for any person, firm or corporation to practice pharmacy in this state or to permit prescriptions to be compounded and/or dispensed by persons other than those duly licensed by the board to practice pharmacy in this state; provided, that any person who holds a professional degree in pharmacy from a school of pharmacy recognized by the board who is serving his or her internship under the immediate direct supervision of a pharmacist on the premises registered by the board and any person who is enrolled in a school of pharmacy recognized by the board working under the immediate and direct supervision of a pharmacist on the premises registered by the board pursuing his or her education as a pharmacist shall be permitted to compound and/or dispense prescriptions. In order to be considered enrolled in a school of pharmacy and pursuing his or her education as a pharmacist, a person shall not be absent from the school of pharmacy for more than two consecutive semesters or three consecutive quarters, dependent upon the system in use in said school of pharmacy. Any bona fide resident of this state who shall furnish proof to the board in person by affidavits from two pharmacists licensed by the State Board of Pharmacy, neither of whom shall be related to the applicant by blood or marriage, within a period of 90 days subsequent to August 26, 1966, establishing the fact that he or she has filled prescriptions under the supervision of a licensed pharmacist over a period of at least 15 successive years next preceding the offer of such proof shall be issued an assistant's certificate which will authorize the person to practice pharmacy in this state; provided, that the person shall be under the supervision of a licensed pharmacist at all times, and such person shall be subject to all the provisions of this chapter governing the practice of pharmacy in this state, including, but not limited to, the revocation or suspension of such certificate for violations of the provisions of this chapter; and provided further, that such person shall pay an original registration fee to be determined by the board, but the fee shall not be less than twenty-five dollars (\$25) nor more than fifty dollars (\$50) upon the issuance of such certificate. All certificates so issued shall expire on December 31 of even-numbered years. In order to continue to obtain a certificate as a pharmacist's assistant, a biennial renewal fee in an amount determined by the board shall be paid, but the fee shall not be less than twenty-five dollars (\$25) nor more than one hundred fifty dollars (\$150). This renewal fee shall be paid to the secretary of the board and shall be due on October 31 and delinquent after December 31 of even-numbered years. The payment of the renewal fee shall entitle the holder thereof to renewal of his or her certificate at the discretion of the board. If any pharmacist's assistant fails to pay a renewal fee on or before the due date, the holder of the certificate may be reinstated as a pharmacist's assistant only upon payment of a penalty of ten dollars (\$10) for each lapsed month and all lapsed fees, provided the lapsed time of certification shall not exceed five years, in which case reinstatement may be had only upon satisfactory examination by the board. As used in this section, the term "supervision" shall be construed to mean that the supervising licensed pharmacist shall be either personally present or on call and available for consultation at all times, or a licensed pharmacist designated by the supervising licensed pharmacist shall be either personally present or on call and available for consultation at all times.

(b) Notwithstanding Section 20-2-51 or any other law to the contrary, each person licensed by the board to practice pharmacy may distribute or dispense controlled substances during the biennial period for which the person is licensed. (Acts 1966, Ex. Sess., No. 205, p. 231, § 9; Acts 1985, No. 85-702, p. 1151, § 1; Act 2005-57, p. 84, §3; Act 2009-576, p.1688, §1.)

§ 34-23-51. Application for license; qualifications of applicants; examination of applicants; license by reciprocity.

Every person who desires to practice pharmacy within this state shall file with the secretary of the board his or her written application for licensure upon forms furnished by the board not less than 10 days prior to his or her examination. The application shall be accompanied by an examination and registration fee for residents and nonresidents of this state, the fees to be set by the board. The application shall be accompanied by two recent photographs of the applicant, no larger than 2 1/2 x 3 1/4 inches and certified on the back of each photograph by a notary public. The applicant shall furnish satisfactory proof that he or she is at least 19 years of age, of good moral character, and that he or she holds a professional degree from a division, school, college, or a university department of pharmacy recognized by the State Board of Pharmacy. Each applicant shall also be a citizen of the United States or, if not a citizen of the United States, a person who is legally present in the United States with appropriate documentation from the federal government. The applicant shall have completed an approved practical training program under the supervision of a licensed pharmacist in a site recognized by the board as qualified for training pharmacy externs and interns, the training standards to be established by the board as long as the standards are not less than those set by the National Association of Boards of Pharmacy. The completion of the practical training requirements shall be attested by affidavit from the licensed pharmacist preceptor under whom the training is served. The applicant shall pass an examination administered by the board in subjects consistent with those required by the National Association of Boards of Pharmacy and in accordance with the rules and regulations of the board. In case of failure of a first examination, the applicant shall have within three years the privilege of a second and third examination. In case of failure in the third examination, the applicant shall be eligible for only one additional examination and this only after he or she has satisfactorily completed additional preparation as directed and approved by the board. An applicant may be admitted to the examination provided all of the foregoing requirements are met, and in addition, that affidavits attesting to the prescribed practical training program have been presented to the secretary prior to the examination. An application for examination by the board may be denied if the applicant is proven to have been involved in any violation of this chapter. An applicant who has been expelled from an examination for cribbing, cheating, or other dishonest conduct shall not be permitted to complete the examination applied for and shall not be permitted to file a new application for examination during the balance of the same calendar year or the calendar year next following the expulsion. The board may issue a license without examination to an applicant who furnishes satisfactory proof that he or she has been licensed to practice pharmacy by examination in another state that under like conditions grants reciprocal licensure without examination to pharmacists duly licensed by examination in this state, that he or she is a person of good moral character and temperate habits, and provided that the requirements in the state from which the applicant is reciprocating were no less than the requirements of the National Association of Boards of Pharmacy. The application shall be accompanied by a fee set by the board. Each applicant for licensure by reciprocity shall be personally interviewed by two or more members of the board before being granted a license, and the applicant shall pass a written examination on the laws governing the practice of pharmacy in this state. The applicant shall be approved for reciprocity by the board prior to the time that he or she begins the duties of a licensed pharmacist in this state. No applicant shall be granted reciprocal licensure unless all evidence and supporting documents of licensure in the state from which the applicant is reciprocating are approved as meeting the requirements for reciprocity of the National Association of Boards of Pharmacy. The board shall set and collect a fee for submitting and certifying grades for reciprocity in other states. (Acts 1966, Ex. Sess., No. 205, p. 231, §11; Acts 1975, 3rd Ex. Sess., No. 147, p. 393; Acts 1989, No. 89-235, p. 303, § 3; Acts 1998, No. 98-643, p. 1414, §1; Acts 2009-36, p. 126, §3.)

§ 34-23-52. Expiration and renewal of certificate; continuing education.

(a) All certificates of licensure shall expire on December 31 of even-numbered years. Every licensed pharmacist in order to continue to be licensed shall pay a biennial renewal fee to be determined by the board, but the fee shall not be less than twenty-five dollars (\$25) nor more than one hundred fifty dollars (\$150) to the secretary of the board, the fee being due on October 31 and delinquent after December 31 of even-numbered years except, that holders of life certificates to practice pharmacy previously issued shall not be required to pay a renewal fee. The payment of the renewal fee shall entitle the registrants to renewal of their certificates at the discretion of the board. If any pharmacist shall fail to pay a renewal fee on or before the due date, the holder of the certificate may be reinstated as a licensed pharmacist only upon payment of a

penalty of ten dollars (\$10) for each lapsed month and all lapsed fees, 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.

(b) In addition to any fee requirements, each pharmacist is required to complete 15 hours of continuing education per calendar year, of which three hours shall be live presentation. (Acts 1966, Ex. Sess., No. 205, p. 231, § 13; Acts 1985, No. 85-702, p. 1151, § 1; Acts 2004-450, p. 801, §1.)

§ 34-23-53. Training program for candidates for licensure.

Candidates for licensure as pharmacists shall complete a practical training program as prescribed by the board in keeping with standards established by the national accreditation agencies. The candidate shall apply to the board for proper reporting forms and shall ascertain that the preceptor under whom he or she proposes to take his or her practical training is a qualified preceptor. The candidate shall receive credit for experience gained only in an approved site under the supervision of an approved preceptor. The candidate must keep records as prescribed by the board of all professional experience gained, and upon request, must report to the board and furnish information relative to the practical experience gained. The board may accept internship affidavits from other states, provided the internship requirements are no less than requirements of the National Association of Boards of Pharmacy. (Acts 1966, Ex. Sess., No. 205, p. 231, § 27; Acts 1975, 3rd Ex. Sess., No. 147, p. 393; Act 98-643, p. 1414, §1.)

ARTICLE 3.

PHARMACIES.

§ 34-23-70. Management; display of permit and license; poisons; prescription requirements; violations

(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.

(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) No person shall fill or compound a prescription or drug order in an institution unless he 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.

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 profession in a licensed hospital or similar institution.

Nothing in this act shall authorize the Board of Pharmacy 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) 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) 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) 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) 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, or its inspectors.

(l) 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) Any person who violates any of the provisions of this section shall be guilty of a misdemeanor. (Acts 1966, Ex. Sess., No. 205, p. 231, § 15; Acts 1989, No. 89-747, p. 1513, §1; Act 2009-772, p. 2385, §1; Act 2012-553, p. 1631, §1; Act 2013-198, §1.)

§ 34-23-71. Requirements for prescription rooms.

Any new pharmacy or any existing pharmacy which is to be remodeled or which is to be moved to a new location other than a hospital pharmacy must comply with the following requirements for the prescription room area: That portion or part of the entire licensed pharmacy which is to be occupied by the prescription compounding or dispensing department, including that portion or part thereof utilized for the sale of restricted drugs, shall be not less than 240 square feet. The surface of the prescription compounding counter shall be not less than 24 inches in width and not less than 16 square feet of unobstructed working space for one pharmacist and not less than 24 square feet of total working space where two or more pharmacists are to be on duty at any one time. The aisle space or floor area to be occupied by a dispensing pharmacist shall extend the full length of the prescription compounding counter, and it shall be clear and unobstructed for a minimum

distance of 36 inches from the working side of the prescription compounding counter. (Acts 1966, Ex. Sess., No. 205, p. 231, § 16.)

§ 34-23-72. Internship training sites.

Every site approved by the State Board of Pharmacy for intern training shall be managed so that the intern is provided with ample opportunity to meet the training requirements established by the board. The site must have in its employ, or have an arrangement with, a pharmacist who is registered as a preceptor. A site which meets these qualifications may be approved for internship training by the board. (Acts 1966, Ex. Sess., No. 205, p. 231, § 25; Act 98-643, p. 1414, §1.)

§ 34-23-73. Preceptor qualifications.

Every pharmacist serving as a preceptor shall have expressed a willingness to serve as a preceptor. Pharmacist preceptors shall be approved by the board and shall be willing to cooperate with the board in developing the necessary training requirements and shall provide appropriate documentation to the board. Each preceptor shall certify as to the commencement and completion of the training period and may make recommendations to the board concerning the competency of his or her trainee. The preceptor shall report to the board from time to time as requested on the progress of any intern or extern under his or her supervision. It shall be his or her responsibility in a supervisory capacity to see that each intern or extern receives proper training under the objectives of the board for this practical training program. (Acts 1966, Ex. Sess., No. 205, p. 231, § 26; Act 98-643, p. 1414, §1.)

§ 34-23-74. Hospitals and related institutions; automated dispensing systems.

(a) Except as otherwise provided in subsection (b), every pharmacy located in a hospital, skilled nursing home, or other related institution in this state shall be under the supervision of a licensed pharmacist. In general hospitals, skilled nursing homes, and extended care facilities not operating a pharmacy, the drug or medicine room shall be under the direct supervision and direction of a consulting pharmacist or a member of the medical staff who shall be a licensed practitioner of medicine. In nursing homes which are not classified by the State Board of Health as skilled nursing homes, maternity homes, homes for the aged, domiciliary institutions, and all related institutions except those operated by and in conjunction with a licensed hospital, medicines or drugs bearing the wording on the label "caution, federal law prohibits dispensing without prescription" or similar wording that causes the medicines or drugs to be known as prescription legend drugs shall be furnished by a licensed pharmacy on the prescription of a licensed practitioner of medicine for individual patients, and there shall be no prescription legend drugs on the premises of these institutions other than those so prescribed except an emergency kit as authorized by the State Board of Health. In hospitals and skilled nursing homes using vending machines or mechanical devices for the storage and dispensing of drugs, the machines or devices shall be stocked only under the supervision of a licensed pharmacist, and the drugs may be dispensed from the machine or device only by an individual acting in accordance with established institutional hospital pharmacy policy. The State Board of Pharmacy may at any time adopt such additional rules and regulations consistent with this chapter as may be deemed necessary after advising with the Alabama Society of Hospital Pharmacists in regard to the storage and handling of drugs and medicines and the disposition of unused portion of drugs and medicines in hospitals and other related institutions under this section.

(b) Notwithstanding the provisions of subsection (a), the use and operation of automated dispensing systems in skilled nursing facilities by a pharmacy holding a permit issued for that purpose is authorized pursuant to rules adopted by the board. (Acts 1966, Ex. Sess., No. 205, p. 231, § 28; Acts 1995, No. 95-398, p. 819, § 1; Act 2013-106, §1.)

§ 34-23-75. Emergency prescription refill.

In the event a pharmacist receives a request for a prescription refill and the pharmacist is unable to readily obtain refill authorization from the prescriber, the pharmacist may dispense a one-time emergency refill of up to a 72-hour supply of the prescribed medication, providing that:

- (1) The prescription is not a medicinal agent listed in Schedule II appearing in Title 20, chapter 2.
- (2) The medication is essential to the maintenance of life or the continuation of therapy in a chronic condition. Only those drugs designed by a joint rule adopted by the board of pharmacy and the board of medical examiners shall be refilled, according to the procedure established in this section.
- (3) The dispensing pharmacist creates a written order containing all the prescription information required by this chapter and Title 20, Chapter 2.
- (4) The dispensing pharmacist notifies the prescriber of the emergency dispensing within 72 hours after such dispensing. (Act 1991, No. 91-554, p. 1023, § 1.)

§34-23-76 Repackaging, relabeling, and storing of non-controlled legend drugs for certain residential care facility patients.

- (a) The Board of Pharmacy may establish by rule protocols allowing a pharmacy in possession of a current retail pharmacy permit to repackage, relabel, and store any non-controlled legend drug for a patient residing in a residential care facility which does not have a pharmacy located on the premises.
- (b) For purposes of this section, a residential care facility means any of the following:

- (1) A convalescent home.
- (2) A nursing home.
- (3) An extended care facility.
- (4) A mental health or psychiatric facility.
- (5) A rehabilitation facility.
- (6) A developmental disability center.
- (7) An assisted living facility.
- (8) A speciality (sic) care assisted living facility. (Acts 2011-520, §1; Effective June 9, 2011)

ARTICLE 4.

BOARD OF PHARMACY

§ 34-23-90. Authority; composition.

- (a) The Alabama State Board of Pharmacy is vested with the authority to carry out the purposes of and enforce this chapter. The board shall consist of five members who are citizens of this state. The members of the board shall be licensed pharmacists who have been licensed in this state for a minimum of five years and who are actively engaged in the practice of pharmacy or pharmacy administration, or both.
- (b) Three members shall be appointed by the Governor. Of the three appointed members, one member shall be engaged in the practice of pharmacy, or pharmacy administration, or both, in a hospital, one in an independent pharmacy, and one in a chain pharmacy. On or before August 1, 1996, and each five years thereafter, or whenever a vacancy occurs in the designated position for hospital pharmacists, the Alabama Society of Health System Pharmacists, or its successor organization, shall submit a list of three nominees to the Governor. On or before August 1, 1994, and each five years thereafter, or whenever a vacancy occurs in the designated position for a chain pharmacist, the Alabama Pharmacy Association, or its successor organization, shall submit a list of three nominees to the Governor. On or before August 1, 1997, and each five years thereafter, or whenever a vacancy occurs in the designated position for the independent pharmacist, the independent pharmacist members of the Alabama Pharmacy Association, or its successor organization, shall submit a list of three nominees to the Governor. From the names submitted to the Governor, the Governor shall appoint a replacement on or before December 31 of the same year the nominations are received, for the member or members whose term or terms are expiring. Background information shall be provided for each nominee for an appointed position.
- (c) On or before December 1, 1995, and each five years thereafter, and on or before December 1, 1998, and each five years thereafter, or whenever a vacancy occurs in a nondesignated position, the Board of Trustees of the Alabama Pharmacy Association, or its successor organization, shall select a committee of five

pharmacists who are members of the association to serve as a nominating committee. No one on the committee shall be a candidate. The committee shall receive names of pharmacists actively engaged in pharmacy practice or administration, or both, from companies and individuals, and shall narrow the list of nominees to two names to be placed on a ballot to be voted on by all Alabama pharmacists. The election procedure for a nondesignated slot shall be as follows: Each candidate shall provide a biographical sketch of not more than 150 words, which shall include his or her most recent practice experience. The board shall mail election ballots and a biographical sketch of the candidates to Alabama licensed pharmacists by September 1. Completed ballots returned to the board postmarked by October 1 shall be tabulated. A pharmacist receiving a majority of the ballots received shall be considered the winner. If a runoff election is necessary, the runoff ballots shall be mailed to licensed pharmacists by November 1 and returned postmarked by December 1. A canvassing committee consisting of a representative from the Alabama Pharmacy Association, or its successor organization, Alabama Society of Health System Pharmacists, or its successor organization, Auburn University School of Pharmacy, and Samford University School of Pharmacy shall tabulate the ballots.

(d) Any vacancies occurring on the board other than by expiration of term shall be filled by election or appointment only for the unexpired term and shall be filled by the same procedure that the replaced member was elected or appointed. Each member of the board shall serve a term of five years beginning on January 1 following appointment and terminating on December 31 of his or her fifth year as a member of the board.

(e) No pharmacist shall serve two full terms consecutively.

(f) The Governor, upon recommendation of the board, may remove a member of the board upon proven charges of inefficiency, incompetency, immorality, or professional misconduct. The replacement member shall be elected or appointed by the same procedure that the removed member was elected or appointed. Appointees to the board shall within 30 days after their appointment or election take an oath or make affirmation before a properly qualified officer that they will faithfully and impartially perform the duties of their office. This oath or affirmation shall be filed with the Secretary of State. At its last regular meeting in each calendar year, the board shall organize by electing for a term of one year, effective the following January 1, a president, a vice-president, and a treasurer who shall be members of the board. No member shall serve more than two years in the same office on the board during a five-year term. The board shall also elect a secretary who shall not serve as a member of the board and the board shall have the authority to fix the amount of the secretary's remuneration. If a board member is selected as secretary, the board member shall resign from the board and a replacement on the board shall be selected by the same procedure by which the resigned member was originally elected or appointed. The secretary shall not be employed during the service by any registrant of the board.

(g) For the purpose of this section, a chain pharmacy shall be defined as any retail pharmacy employing in Alabama a minimum of 40 full-time equivalent pharmacists. A chain pharmacist is defined as a pharmacist employed on a full-time basis by a chain pharmacy for a minimum of three years.

(h) It is the intent of the Legislature that the composition of the board reflect the demographics of the pharmacy profession. For vacancies occurring after March 18, 2005, the nominating organizations and the appointing authorities shall select those persons whose appointments ensure that the membership of the board is inclusive and reflects the racial, gender, geographic, urban/rural, and economic diversity of this state. (Acts 1966, Ex. Sess., No. 205, p. 231, § 3; Acts 1981, No. 81-810, p. 1448, § 1; Acts 1989, No. 89-235, p. 303, § 3; Acts 1993, No. 93-671, p. 1209, § 3; Act 2001-247, p. 293, § 3; Act 2005-57, p. 84, § 3; Act 2009-36; p. 126, § 3.)

§ 34-23-91. Duties of officers; bonds of secretary and treasurer; compensation and expenses; meetings; quorum; funds and disbursements; books and records.

The president of the board shall preside at all of the board's meetings. The vice-president shall preside in the absence or inability of the president. The secretary of the board shall be the executive officer in charge of the board's office. The secretary shall make, keep, and be in charge of all records and record books required to be kept by the board, including a register containing all information which shall be required under this chapter. The secretary shall attend to the correspondence of the board and perform any other duties the board may require in keeping with the office of secretary. The secretary shall receive and record all fees collected under this chapter and, at regular intervals as ordered by the board, shall pay the fees to the treasurer of the board for its use. The secretary may have any forms printed and office supplies furnished as necessary to implement this chapter. The secretary and treasurer of the board shall each furnish bond in an amount to be fixed by the board and shall be conditioned upon the faithful performance and discharge of their

respective official duties. The members of the board shall be paid the same per diem and travel allowance as is paid by law to state employees while engaged in the performance of the duties of the board, in addition to any daily compensation or allowance determined by the Board. The board shall conduct meetings at least three times annually and more often when deemed necessary for the examination of applicants for licensure and for the transaction of business as may legally come before it. Public notice of all stated meetings shall be given at least 30 days in advance of the meetings. At all meetings of the board, a majority shall constitute a quorum. The members of the board shall determine the place of meetings of the board. The treasurer of the board shall have custody of all funds derived from the various provisions of this chapter. All disbursements shall be made by check as authorized by vouchers signed by the president and secretary of the board. The books and records of the board as made and kept by the secretary or under his supervision shall be prima facie evidence of the matter therein recorded in any court. (Acts 1966, Ex. Sess., No. 205, p. 231, § 4; Acts 1971, No. 1952, p. 3171, §1; Acts 1989, No. 89-235, p. 303, §3; Acts 1993, No. 93-671, p.1209, § 3.)

§ 34-23-92. Powers and duties generally.

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 and such other drug inspectors 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 shall be entitled to witness fees from Board of Pharmacy 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 is performed.

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

(10) The board shall 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 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 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 \$1,000.00 for each such violation(s) 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 therefore, the secretary of the board shall furnish, under its seal and signed by him, a certified copy of his license or permit, regulation or rule. 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. (Acts 1966, Ex. Sess., No. 205, p. 231, § 5; Acts 1989, No. 89-235, p. 303, §3; Act 2009-576, p. 1688, §1.)

§ 34-23-93. Assisting prosecuting officers; legal counsel.

The board and its members and officers shall assist prosecuting officers in the enforcement of this chapter, and it shall be the duty of the board, its members and officers to furnish the proper prosecuting officers with such evidence as it or they may ascertain to assist them in the prosecution of any violation of this chapter, and the board is authorized for such purposes to make such reasonable expenditures from the funds of the board as it may deem necessary to ascertain and furnish such evidence. The attorney general of the state shall be the attorney for the board, but the board may in its discretion employ other counsel. It shall be the duty of the district attorney of the judicial circuit wherein any offense is committed to prosecute violations of this chapter. (Acts 1966, Ex. Sess., No. 205, p. 231, § 6.)

§ 34-23-94. Judicial review of orders.

From any order of the board any party affected thereby may appeal such ruling to the circuit court of the county where the party aggrieved resides. The notice of appeal shall be filed within 30 days from the receipt of such order or ruling. Appeals shall be governed by judicial review provisions of the Alabama Administrative Procedure Act. (Acts 1966, Ex. Sess., No. 205, p. 231, § 22; Acts 1985, 2nd Ex. Sess., No. 85-1002, p. 380, §1.)

ARTICLE 5.

THIRD PARTY PRESCRIPTION PROGRAM.

§ 34-23-110. Short title.

This article shall be known and may be cited as the "Third Party Prescription Program Act." (Acts 1981, No. 81-337, p. 477, § 1.)

§ 34-23-111. "Third Party Prescription Program" defined.

As used in this article, the term "third party prescription program" shall mean any system of providing for the reimbursement of pharmaceutical services under a contractual arrangement or agreement between a provider of such services and another party who is not the consumer of those services. Such programs may include, but not be limited to, employee benefit plans whereby a consumer receives prescription drugs or other pharmaceutical services and those services are paid for by an agent of the employer or others. (Acts 1981, No. 81-337, p.477, § 2.)

§ 34-23-112. Required contractual provisions.

Any agreement or contract entered into in this state between the program administrator of a third party program and a pharmacy shall include a statement of the method and amount of reimbursement to the pharmacy for services rendered to persons enrolled in the program, the frequency of payment by the program administrator to the pharmacy for such services rendered, and a method for the adjudication of complaints or the settlement of disputes between the parties. (Acts 1981, No. 81-337, p. 477, § 3.)

§ 34-23-113. Cancellation of program; use of identity card after cancellation.

(a) The administrator of a program shall notify all pharmacies enrolled in said program of any cancellation of coverage of benefits of any group enrolled in the program at least 30 days prior to the effective date of such cancellation.

(b) All persons enrolled in a program shall be notified of its cancellation, and the administrator of the program shall make every reasonable effort to gain possession of any plan identification cards such persons may have been issued pursuant to the provisions of the program.

(c) Any person who utilizes a program identification card to obtain services from a pharmacy after having received notice of the cancellation of his benefits shall be liable to the program administrator for all money paid by the program administrator for any services received pursuant to the illegal use of said identification card. (Acts 1981, No. 81-337, p. 477, § 4.)

§ 34-23-114. Denial of payment.

(a) No program administrator shall deny payment for services to any pharmacy which may have resulted from the fraudulent or illegal use of any identification card by any person unless the pharmacy has been notified that the card has been canceled or discontinued and that the program administrator has been unsuccessful in attempting to regain possession of the card.

(b) No program administrator shall withhold any payment to any pharmacy beyond the time period specified in the payment schedule provisions of the agreement, except that individual claims for payment may be returned to the pharmacy for reasons such as incomplete or illegible information and may then be resubmitted by the pharmacy to the program administrator after appropriate corrections have been made. (Acts 1981, No. 81-337, p. 477, § 5.)

§ 34-23-115. Reimbursement rates.

No agreement between a program administrator and a pharmacy shall establish reimbursement rates or procedures that result in reimbursement rates for services rendered to persons covered by the plan which are less than the usual and customary rates paid by consumers not covered by a third party plan for the same or similar services. (Acts 1981, No. 81-337, p. 477, § 6.)

§ 34-23-116. Article not applicable to certain services.

This article shall not apply to any services rendered pursuant to provisions of the Alabama Medicaid Program, to the Public Education Employees' Health Insurance Plan, or to any corporation organized under the provisions of Title 10, Chapter 4, Article 6, for establishment and operation of health care service plans. (Act 1981, No. 81-337, p. 477, §7; Acts 1983, No. 83-637, p. 986, §§1, 2; Act 2012-478, p. 1325; §1.)

§ 34-23-117. No programs to be instituted until notice given.

After June 27, 1981, no third party prescription programs shall be instituted in this state unless:

(1) The program administrator has given written notice of the provisions of the particular program to all pharmacies in this state as defined in section 34-23-1.

(2) All pharmacies in this state as defined by section 34-23-1 have had 30 days from the date of said

notice to enroll in that particular program. (Acts 1981, No. 81-337, p. 477, § 8.)

§ 34-23-118. Compliance with article required of all programs.

After June 27, 1981, no third party prescription program shall be instituted, nor shall existing agreement or contract be renewed unless they are in compliance with the provisions of this article. (Acts 1981, No. 81-337, p. 477, § 11.)

ARTICLE 6.

PHARMACY TECHNICIANS

§34-23-130. Definitions.

As used in this article, the following terms shall have the following meanings:

- (1) **PHARMACY FUNCTIONS.** Those functions performed in a pharmacy department which do not require the professional judgment of a licensed pharmacist.
- (2) **PHARMACY TECHNICIAN.** An individual, other than an intern, extern, or an assistant pharmacist, who performs pharmacy functions under the direct supervision of a licensed pharmacist.
- (3) **SUPERVISION.** The direct on-site overseeing of the performance of assigned or delegated duties or functions. (Acts 1996, No. 96-496, p. 625, §1.)

§ 34-23-131. Registration and supervision; rules and regulations; continuing education.

- (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 fee.
- (d) In addition to any other registration requirements, a pharmacy technician shall complete three hours of continuing education annually, of which one hour shall be live presentation. (Act 1996, No. 96-496, p. 625; §2; Act 2004-450, p. 801, §1.)

§ 34-23-132. Revocation or suspension of registration; probation.

The board shall revoke or suspend the registration of a pharmacy technician or place on probation a pharmacy technician for any of, but not limited to, the following reasons:

- (1) Willful violation of any provision of this article or the Alabama Uniform Controlled Substances Act.
- (2) Willful violation of any rule or regulation promulgated in accordance with this article or the Alabama Uniform Controlled Substances Act.
- (3) Action which threatens the public health, safety, or welfare.
- (4) Conviction of a felony or misdemeanor involving moral turpitude.
- (5) Conviction of a felony or misdemeanor involving a drug related offense of a legend drug or controlled substance.
- (6) Obtaining the pharmacy technician registration by fraudulent means.

(7) 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 cause the drugs to be classified as prescription legend drugs. (Acts 1996, No. 96-496, p. 625, §3.).

ARTICLE 7.

COMPOUNDING OF DRUGS.

§ 34-23-150. Definitions.

As used in this article, the following terms shall have the following meanings:

- (1) **BOARD.** The Alabama State Board of Pharmacy.
- (2) **COMPONENT.** Any ingredient used in the compounding of a drug product.
- (3) **COMPOUNDING.** The preparation, mixing, assembling, packaging, and labeling of a drug or device as the result of a licensed practitioner's prescription drug order or initiative based on the practitioner/patient/pharmacist relationship in the course of professional practice.
 - a. Compounding may also be for the purpose of, or as incident to, research, teaching, or chemical analysis.
 - b. Compounding includes the preparation of drugs or devices in anticipation of prescription drug orders based on routine, regularly observed prescribing patterns.
 - c. Reconstitution of commercial products is not considered compounding for purposes of this article.
- (4) **COMPOUNDED OVER THE COUNTER (OTC) PRODUCTS.** A medical product that is prepared, packaged, and labeled in a pharmacy that can be sold by the pharmacy without a prescription.
- (5) **MANUFACTURING.** The production, preparation, propagation, conversion, or processing of a drug or device, either directly or indirectly, by extraction from substances of natural origin or independently by means of chemical or biological synthesis and includes any packaging or repackaging of the substance or substances or labeling or relabeling of its container, and the promotion and marketing of such drugs or devices. Manufacturing also includes any preparation of a drug or device that is given or sold for resale by a pharmacy, practitioner, or other person. The distribution of inordinate amounts of compounded products without a prescriber/patient/pharmacist relationship is considered manufacturing.
- (6) **PHARMACY TECHNICIAN.** A person, registered with the board, who assists the pharmacist in the practice of compounding.
- (7) **REASONABLE AMOUNTS OF COMPOUNDED PRODUCTS IN INVENTORY.** The amount that is required to meet historical dispensing needs. (Act 2003-389, p.1094, §1.)

§ 34-23-151. Continuing education; technician assistance; duties of pharmacist.

- (a) Any pharmacist who engages in drug compounding shall be proficient in compounding and shall continually expand his or her compounding knowledge by participating in seminars or studying appropriate literature, or both.
- (b) Pharmacy technicians may assist pharmacists in the preparation of compounds. When a written procedure for a compound is not on file at the pharmacy, a pharmacist must direct the preparation of the compound. At all times, a pharmacist shall verify the weight or volume of all active ingredients of a compound. While compounding, there shall be no more than three technicians per pharmacist.
- (c) A pharmacist shall have responsibility to do all of the following:
 - (1) Verify all prescriptions.
 - (2) Approve or reject all components of the compounded product, drug product containers, closures, and labeling.
 - (3) Prepare and review all compounding records to assure that no errors have occurred in the compounding process.
 - (4) Assure the proper maintenance, cleanliness, and use of all equipment used in a prescription compounding practice.

(5) Assure that only personnel authorized by the supervising pharmacist shall be in the immediate vicinity of the drug compounding operation. (Act 2003-389, p. 1094, §2. Effective September 1, 2003.)

§ 34-23-152. Designation and maintenance of compounding area.

Any pharmacy engaged in compounding shall have a specifically designated and adequate area or space for the orderly compounding of prescriptions. The area used for the compounding of drugs shall be maintained in a good state of repair. The compounding area shall have cleanable surfaces to include walls, ceilings, and floors. Adequate lighting and ventilation shall be provided in all compounding areas. Potable water shall be supplied under continuous positive pressure in a plumbing system free of defects that could contribute contamination to any compounded drug product. Areas used for compounding shall be maintained in a clean and sanitary condition. (Act 2003-389, p. 1094, §3; Act 2006-543, p. 1260, §1; Act 2006-573, p. 1506, §1.)

§ 34-23-153. Use, maintenance, and inspection of compounding equipment.

Equipment used in the compounding of drug products shall be of appropriate design and capacity, as well as suitably located to facilitate operations for its intended use, cleaning, and maintenance. Compounding equipment shall be of suitable composition so the surfaces that contact components shall not be reactive, additive, or absorptive so as to alter the purity of the product compounded. Equipment and utensils used for compounding shall be cleaned and sanitized prior to use to prevent contamination. Equipment and utensils shall be stored in a manner to protect from contamination. Automated, mechanical, electronic, limited commercial scale manufacturing, or testing equipment and other types of equipment may be used in the compounding of drug products. If such equipment is used, it shall be routinely inspected, calibrated, if necessary, or checked to ensure proper performance. Immediately prior to the initiation of compounding operations, the equipment and utensils shall be inspected by the pharmacist and determined to be suitable for use. When potent or hazardous drugs, such as antibiotics, cytotoxins, and steroid hormones, are involved, appropriate measures shall be utilized in order to prevent cross-contamination and proper disposal procedures shall be followed. Measures shall include either the dedication of equipment for such operations or the meticulous cleaning of equipment prior to its use for the preparation of other drugs. (Act 2003-389, p. 1094, §4.)

§ 34-23-154. Drug components to meet certain requirements.

Pharmacists compounding prescriptions shall use their professional judgment in first receiving, storing, or using drug components that meet official compendia requirements or other high quality sources. Bulk drugs and other chemicals or materials used in the compounding of drugs shall be stored in adequately labeled containers in a clean, dry area or, if required, under proper refrigeration. (Act 2003-389, p. 1094, §5.)

§ 34-23-155. Drug product containers and closures.

Drug product containers and closures shall be handled and stored in a manner to prevent contamination and to permit inspection and cleaning of the work area. Containers and closures shall be of suitable material in order not to alter the compounded drug as to quality, strength, or purity. (Act 2003-389, p. 1094, §6.)

§ 34-23-156. Compounding procedures.

The board shall establish written procedures for the compounding of drug products to assure that the finished products have the identity, strength, quality, and purity they purport to have or are represented to possess. The procedures shall include, but not be limited to, a listing of the components, their amounts in weight or volume, the lot number of the components, if available, the order of component mixing, a description of the compounding process, and a designated name for the finished product. The procedures shall be followed in the execution of the compounding procedure. Components shall be accurately weighed,

measured, or subdivided, as appropriate. The operations shall be checked and rechecked by the compounding pharmacist at each stage of the process to ensure that each weight and measure is correct as stated in the written compounding procedures. Pharmacists shall determine that all finished products have an acceptable degree of weight variation among capsules, and shall assure a reasonable uniformity and integrity of all compounded products. (Act 2003-389, p. 1094, §7.)

§ 34-23-157. Components transferred to nonoriginal container; advance product preparation; labeling.

(a) If a component is transferred from the original container to another container, including, but not limited to, a powder being taken from the original container and stored in another container, the new container shall be identified with the following information:

- (1) Component name and supplier.
- (2) Lot number and expiration date, if available.
- (3) Strength and concentration.

(b) Products prepared in anticipation of a prescription prior to receiving a valid prescription shall be prepared in reasonable amounts. Products shall be labeled or documentation referenced with all of the following information:

- (1) A complete list of ingredients or designated name of the preparation.
- (2) Preparation date.
- (3) Beyond use date.
- (4) Storage under conditions dictated by composition and stability, including storage in a clean, dry place or in the refrigerator.
- (5) Batch or lot number.

(b) Upon the completion of the drug preparation operation, the pharmacist shall examine the product for correct labeling. The prescription label shall contain all of the information required of other prescriptions. (Act 2003-389, p. 1094, §8.)

§ 34-23-158. Retention of records.

Any procedures or other records required to comply with good compounding practices shall be retained for the same period of time as required for retention of prescription records. All records required to be retained under good compounding practices, or copies of such records, shall be readily available for authorized inspection. Computer information and the hard copy of the prescription shall indicate that the prescription is to be compounded. Adequate records are required to be kept of any controlled dangerous substances or scheduled drugs which are used in compounding. (Act 2003-389, p. 1094, §9.)

§ 34-23-159. Preparation of compounded drug products for over the counter sale.

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 after professional interaction or consultation between the pharmacist and the consumer. 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. (Act 2003-389, p. 1094, §10.)

§ 34-23-160. Preparation of compounded drug products for prescriber's office use; labeling.

(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 consumer. 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 include the phrase "For Office Use." (Act 2003-389, p. 1094, §11.)

§ 34-23-161. Prescriptions for animals.

Drugs for animals may be compounded based upon an order or prescription. Prescriptions for animals shall be handled and filled in the same manner as prescriptions for humans. (Act 2003-389, p. 1094, §12.)

§ 34-23-162. Rules and regulations.

The board shall promulgate such rules and regulations as are necessary for the implementation, administration, and enforcement of this article. (Act 2003-389, p. 1094, §13.)

ARTICLE 8.

PHARMACY AUDIT INTEGRITY ACT

§ 34-23-180. Short title.

This article shall be known and may be cited as "The Pharmacy Audit Integrity Act."

§ 34-23-181. Definitions.

The following words shall have the following meanings as used in this article:

(1) **HEALTH BENEFIT PLAN.** Any individual or group plan, employee welfare benefit plan, policy, or contract for health care services issued, delivered, issued for delivery, or renewed in this state by a health care insurer, health maintenance organization, accident and sickness insurer, fraternal benefit society, nonprofit hospital service corporation, nonprofit medical service corporation, health care service plan, or any

other person, firm, corporation, joint venture, or other similar business entity that pays for insureds or beneficiaries in this state. The term includes, but is not limited to, entities created pursuant to Article 6 of Chapter 4 of Title 10. A health benefit plan located or domiciled outside of the State of Alabama is deemed to be subject to this article if it receives, processes, adjudicates, pays, or denies claims for health care services submitted by or on behalf of patients, insureds, or beneficiaries who reside in Alabama.

(2) **PHARMACY.** A place licensed by the Alabama State Board of Pharmacy 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.

(3) **PHARMACY BENEFIT MANAGEMENT PLAN.** An arrangement for the delivery of pharmacist services in which a pharmacy benefit manager undertakes to administer the payment or reimbursement of any of the costs of pharmacist services for an enrollee on a prepaid or insured basis that contains one or more incentive arrangements intended to influence the cost or level of pharmacist services between the plan sponsor and one or more pharmacies with respect to the delivery of pharmacist services and requires or creates benefit payment differential incentives for enrollees to use under contract with the pharmacy benefit manager.

(4) **PHARMACY BENEFIT MANAGER.** A business that administers the prescription drug or device portion of pharmacy benefit management plans or health insurance plans on behalf of plan sponsors, insurance companies, unions, and health maintenance organizations. The term includes a person or entity acting for a pharmacy benefit manager in a contractual or employment relationship in the performance of pharmacy benefits management for a managed care company, nonprofit hospital or medical service organization, insurance company, or third-party payor.

(5) **PHARMACIST SERVICES.** Offering for sale, compounding, or dispensing of prescriptions, drugs, medicines, chemicals, or poisons pursuant to a prescription. Pharmacist services also includes the sale or provision of, counseling of, or fitting of medical devices, including prosthetics and durable medical equipment.

§ 34-23-182. Purpose.

The purpose of this article is to establish minimum and uniform standards and criteria for the audit of pharmacy records by or on behalf of certain entities.

§ 34-23-183. Application.

This article shall apply to any audit of the records of a pharmacy conducted by a managed care company, nonprofit hospital or medical service organization, health benefit plan, third-party payor, pharmacy benefit manager, a health program administered by a department of the state, or any entity that represents those companies, groups, or department.

§ 34-23-184. Audit procedures; report.

(a) The entity conducting an audit shall follow these procedures:

(1) The pharmacy contract shall identify and describe in detail the audit procedures.

(2) The entity conducting the on-site audit shall give the pharmacy written notice at least two weeks before conducting the initial on-site audit for each audit cycle. If the pharmacy benefit manager does not include their auditing guidelines within their provider manual, then the notice must include a documented checklist of all items being audited and the manual, including the name, date, and edition or volume, applicable to the audit and auditing guidelines. For on-site audits a pharmacy benefit manager shall also provide a list of material that is copied or removed during the course of an audit to the pharmacy. The

pharmacy benefit manager may document this material on either a checklist or on an audit acknowledgement form. The pharmacy shall produce any items during the course of the audit or within 30 days of the on-site audit.

(3) The entity conducting the on-site audit may not interfere with the delivery of pharmacist services to a patient and shall utilize every effort to minimize inconvenience and disruption to pharmacy operations during the audit process.

(4) An audit that involves clinical or professional judgment shall be conducted by or in consultation with a licensed pharmacist.

(5) The audit shall not consider as fraud any clerical or record-keeping error, such as a typographical error, scrivener's error, or computer error regarding a required document or record; however, such errors may be subject to recoupment. The pharmacy shall have the right to submit amended claims through an online submission to correct clerical or record-keeping errors in lieu of recoupment of a claim where no actual financial harm to the patient or plan has occurred, provided that the prescription was dispensed according to prescription documentation requirements set forth by the Alabama Pharmacy Act and within the plan limits. The pharmacy shall not be subject to recoupment of funds by the pharmacy benefits manager unless the pharmacy benefits manager can provide proof of intent to commit fraud or such error results in actual financial harm to the pharmacy benefits manager, a health insurance plan managed by the pharmacy benefits manager, or a consumer. A person shall not be subject to criminal penalties for errors provided for in this subsection without proof of intent to commit fraud, waste, or abuse.

(6) An entity conducting an audit shall not require any documentation that is not required by state and federal law or Alabama Medicaid. The information shall be considered to be valid if documented on the prescription, computerized treatment notes, pharmacy system, or other acceptable medical records.

(7) Unless superseded by state or federal law, auditors shall only have access to previous audit reports on a particular pharmacy conducted by the auditing entity for the same pharmacy benefits manager, health plan, or insurer. An auditing vendor contracting with multiple pharmacy benefits managers or health insurance plans shall not use audit reports or other information gained from an audit on a particular pharmacy to conduct another audit for a different pharmacy benefits manager or health (sic) insurance plan.

(8) Audit results shall be disclosed to the health benefit plan in a manner pursuant to contract terms.

(9) A pharmacy may use the records of a hospital, physician, or other authorized practitioner of the healing arts for drugs or medicinal supplies written or transmitted by any means of communication for purposes of validating the pharmacy record with respect to orders or refills of a legend or narcotic drug.

(10) Reasonable costs associated with the audit shall be the responsibility of the auditing entity with the exception of Alabama Medicaid if the claims sample exceeds 100 unique prescription hard copies.

(11) A finding of an overpayment or an underpayment may be a projection based on the number of patients served having a similar diagnosis or on the number of similar orders or refills for similar drugs, except that recoupment shall be based on the actual overpayment or underpayment of actual claims.

(12) A finding of an overpayment may not include the cost of the drugs that were dispensed in accordance with the prescriber's orders, provided the prescription was dispensed according to prescription documentation requirements set forth by the Alabama Pharmacy Act and within the plan limits. A finding of an overpayment may not include the dispensing fee amount unless:

- a. A prescription was not actually dispensed.
- b. The prescriber denied authorization.
- c. The prescription dispensed was a medication error by the pharmacy.
- d. The identified overpayment is solely based on an extra dispensing fee.

(13) Each pharmacy shall be audited under the same standards and parameters as other similarly situated pharmacies audited by the entity and must be audited under rules applicable to the contractor and time period of the prescription.

(14) Where not superseded by state or federal law, the period covered by an audit may not exceed two years from the date the claim was submitted to or adjudicated by a managed care company, nonprofit hospital or medical service organization, health benefit plan, third-party payor, pharmacy benefit manager, a health program administered by a department of the state, or any entity that represents those companies, groups, or department. An audit may not be conducted six months past the date the pharmacy benefit management plan terminated its contract to adjudicate claims with a pharmacy benefit manager, health plan administrator, or any other entity representing those companies.

(15) An audit may not be initiated or scheduled during the first five calendar days of any month.

(b) The entity shall provide the pharmacy with a written report of the audit and comply with the following requirements:

(1) The preliminary audit report shall be delivered to the pharmacy within 90 days after the conclusion of the audit, with a reasonable extension to be granted upon request.

(2) A pharmacy shall be allowed at least 30 days following receipt of the preliminary audit report in which to produce documentation to address any discrepancy found during the audit, with a reasonable extension to be granted upon request.

(3) A final audit report shall be delivered to the pharmacy within 180 days after receipt of the preliminary audit report or final appeal, as provided for in Section 34-23-185, whichever is later.

(4) The audit documents shall be signed by the auditors assigned to the audit. The acknowledgement or receipt shall be signed by the auditor and the audit report shall contain clear contact information of the representative of the auditing organization.

(5) Recoupments of any disputed funds, or repayment of funds to the entity by the pharmacy if permitted pursuant to contractual agreement, shall occur after final internal disposition of the audit, including the appeals process as set forth in Section 34-23-185. If the identified discrepancy for an individual audit exceeds twenty-five thousand dollars (\$25,000), future payments in excess of that amount to the pharmacy may be withheld pending finalization of the audit.

(6) Interest shall not accrue during the audit period.

(7) Each entity conducting an audit shall provide a copy of the final audit report, after completion of any review process, to the plan sponsor in a manner pursuant to a contract.

§ 34-23-185 Appeals.

(a) Each entity conducting an audit shall establish a written appeals process under which a pharmacy may appeal an unfavorable preliminary audit report to the entity.

(b) If, following the appeal, the entity finds that an unfavorable audit report or any portion thereof is unsubstantiated, the entity shall dismiss the audit report or that portion without the necessity of any further action.

(c) If, following the appeal, any of the issues raised in the appeal are not resolved to the satisfaction of either party, that party may ask for mediation of those unresolved issues unless other remedies are granted under the terms of the contract. A certified mediator shall be chosen by agreement of the parties from the mediators list maintained by the Alabama Supreme Court. The cost of mediation shall be borne by agreement of the parties or by the decision of the mediator.

§ 34-23-186. Extrapolation.

Notwithstanding any other provision in this article or state or federal law, the entity conducting the audit may not use the accounting practice of extrapolation in calculating recoupments or penalties for audits. An extrapolation audit means an audit of a sample of prescription drug benefit claims submitted by a pharmacy to the entity conducting the audit that is then used to estimate audit results for a larger batch or group of claims not reviewed by the auditor. Future fills or refills beyond the current claim date may not be subject to recoupment due to an assumption of error under extrapolation procedure.

§34-23-187. Fraud, willful misrepresentation, or waste abuse.

This article does not apply to any audit, review, or investigation that involves alleged fraud, willful misrepresentation, or waste abuse. (Act 2012-306, p. 668, §8.)

RULES OF ALABAMA STATE BOARD OF PHARMACY

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680-X-2-.01. STATE-WIDE CIRCULATION for RULES and REGULATIONS. (Repealed)

Author: James W. McLane
Statutory Authority: Code of Alabama 1975, §34-23-92.
History: Filed June 1, 1982. Repealed: Filed August 23, 1994; effective September 27, 1994.

680-X-2-.02. EXAMINATION GRADES.

On examinations administered by the board for licensure to practice pharmacy in the State of Alabama, each applicant shall be required to obtain at least 75 on any Alabama prepared practical examination covering state and federal law combined with an oral interview, and a general average of 75 on all National Boards of Pharmacy examinations.

Author: Jerry Moore, Executive Secretary
Statutory Authority: Code of Alabama 1975, §34-23-92
History: Filed June 1, 1982. Amended: Filed March 12, 1986. Amended: Filed August 23, 1994; effective January 1, 1995.

680-X-2-.03. SOURCES of INFORMATION.

The secretary is instructed not to reveal the source of any information which may be given to him, to any member of the Board, or to the State Drug Inspectors, with respect to any violations of law, except in or to a court of justice.

Author: James W. McLane
Statutory Authority: Code of Alabama 1975, §34-23-92.
History: Filed: January 18, 1967; Effective March 30, 1967; Amended June 1, 1982.

680-X-2-.04. PRESCRIPTION DEPARTMENT TECHNICAL EQUIPMENT.

(1) Every pharmacy licensed in this State shall have on hand the following technical equipment; the last edition and/or revision of "Facts and Comparison" or any reference book or electronic media sufficient to meet the level of its pharmacy practice; hot and cold running water in the prescription area; a prescription balance with appropriate sensitivity and appropriate weights.

(2) Every satellite pharmacy of licensed institutional pharmacies shall have all of the above with the exception of weight equipment. In addition, community pharmacies shall have on hand an exempt narcotic register.

(3) In addition, all pharmacies shall have on hand any technical equipment commensurate with its level and type of practice, i.e. hoods for I.V. preparations.

Author: Jerry Moore, R.Ph. Executive Director
Statutory Authority: Code of Alabama 1975, §34-23-92
History: Filed June 1, 1982. Amended: Filed May 11, 1987; Effective Date: June 15, 1987; Amended September 20, 1999; Effective October 25, 1999.

680-X-2-.05. PRESCRIPTION FILES.

In order to facilitate the inspection of records, each prescription on file must bear the initials of the person who compounded and/or dispensed it, as well as the number of the prescription and the date it was dispensed.

Author: James W. McLane
Statutory Authority: Code of Alabama 1975, §34-23-92
History: Filed: January 18, 1967; Effective March 30, 1967. Filed: June 1, 1982.

680-X-2-.06. ABSENCE of LICENSED PHARMACIST SUPERVISING an ASSISTANT.

In the event a licensed pharmacist who is supervising an assistant has left the premises, a sign shall be posted in a prominent place on the prescription counter, easily viewed by the public, giving the pharmacist's name, the hours he will be away from the premises, and the address and telephone number where he can be reached; or, if an alternate supervising pharmacist is being used, the sign shall give that pharmacist's name, address and telephone number where he can be reached. The supervising pharmacist must be able to return to the store premises within a reasonable period of time. The State Board of Pharmacy defines reasonable in this context to mean no longer than thirty minutes following a request for his appearance.

Author: James W. McLane

Statutory Authority: Code of Alabama 1975, §34-23-92

History: Filed: January 18, 1967; Effective: March 30, 1967. Filed June 1, 1982.

680-X-2-.07. MAIL ORDER PRESCRIPTIONS.

(1) Every applicant for a Mail Order Permit or Permits pursuant to the provisions of Code of Alabama 1975, §§34-23-30, 34-23-31, shall obtain a permit biennially. On the first registration by a Pharmacy located outside of the State of Alabama, the provisions of Code of Alabama 1975, §34-23-30 shall apply to such first registration.

(2) Registration. No Nonresident Pharmacy shall ship, mail or deliver prescription drugs and/or devices to a patient in this state unless registered by the Alabama State Board of Pharmacy.

(3) Agent of Record. Each Nonresident Pharmacy that ships, mails, or delivers prescription drugs and/or devices to a patient in the state of Alabama shall designate a resident agent in Alabama for service of process. Any such Nonresident Pharmacy that does not so designate a registered agent and that ships, mails or delivers prescription drugs and/or devices in the state of Alabama shall be deemed an appointment by such Nonresident Pharmacy of the Secretary of State to be its true and lawful attorney upon whom may be served all legal process in any action or proceedings against such pharmacy growing out of or arising from such delivery. A copy of any such service of process shall be mailed to the Nonresident Pharmacy by the complaining party by certified mail, return receipt requested, postage prepaid, at the address of such Nonresident Pharmacy as designated on the pharmacy's application for registration in this state. If any such pharmacy is not licensed in this state, service on the Secretary of State of Alabama only shall be sufficient service.

(4) Conditions of Registration. As conditions of receiving a permit, the Nonresident Pharmacy or a renewal if applicable must comply with the following:

(a) Be registered and in a good standing in the State in which such pharmacy is located;

(b) Maintain, in readily retrievable form, records of legend drugs and/or devices dispensed to Alabama patients;

(c) Supply upon request, all information needed by the Alabama Board of Pharmacy to carry out the Board's responsibilities under the statutes and regulations pertaining to Nonresident Pharmacies;

(d) Maintain pharmacy hours that permit the timely dispensing of drugs to Alabama patients and provide reasonable access for the Alabama patients to consult with a licensed pharmacist about such patients' medications.

(e) Provide toll-free telephone communication consultation between an Alabama patient and a pharmacist at the pharmacy who has access to the patient's records, and ensure that said telephone number(s) will be placed upon the label affixed to each legend drug container.

(f) Designate a supervising pharmacist who shall be licensed by the Alabama State Board of Pharmacy. The supervising pharmacist shall be responsible for ensuring that the holder of the permit referenced herein complies with the requirements of this rule and all applicable statutory provisions and rules. If there is a change of the designated Supervising Pharmacist, the permit holder shall notify the Board by filing the "Notice of Change of Supervising Pharmacist" form provided by the Board. If the permit holder is unable to maintain a designated supervising pharmacist, the permit holder shall notify the Board within ten (10) days with an action plan to designate another pharmacist as supervising pharmacist. A permit holder without a designated supervising pharmacist after the ninety (90) day action plan has expired may contact the Board for additional time.

5. Compliance. Each nonresident Pharmacy shall comply with the following:

(a) All statutory and regulatory requirements of the State of Alabama for controlled substances, including those that are different from federal law or regulation.

(b) All the statutory and regulatory requirements of the state of Alabama regarding drug product selection laws.

(c) Labeling of all prescriptions dispensed, to include but not limited to identification of the product and quantity dispensed.

(d) All the statutory and regulatory requirements of the State of Alabama for the dispensing of prescriptions in accordance with the quantities indicated by the prescriber.

6. Policy and Procedure Manual. Each Nonresident Pharmacy shall develop and provide the resident board of pharmacy with a policy and procedure manual that sets forth:

- (a) Normal delivery protocols and times;
- (b) The procedure to be followed if the patient's medication is not available at the Nonresident Pharmacy, or if delivery will be delayed beyond the normal delivery time;
- (c) The procedure to be followed upon receipt of a prescription for an acute illness, which policy shall include a procedure for delivery of the medication to the patient from the Nonresident Pharmacy at the earliest possible time (i.e. courier delivery), or an alternative that assures the patient the opportunity to obtain the medication at the earliest possible time;
- (d) The procedure to be followed when the Nonresident Pharmacy is advised that the patient's medication has not been received within the normal delivery time and that the patient is out of medication and requires interim dosage until mailed prescription drugs become available.

7. Disciplinary Action. Except in emergencies that constitute an immediate threat to public health and require prompt action by the Board, the Alabama Board of Pharmacy shall file a complaint against any Nonresident Pharmacy that violates any statute or regulation of Alabama for conduct which causes serious bodily or psychological injury to a resident of this state. This complaint shall be filed with the Board in which the Nonresident Pharmacy is located. If the Board in the state in which the Nonresident Pharmacy is based fails to resolve the violation complained of within a reasonable time, (not less than forty-five (45) days from the date that the complaint is filed), disciplinary proceedings may be instituted in Alabama before the Board.

Author: Mark Conradi, R.Ph., J.D., Board President

Statutory Authority: Code of Alabama 1975, §34-23-92

History: Adopted July 17, 1967; Effective October 1, 1967; Amended: Filed June 1, 1982; Amended: April 15, 1986; Amended: Filed March 28, 1990; Effective: September 1, 1990; Amended 17 December 2004; Effective 18 January 2005; Amended 19 March 2014; Effective 9 June 2014.

680-X-2-.08. PHARMACIST CONSULTANTS OF PHARMACEUTICAL SERVICES.

An increasing number of pharmacists are serving as pharmacy consultants to, or serving as coordinators of pharmaceutical services solely directed in the area of consultation to health care professionals regarding medication/treatment regimens and not to include management consultation, in long term care facilities, assisted living facilities, nursing homes, domiciliaries, homes for the aged, governmental agencies and other places where a pharmacy permit is not held. The Alabama State Board of Pharmacy has the responsibility to maintain standards of professional conduct and to regulate professional practice. Due to the complexity of state and federal regulations pertaining to the provision of pharmaceutical care to the residents of long term care facilities and other facilities, and in the interest of protecting the public health of the citizens of Alabama residing in these facilities, and to insure the availability of qualified and competent consultant pharmacists, the Board of Pharmacy hereby promulgates the following rules and regulations:

(a) Requirements:

1. The Board of Pharmacy shall maintain a roster of all pharmacist consultants of pharmaceutical services, solely directed in the area of consultation to health care professionals regarding medication/treatment regimens and not to include management consultation. All persons serving as consultants shall be a pharmacist registered and licensed by the State Board of Pharmacy in Alabama.

2. Location with on-site pharmacy: Any pharmacist consultant to long term care facilities, nursing homes, domiciliaries, homes of the aged, government agencies, and any other pharmaceutical consultation practice shall register initially and biennially which shall expire on December 31 of even-numbered years in each instance such practice with the Alabama State Board of Pharmacy on forms provided by the Board.

3. Location without on-site pharmacy: Any pharmacist providing pharmaceutical consultation to, or coordinating pharmaceutical services, solely directed in the area of consultation to health care professionals regarding medication/treatment regimens and not to include management consultation, in long term care facilities, assisted living facilities, nursing homes, domiciliaries, homes for the aged, governmental agencies, and any other place where a pharmacy permit is not held shall register initially and biennially which shall expire on December 31 of even-numbered years in each instance such practice and place with the Alabama State Board of Pharmacy on forms provided by the Board.

4. All pharmacist consultants to long term care facilities, assisted living facilities, nursing homes, domiciliaries, homes of the aged, government agencies, and all other pharmaceutical consultants are required to successfully complete not less than twelve (12) live integrated hours to be approved by the Board not less than biennially in even-numbered years. The required consultant pharmacist hours may not be carried over from one year to another. Not less than one (1) integrated hour shall be approved for any

consultant recertification continuing education program. Programs approved for consultant recertification shall cover clinical, administrative, or regulatory topics related to consultant pharmacy.

5. After January 1, 1996, pharmacists who have not successfully completed an initial certification course for consultants which has been approved by the Board will not be registered or reregistered as consultants with the Board until they have completed said course. Pharmacists must have taken the initial consultant certification course and have successfully completed an examination with a passing score of 75. The initial certification course shall be a ten (10) hour approved course consisting of the following subject matters:

(i) Regulations and laws, both state and federal, pertaining to services provided by consultant pharmacists.

(ii) Policy and Procedures.

(iii) Administrative Responsibilities.

(iv) Professional Responsibilities.

(v) Consultant Pharmacy Opportunities - History and Overview.

(vi) Drug Regimen Review.

(vii) Ethics in Consultant Pharmacy

(viii) Impact of Consultant Pharmacy on the Total Healthcare System.

(ix) Drug Therapy/Disease State Monitoring.

Author: Herb Bobo, R.Ph, Secretary

Statutory Authority: Code of Alabama 1975, §34-23-92.

History: Filed June 1, 1982; Amended September 2, 1994; Effective January 1, 1995;

Amended: Filed July 24, 2012; effective August 28, 2012.

680-X-2-.09. TRAINING for PRECEPTORS.

In accordance with Section 34-23-73, Title 34, Chapter 23, Code of Alabama 1975, in order to be approved as a preceptor, a Pharmacist must have been licensed to practice pharmacy for a minimum of two (2) years. All Pharmacists who have been approved by the Alabama State Board of Pharmacy as Preceptors must attend a training seminar for Preceptors at least once every three years or be approved by the School of Pharmacy for curriculum hours. Such training seminar shall have prior approval of the Board.

Author: Herb Bobo, R.Ph, Secretary

Statutory Authority: Code of Alabama 1975, §34-23-92

History: Filed June 1, 1982; Amended: Filed July 17, 1995; operative August 21, 1995; Effective 1 January 1996; Amended: Filed December 2, 1998; effective January 6, 1999. **Amended:** Filed July 24, 2012; effective August 28, 2012.

680-X-2-.10. REPORTING PLACE of EMPLOYMENT, INTERNS & EXTERNS.

In accordance with §27(a) of Code of Alabama 1940, Recompiled 1958, as amended in 1966, all pharmacy candidates who are working either as Interns or Externs shall report their place of employment to the Alabama State Board of Pharmacy within 10 days of such employment, and any change in such employment shall be reported to the Alabama State Board of Pharmacy within 10 days of such change.

Author: James W. McLane

Statutory Authority: Code of Alabama 1975, §34-23-92.

History: Filed June 1, 1982.

680-X-2-.11. PHARMACY KEYS OR OTHER CONTROLLED ACCESS DEVICE OR METHOD.

(1) Any pharmacy doing business within the State of Alabama must be physically enclosed, secured and locked when not open for business, except in the temporary absence of the pharmacist on duty as provided for in §34-23-70(a), Title 34, Chapter 23, Code of Alabama 1975. At all times registered Pharmacists designated by the licensee must have all keys or other controlled access device or method in their possession. The owner of the pharmacy may designate one (1) unregistered person to have a key or other controlled access device or method to the pharmacy and still be considered to be in their possession. The Supervising Pharmacist must agree to this arrangement. The enclosed and secured area must encompass all drugs, products, and devices, the character of which require dispensing or sale by a registered Pharmacist, and include store rooms used for receiving or storing these items. The permit holder (owner)

must execute a signed agreement with the individual in possession of a key or other controlled access device or method to the pharmacy and must submit a copy to the Board of Pharmacy for approval prior to issuing a key or other controlled access device or method to any person that does not hold an active pharmacist license in the State of Alabama. Forms for this purpose may be obtained from the Board of Pharmacy. Further, if the municipality or other government authority in the jurisdiction where a pharmacy is located requires compliance with a Fire Code that mandates making a key or other controlled access device or method to the premises available to First Responders, the permit holder (owner) must execute a signed agreement with the highest ranking official of the agency that wants access to the key or other controlled access device or method and submit a copy to the Board of Pharmacy for approval prior to providing access to a key or other controlled access device or method; the Knox Box or other system for accessing the key or other controlled access device or method must have a working tamper protection system that is connected to an alarm system that will notify the permit holder (owner) or the Supervising Pharmacist if an attempt is made to remove the key or other controlled access device or method by unauthorized persons.

(2) Where the Pharmacist does not have access to the prescription department by other entrances after normal operating hours of the entire store the owner shall have an action plan that allows the pharmacist to gain access in case of an emergency.

Author: Herb Bobo R.Ph, Secretary

Statutory Authority: Code of Alabama 1975, §34-23-92

History: Filed June 1, 1982; Filed January 30, 2012; Effective March 5, 2012.

680-X-2-.12. SUPERVISING PHARMACIST.

(1) Every Pharmacy shall be under direct supervision and control of a registered Pharmacist who shall be designated the supervising pharmacist. The supervising pharmacist shall be responsible for no more than one Pharmacy and in which Pharmacy he/she practices. With the approval of the Board, it shall not be deemed to be supervising more than (1) pharmacy when a pharmacist is supervising a pharmacy and, also, an institutional pharmacy that is open less than fifteen (15) hours per week, or a pharmacy that is not an institutional pharmacy that is open no more than the minimum number of hours allowed by the Board. The supervising pharmacist shall be on duty a minimum of 50% of the hours the pharmacy is in operation or at least thirty (30) hours per week, whichever is less.

(2) Whenever a registered Pharmacist assumes the duties of a supervising pharmacist, he/she shall, within (10) days, so advise the Board by completing the "Notice of Change of Supervising Pharmacist" form provided by the Board. The name of the supervising pharmacist shall be placed in a conspicuous place in the prescription department so that it is clearly visible to the public.

(3) Whenever there is a new supervising pharmacist, he/she shall be required to take an inventory of all controlled substances as defined in Title 20, Chapter 2, Code of Alabama 1975, within fifteen (15) days.

(4) The supervising pharmacist shall be responsible for the following:

(a) Supervising of personnel in the prescription department to include ensuring that all licenses and registrations of pharmacists and technicians working in the pharmacy are current and in good standing with the Board.

(b) Maintenance of accurate records of all prescription medication received and dispensed.

(c) Maintaining the security of the prescription department and its contents.

(d) Ensuring that only pharmacists registered with the Board of Pharmacy provide professional consultation with patients and/or physicians.

(e) Ensuring that only pharmacists registered with the Board of Pharmacy accept telephone prescriptions.

(f) Operating the prescription department in a clean and orderly manner.

(g) Maintenance of inspection records provided by the Board or its staff, and where discrepancies are noted, within fifteen (15) days of receiving notice of such discrepancy, submit in writing to the Board, the steps taken or proposed to eliminate the discrepancy. Failure to submit such report to eliminate discrepancies

is grounds for disciplinary action by the Board.

(h) Ensuring that the prescription department is operated at all times with good pharmaceutical practices.

(i) Ensuring compliance with the provisions for the Pharmacy Practice Act, Rules of the Alabama State Board of Pharmacy and the Controlled Substances Act.

(j) Notifying the Board by letter, e-mail or facsimile within ten (10) days when duties as a supervising pharmacist are terminated.

(5) Nothing in this rule shall diminish the corresponding responsibility that all pharmacists have to perform their professional duties including proper recordkeeping.

(6) If the actions of the permit holder have deemed to contribute to or cause a violation of any provision of this section, the Board may hold the permit holder responsible and/or absolve the supervising pharmacist from the responsibility of that action.

(7) The permit holder is responsible and accountable for assuring the supervising pharmacist is working the designated hours set by the Board and for the renewal of the pharmacy permit.

(8) If the permit holder is unable to maintain a designated supervising pharmacist, the permit holder shall notify the Board within ten (10) days with an action plan to designate another pharmacist as supervising pharmacist. This plan can be for a period not to exceed ninety (90) days before the permit is in violation for operating without a supervising pharmacist.

(9) A permit holder without a designated supervising pharmacist after the ninety (90) day period may be asked to close until such time as a designated supervising pharmacist can assume the duties.

Author: Herb Bobo, R.Ph, Secretary

Statutory Authority: Code of Alabama 1975, §34-23-92.

History: Filed: June 1, 1982; Amended: Filed June 8, 1989; Effective 31 July 1989; September 29, 1992. Amended: Filed July 26, 1996; operative August 30, 1996; effective January 1, 1997. Amended: Filed November 29, 2007; effective January 3, 2008.

680-X-2-13. PRESCRIPTION LABELS.

In addition to existing State and Federal regulations, the label of every prescription dispensed in this state shall bear as a minimum, the name and address of the Pharmacy from which the prescription was dispensed, the prescriber's directions for use, the name of the drug as it is dispensed and the strength per dosage unit. When the prescription is a manufacturer's mixture of ingredients or one with a common given name, only the name of the mixture need be indicated. However, in the absence of a name, the term "Prescriber's Mixture" may be used when the list of ingredients contained therein, exceed what can be reasonably included on the prescription label. Any additional information that is a true statement of fact may be included as deemed essential for proper storage, handling, safety and/or usage of the prescription. The drug name and strength per dosage unit may be excluded from the label at the request of the prescribing physician. The prescriber's directions for use may be excluded on prescription labels for hospital inpatients. The institutional name shall not be required on individual unit dose units or floor stock medication which is controlled with proof-of-use sheets.

Author: James W. McLane

Statutory Authority: Code of Alabama 1975, §34-23-92

History: Filed June 1, 1982.

680-X-2-14 THE ROLE OF TECHNICIANS in PHARMACIES in ALABAMA.

(1) Title 34, Chapter 23, Code of Alabama 1975, specifies that only persons licensed by the Board of Pharmacy may practice pharmacy. The practice of pharmacy shall mean the interpretation and evaluation of prescription orders; the compounding, dispensing, administering and labeling of drugs and devices; the participation in drug selection and drug utilization reviews and drug therapy management; the proper and safe storage of drugs and devices and the maintenance of proper records; the responsibility for advising, where necessary or where regulated, of therapeutic values, content, hazards and use of drugs and devices; and the

offering or performing of those acts, services, operations or transactions necessary in the conduct, operation, management and control of pharmacy.

(2) The only other persons who may perform the above tasks other than a licensed pharmacist, and then only under the immediate direct supervision of a pharmacist, are the following:

- (a) A person serving an internship who holds a professional degree in pharmacy from a school of pharmacy recognized by the Board.
- (b) A person serving an externship who is enrolled in a school of pharmacy recognized by the Board.
- (c) A person who holds an assistant's license.

(3) It is ruled by the Board of Pharmacy that three (3) technicians, one of which shall be certified by any credentialing organization approved by the Board, on duty are sufficient in the prescription area of a retail pharmacy or an institutional pharmacy for each full time licensed pharmacist on duty. Nothing in this rule shall prevent a pharmacy from employing technicians to perform supervised tasks not requiring professional judgment.

- (4) In order to adequately protect the public health, technicians shall not:
 - (a) Communicate, orally or in writing, any medical, therapeutic, clinical or drug information, or communicate any information recorded on a patient profile that requires professional judgment.
 - (b) Document the receipt of a controlled substance into inventory.
 - (c) Accept by oral communication a new prescription of any nature.
 - (d) Prepare a copy of a prescription or read a prescription to another person.
 - (e) Provide a prescription or medication to a patient without a pharmacist's verification as to the correctness of the prescription or medication. For the purpose of this rule, verification shall mean that the licensed pharmacist shall be aware of the patient profile, DUR, computer overrides and drug interactions as well as the correctness of the selected medication and labeling.
 - (f) Counsel a patient on medications or perform a drug utilization review.
 - (g) Perform any task that requires the professional judgment of a pharmacist.
 - (h) Perform any task that is in violation of any federal, state or local pharmacy regulations.

(5) Written control procedures and guidelines for supervision of technicians by a licensed pharmacist and for performance of tasks by technicians shall be established and made available for review by the Board of Pharmacy.

- (6) In order to be registered as a pharmacy technician in this state, an applicant shall:
 - (a) Have submitted a written application on a form provided by the Board of Pharmacy
 - (b) Have attained the age of seventeen (17).

(7) No pharmacist whose license has been denied, revoked, suspended, or restricted for disciplinary purposes shall be eligible to be registered as a pharmacy technician.

- (8) All technicians shall wear a name tag, identifying them as such, while on duty.

(9) Each technician registered by the Board shall notify the board in writing within 10 days on change of employment. The notice shall contain his/he name, registration number, the name of the pharmacy where formerly employed and the name of the pharmacy where currently employed.

(10) All pharmacy technicians shall register with the Alabama State Board of Pharmacy. This registration shall expire on December 31 of odd numbered years. Effective January 1, 2006, the initial registration fee and renewal fee shall be sixty dollar (\$60). All pharmacy technicians shall pay the renewal fee biennially with this fee being due on October 31 and delinquent after December 31 of odd numbered years. All pharmacy technician registrations shall expire on December 31 biennially in odd-numbered years. The payment of the renewal fee shall entitle the registrant to renewal of their registration at the discretion of the

Board. If any pharmacy technician shall fail to pay a renewal fee on or before December 31 of any year, such registration shall become null and void, and the holder of such registration may be reinstated as a pharmacy technician only upon payment of a penalty of Ten Dollars (\$10.00) for each lapsed year and all lapsed fees for each lapsed year, provided the lapsed time of registration shall not exceed five (5) years, in which case reinstatement may be had only upon satisfactory examination by the Board. In the event an application for renewal of a pharmacy technician's registration is not received by December 31 of any odd numbered year but is received at the Board office no later than January 31 of the following year, a non-disciplinary administrative penalty in the amount of \$30.00 must be paid in order to renew. This penalty is in addition to any penalty referenced above.

(a) Every pharmacy technician registered by the Alabama State Board of Pharmacy shall, prior to reregistration, complete three (3) hours of continuing education annually, one hour of which shall be 'live' presentation.

(11) The Alabama State Board of Pharmacy shall refuse to issue a pharmacy technician registration whenever the Board finds by the preponderance of the evidence any of the following:

(a) That the applicant does not possess good moral character.

(b) That the applicant has willfully violated any of the provisions of Code of Alabama (1975), §34-23-1 et seq., or the Alabama Uniform Controlled Substances Act.

(c) That the applicant has willfully violated any rule or regulation promulgated in accordance with the provisions of Code of Alabama (1975), §34-23-1 et seq., or in accordance with the Alabama Uniform Controlled Substances Act.

(d) That the applicant has engaged in conduct which threatens the public health, safety or welfare.

(e) That the applicant has been convicted of a felony or a misdemeanor involving moral turpitude. 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.

(f) That the applicant has been convicted of a felony or misdemeanor involving a drug related offense of a legend drug or controlled substance. 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.

(g) That the applicant has been convicted of any crime or offense that reflects the inability of the applicant to engage in the performance of pharmacy technician functions with due regard for the health and safety to the public. 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.

(h) That the applicant has attempted to obtain a pharmacy technician registration by fraudulent means.

(i) That the applicant has violated any 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.

(j) That the applicant is unable to engage in the performance of pharmacy technician functions with reasonable skill and safety 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.

(k) The suspension, revocation or probation by another state of the applicant's license, permit or registration to practice as a pharmacy technician. A certified copy of the record of suspension, revocation or probation of the State making such suspension, revocation or probation shall be conclusive evidence of the suspension, revocation or probation.

(l) That the applicant refused to appear before the Board after having been ordered to do so in writing by the Executive Officer or President of the Board.

(m) That the applicant made any fraudulent or untrue statement to the Board.

Author: Herb Bobo, R.Ph, Secretary

Statutory Authority: Code of Alabama 1975, §34-23-92.

History: Filed June 1, 1982. Amended: Filed May 30, 1990. Repealed and Replaced: Filed July 26, 1996; operative August 30, 1996; effective January 1, 1997. Amended: Filed February 13, 1997; effective March 20, 1997; Amended: Filed September 20, 1999; effective October 25, 1999. Amended: Filed April 11, 2001; effective May 16, 2001; operative January 1, 2002. Amended: Filed July 1, 2002; effective

August 5, 2002. Amended: Filed January 6, 2005; effective February 10, 2005; Amended: Filed November 1, 2005; refilled December 22, 2005; effective December 22, 2005. Amended: Filed September 22, 2009; effective October 27, 2009. Amended: Filed December 8, 2009; effective January 12, 2010. Amended: Filed January 30, 2012; effective March 5, 2012.

680-X-2-.15. USE of COMPUTERS for RECORD-KEEPING in PHARMACIES in ALABAMA.

(1) Title 34, Chapter 23 of the Code of Alabama specifies the Power and Duty of the Board to adopt Rules concerning the records and reports to be kept and made by a pharmacy.

(a) The computerized system shall provide for the storage and retrieval of original prescription orders as follows:

1. The original prescription number.
2. The prescribing practitioner's name.
3. Full name and address of the patient.
4. Date the original prescription was issued and the date it was dispensed, if different from the date of issue.
5. Name, strength, dosage form, and quantity of drug dispensed.
6. Total number of refills authorized by the prescriber.
7. Quantity dispensed.
8. In the case of controlled substance, the DEA registration number and the Alabama Controlled Substances number of the prescribing practitioner.
9. Identification of the dispensing pharmacist.

(b) The computerized system shall provide for the retrieval of the refill history of all prescriptions entered into the computer. This refill history shall include:

1. The name of the drug.
2. Date of all refills.
3. Quantity dispensed originally and on each refill.
4. Identification of the dispensing pharmacist originally and for each refill.
5. The total number of refills dispensed to date for that prescription order.

(c) Documentation of the fact that the refill information entered into the computer each time a pharmacist refills an original prescription order for a Schedule III, IV, or V controlled substance is correct must be provided by the individual pharmacist who makes use of such a system in either of two ways.

1. If such a system provides a hard-copy printout of each day's controlled substance prescription order refill data, that printout shall be verified, dated, and signed. The individual pharmacist must verify that the data indicated is correct and then sign this document in the same manner as he or she would sign a legal document. This printout of the day's controlled substance prescription order refill data must be provided to each pharmacy using such a computerized system within seventy two hours of the date on which the refill was dispensed; or in lieu of such a printout, the pharmacy shall maintain a bound log book, or separate file, in which each individual pharmacist involved in such dispensing shall sign a statement each day in the same manner as he or she would sign a legal document, attesting to the fact that the refill information entered into the computer that day has been reviewed by him or her and is correct as shown.

(d) Any such computerized system shall have the capability producing a printout of any refill data which the user pharmacy is responsible for maintaining under the Alabama Controlled Substances Act and its implementing regulations. For example, this would include a refill-by-refill audit trail for any specified strength and dosage form of any controlled substance (by either brand, generic name, or both). Such a printout must include the name of the prescribing practitioner, name and address of the patient, quantity dispensed on each refill, date of dispensing on each refill, name or identification code of the dispensing pharmacist, and the number of the original prescription order.

(e) In any computerized system employed by a user pharmacy, the central record keeping location must be capable of sending the printout to the pharmacy within two business days; and if an Inspector of the Alabama State Board of Pharmacy or DEA special agent or compliance investigator request a copy of such printout from the user pharmacy, it must, if requested to do so by the Inspectors of the Alabama State Board of Pharmacy, the agent or investigator, verify the printout transmittal capability of its system by documentation

(e.g., postmark).

(f) In the event that a pharmacy which employs such a computerized system experiences system down-time, the pharmacy must have an auxiliary procedure which will be used for documentation of refills of Schedule III, IV, and V controlled substance prescription orders. This auxiliary procedure must insure that refills are authorized by original prescription order; that the maximum number of refills have not been exceeded; and that all of the appropriate data is retained for on-line entry as soon as the computer system is available for use again.

(g) Each pharmacy shall maintain its own series of consecutive numbered prescriptions. A series of numbers cannot be shared with another pharmacy, even if they are using the same computer.

(h) In addition to the controlled substances printout referred to in paragraph (c), a printout shall be obtained at least weekly of all new and refill prescription activity of the pharmacy for this period.

(i) All documentation required under this rule shall be kept in a separate binder and retained for two years.

(2) Computer systems for the storage and retrieval of prescriber's orders for legend drugs prescribed for in-patients does not replace the requirement that the practitioners orders be written and retained as a permanent record of the institution. Institution shall provide sufficient alternate records to maintain adequate controls and accountability.

Author: Jerry Moore, R.Ph.

Statutory Authority: §34-23-92, Code of Alabama 1975

History: Filed June 1, 1982; Amended: Filed February 13, 1997; effective March 20, 1997.

680-X-2-.16. PRACTICAL TRAINING PROGRAMS STANDARDS.

(1) The practical training experience required prior to licensure shall be referred to as externship/internship.

(2) The minimum externship/internship required for licensure shall be fifteen hundred (1500) hours. This may be obtained through a college-structured program or through a non-structured program, all under the supervision of a registered preceptor. Four hundred (400) hours of the minimum total requirement may become attainable after completing the requirements of the second professional year. The four hundred (400) hours must be completed in a traditional pharmacy setting, with a Board approved preceptor, so that the emphasis is on the distribution of medicines, prescriptions and medical supplies. An extern/ intern must be employed a minimum of four (4) hours a week; however, no less than one (1) hour will be accepted for a particular day. Externs/Interns shall submit to the Board of Pharmacy adequate documentation demonstrating compliance with the traditional hours requirements of this section. The School of Pharmacy shall certify that the intern has completed 1100 hours of internship plus any traditional hours gained during school rotations. The Board will accept hours from preceptors approved by the School of Pharmacy for the training of their students as part of the curriculum. The applicable School of Pharmacy, shall furnish the certification to the Board upon graduation of the student.

(3) An applicant for licensure, lacking the minimum 1500 hours in the manner stated, may be admitted to the examination only if all the requirements of Section 34-23-51 are met other than the requirement of practical pharmacy training. Those applicants, so admitted, who pass the examination administered by the Board shall be required to file affidavits attesting to the prescribed practical training program prior to being issued a license to practice pharmacy.

(4) Practical training externship/internship report, along with a preceptor affidavit, must be submitted to the Board for any traditional hours earned outside of the curriculum prior to the issuance of a license to practice pharmacy.

(5) Externship/Internship registration shall be limited to those persons who are actively engaged in meeting the academic or practical experience requirements for licensure examination. In order to be considered enrolled in a school of pharmacy, a person shall not be absent from school for more than two (2) consecutive semesters or three (3) consecutive quarters or be approved by the Board if outside of these

parameters. Any person, working as an extern/intern, must obtain a permit from the Board before assuming duties in a pharmacy. In order to be favorably considered for an extern/intern permit, a person must have completed two (2) academic years in pre-pharmacy and has attended classes in the first professional year of an approved school of pharmacy.

(6) Externship/Internship may be acquired only under the supervision of a preceptor who may supervise no more than three (3) externs/interns at any one time.

(7) The term supervision shall mean that at the site where externship/internship is being obtained, the preceptor shall be in personal contact with and actually giving professional instructions to the extern/intern during the entire period of such externship/internship. At all times, a person, who is serving an externship/internship, must be under the immediate direct supervision of a registered pharmacist on the premises.

(8) All candidates for licensure, who are working either as externs or interns, outside of the school curriculum, shall report their place of employment and/or practice site to the Board of Pharmacy within ten (10) days of such employment. Any change in such employment or practice site shall be reported to the Board within ten (10) days of the change.

(9) A pharmacy extern/intern, having served part or all of his/her required time in a site outside of this state and not as part of their school curriculum, shall be given credit provided the externship/internship requirements for the other state are no less than the requirements of the Alabama State Board of Pharmacy. The affidavits must be submitted through the Board of Pharmacy of the state where the time was performed and certified as meeting the requirements by the Board of Pharmacy of that state.

(10) The School of Pharmacy shall notify the Board within ten (10) days of a student's change of status.

Author: Donnie Calhoun, R.Ph, President

Statutory Authority: §34-23-92, Code of Alabama 1975

History: Filed December 10, 1984. Amended: Filed March 12, 1986; August 10, 1989; March 13, 1990; June 14, 1990. Amended: Filed August 1, 1997; operative September 5, 1997; effective October 3, 1997. Amended: Filed December 2, 1998; effective January 6, 1999. Amended: Filed January 31, 2011; effective March 7, 2011. Amended: Filed July 24, 2012; effective August 28, 2012. Amended: Filed December 21, 2012; effective January 25, 2013.

680-X-2-.17. RECIPROCITY.

(1) The Board may issue a license without examination to an applicant who furnishes satisfactory proof that he/she has been licensed to practice pharmacy by examination in another state that under like conditions grants reciprocal licensure without examination to pharmacists duly licensed by examination in this state.

(2) The application must be accompanied by a fee of \$300.00.

Author: Jerry Moore, R.Ph, Executive Secretary

Statutory Authority: Code of Alabama 1975, §34-23-92.

History: Filed: December 10, 1984; Amended: Filed: January 24, 1995; Effective February 28, 1995; Amended: Filed October 29, 1996; operative December 3, 1996; effective January 1, 1997.

680-X-2-.18. INSTITUTIONAL PHARMACIES.

(1) APPLICABILITY: In addition to existing State and Federal Regulations, the following Rules are applicable to all Institutions and Institutional Pharmacies as defined in Section 2 below.

(2) DEFINITIONS.

(a) "Institutional Facility" means any organization whose primary purpose is to provide a physical environment for inpatients to obtain health care services, including but not limited to a:

1. Hospital;
2. Convalescent Home;
3. Nursing Home;

4. Extended Care Facility;
5. Mental Health Facility;
6. Rehabilitation Center;
7. Psychiatric Center;
8. Developmental Disability Center;
9. Drug Abuse Treatment Center;
10. Family Planning Clinic;
11. Penal Institution;
12. Hospice;
13. Public Health Facility;
14. Athletic Facility.

(b) "Institutional Pharmacy" means that physical portion of an Institutional Facility that is engaged in the compounding, dispensing, and distribution of drugs, devices, and other materials used in the diagnosis and treatment of injury, illness, and disease (hereinafter referred to as "Drugs"); and which is registered with the State Board of Pharmacy.

(3) PERSONNEL:

(a) Each Institutional Pharmacy shall be directed by a pharmacist, hereinafter referred to as the Supervising Pharmacist, who is licensed to engage in the practice of pharmacy in this State.

(4) ABSENCE OF PHARMACIST:

(a) During such times as an Institutional Pharmacy may be unattended by a pharmacist, arrangements shall be made in advance by the Supervising Pharmacist for provision of Drugs to the medical staff and other authorized personnel of the Institutional Facility by use of a locked cabinet or other enclosure constructed and located outside of the pharmacy area and, in emergency circumstances, by access to the Pharmacy. A pharmacist shall be available after hours in accordance with established Institutional Policy.

(b) In the absence of a pharmacist, Drugs shall be stored in a cabinet/enclosure constructed and located outside of the Pharmacy area, to which only specifically authorized personnel may obtain access by key or combination, and which is sufficiently secure to deny access to unauthorized persons. The Supervising Pharmacist shall, in conjunction with the appropriate committee of the Institutional Facility, develop inventory listings of those Drugs to be included in such cabinet/enclosure and determine who may have access, and shall ensure that:

1. The Drugs are properly labeled;
2. Only prepackaged Drugs are available, in amounts sufficient for immediate therapeutic requirements;
3. Whenever access to the cabinet/enclosure occurs, written orders of an authorized practitioner and proofs of use are provided;
4. All drugs therein are inventoried regularly based on institutional policy, but no less than every thirty (30) days;
5. A complete audit of all activity concerning such cabinet/enclosure is conducted no less than once per month; and
6. Written policies and procedures are established to implement the requirements of this Section 4.

(c) Whenever any Drug is not available from floor supplies or cabinet/enclosure, and such Drug is required to treat the immediate needs of a patient whose health would otherwise be jeopardized, such Drug may be obtained from the Pharmacy in accordance with the requirements of this Section 4. One supervisory nurse or physician in any given shift is responsible for obtaining Drugs from the pharmacy. The responsible person shall be designated in writing by the appropriate committee of the Institutional Facility. Removal of any Drug from the Pharmacy by an authorized designee must be pursuant to written orders of an authorized practitioner and must be recorded on a suitable form showing patient name, room number, name of Drug, strength, amount, date, and time and signature of designee. The form shall be left with the container from which the drug was removed.

(d) For an Institutional Facility that does not have an Institutional Pharmacy, Drugs may be provided for use by authorized personnel by emergency kits located at such Facility, provided, however, such kits meet the following requirements:

1. The contents of the Emergency kit shall consist of those Drugs needed to effectively manage a critical care incident or need of a patient. A copy of the list of the contents of the emergency kit shall be

maintained both at the institution and the pharmacy supplying the drugs.

2. All emergency kit drugs shall be provided and sealed by a pharmacist who is licensed to engage in the practice of pharmacy in this state;

3. The supplying pharmacist and the medical staff of the Institutional Facility shall jointly determine the Drugs, by identity and quantity, to be included in emergency kits;

4. Emergency kits shall be stored in secured areas to prevent unauthorized access, and to ensure a proper environment for preservation of the Drugs within them;

5. The exterior of each emergency kit shall be labeled so as to clearly indicate that it is an emergency drug kit and that it is for use in emergencies only. The label shall contain a listing of the Drugs contained in the kit, including name, strength, quantity, and expiration date of the contents, and the name, address(es), and telephone number(s) of the supplying pharmacist;

6. Drugs shall be removed from emergency kits only pursuant to a valid written order of an authorized practitioner;

7. Whenever an emergency kit is opened, the supplying pharmacist shall be notified and the pharmacist shall stock and reseal the kit within a reasonable time but not more than 72 hours, so as to prevent risk of harm to patients; and

8. The expiration date of an emergency kit shall be the earliest date of expiration of any Drugs supplied in the kit. Upon the occurrence of the expiration date, the supplying pharmacist shall replace the expired Drug.

(e) For an institutional Facility that does not have an institutional pharmacy, Drugs may be stored in a cabinet/enclosure to which only authorized personnel may obtain access by key, combination, or access code and which is sufficiently secure to deny access to unauthorized persons, provided, however, such cabinet/enclosure meet the following requirements:

1. Definition of Stat Cabinet - A Stat Cabinet consists of non-controlled drugs needed to effectively manage a patient's drug regimen which are not available from any other authorized source in sufficient time to prevent risk of harm to patient by delay resulting from attaining such Drugs from other sources.

2. Each facility may maintain one "stat" cabinet/enclosure for the purpose of keeping a minimum amount of stock medications that may be needed quickly or after regular duty hours. If a facility wants more than one "stat" cabinet/enclosure, it must be approved by the Alabama State Board of Health and the Alabama State Board of Pharmacy.

3. The number of drugs provided by a pharmacy to a long term care facility shall be limited to fifty (50). There shall be a limited number of doses of any medication, not to exceed a 48 hour supply, of any drug dosage form per fifty (50) beds, and shall be packaged in an appropriate manner in the "stat" cabinet based on the established needs of the facility. Need for such medications shall be reviewed by the pharmacist annually.

4. There must be a list of contents, approved by the appropriate committee and a pharmacist giving the name and strength of the Drug and the quantity of each. Contents of the "stat" cabinet shall be properly labeled with name, strength and expiration date.

5. There shall be records available to show amount received, name of resident and amount used, prescribing physician, time of administration, name of individual removing and using the medication and the balance on hand.

6. There shall be written procedures for utilization of the "stat" cabinet with provisions for prompt replacement of used items.

7. The pharmacist shall inspect the "stat" cabinet at least monthly replacing outdated Drugs and reconciliation of its prior usage. Information obtained shall be included in a monthly report.

(5) DRUG DISTRIBUTION AND CONTROL:

(a) The Supervising Pharmacist shall establish written procedures for the safe and efficient distribution of Drugs and for the provision of pharmaceutical care. An annual updated copy of such procedures shall be on hand for inspection by the Board of Pharmacy.

(b) All of the activities and operations of each Institutional Pharmacy shall be personally and directly supervised by its Supervising Pharmacist or a designated pharmacist. All functions and activities of technicians shall be personally and directly supervised by a registered pharmacist to insure that all functions and activities are performed competently, safely, and without risk of harm to patients. There shall be not more than three (3) technicians, at least one of which shall be certified by any credentialing organization approved by the Board, on duty in the prescription area for each full time licensed pharmacist on duty. Nothing in this rule shall prevent an institutional pharmacy from employing technicians to perform supervised tasks not requiring professional judgment.

(c) Whenever patients bring drugs into an Institutional Facility, such drugs shall not be administered unless they can be precisely identified. Administration shall be pursuant to a practitioner's order only. If such Drugs are not to be administered, they shall be given to an adult member of the patient's immediate family for removal from the Institution or follow written policy provided by the Supervising Pharmacist.

(d) Investigational Drugs for inpatient use shall be stored in and dispensed from the Pharmacy only. Complete information on all investigational drugs stored or dispensed shall be maintained in the Pharmacy.

(e) The Supervising Pharmacist shall develop and implement a recall procedure that can be readily activated to assure the medical staff of the Institutional Facility and the Pharmacy staff that all drugs included on the recall intended for use within the facility are returned to the Pharmacy for proper disposition.

Author: Herb Bobo, R.Ph, Secretary

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680-X-2-.19. PARENTERAL THERAPY.

(1) Purpose: Whereas the Alabama State Board of Pharmacy is charged with the duty and responsibility to control the compounding and distribution of prescription drug products in the State of Alabama, and is further charged to protect the citizens from inferior drug products and inappropriate compounding procedures. This rule shall provide guidelines and regulations for the compounding and distributing of parenteral products in Alabama, and to assure the citizens of Alabama of sterile parenteral products that are dispensed or prepared by qualified pharmacists using acceptable pharmaceutical techniques and equipment.

(2) Registration and Certification, Pharmacies: All pharmacies engaged in the compounding of parenterals shall be registered with the Alabama State Board of Pharmacy biennially which shall expire on December 31 of even-numbered years and receive a permit in accordance with Code of Alabama 1975, §34-23-30. Such pharmacies shall be certified, further, by the Alabama State Board of Pharmacy as a parenteral pharmacy.

(3) Registration and Certification, Pharmacists: All pharmacists engaged in compounding and dispensing of Parenteral Solutions including cytotoxic agents shall register biennially which shall expire on December 31 of even-numbered years with the Board of Pharmacy in accordance with the Code of Alabama 1975, §§34-23-51, 34-23-52. After January 1, 1994, pharmacists who have not successfully completed a certifying course for parenteral pharmacists which has been approved by the Board, will not be registered as parenteral pharmacists with the Board until they have completed said certifying course. Programs submitted for certification shall be a minimum of five (5) contact hours, including didactic and hands on experience. All programs certified by the Board shall require a written exam as a part of the training.

(a) It shall be the responsibility of the supervising pharmacist to verify the parenteral certification of pharmacists involved in the preparation of parenteral products.

(b) Effective January 1, 1994, the annual one (1) hour of mandatory parenteral continuing education will no longer be required.

(4) Compounding Area for Parenteral Solutions: The parenteral pharmacy shall have a designated area complying with the clean room concept and contain a certified laminar air flow hood with the intact HEPA filters and shall:

(a) Have cleanable surfaces, walls and floors.

(b) Be ventilated with a filtered air source to inhibit the induction of particulate matter from areas outside the clean room.

(c) The laminar air flow hood shall be certified annually, in accordance with Federal Standard 209(b), Clean Room and Work Station Requirements, Controlled Environment, as approved by the Commission, Federal Supply Services, United States General Services Administration, as amended, (available from the U.S. General Services Administration, Specifications Activity, Printed Materials Supply Division, Building 197, Naval Weapons Plant, Washington, D.C. 20407). Certification records must be

retained for at least 2 years.

(d) The pharmacy shall be arranged in such a manner that the laminar flow hood is located in an area which is exposed to minimal traffic flow, and is separate from any area used for bulk storage of items not related to the compounding of parenteral solutions. There shall be no obstruction of the intake of the laminar flow hood.

1. There shall be sufficient space, well separated from the laminar flow hood area, for the storage of bulk materials, equipment and waste materials.

(e) A sink with hot and cold running water must be within or adjacent to the parenteral solution compounding area.

(f) There shall be a refrigerator and/or freezer of sufficient capacity to meet the storage requirement for all material requiring refrigeration.

(5) Laminar Flow Biological Safety Cabinet: In all pharmacies preparing parenteral cytotoxic agents, all compounding shall be conducted within a certified Class II Type A or Class II Type B vertical laminar air flow hood. The pharmacy must ensure that contaminated air plenums that are under positive air pressure are leak tight. The hood must be certified annually in accordance with the National Sanitation Foundation International Standard 49 for Class II (Laminar Flow) Biohazard Cabinetry, as revised (available from the National Sanitation Foundation International, 789 North Dixboro Road, P.O. Box 130140, Ann Arbor, Michigan 48113-0140) or manufacturer's specifications. Certification records must be retained for at least two (2) years.

(6) Labeling Requirements: In addition to existing labeling requirements, parenteral products labels shall include:

(a) Telephone number of the pharmacy when the parenteral product will be administered outside of the facility in which it was prepared.

(b) Names and amounts of all ingredients contained in the parenteral products, including primary solution.

(c) Instructions for storage and handling including expiration date and date prepared.

(d) All cytotoxic agents shall bear a special label regarding proper disposal.

(7) Recordkeeping Requirements: Pharmacies engaged in the practice of compounding and dispensing of parenteral solutions shall have on the premises or readily accessible, a patient record for each patient being treated with parenteral therapy. In addition to existing recording requirements, the following records shall be maintained.

(a) Records of the furnishing of all medications.

(b) Information relevant to the patient's parenteral therapy shall include but not be limited to:

1. Patient's name, age, sex and address; telephone number of location where patient is receiving parenteral therapy.

2. Primary diagnosis related to need for prescribed therapy; secondary diagnosis.

3. Summary of most recent hospitalization and/or previous history.

4. Medication history, including current diet/medication regimen and drug/food allergies.

(c) Progress notes documenting contact with the patient or physician relative to parenteral therapy.

(d) Laboratory data relevant to parenteral therapy.

(8) Protective Clothing: When preparing cytotoxic agents, gowns and gloves shall be worn. In addition, spill kits shall be available.

(9) Training of Staff, Patient and Caregiver: Consultation shall be available on a 24-hour basis to the patient and/or primary caregiver concerning proper use of parenterals and related supplies furnished by the pharmacy.

(a) The Supervising Pharmacist shall insure that all pharmacists engaged in dispensing or preparing compounded parenteral solutions are registered with the Board of Pharmacy and currently certified

as parenteral pharmacists by the Board.

(10) Disposal of Waste Material: Pharmacies providing parenteral services shall have written policies and procedure for the disposal of medical waste, infectious materials and/or materials containing cytotoxic residues including spills. The procedures shall include cleanup of spills and shall be in conformance with local health jurisdiction. The pharmacy shall ensure the return of such materials or shall communicate the proper destruction of such materials to the caregiver.

(11) Quality Assurance: The Supervising Pharmacist is responsible for developing and maintaining a quality assurance program that insures a clean and sanitary environment for the preparation of sterile products. Documentation of such activities shall be available. The Quality Assurance Program shall include at least the following:

- (a) Cleaning and sanitization of the parenteral medication preparation area.
- (b) Surveillance of parenteral solutions for microbiological contamination and actions taken in the event that testing for contamination proves positive.
- (c) Periodic documentation of the room and refrigerator temperatures in which compounded parenteral products are stored.
- (d) Steps to be taken in the event of a drug recall.
- (e) Justification of expiration dates for compounded parenteral products.

(12) Policies and Procedures: Pharmacies engaged in the practice of compounding and dispensing parenteral solutions shall have written policies and procedures which describe the methods employed by the pharmacy in all areas of the pharmacy's parenteral therapy services.

(13) Reference Materials: Pharmacies engaged in the practice of compounding and dispensing of parenteral solutions shall have current reference materials located in or immediately available to the pharmacy. The pharmacy shall have adequate reference materials related to the compounding and dispensing of parenteral products.

Some suggested sources include:

Handbook on Injectable Drugs (ASHP)
King's Guide to Parenteral Admixtures
AHFS Drug Information
Facts and Comparisons
Hansten's Drug Interactions
Remington Practice of Pharmacy

Author: Herb Bobo, R.Ph, Secretary

Statutory Authority: Code of Alabama 1975, §34-23-92

History: Filed: July 18, 1989; Effective: September 15, 1989. Amended: Filed January 25, 1993; Amended: Filed March 19, 1993; Effective January 1, 1994; Amended July 18, 2012; Effective August 27, 2012; Amended: Filed July 24, 2012; effective August 28, 2012.

680-X-2-.20. NUCLEAR PHARMACY.

(1) Purpose and Scope: It is unlawful to receive, possess or transfer radioactive drugs, except in accordance with appropriate pharmacy statute(s) and rule(s). It is also unlawful for any person to provide radiopharmaceutical services unless he/she is a pharmacist or a person acting under the direct supervision of a pharmacist acting in accordance with appropriate pharmacy statute(s) and the State Board of Pharmacy rule(s) and rules of the State Board of Health relating to radiation control. No person may receive, acquire, possess, use, transfer or dispose of any radioactive materials except in accordance with the conditions of a radioactive materials license issued by the State Board of Health. The requirements of these Nuclear Pharmacy Regulations are in addition to, and not in substitution for, other applicable provisions of regulations of the State Board of Pharmacy and the State Board of Health.

(2) Definitions: For the purpose of this rule, the following words and phrases pertaining to the practice of nuclear pharmacy shall have the respective meanings ascribed by this action:

- (a) Nuclear Pharmacy - A pharmacy which provides a radiopharmaceutical service.
- (b) Nuclear Pharmacist - An actively licensed pharmacist who has met the training qualifications as described in the rule.

(c) Radiopharmaceutical Service - Shall include, but shall not be limited to, the procurement, storage, preparation, labeling, quality assurance testing, distribution, record keeping or disposal of radiopharmaceuticals.

(d) Radiopharmaceutical - Any substance defined as a drug in Code of Alabama 1975, §34-23-1(11) which exhibits spontaneous disintegration of unstable nuclei with the emission of nuclear particles or photons and includes any such drug which is intended to be made radioactive. This definition includes nonradioactive reagent kits and nuclide generators which are intended to be used in the preparation of any such substance but does not include drugs such as carbon-containing compounds or potassium containing salts which contain trace quantities of naturally occurring radionuclides.

(e) Radiopharmaceutical Quality Assurance - Includes, but is not limited to, the performance of appropriate chemical, biological and physical tests on radiopharmaceuticals, and the interpretation of the resulting data to determine their suitability for use in humans and animals, including internal test assessment authentication of product history and the keeping of proper records.

(f) Authentication of Product History - Includes, but is not limited to, identifying the purchasing source, the ultimate fate, and intermediate handling of any component of a radiopharmaceutical or other drug.

(3) Registration and Certification of Pharmacies: The application for a certificate to operate a nuclear pharmacy shall only be issued to a pharmacy registered by the Alabama State Board of Pharmacy and to a licensed, certified nuclear pharmacist. Re-certification shall be biennially which shall expire on December 31 of even-numbered years on forms provided by the Board. Each nuclear pharmacy shall designate a licensed, certified nuclear pharmacist as the Supervising Pharmacist.

(4) Registration and Certification of Pharmacists: All pharmacists engaged in the practice of nuclear pharmacy shall have training or shall have demonstrated previous training in the safe handling of radioactive pharmaceuticals. They must be registered with and certified by the Alabama State Board of Pharmacy. Applications and re-certification with the Board is required biennially which shall expire on December 31 of even-numbered years on forms provided by the Board. Satisfactory completion of no less than two (2) hours of continuing education prior to re-certification earned in the previous calendar year related to nuclear pharmacy shall be required.

(5) General requirements: A licensed, certified nuclear pharmacist shall personally supervise the operation of only one nuclear pharmacy during all times the radiopharmaceutical services are being performed.

(a) The nuclear pharmacy area shall be secured from access by unauthorized personnel.

(b) Each nuclear pharmacist shall maintain accurate records of the acquisition, inventory, distribution, and disposal of all radiopharmaceuticals.

(c) All nuclear pharmacies shall provide a secure radioactive storage and decay area.

(d) All nuclear pharmacies shall comply with all applicable laws and regulations of federal and state agencies for the procurement, secure storage, inventory, preparation, distribution and disposal of radiopharmaceuticals and other drugs.

(e) Radiopharmaceuticals are to be dispensed only upon a prescription or medication order, from a licensed medical practitioner or his/her authorized agent authorized to possess, use and administer radiopharmaceuticals.

(f) A nuclear pharmacist may transfer radioactive materials to an *authorized user in accordance with all applicable laws and regulations.

(g) A nuclear pharmacy, upon receiving an oral order for a radiopharmaceutical, shall immediately have the order reduced to writing or recorded in a data processing system which writing or records shall contain at least the following:

1. The name of the authorized user or his/her agent.
2. The date of distribution and the time of calibration of the radiopharmaceutical.
3. The name of the procedure.
4. The name of the radiopharmaceutical.
5. The dose or quantity of the radiopharmaceutical.
6. The prescription number assigned to the order for the radiopharmaceutical.
7. Any specific instructions.
8. The initials of the person dispensing the radiopharmaceutical.

9. Whenever an order is for a therapeutic or blood-product radiopharmaceutical, the patient's name must be obtained and recorded.

(h) In addition to other labeling requirements of the state laws and rules of the Board of Pharmacy for nonradioactive pharmaceuticals, the immediate outer shield of a radiopharmaceutical to be distributed shall also be labeled with:

1. The standard radiation symbol.
2. The words, "Caution Radioactive Material".

(*) *"Authorized user" means a practitioner of the healing arts who is identified as an authorized user on a license issued by the State Board of Health that authorizes the medical use of radioactive material, hazards, and the applicable regulations of the U.S. Nuclear Regulatory Commission.*

3. The name of the procedure.
4. The prescription number of the radiopharmaceutical and a suitable lot number for traceability.
5. The radionuclide and chemical form.
6. The amount of radioactivity and the calibration date and time.
7. The expiration date and time.
8. The volume dispensed if liquid chemical form.
9. The number of items or weight if solid chemical form.
10. The number of ampules or vials if gaseous chemical form.
11. Molybdenum-99 content to USP limits.
12. The name of the patient, or the words, "Physician's Use Only", in the absence of a patient name.

(i) The immediate inner container label of a radiopharmaceutical to be distributed shall also be labeled with:

1. The standard radiation symbol.
2. The words, "Caution Radioactive Material".
3. The radionuclide.
4. The chemical form.
5. The name of the procedure.
6. The prescription number of the radiopharmaceutical.

(6) Minimum Requirement for Space, Equipment, Supplies, and Publication: In order to insure compliance with general safety requirements as set forth above, the following minimum requirements shall be met by a nuclear pharmacy, which operates pursuant to a permit issued by the Alabama Board of Pharmacy, and engages in providing radiopharmaceutical services. These requirements are in addition to the minimum requirements for space, equipment and supplies for other types of pharmacies, and those requirements of the State of Alabama Department of Public Health, Radiological Health Branch, for the control of radiation. Such minimum permit requirements are set forth as follows:

(a) Space - The area for the storage, compounding, distribution and disposal of radiopharmaceuticals shall be adequate to completely separate such nonradioactive pharmaceuticals from pharmacy areas.

(b) Equipment:

1. Fume hood
2. Shielded radiation containment drawing section
3. Dose calibrator
4. Well scintillation counters
5. Area rate meters
6. Geiger-Mueller (GM) survey meters
7. Refrigerator
8. Microscope
9. Hemocytometer
10. Leaded glass syringe and vial shields
11. Personnel radiation detection devices
12. Radioactive storage container and/or storage vault for waste materials

- (c) Supplies:
1. Syringes and vials required to perform practice
 2. Disposable gloves and protective lab coats
 3. Appropriate supplies to ensure aseptic technique
 4. Appropriate supplies to perform thin layer chromatography
 5. Lead transport shields for syringes and vials
 6. D.O.T. Type 7A approved transport containers and other labels and supplies for shipping radioactive materials.

(7) Training Qualifications: A pharmacist licensed to practice pharmacy in this state, who performs a radiopharmaceutical service, shall, prior to engaging in such specialized practice, meet the minimum training requirements of didactic study, training and experience in the handling of radioactive material.

(a) A licensed pharmacist seeking to practice nuclear pharmacy in this state, shall submit to the Board of Pharmacy, a certificate of training and a course outline from an accredited college of pharmacy, or other program recognized by the State of Alabama Department of Public Health, Radiological Health Branch and the Alabama Board of Pharmacy, and a certificate of such training which provides a minimum of 200 clock hours of formal didactic training. To satisfy the basic instruction requirement, 200 hours of classroom and laboratory training shall include:

1. Radiation physics and instrumentation
2. Radiation Protection
3. Mathematics pertaining to the use and measurement of radioactivity
4. Radiation Biology
5. Radiopharmaceutical chemistry

(b) The minimum on-the-job training which shall be included in a radiopharmacy internship is five hundred (500) hours of training and experience in the handling of unsealed radioactive material under the supervision of a licensed nuclear pharmacist. The training and experience shall include, but shall not be limited to the following:

1. Ordering, receiving and unpackaging radioactive material safely, including performing related radiation surveys.
2. Calibrating dose calibrators, scintillation detectors, and radiation monitoring equipment.
3. Calculating, preparing and verifying patient doses while maintaining radiation safety standards of shielding.
4. Following appropriate internal control procedures to prevent mislabeling.
5. Learning emergency procedures to handle and contain spilled materials safely, including related decontamination procedures and surveys.
6. Eluting Technetium-99 from generator systems, assaying the eluate for technetium-99m, for molybdenum-99 contamination, and processing the eluate with reagent radiopharmaceuticals.
7. Clinical practice concepts.

Author: Herb Bobo, R.Ph, Secretary

Statutory Authority: Code of Alabama 1975, § 34-23-92.

History: Adopted: June 8, 1989; Effective July 31, 1989; Amended July 18, 2012; Effective August 28, 2012.

680-X-2-.21. PATIENT COUNSELING.

(1) Pharmacists, because of their strategic position in the health care system, have traditionally provided drug information to their patients and to other health care professionals. In the best interest of the public health, the patient must be offered counseling for all new prescriptions and, where appropriate, for refill prescriptions. The offer to counsel shall be made by the pharmacist or the pharmacist's designee in a face to face oral communication with the patient, or the patient's representative, unless in the professional judgment of the pharmacist, it is deemed inappropriate or unnecessary. If it is deemed inappropriate or unnecessary by the pharmacist, it would be permissible for the offer to counsel to be made in a written communication, by telephone, or in a manner determined by the pharmacist to be appropriate. Said counseling must be performed by the pharmacist or properly supervised pharmacist intern. A printed statement shall be included

with every prescription listing the pharmacy's telephone number, for the patient to call with questions about their medication.

(2) Each new prescription and, where appropriate, refill prescription, should be reviewed for, but not limited to, the following:

- (a) therapeutic duplication;
- (b) drug-disease contraindication where indicated;
- (c) drug-drug interaction;
- (d) incorrect dosage/duration;
- (e) drug allergy interactions; and
- (f) clinical abuse/misuse.

(3) Pharmacists may discuss, but are not limited to, the following:

- (a) Name and description of the medication;
- (b) Dosage form, dosage, route of administration and duration of therapy;
- (c) Special directions, precautions for preparation, administration and use by the patient;
- (d) Common severe side effects, adverse effects or interactions, and therapeutic contraindications;
- (e) Techniques for self monitoring;
- (f) Proper storage;
- (g) Refill information; and
- (h) Action in the case of missed dose.

(4) Pharmacists or the pharmacist's designee, in a face to face communication, in institutional settings, shall offer to give an oral consultation with all new prescriptions and, where appropriate, for refill prescriptions dispensed to homeward-bound patients or the patient's representative. Said counseling must be performed by the pharmacist or properly supervised pharmacist intern. If the patient or the patient's representative are unavailable, the pharmacist shall make known the fact that a consultation is available and how he/she may be reached.

(5) Each pharmacy shall maintain patient medication profiles.

(6) Patient Medication Profiles shall be maintained in accordance with state and federal requirements. A pharmacist or pharmacist's designee shall, verbally or in writing, make a reasonable effort to obtain information for the patient medication profile. Each profile shall include at least the following information, when available:

- (a) Patient name, age, gender, address and phone number;
- (b) Individual patient history, including a list of prescription medications and devices, where appropriate; and
- (c) Pharmacist comments.

(7) Supervising pharmacists/directors shall be responsible to the Board for the provision of the rule.

(8) Each pharmacy shall have the latest edition and/or revision of "Facts and Comparisons" or any reference book or electronic media sufficient to meet the level of its pharmacy practice.

(9) Nothing in this rule shall prohibit the pharmacist from charging, and being reimbursed, for the provision of the above described professional service. The pharmacist should identify any fee for counseling in an itemized bill.

Author: Jerry Moore, Executive Secretary

Statutory Authority: Code of Alabama 1975, §34-23-92.

History: Original rule filed: December 29, 1989. Amended: Filed: March 29, 1990; Effective September 1, 1990. Amended: Filed: December 7, 1992; Effective February 1, 1993. Amended: Filed October 29, 1996; operative December 3, 1996; effective January 1, 1997. Amended: Filed September 20, 1999; effective October 25, 1999.

680-X-2-22. CODE OF PROFESSIONAL CONDUCT.

(1) Pharmacists and pharmacies are expected to conduct themselves in a professional manner at all times. The following code provides principles of professional conduct for pharmacists and pharmacies to guide them in their relationship with patients, fellow practitioners, other health professionals and the public.

(2) Violations of any provisions of this rule shall be deemed grounds for disciplinary action whenever the Board shall find a preponderance of evidence to such violations.

(a) A pharmacist and a pharmacy should hold the health and safety of patients to be of first consideration and should render to each patient the full measure of professional ability as an essential health practitioner.

(b) A pharmacist and a pharmacy should never knowingly condone the dispensing, promoting, or distributing of drugs or medical devices, or assist therein, that are not of good quality, that do not meet standards required by law, or that lack therapeutic value for the patient.

(c) A pharmacist and a pharmacy should always strive to perfect and enlarge professional knowledge. A pharmacist and a pharmacy should utilize and make available this knowledge as may be required in accordance with the best professional judgment.

(d) A pharmacist and a pharmacy has the duty to observe the law, to uphold the dignity and honor of the profession, and to accept its ethical principles. A pharmacist and a pharmacy should not engage in any activity that will bring discredit to the profession and should expose, without fear or favor, illegal or unethical conduct in the profession.

(e) A pharmacist and a pharmacy should respect the confidential and personal nature of professional records; except where the best interest of the patient requires or the law demands, a pharmacist and a pharmacy should not disclose such information to anyone without proper patient authorization.

(f) A pharmacist and a pharmacy should not agree to practice under terms or conditions that interfere with or impair the proper exercise of professional judgment and skill, that cause a deterioration of the quality of professional services, or that require consent to unethical conduct.

(g) A pharmacist and a pharmacy should strive to provide information to patients regarding professional services truthfully, accurately, and fully and should avoid misleading patients regarding the nature, cost or value of these professional services.

(h) A pharmacist and a pharmacy should never offer or participate in the offering a financial award or benefit, not related to competitive retail pricing of any drug, to induce or encourage any individual to transfer a prescription from one pharmacy to another.

Author: Herb Bobo, R.Ph. Secretary

Statutory Authority: Code of Alabama 1975; §34-23-92.

History: Original rule filed: May 30, 1990; Effective July 30, 1991; Amended: May 9, 2011; effective June 13, 2011. Amended: December 16, 2011; effective January 20, 2012.

Editor's Note: This new rule was disapproved by the Joint Committee on Administrative Regulation Review on July 17, 1990. The full Legislature failed to sustain the suspension by the Joint Committee, (HJR 43), at the 1991 Regular Session. (See Code of Alabama 1975, §§41-22-23, 41-22-24.)

680-X-2-.23. DRUG MANUFACTURERS; WHOLESALE DISTRIBUTORS.

(1) Section 1. Definitions.

(a) **DRUG OUTLET**-All pharmacies, hospitals, drug abuse treatment centers, retail stores, penal institutions, and state jurisdictions that are engaged in delivery or distribution of drugs.

(b) **LEGEND DRUGS**-Any drug, medicine, device, chemical or poison bearing on the label the words, "CAUTION: Federal Law prohibits dispensing without prescription," or similar wording indicating that such drug, medicine, device, chemical or poison may be sold or dispensed only upon the prescription of a licensed medical practitioner.

(c) **MANUFACTURER**-Every person, except a pharmacy, in this state who prepares, derives, produces, compounds, packages or repackages any drug, medicine, chemical or poison.

(d) **PRINCIPALS**-Officers, directors and primary stockholders of a business entity or corporation.

(e) **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 uses 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.

(f) **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 such purposes.

(g) **WHOLESALE DRUG DISTRIBUTOR**-Every person in this state 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 (a) intracompany sales, (b) manufacturer and distributor sales representatives who distribute drug samples, (c) charitable organizations distributing to non-profit 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, and (f) the sale, purchase, or trade of a drug, an offer to sell, purchase, or trade a drug, or the dispensing of a drug pursuant to a prescription.

(h) **CHARGE BACK**-A process whereby a wholesale drug distributor is reimbursed for preferential pricing.

(i) **BLOOD** - Whole blood collected from a single donor and processed either for transfusion or further manufacturing.

(j) **BLOOD COMPONENT** - That part of blood separated by physical or mechanical means.

(k) **DRUG SAMPLE** - A unit of a drug that is not intended to be sold and is intended to promote the sale of the drug.

(l) **INTRACOMPANY SALES** - Any transaction or transfer between any division, subsidiary, parent and/or affiliated or related company under the common ownership and control of a corporate entity.

(2) Section 2. **Standards.**

(a.) Storage Conditions:

1. All facilities at which drugs or medicines are repackaged, wholesaled, stored, held, sold, offered for sale, exposed for sale or kept for sale must provide storage areas that ensure proper lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security conditions. These storage area facilities must be kept free from infestation by insects, rodents, birds, or vermin of any kind and be maintained in a clean and orderly condition. All drugs or medicines must be stored at appropriate temperatures and under appropriate conditions in accordance with the requirements, if any, in the labeling of such drugs or medicines or with requirements in the current edition of an official compendium. If no storage requirements are established for a drug or medicine they may be held at "controlled" room temperature as defined in an official compendium to help ensure that the identity, strength, quality, and purity of the same are not adversely affected. Appropriate manual, electromechanical, or electronic temperature and humidity recording equipment, devices, and/or logs shall be utilized to document proper storage of drugs. A separate quarantine storage section must be provided for drugs or medicines that are deteriorated, outdated, misbranded, or otherwise adulterated, or that are in immediate or sealed secondary containers that have been opened. All incoming and outgoing drug shipments must be visually examined for identity and to prevent the acceptance or distribution of contaminated or damaged product.

(b.) Facilities:

1. All buildings in which drugs or medicines are wholesaled, repackaged, stored, held, sold, offered for sale, exposed for sale, or kept for sale must be of suitable size, construction and location to facilitate cleaning, maintenance, and proper operations. Buildings must meet all applicable federal, state and local standards. A facility may not be located in a residence.

(c.) Security:

1. All facilities used for wholesale drug distribution shall be secure from unauthorized entry.
2. All wholesale drug distribution centers must be equipped with an alarm system to detect entry after hours.
3. Wholesale drug distributors must ensure that access from outside their premises is reduced

to a minimum and well controlled. This includes, but is not limited to, the installation of adequate lighting at the outside perimeter.

4. Internal security policies must be developed to provide reasonable protection against theft by personnel. These policies shall provide protection against computer theft and crimes.

5. Entry into areas where drugs are held shall be limited to authorized personnel.

(d.) Examination of Drugs and Medicines:

1. Upon receipt, each outside shipping container shall be visually examined for identity and to prevent the acceptance of contaminated drugs or drugs that are otherwise unfit for distribution. This examination shall be adequate to reveal container damage that would suggest possible contamination or other damage to the contents.

2. Each outgoing shipment shall be carefully inspected for identity of the drug products and to ensure that there is no delivery of drugs that have been damaged in storage or held under improper conditions.

3. The recordkeeping requirements of this Rule shall be followed for all incoming and outgoing shipments.

(e.) Recordkeeping:

1. Wholesale drug distributors shall establish and maintain inventories and records of all transactions regarding the receipt and distribution or other disposition of drugs. These records shall include the following:

(i) The source of the drugs, including the name and principal address of the seller or transferor, and the address of the location from which the drugs were shipped;

(ii) The identity and quantity of the drugs received and distributed or disposed of; and

(iii) The dates of receipt and distribution or other disposition of the drugs.

2. Inventories and records shall be made available for inspection and photocopying by authorized personnel for a period of two years following disposition of the drugs.

3. Records described in this Rule that are kept at the inspection site or that can be immediately retrieved by computer or other electronic means shall be readily available for authorized inspection during the retention period. Records kept at a central location apart from the inspection site and not electronically retrievable shall be made available for inspection within two (2) working days of a request by authorized personnel.

4. All charge back transactions shall be maintained separately from all other records

5. Copies of records and reports required by the Drug Enforcement Administration concerning increases in purchases or high or unusual volumes purchased by pharmacies, shall be forwarded to the Board of Pharmacy.

(f) Inspections:

1. Wholesale drug distributors shall permit the Board of Pharmacy and authorized Federal and State and Municipal law enforcement officials to enter and inspect their premises and delivery vehicles, and to audit their records and written operating procedures at reasonable times and in a reasonable manner, to the extent authorized by law. Such officials shall be required to show appropriate identification prior to being permitted access to wholesale drug distributors' premises and delivery vehicles.

(g) Written Policies and Procedures:

1. Wholesale drug distributors shall establish, maintain, and adhere to written policies and procedures, which shall be followed for the receipt, security, storage, inventory and distribution of drugs, including policies and procedures for identifying, recording and reporting losses or thefts, and for correcting all errors and inaccuracies in inventories. Wholesale drug distributors shall include in their written policies and procedures the following:

(i) A procedure to ensure that wholesale drug distributors prepares for, protect against, and handle any crisis that affects security or operation of any facility in the event of strike, fire, flood, or other natural disaster or any other situation of local, state, or national emergency.

(ii) A procedure to ensure that any outdated drugs shall be segregated from other drugs and either returned to the manufacturer or destroyed. This procedure shall provide for written documentation of the disposition of the outdated drugs and shall be maintained for two (2) years after the disposition of the same.

(iii) A procedure whereby the oldest approved stock of a drug product is distributed first. The procedure may permit deviation from this requirement, if such deviation is temporary and appropriate.

(iv) A procedure to be followed for handling recalls and withdrawals of drugs which shall be adequate to deal with recalls and withdrawals due to:

(I) Any action initiated at the request of the Food and Drug Administration or other Federal, State or Municipal law enforcement or other governmental agency, including the Alabama State Board of Pharmacy.

(II) Any voluntary action by the manufacturer to remove defective or potentially defective drugs from the market; or

(III) Any action undertaken to promote public health and safety by replacing existing merchandise with an improved product or new package design.

(h) Returned, Damaged and Outdated Drugs:

1. Any drug that is outdated, damaged, deteriorated, misbranded or adulterated shall be quarantined and physically separated from other drugs until destroyed or returned to the supplier.

2. Any drug whose immediate or sealed outer or secondary container has been opened or used shall be identified as such, and shall be quarantined and physically separated from other drugs until destroyed or returned to the supplier.

3. If the conditions under which a drug has been returned casts doubt on the drug's safety, identity, strength, quality, or purity, then the drug shall be destroyed or returned to the supplier, unless examination, testing, or other investigation proves that the drug meets appropriate standards of safety, identity, strength, quality, and purity.

(i) In determining whether the conditions under which a drug has been returned casts doubt on the drug's safety, identity, strength, quality, or purity, then the wholesale distributor shall consider, among other things, the conditions under which the drug has been held, stored or shipped before or during its return and the condition of the drug and its container, carton or labeling as a result of storage or shipping.

(ii). Responsibility for Operation:

1. A wholesale drug distribution operation should maintain a list of principals and persons in charge (including officers, directors, or primary stockholders) including a list of their duties and their qualifications.

2. All applicants for a permit as a controlled substance wholesale drug distributor must be registered with the Board of Pharmacy and with the U.S. Drug Enforcement Administration and comply with all DEA regulations.

3. The Board of Pharmacy shall consider, at a minimum, the following factors in reviewing the qualifications of those persons who engage in the wholesale distribution of drugs within Alabama:

(i) Any convictions of the applicant under any Federal, State, or Municipal laws relating to drug samples, wholesale or retail drug distribution, or distribution of controlled substances;

(ii) Any felony convictions of the applicant under Federal, State, or Municipal laws;

(iii) The applicant's past experience in the manufacturing or distribution of drugs, including controlled substances;

(iv) The furnishing by the applicant of false or fraudulent material in any application made in connection with drug manufacturing or distribution;

(v) Suspension or revocation by Federal, State or Municipal government of any license currently or previously held by the applicant for the manufacturing or

distribution of any drugs, including controlled substances;

(vi) Compliance with licensing requirements under previously granted licenses, if any;
(vii) Compliance with the requirements to maintain and/or make available to the State licensing authority or to Federal, State, or Municipal law enforcement officials those records required to be maintained by wholesale drug distributors; and

(viii) Any other factors or qualifications the Board of Pharmacy considers relevant to and consistent with public health and safety.

4. The Board of Pharmacy reserves the right to deny a license to an applicant if it determines that the granting of such a license would not be in the public interest.

(j) Personnel:

1. The Alabama State Board of Pharmacy shall require that personnel employed in wholesale distribution have appropriate education and/or experience to assume responsibility for positions related to compliance with State licensing requirements.

(k) Violations:

1. It shall be a violation of these rules for a wholesale drug distributor to distribute legend drugs directly to an employee, consumer, or a patient, or to operate in such a manner as to endanger the public health.

2. Conviction of any Federal, State or Municipal drug laws or regulations or violation of any provisions of this Rule may be grounds for the revocation, suspension, probation or refusal to issue the permit granted to wholesale drug distributors by the Board of Pharmacy and/or the imposition of a fine not to exceed the sum of \$1,000.00 for each such conviction or violation.

3. Wholesale drug distributors shall operate in compliance with applicable Federal, State and Municipal laws and regulations.

Author: Vance L. Alexander, R.Ph, President

Statutory Authority: Code of Alabama 1975, §34-23-92.

History: Original rule filed: December 29, 1989. Amended: Filed: March 28, 1990; Effective September 1, 1990. Amended: Filed: October 18, 1991; Effective January 1, 1992. Amended: Filed: August 5, 1992; Effective September 11, 1992. Amended: May 20, 1996; effective June 24, 1996; operative August 15, 1996.

680-X-2-.24 PRECURSOR DRUGS.

(1) LISTED PRECURSOR CHEMICALS:

(a) All substances listed as precursor chemicals in any regulation set forth in the Code of Federal Regulations shall be considered and designated as a precursor chemical with the exception of those precursor chemicals designated or deleted as such under federal law to which the Board objects, after notice, in the manner provided in Code of Alabama (1975), § 20-2-181(c), all precursor chemicals listed in any federal regulation shall be considered and designated as precursor chemicals pursuant to the provisions of Code of Alabama (1975), § 20-2-180, et seq.

(2) LICENSE.

(a) Beginning in 2011 and every two years thereafter, any individual, corporation, partnership, association or other entity who is a manufacturer, wholesaler, retailer or other person who sells, transfers, manufactures, purchases for resale or otherwise furnishes any listed precursor chemicals as defined or designated by any federal or state law or rule must obtain a license. The license shall be issued only after the filing of an application with the Alabama State Board of Pharmacy and Board approval. The application shall contain information as required by and in conformity with any applicable federal or state law or rule.

(b) A biennial license fee in the amount of \$500.00 shall be paid by all licensees to the Alabama State Board of Pharmacy by December 31 of any even numbered year. If not received by December 31, but is received in the Board's office no later than January 31 of the following year, a non-disciplinary administrative penalty of fifty percent (50%) of the prevailing renewal fee must be paid by January 31 of the following year in order to renew. This penalty shall be in addition to the prevailing renewal fee.

(3) PERMIT.

(a) A permit must be obtained from the Alabama State Board of Pharmacy each time any individual, corporation, partnership, association or other entity having a legitimate need for using any listed precursor chemical as defined or designated by law or rule of the Alabama State Board of Pharmacy obtains such chemical(s). The permit shall be issued only after the filing of an application with the Alabama State Board of Pharmacy and the Board's approval of that application. The application shall contain information as required by and conform with the requirements of all applicable laws or rules of the Alabama State Board of Pharmacy.

(b) A permit fee in the amount of \$35.00 shall be paid to the Alabama State Board of Pharmacy each time any individual, corporation, partnership, association or other entity obtains any listed precursor chemical.

Author: Herb Bobo, R.Ph, Secretary
Statutory Authority: Code of Alabama (1975), § 34-23-92(6) and § 20-2-181
History: Adopted: October 7, 1991; Effective January 1, 1992; Amended: Filed September 15, 1992; Effective October 9, 1992; Amended September 4, 1999; Effective November 1, 1999; Amended: Filed October 20, 2005; Effective February 17, 2006; Amended: Filed July 8, 2010; effective August 12, 2010; operative September 1, 2010. Amended: Filed August 26, 2011; effective September 30, 2011; operative October 3, 2011.

680-X-2-25. DRUG MANUFACTURERS; WHOLESALE DRUG DISTRIBUTORS; PERMIT FEES.

(1) PERMIT.

(a) A biennial permit must be obtained from the Alabama State Board of Pharmacy by any manufacturer bottler, packager, repackager, or wholesale drug distributor of medicines, chemicals or poisons for medicinal purposes. The permit shall be issued only after the filing of an application on a form furnished by the Alabama State Board of Pharmacy and the Board's approval of that application. The application shall be accompanied by the fee set forth in paragraph (b). The application shall contain information as required by and conform with the requirements of all applicable laws or rules of the Alabama State Board of Pharmacy.

(b) The fee for the biennial permit shall be in the amount of \$500.00. The fee for any renewal permit shall be in the amount of \$500.00. The fee to transfer ownership of the permit shall be in the amount of \$250.00.

(c) All permits issued by the Alabama State Board of Pharmacy shall become due on October 31 and shall become null and void on 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, at which time the previous permit shall become null and void. A penalty of twenty-five dollars (\$25.00) for each overdue month shall be assessed in addition to the permit fee for renewal of delinquent permits.

Author: Jerry Moore, R.Ph., J.D., Executive Director
Statutory Authority: Code of Alabama 1975, §34-23-92.
History: Adopted October 18, 1991; Effective January 1, 1992; Amended: Filed January 6, 2005; effective February 10, 2005.

680-X-2-26. EMERGENCY PRESCRIPTION REFILL.

(1) If a pharmacist received a request for a prescription refill, the original of which is maintained in the pharmacy files, and the pharmacist is unable to readily obtain refill authorization from the prescriber, the pharmacist may dispense a one-time emergency refill of up to a 72 hour supply of the prescribed medication, provided that:

- (a) The prescription is not a medicinal agent listed in Schedule II appearing in Title 20 Chapter 2.
- (b) The prescription is not a medicinal agent listed in Schedule III appearing in Title 20 Chapter 2.
- (c) The medication is essential to the maintenance of life or the continuation of therapy in a chronic condition including but not limited to drugs listed in the following categories, according to the latest

edition of Facts and Comparisons, U.S.P./N.F., P.D.R. or A.M.A. Drug evaluation:

1. Blood Modifiers
 - (I) Iron Products
 - (I) Oral Iron
 - (II) Parenteral Iron
 - (III) Iron Combinations (with Vitamins, with Liver, with B12) and Intrinsic Factor
 - (ii) Folic Acid
 - (I) Leucovorin Calcium
 - (iii) Vitamin B12
 - (I) Cyanocobalamin
 - (II) Hydroxocobalamin
 - (III) Liver Preparations
 - (iv) Vitamin K
 - (v) Recombinant Human Erythropoietin
 - (vi) Colony Stimulating Factors
 - (I) Filgrastim
 - (II) Sargramostim
 - (vii) Antiplatelet Agents
 - (I) Dipyridamole
 - (II) Ticlopidine
 - (viii) Anticoagulants
 - (I) Heparin
 - (II) Coumarin and Indandione Derivatives
 - (ix) Heparin Antagonist
 - (I) Protamine Sulfate
 - (x) Tissue Plasminogen Activator
 - (xi) Thrombolytic Enzymes
 - (xii) Hemorheologic Agent
 - (xiii) Antithrombin
 - (xiv) Antihemophilic Products
 - (I) Antihemophilic factor
 - (II) Anti-inhibitor coagulant complex
 - (III) Factor IX complex (Human)
 - (xv) Hemostatics
 - (I) Systemic
 - (II) Topical
 - (xvi) Plasma Protein Fractions
 - (xvii) Dextran Adjunct
 - (xviii) Plasma Expanders
 - (xix) Perfluorochemical Emulsion

- (xx) Hemin
- 2. Hormones
 - (I) Sex Hormones
 - (I) Estrogens
 - (II) Progestins
 - (III) Estrogens and Progestins, Combined
 - (IV) Oral Contraceptives
 - (V) Levonorgestrel Implant
 - (VI) Intrauterine Progesterone
 - (VII) Androgens
 - (VIII) Anabolic Steroids
 - (IX) Estrogen and Androgen Combinations
 - (X) Ovulation Stimulants
 - (XI) Gonadotropins
 - (XII) Chorionic Gonadotropin
 - (XIII) Gonadotropin Releasing Hormones
 - (XIV) Danazol
 - (ii) Growth Hormone
 - (iii) Pituitary (Growth Hormone) Test
 - (iv) Octreotide Acetate
 - (v) Posterior Pituitary Hormones
 - (I) Vasopressin Derivatives
 - (II) Oxytocics
 - (vi) Uterine Relaxant
 - (vii) Abortifacients
 - (I) Prostaglandins
 - (II) Sodium Chloride
 - (viii) Adrenal Cortical Steroids
 - (I) Corticotropin (ACTH)
 - (II) Mineralocorticoids
 - (III) Glucocorticoids
 - (ix) Adrenal Steroid Inhibitors
 - (x) Pituitary Function Test
 - (xi) Antidiabetic Agents
 - (I) Insulin
 - (II) Sulfonylureas
 - (xii) Glucose Elevating Agents
 - (I) Glucagon
 - (II) Diazoxide
 - (III) Glucose
 - (xiii) Alglucerase

- (xiv) Thyroid Drugs
 - (I) Thyroid Hormones
 - (II) Iodine Products
 - (III) Antithyroid Agents
- (xv) Calcitonin
- (xvi) Etidronate Disodium

- (xvii) Gallium Nitrate

- 3. Diuretics and Cardiovasculars
 - (I) Diuretics
 - (I) Carbonic Anhydrase Inhibitors
 - (II) Thiazides and Related Diuretics
 - (III) Loop Diuretics
 - (IV) Potassium Sparing Diuretics
 - (V) Diuretic Combinations
 - (VI) Osmotic Diuretics
 - (VII) Nonprescription Diuretics
 - (ii) Cardiac Glycosides

 - (iii) Amrinone

 - (iv) Antianginal Agents
 - (I) Combinations

 - (v) Antiarrhythmic Agents

 - (vi) Calcium Channel Blocking Agents

 - (vii) Peripheral Vasodilators
 - (I) Combinations
 - (viii) Drugs used in Shock
 - (ix) Beta-Adrenergic Blocking Agents
 - (x) Alpha-Beta Adrenergic Blocking Agents
 - (xi) Antihypertensives
 - (I) Antiadrenergic Agents
 - I. Centrally Acting
 - II. Peripherally Acting
 - (II) Vasodilators
 - (III) Angiotensin Converting Enzyme Inhibitors
 - (IV) Agents for Pheochromocytoma
 - (V) Agents for Hypertensive Emergencies
 - (VI) Miscellaneous Agents
 - (VII) Combinations

 - (xii) Potassium Removing Resins

 - (xiii) Cardioplegia Solution

 - (xiv) Salt Substitutes

 - (xv) Edentate Disodium

- (xvi) Antihyperlipidemic Agents
- 4. Respiratory Drugs
 - (I) Bronchodilators
 - (I) Sympathomimetics
 - (II) Xanthine Derivatives
 - (ii) Respiratory Inhalant Products
 - (I) Corticosteroids
 - (II) Mucolytics
 - (III) Anticholinergics
 - (IV) Miscellaneous
 - (iii) Nasal Decongestants
 - (I) Combinations
 - (iv) Intranasal Steroids
 - (v) Alpha Proteinase Inhibitor
 - (vi) Lung Surfactants
 - (vii) Antihistamines
 - (I) Miscellaneous Preparations
 - (II) Combined Preparations
 - (viii) Antitussives
 - (I) Narcotic
 - (II) Nonnarcotic
 - (ix) Expectorants
 - (x) Respiratory Combination Products
 - (I) Antiasthmatic Combinations
 - I. Xanthine Combinations
 - A. Capsules and Tablets
 - B. Liquids
 - II. Xanthine Sympathomimetic Combinations
 - A. Capsules and Tablets
 - B. Liquids
 - (xi) Upper Respiratory Combinations
 - (I) Decongestant Combinations
 - (II) Pediatric Decongestant Combinations
 - (III) Antihistamine and Analgesic Combinations
 - (IV) Decongestants and Antihistamines
 - I. Sustained Release
 - II. Pediatric sustained release
 - III. Capsules and Tablets
 - IV. Liquids
 - V. Pediatric
 - (V) Decongestant, Antihistamine and Analgesic Combinations
 - I. Pediatric
 - (VI) Decongestant, Antihistamine and Anticholinergic Combinations

- I. Sustained release
 - II. Miscellaneous
 - III. Pediatric
 - (VII) Cough Preparations
 - I. Antitussive Combinations
 - A. Capsules and Tablets
 - B. Liquids
 - II. Expectorant Combinations
 - A. Capsules and Tablets
 - B. Liquids
 - III. Antitussives and Expectorants
 - A. Narcotic
 - B. Nonnarcotic
 - IV. Antitussive and Expectorant Combinations
 - A. With Decongestants
 - B. With Antihistamines
 - C. With Decongestants and Antihistamines
 - V. Pediatric
5. Central Nervous System Drugs
- (I) CNS Stimulants
 - (i) Analeptics
 - (II) Amphetamines
 - (III) Anorexiant
 - (IV) Nonprescription Diet Aids
 - (ii) Analgesics
 - (I) Narcotic Agonist Analgesics
 - (II) Narcotic Analgesic Combinations
 - (III) Narcotic Agonist-Antagonist Analgesics
 - (IV) Central Analgesics
 - (V) Acetaminophen
 - (VI) Salicylates
 - (VII) Nonnarcotic Analgesic Combinations
 - (VIII) Nonsteroidal Anti-Inflammatory Agents
 - (IX) Antirheumatic Agents
 - (X) Agents for Gout
 - (XI) Agents for Migraines
 - I. Combinations
 - (iii) Antiemetic/Antivertigo Agents
 - (I) Antidopaminergics
 - (II) Anticholinergics
 - (III) Miscellaneous
 - (IV) Combinations
 - (iv) Psychotherapeutic Drugs
 - (I) Antianxiety Agents
 - I. Benzodiazepines
 - II. Miscellaneous
 - (II) Antidepressants
 - I. Tricyclics

- II. MAO Inhibitors
- (III) Antipsychotic Agents
 - I. Phenothiazines
 - II. Thioxanthenes
- (IV) Miscellaneous Psychotherapeutic Agents
 - I. Agents
 - (V) Sedative and Hypnotics
 - (VI) Nonbarbiturates
 - I. Benzodiazepines
 - (VII) Nonprescription Sleep Aids
 - (VIII) Barbiturates
- (v) General Anesthetics
 - (I) Barbiturates
 - (II) Nonbarbiturates
 - (III) Gases
 - (IV) Volatile Liquids
 - (vi) Anticonvulsants
 - (I) Hydantoins
 - (II) Succinimides
 - (III) Oxazolidinediones
 - (IV) Benzodiazepines
 - (V) Miscellaneous
 - (vii) Muscle Relaxants
 - (I) Adjuncts to Anesthesia
 - I. Nondepolarizing Agents
 - II. Depolarizing Agents
 - (II) Skeletal
 - (III) Skeletal Combinations
 - (viii) Antiparkinson Agents
 - (I) Anticholinergics
- 6. Gastrointestinal Drugs
 - (I) Antacids
 - (I) Combinations
 - (ii) Sucralfate
 - (iii) Gastrointestinal Anticholinergics/Antispasmodics
 - (I) Combinations
 - (iv) Histamine H2 Antagonists
 - (v) Prostaglandins
 - (vi) Antiflatulents
 - (vii) GI Stimulants
 - (I) Metoclopramide
 - (II) Dexpanthenol
 - (viii) Digestive Enzymes
 - (ix) Gastric Acidifiers

- (x) Choleretics
- (xi) Hydrocholeretics
- (I) Combinations
- (xii) Miscellaneous Digestive Products
- (xiii) Gallstone Solubilizing Agents
 - (I) Chenodiol
 - (II) Ursodiol
 - (III) Monoctanoin
- (xiv) Laxatives
 - (I) Saline
 - (II) Stimulant
 - (III) Bulk
 - (IV) Emollient
 - (V) Fecal Softeners
 - (VI) Hyperosmolar Agents
 - (VII) Enemas
 - (VIII) CO₂ Releasing Suppositories
 - (IX) Bowel Evacuants
 - (X) Lactulose
 - (XI) Combinations
- (xv) Antidiarrheals
 - (I) Diphenoxylate/Atropine
 - (II) Loperamide
 - (III) Bismuth Subsalicylate
 - (IV) Combinations
- (xvi) Mesalamine
- 7. Antineoplastic Agents
 - (I) Chemotherapeutic Regimens
 - (ii) Alkylating Agents
 - (I) Nitrogen Mustards
 - I. Mechlorethamine HCl
 - II. Chlorambucil
 - III. Melphalan
 - IV. Cyclophosphamide
 - V. Uracil Mustard
 - (II) Nitrosoureas
 - I. Lomustine
 - II. Carmustine
 - III. Streptozocin
 - (III) Thiotepa
 - (IV) Busulfan
 - (V) Pipobroman
 - (VI) Cisplatin
 - (iii) Antimetabolite
 - (I) Methotrexate
 - (II) Fluorouracil and Floxuridine
 - (III) Cytarabine

- (IV) Mercaptopurine
- (V) Thioguanine

- (iv) Hormones
 - (I) Androgens
 - I. Testolactone
 - (II) Progestins
 - I. Megestrol Acetate
 - II. Medroxyprogesterone Acetate
 - (III) Estrogens
 - I. Diethylstilbestrol Diphosphate
 - II. Polyestradiol Phosphate
 - (IV) Estrogen/Nitrogen Mustard
 - I. Estramustine Phosphate
 - (V) Antiestrogen
 - I. Tamoxifen
- (VI) Gonadotropin Hormone-Releasing Antigen
 - I. Leuprolide Acetate

- (v) Antibiotics
 - (I) Bleomycin Sulfate
 - (II) Doxorubicin HCl
 - (III) Daunorubicin HCl
 - (IV) Mitoxantrone HCl
 - (V) Mitomycin
 - (VI) Dactinomycin
 - (VII) Plicamycin
- (vi) Mitotic Inhibitors
 - (I) Etoposide
 - (II) Vincristine Sulfate
 - (III) Vinblastine Sulfate

- (vii) Radiopharmaceuticals
 - (I) Sodium Iodide I
 - (II) Sodium Phosphate P
 - (III) Chromic Phosphate P

- (viii) Miscellaneous
 - (I) Interferon Alfa-2a
 - (II) Interferon Alfa-2b
 - (III) Hydroxyurea

- (IV) Procarbazine HCl
- (V) Dacarbazine
- (VI) Mitotane
- (VII) Asparaginase

- (vix) NCI Investigational Agents

(d) The dispensing pharmacist creates a written prescription order containing all of the prescription information required by federal and state statutes, rules and regulations.

(e) The dispensing pharmacist notifies the prescriber orally or in writing of the emergency dispensing within seventy-two (72) hours after such dispensing.

(2) This rule is adopted jointly by the Board of Pharmacy and Board of Medical Examiners.

Author: Jerry Moore, Executive Secretary

Statutory Authority: Code of Alabama 1975, §34-23-92
History: Adopted: October 5, 1993; Effective: November 25, 1993.

680-X-2-.27. PRIVATE CONSULTATION AREAS for PHARMACIES.

(1) Since the implementation of patient consultation requirements as a result of OBRA '90 guidelines, it has become evident that the current setup in pharmacies is not conducive to proper communication with patients by pharmacists. Research shows that private consultation areas will facilitate proper consultation with patients by pharmacists and the resultant patient outcomes will be enhanced. Therefore, in order to protect the health of the public and enhance their medication outcomes, private consultation areas must be furnished by pharmacy owners.

(2) The size of the consultation area must be large enough to accommodate the participants and must be entirely devoted to enhancing patient outcomes and not a storage room for merchandise or other non-related items. The area must be accessible by the patient from outside of the pharmacy area without having to traverse a stock room or pharmacy area and must have the capability of being private to both sounds and viewing by unauthorized parties. The area must be away from checkout areas and flows of traffic that would present a barrier to patient communication.

(3) All new pharmacies that open after January 1, 1997, must be in compliance before a permit is issued. All pharmacies that are relocated after January 1, 1997, shall be in compliance. All existing pharmacies must be in compliance on or before January 1, 2005.

Author: Jerry Moore, R.Ph, Executive Secretary

Statutory Authority: Code of Alabama 1975; §34-23-92.

History: New Rule: Filed: August 1, 1995; operative September 5, 1995; Effective January 1, 1996.

680-X-2-.28 TEMPORARY ABSENCES OF PHARMACISTS DURING BREAK AND MEAL PERIOD

(1) This rule is to allow pharmacists to have breaks and meal periods without unreasonably impairing the ability of a pharmacy to remain open.

(2) In any pharmacy that is staffed by a single pharmacist, the pharmacist may leave the pharmacy area or department, temporarily, for breaks and meal periods without closing the pharmacy and removing interns/externs and technicians from the pharmacy, if the pharmacist reasonably believes that the security of the controlled substances will be maintained in his or her absence.

(a) If, in the professional judgment of the pharmacist, the pharmacist determines that the pharmacy should be closed during his or her absence, then the pharmacist shall close the pharmacy area or department and remove all interns/externs and technicians from the pharmacy during his or her absence.

(3) During the pharmacist's temporary absence, no prescription medication may be provided to a patient or to a patient's agent unless the prescription medication is a new or refill medication that the pharmacist has checked, released for furnishing to the patient and was determined not to require the consultation of a pharmacist.

(4) During such times that the pharmacist is temporarily absent from the pharmacy area or department, the interns/externs and technicians may continue to perform the non-discretionary duties authorized to them by any applicable law or rule. However, any duty performed by an intern/extern or technician shall be reviewed by a pharmacist upon his or her return to the pharmacy.

(5) The temporary absence authorized by this rule shall be limited to thirty (30) minutes. The pharmacist shall remain within the facility during the break period and be available to handle all emergency situations.

(6) The pharmacy shall have written policies and procedures regarding the operations of the pharmacy area or department during the temporary absence of the pharmacist for breaks and meal periods. The policies and procedures shall include the authorized duties of interns/externs and technicians, the pharmacist's responsibility for maintaining the security of the pharmacy. The policies and procedures shall be open to inspection by the Board or its designee at all times during business hours.

Author: Jerry Moore, R.Ph., J.D., Executive Director

Statutory Authority: Code of Alabama 1975, §34-23-92.

History: New Rule: Filed April 11, 2001; effective May 16, 2001; operative June 1, 2001.

Amended: July 1, 2002; effective August 5, 2002.

680-X-2-29. SCORE TRANSFER.

(1) The board may issue a license without an additional North American Pharmacist Licensure Examination (NAPLEX) if, at the time the examination is taken, the applicant designates that the score is to be transferred to Alabama. The applicant is then required to take the Alabama MultiState Pharmacy Jurisprudence Exam (MPJE), obtain an average of 75 and participate in an oral interview conducted by the Board. He or she shall furnish satisfactory proof that he or she holds a professional degree from a division, school, college or a university department of pharmacy recognized by the State Board of Pharmacy. The state from which the score is being transferred must accept a score transfer from the State of Alabama.

(2) The application must be accompanied by a fee of \$300.00.

Author: Herb Bobo, R.Ph, Secretary

Statutory Authority: §34-23-92, Code of Alabama 1975

Adopted: New Rule: Filed December 2, 1998; effective January 6, 1999. **Amended:**
December 16, 2011; effective January 20, 2012.

680-X-2-30 CENTRAL PRESCRIPTION FILLING

(1) Purpose. The purpose of this section is to provide standards for centralized prescription filling by a retail pharmacy.

(2) Definitions. The following words and terms, when used in this section, shall have the following meanings, unless the context clearly indicates otherwise. Any term not defined in this section shall have the definition set out in the Act.

(a) **ACT.** The Code Alabama 1975, Title 34 Chapter 23, Practice of Pharmacy Act 205 and The Code of Alabama 1975, Title 20 Chapter 2, Alabama Uniform Controlled Substances Act 1407.

(b) **CENTRAL PRESCRIPTION FILLING.** The filling of a new or refilling of a prescription drug order by one pharmacy licensed by the Alabama State Board of Pharmacy at the request of another pharmacy licensed by the Alabama State Board of Pharmacy for delivery to the patient or patient's agent, pursuant to the lawful order of a practitioner.

(c) **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.

(3) Operational standards.

(a) General requirements.

1. A retail pharmacy may outsource a prescription drug order filling to another retail pharmacy provided the pharmacies:

(i) Have the same owner; or

(ii) Have entered into a written contract or agreement which outlines the services to be provided and the responsibilities and accountabilities of each pharmacy in compliance with federal and state laws and regulations; and

(iii) Share a common electronic file or have appropriate technology or interface to allow access to sufficient information necessary or required to fill or process a prescription drug order.

(2) The supervising pharmacist of the filling pharmacy shall assure that:

(i) The pharmacy maintains and uses adequate storage or shipment containers and shipping processes to ensure drug stability and potency. Such shipping processes shall include the use of appropriate packaging material and/or devices to ensure that the drug is maintained at an appropriate temperature range to maintain the integrity of the medication throughout the delivery process; and

(ii) The filled prescriptions are shipped in containers, which are sealed in a manner as to show evidence of opening or tampering.

(iv) The filling pharmacy shall comply with the provisions of the Code of Alabama 1975, Title 34 Chapter 23, Practice of Pharmacy Act 205 and the Code of Alabama 1975, Title 20 Chapter 2, Alabama Uniform Controlled Substances Act 1407.

3. Any filled prescription, which was not picked up, must be put into the dispensing pharmacy's inventory.

4. No licensed pharmacist or central fill pharmacy operating within this state shall accept for refund purposes or otherwise any unused portion of any filled prescription.
5. Schedule I & II drugs may not be centrally filled.
- (4) Notification to patients. A pharmacy that outsources prescription filling to another pharmacy shall:
 - (a) Prior to outsourcing their prescription:
 1. Notify patients that their prescription may be outsourced to another pharmacy;
 2. Give the name of that pharmacy or if the pharmacy is part of a network of pharmacies under common ownership and any of the network pharmacies may fill the prescription, the patient shall be notified of this fact. Such notification may be provided through a one-time written notice to the patient or through use of a sign in the pharmacy.
 - (5) Prescription Labeling. The filling pharmacy shall:
 - (a) Place on the prescription label a 'Unique Identifier' of the pharmacy filling the prescription and name and address of the pharmacy that dispenses the filled prescription.
 - (b) Indicate in some manner which pharmacy filled the prescription (e.g., "Filled by ABC Pharmacy for XYZ Pharmacy"); and
 - (c) Comply with all other labeling requirements of federal and state statutes.
 - (6) Records:
 - (a) Records may be maintained in an alternative data retention system, such as a data processing system or direct imaging system provided:
 1. The records maintained in the alternative system contain all the information required on the manual record; and
 2. The State Board of Pharmacy and its drug inspectors shall enforce all provisions of this rule. Prescriptions, orders and records required by this chapter and stocks of controlled substances enumerated in Schedules I, II, III, IV, and V shall be open for inspection only to federal, state, county and municipal officers whose duty it is to enforce the laws of this state or of the United States relating to controlled substances. No officer having knowledge by virtue of his/her office of any such prescription, order or record shall divulge such knowledge, except in connection with a prosecution or proceeding in court or before a licensing board or officer, to which prosecution or proceeding the person to whom such prescriptions, orders or records relate is a party.
 3. Each pharmacy shall comply with all the laws and rules relating to the maintenance of records and be able to produce an audit trail showing all prescriptions filled or dispensed by the pharmacy.
 4. The dispensing pharmacy shall maintain records which indicate the date:
 - (i) The request for filling was transmitted to the filling pharmacy; and
 - (ii) The filled prescription was received by the dispensing pharmacy and the name of the person accepting delivery.
 5. The filling pharmacy shall maintain records which:
 - (i) Track the prescription drug order during each step in the filling process and identify the name(s), initials, or identification code(s) and specific activity(ies) of each pharmacist or pharmacy technician who performed any portion of the process including, transmission, filling, dispensing, or delivery; and
 - (I) Records which indicate;
 - (II) The date the prescription was shipped to the dispensing pharmacy;
 - (III) The name and address where the prescription was shipped; and
 - (IV) The method of delivery (e.g., private, common, or contract carrier).
 - (7) Policies and Procedures. A policy and procedure manual as it relates to centralized filling shall be maintained at both the filling and dispensing pharmacies and be available for inspection. Each pharmacy is

required to maintain only those portions of the policy and procedure manual that relate to that pharmacy's operations. The manual shall:

- (a) Outline the responsibilities of each of the filling and dispensing pharmacies;
- (b) Include a list of the name, address, telephone numbers, and all license/registration numbers of the pharmacies involved in centralized prescription filling; and
- (c) Include policies and procedures for:
 - 1. Notifying patients that their prescription may be outsourced to another pharmacy for centralized prescription filling and the name of that pharmacy;
 - 2. Protecting the confidentiality and integrity of patient information;
 - 3. Dispensing prescription drug orders when the filled order is not received or the patient comes in before the order is received;
 - 4. Complying with federal and state laws and regulations;
 - 5. Operating a continuous quality improvement program for pharmacy services designed to objectively and systematically monitor and evaluate the quality and appropriateness of patient care, pursue opportunities to improve patient care, and resolve identified problems.
 - 6. Annually reviewing the written policies and procedures and documenting such review.

Author: Jerry Moore, R.Ph., J.D., Executive Director

Statutory Authority: Code of Alabama 1975, §34-23-92

History: New Rule: Filed February 13, 2003; effective March 20, 2003.

680-X-2-.31 REGULATION OF DAILY OPERATING HOURS.

Any person who receives a community pharmacy permit pursuant to §34-23-30, and commences to operate such an establishment shall, for the benefit of the public health and welfare, keep the prescription department of the establishment open for a minimum of twenty (20) hours per week. A pharmacy may apply to the Board for a waiver or exception under special circumstances. A representative from the pharmacy may be required to appear before the Board in order for this waiver or exception to be considered. A sign in block letters not less than one inch in height shall be displayed either at the main entrance of the establishment or at or near the place where prescriptions are dispensed in a prominent place that is in clear and unobstructed view. Such sign shall state the hours the prescription department is open each day.

Author: Kenny Sanders, R.Ph, President

Statutory Authority: Code of Alabama 1975, §34-23-92

History: New Rule: Filed January 6, 2005; effective February 10, 2005. Amended: Filed March 25, 2013; effective April 29, 2013.

680-X-2-.32 PRESCRIPTIONS BY ELECTRONIC MEANS.

(1) The following requirements shall apply to any prescription, as that term is defined in Code of Alabama (1975) §34-23-1(21), for non-controlled legend drugs transmitted by electronic means.

(a) The prescription must include the patient's name and address, the drug prescribed, strength per dosage unit, directions for use, and the name of the prescriber or authorized agent. To the extent not include above, the prescription must comply with any applicable provisions of the Alabama Pharmacy Practice Act or Board Rule now existing or later amended or changed.

(b) Prescriptions may be transmitted directly to the pharmacy or transmitted over an e-prescription network approved by the Board. All such transmissions must ensure appropriate security and authenticity to include the following:

- 1. An electronic signature process enabling the pharmacy to ensure the identity of the prescriber;
- 2. Date and time stamp;
- 3. Transmitting system identifier;
- 4. Prescriber internal sender identification; and
- 5. Pharmacy internal receiver identification.

(c) Any pharmacy receiving a prescription shall comply with all requirements for record keeping and prescription information mandated by the provisions of the Alabama Pharmacy Practice Act or Board Rule now existing or later amended or changed except that for the purpose of the substitution of drugs or brands of drugs as set forth in Code of Alabama (1975) §34-23-8, a prescription transmitted by electronic means shall not be considered a written prescription.

(d) Prescriptions for controlled substances, whether scheduled pursuant to state or federal law shall not be authorized until the Drug Enforcement Agency has adopted applicable regulations, at which time all prescriptions for controlled substances must comply with the provisions of any such regulation or any later amendments or changes thereto.

Author: James S. Ward

Statutory Authority: Code of Alabama 1975, §34-23-1 (21) and §34-23-92(6)

History: New Rule: Filed January 13, 2006; effective February 17, 2006. **Amended:** Filed July 21, 2006; effective August 25, 2006.

680-X-2-.33 INTERNET PHARMACIES

A pharmacist shall make every reasonable effort to ensure that any order, regardless of the means of transmission, has been issued for a legitimate medical purpose by an authorized practitioner. A pharmacist shall not dispense a prescription drug if the pharmacist has knowledge, or reasonably should have known under the circumstances, that the order for such drug was issued on the basis of an internet-based questionnaire, an internet-based consultation, or a telephonic consultation, all without a valid preexisting patient-practitioner relationship.

Author: James S. Ward, J.D.

Statutory Authority: Code of Alabama 1975, §34-23-92

History: New Rule: Filed March 17, 2006; effective April 21, 2006.

680-X-2-.34 FEES FOR APPLICANTS FOR PHARMACIST LICENSE AND BIENNIAL LICENSE RENEWAL.

(1) The fee for licensure examination shall be \$300.00.

(2) The fee for initial registration for licensure shall be \$100.00.

(3) The fee for biennial renewal of a pharmacist license will be \$100.00. Upon verification of fifty (50) years of licensure in this state the renewal fee shall be no more than twenty-five dollars (\$25.00).

(4) All fees required above shall not be refundable.

(5) Penalties for late renewal of a pharmacist license shall be governed by the provisions of the Alabama Pharmacy Practice Act.

Author: Kenny Sanders, R.Ph, President

Statutory Authority: Code of Alabama 1975, §34-23-92.

History: New Rule: Filed March 17, 2006; effective April 21, 2006. **Amended:** Filed July 23, 2013; effective August 27, 2013.

680-X-2-.35 FEES FOR INITIAL PHARMACY PERMITS, BIENNIAL PERMIT RENEWAL, AND TRANSFER OF OWNERSHIP.

(1) The application fee for a new pharmacy permit shall be \$200.00

(2) The fee for biennial renewal of a pharmacy permit shall be \$100.00

(3) The fee for transfer of ownership of a pharmacy permit shall be \$50.00

(4) All fees required above shall not be refundable.

(5) Penalties for late renewal of a pharmacy permit shall be governed by the provisions of the

Alabama Pharmacy Practice Act.

Author: Louise F. Jones, Executive Director

Statutory Authority: Code of Alabama 1975, §34-23-92.

History: New Rule: Filed March 17, 2006; effective April 21, 2006.

680-X-2-.36 CONTINUING EDUCATION for PHARMACISTS.

(1) Pharmacists shall complete fifteen (15) hours of continuing education every year as a condition of licensure renewal. By submitting the biennial renewal, a pharmacist is representing their compliance with this requirement by the end of the relevant calendar year.

(2) In order to receive credit for continuing education, the continuing education shall be previously approved by the Board. Any requests for approval of continuing education shall be submitted to the Board no less than thirty (30) calendar days prior to offering of the continuing education. A condition of approval shall be that the continuing education is pertinent to the practice of pharmacy. However, this requirement shall not apply to ACPE approved continuing education courses for which a program number is available

(3) Continuing Education may be completed by either attendance or by distance based program, video or by publications; however, a pharmacist must complete at least three (3) hours of live continuing education through attendance at a course(s).

(4) It is the responsibility of each pharmacist to maintain and compile accurate records relating to all continuing education courses or activities they have attended and completed. It shall be the responsibility of each pharmacist to maintain above described documentation and information pertaining to each year for a period of two (2) years and this information shall be submitted to the Board of Pharmacy within thirty (30) calendar days after a request for the same by the Board.

(5) The Board of Pharmacy shall randomly audit the continuing education documentation or information to be maintained or submitted by each pharmacist as described herein to assure compliance with these rules. Failure to maintain the documentation or information set forth in these rules or the submission of false or misleading information or documentation to the Board of Pharmacy or failure to submit requested documentation or information within the time specified by the Board may subject the pharmacist, after hearing, to those penalties outlined in Code of Alabama 1975 §34-23-33.

(6) Upon written request to the Board of Pharmacy, and upon the demonstration of good and sufficient cause, the Board of Pharmacy may grant a waiver or extension of time for the completion of the annual hour requirements for continuing education as set forth herein. The pharmacist who seeks such a waiver or extension shall submit to the Board of Pharmacy any documentation required by the Board which the Board deems appropriate for it to make a decision concerning that waiver or extension.

(7) Any pharmacist who allows their license to lapse for a minimum of one (1) calendar year but not more than five (5) calendar years, shall be required as a condition for reinstatement to provide documentation of their completion of fifteen (15) hours of continuing education in the manner prescribed above for each lapsed calendar year. If a license is lapsed for more than five (5) calendar years, in addition to the examination requirement set forth in Code of Alabama 1975 §34-23-52, the Board may require as a condition for reinstatement any amount of continuing education deemed appropriate.

(8) A pharmacist may carry over and receive credit for twelve (12) hours of continuing education in the succeeding calendar year; however, a pharmacist must obtain in each calendar year no less than three (3) hours live by attendance. For purposes of this rule, attendance shall mean participation in any course where real-time interaction with the presenter is possible.

Author: Louise F. Jones, Executive Director

Statutory Authority: Code of Alabama 1975, §34-23-92.

History: New Rule: Filed July 6, 2006; effective August 10, 2006.

680-X-2-.37 CONTINUING EDUCATION for PHARMACY TECHNICIANS.

(1) Pharmacy Technicians shall complete three (3) hours of continuing education every year as a condition of registration renewal. By submitting the biennial renewal, a pharmacy technician is representing

their compliance with this requirement by the end of the relevant calendar year.

(2) In order to receive credit for continuing education, the continuing education shall be previously approved by the Board. Any requests for approval of continuing education shall be submitted to the Board no less than thirty (30) calendar days prior to offering of the continuing education. A condition of approval shall be that the continuing education is pertinent to the practice of pharmacy. However, this requirement shall not apply to ACPE approved continuing education courses for which a program number is available

(3) Continuing Education may be completed by either attendance or by distance based program, video or by publications; however, a pharmacy technician must complete at least one (1) hour of live continuing education through attendance at a course(s).

(4) It is the responsibility of each pharmacy technician to maintain and compile accurate records relating to all continuing education courses or activities they have attended and completed. It shall be the responsibility of each pharmacy technician to maintain above described documentation and information pertaining to each year for a period of two (2) years and this information shall be submitted to the Board of Pharmacy within thirty (30) calendar days after a request for the same by the Board.

(5) The Board of Pharmacy shall randomly audit the continuing education documentation or information to be maintained or submitted by each pharmacy technician as described herein to assure compliance with these rules. Failure to maintain the documentation or information set forth in these rules or the submission of false or misleading information or documentation to the Board of Pharmacy or failure to submit requested documentation or information within the time specified by the Board may subject the pharmacy technician, after hearing, to those penalties outlined in Code of Alabama 1975 §34-23-132.

(6) Upon written request to the Board of Pharmacy, and upon the demonstration of good and sufficient cause, the Board of Pharmacy may grant a waiver or extension of time for the completion of the annual hour requirements for continuing education as set forth herein. The pharmacy technician who seeks such a waiver or extension shall submit to the Board of Pharmacy any documentation required by the Board which the Board deems appropriate for it to make a decision concerning that waiver or extension.

Author: Herb Bobo, R.Ph, Secretary

Statutory Authority: Code of Alabama 1975, §34-23-92

History: Filed April 20, 2006; Adopted June 20, 2006; Effective August 10, 2006; Amended November 5, 2007; Filed November 29, 2007; Effective January 4, 2008; Amended October 6, 2008; Filed October 9, 2008; Effective November 17, 2008.

680-X-2-.38 LICENSURE OF GRADUATES OF FOREIGN SCHOOLS OF PHARMACY

(1) In addition to complying with all requirements of the Alabama Pharmacy Practice Act relating to licensure, any applicant for pharmacist licensure who is a graduate of a foreign school or college of pharmacy shall comply with the following:

(a) Must successfully obtain and provide to the Board a copy of the Foreign Pharmacy graduate Equivalency Committee Certification.

(b) Must pass a written examination on the laws governing the practice of pharmacy in this state.

(c) Must complete a practical training program as specified in Code of Alabama 1975, Title 34 Chapter 23, Practice of Pharmacy Act 205, §34-23-53 and Board of Pharmacy Rule 680-X-2-.16.

(d) Must demonstrate to the Board the ability to effectively communicate in the English language. In making this assessment, the Board will consider written application materials, oral communication during the interview process and other materials or communications provided by the applicant.

(2) All provisions of the Alabama Pharmacy Practice Act relating to reciprocity shall apply to foreign graduates who possess a license to practice pharmacy in another state.

Author: Louise F. Jones, Executive Secretary/Director

Statutory Authority: Code of Alabama 1975, §34-23-92

History: New Rule: Filed July 6, 2006; effective August 10, 2006.

680-X-2-.39 NON HOSPITAL PHARMACY OFF SITE ORDER ENTRY

(1) The purpose of this Rule is to provide Alabama standards for remote or off-site order entry in any non-hospital pharmacy to which a permit has been issued by the Alabama State Board of Pharmacy ("the Board").

(2) Definitions

(a) **"OFF-SITE ORDER ENTRY PHARMACY"** means a non hospital pharmacy ("pharmacy") which has a valid permit issued by the Board to process legend and controlled substance prescriptions that remotely accesses another pharmacy's electronic data base from outside the pharmacy in order to process prescription drug orders, provided the pharmacy establishes controls to protect the privacy and security of confidential records.

(b) **"OFF-SITE ORDER ENTRY"** does not include the dispensing of a prescription drug order but includes any of the following:

1. Interpreting or clarifying prescription drug orders;
2. Data entering and transferring of prescription drug order information;
3. Performing drug regimen review;
4. Obtaining refill and substitution authorizations;
5. Performing therapeutic interventions; and

6. Providing clinical drug information concerning a patient's prescription.

(c) **"Drug regimen review"** means an evaluation of prescription drug orders and patient profile records for:

1. Known allergies;
2. Rational therapy-contraindications;
3. Reasonable dose and route of administration;
4. Reasonable directions for use;
5. Duplication of therapy;
6. Drug-drug interactions;
7. Drug-food interactions;
8. Proper utilization, including over-utilization or under-utilization.

(3) The Board may approve a request for off-site order entry based on a presentation before the Board.

(4) The supervising pharmacist or the permit holder of the pharmacy shall submit a written request for off-site order entry a minimum of 30 days prior to the Board meeting at which the pharmacy seeks Board approval.

(a) The request shall be accompanied by a policy and procedure manual for off-site order entry which shall be maintained at all pharmacies involved in off-site order entry and be available for inspection. Each pharmacy is required to maintain only those portions of the policy and procedure manual that relate to that pharmacy's operations. The manual shall:

1. Outline the responsibilities of each of the pharmacies;
2. Include a list of the name, address, and telephone numbers of the pharmacies involved in off-site prescription order entry; and
3. Include policies and procedures for:
 - (i) Patient confidentiality and full compliance with HIPAA requirements;
 - (ii) Maintenance of appropriate records to identify the name(s), initials, or identification code(s) and specific activity(ies) of each pharmacist or pharmacy technician who performed any processing and the store it was processed in;
 - (iii) Mechanism for tracking the prescription drug order during each step of the dispensing process;
4. Specify that a pharmacist holding a current license in good standing or a pharmacy technician working under the direct supervision of a pharmacist shall enter prescription drug orders at a location that is a duly licensed pharmacy.
5. Comply with federal and state laws and regulations; and

6. Include procedures for annually reviewing the written policies and procedures for needed modification with documentation of such review.

(5) General requirements.

(a) A Pharmacy may utilize the services of an off-site order entry pharmacy provided the pharmacies:

1. Share a common electronic file or have appropriate technology to allow access to sufficient information necessary or required to process a non-dispensing function; and have;

2. The same owner; or

3. Entered into a written contract or agreement which outlines the services to be provided and the responsibilities and accountabilities of each pharmacy in compliance with federal and state laws and regulations.

(6) All pharmacies involved in off-site order entry approved by the Board shall comply with all applicable provisions of the Alabama Pharmacy Practice Act and/or Board Rule. Nothing in this Rule shall expand allowable duties of pharmacy technicians as set forth in Board Rule 680-X-2.14.

(7) Off-site order entry may only be performed by pharmacies to whom a permit has been issued by the Board and which permit is in good standing.

(8) Notifications to patients.

(a) A pharmacy that outsources off-site prescription order entry to another pharmacy shall prior to outsourcing their prescription:

1. Notify patients that prescription processing may be outsourced to another pharmacy; and

2. Give the name of that pharmacy; or if the pharmacy is part of a network of pharmacies under common ownership and any of the network pharmacies may process the prescription, the patient shall be notified of this fact. Such notification may be provided through a one-time written notice to the patient or through use of a sign in the pharmacy.

(9) Records.

(a) All pharmacies shall maintain appropriate records, which identify, by prescription drug order, the name(s), initials or identification code(s) of each pharmacist or pharmacy technician who performs a processing function for a prescription drug order. Any record generated in this process whether in a hard copy or electronic format shall be maintained for a minimum period of two years from the last date of entry. Such records may be maintained:

1. Separately by each pharmacy and pharmacist; or

2. In a common electronic file as long as the records are maintained in such a manner that the data processing system can produce a printout which lists the functions performed by each pharmacy and pharmacist.

(10) In the operation of the off-site order entry, patient confidentiality and full compliance with HIPAA requirements shall be observed at all times.

(11) This rule does not apply to or allow any step of processing a prescription to be performed outside the physical premises of a pharmacy holding a permit with the Alabama State Board of Pharmacy. The following are expressly prohibited:

(a) Work from home, work from call centers, and work from portable or hand held computers operated outside a location holding a permit with the Alabama State Board of Pharmacy. The Board of Pharmacy may at any time audit the records of any pharmacy holding a permit to ensure compliance with this provision.

(12) Each hard copy prescription must be readily retrievable. Neither the original hard copy prescription, nor a scanned image of the original prescription shall be assigned more than one prescription number. Prescription numbers shall be sequential and shall only be used for numbering prescriptions; specifically they may not be created or used for billing or accounting purposes absent the dispensing of a

prescription drug.

Author: Herb Bobo, R.Ph, Secretary
Statutory Authority: §34-23-92, Code of Alabama 1975
History: New Rule: Filed October 8, 2009; effective November 12, 2009.

680-X-2-.40 NON-DISCIPLINARY PENALTY FOR LATE RENEWAL OF LICENSE, PERMIT, REGISTRATION, CERTIFICATION, OR ANY SIMILAR DOCUMENT ISSUED.

(1) In the event an application for renewal of any type of license, permit, registration, certification or any other similar document issued and required by the Alabama Pharmacy Practice Act, the Alabama Uniform Controlled Substances Act or any applicable Rule and the appropriate renewal fee is not received in the Board's office by December 31 of the applicable year, but is received in the Board's office no later than January 31 of the following year, a non-disciplinary administrative penalty of fifty percent (50%) of the prevailing renewal fee must be paid by January 31 of the following year in order to renew. This penalty shall be in addition to the prevailing renewal fee.

(2) This Rule is adopted pursuant to the Board's authority set forth in Code of Alabama (1975), § 34-23-33(b) and is in lieu of formal disciplinary proceedings.

Author: Herb Bobo, R.Ph, Secretary
Statutory Authority: Code of Alabama 1975, §34-23-92
History: New Rule: Filed July 8, 2010; effective August 12, 2010; operative September 1, 2010. Amended: Filed August 26, 2011; effective September 30, 2011; operative October 3, 2011.

680-X-2-.41 PHARMACY SERVICES PERMITS

(1) The Board may issue on a case by case basis a Pharmacy Service Permit for the limited purpose of allowing pharmacists and pharmacy technicians to provide pharmacy services to patients and clients. Nothing in this rule shall limit the board's ability to issue any Pharmacy Service Permit the Board deems appropriate.

(2) The Board has determined that, at a minimum, the holder of a Pharmacy Service Permit must designate a Supervising Pharmacist who shall be licensed by the Alabama State Board of Pharmacy, on site, who is responsible for ensuring that the processes and compliance standards are maintained within limits set by the Board for the permit holder.

(3) Nothing in this rule restricts the Board from setting pharmacist and technician ratios.

(4) Nothing in this rule shall authorize any individual to perform any activity beyond their scope of practice pursuant to any license or registration issued to them.

(5) In the event the application for a Pharmacy Services Permit is by a non-resident pharmacy, in addition to the requirements set out in Paragraphs (1) through (4) above, if applicable, the applicant must comply with the following requirements:

(a) Complete an application furnished by the Board and be issued the referenced permit. Any application which is not full and complete will not be processed.

(b) Pay the fee set out in Code of Alabama, (1975) §34-23-30.

(c) The Pharmacy Services Permit issued by the Board shall become void on December 31st of even numbered years unless renewed in compliance with Code of Alabama, (1975) §34-23-30.

(d) Submit documentation from the applicant's home state verifying any applicable license or permit is valid and in good standing.

(e) Designate a resident agent in Alabama for service of process. The failure to include this information shall result in the denial of the application.

(f) In the event the applicant will be involved or participate in any remote order processing and not actually shipping, mailing or delivering any drug from its location to a citizen in this State, there shall also be

compliance with the following:

1. All statutory and regulatory requirements of the State of Alabama relating to controlled substances, including those that are different from federal law or regulation.
2. All the statutory and regulatory requirements of the State of Alabama regarding drug product selection laws.
3. All Board of Pharmacy requirements for data submission related to volumes of orders processed as specified at the time of approval.

(g) Submission with the application a policy and procedure manual for Board approval which must, at a minimum, include the following:

1. Hours of operation.
2. On-Call Pharmacist. For the protection of patients, when orders are being processed remotely and no pharmacist is onsite at the resident Pharmacy, a pharmacist must be on-call to respond to situations that arise that cannot be addressed through remote services, such as patient needing a specific medication which is not available until the resident Pharmacy opens, or a healthcare provider urgently needing information that cannot be provided by the pharmacists performing remote order processing.
3. Procedures to be following in case of downtime.
4. The system to be used to identify and respond to medication errors arising from mistakes from remote order processing.
5. The system to be used to insure initial and ongoing quality of remote order processing.
6. The means by which compliance with HIPAA requirements will be met.

(h) Designate a supervising pharmacist who shall be responsible for ensuring compliance with this rule and all applicable laws and rules.

(i) Compliance with any other requirement deemed necessary by the Board, to include but not limited to required technician to pharmacist ratios.

Author: Kenny Sanders, R.Ph., President
Statutory Authority: Code of Alabama 1975, § 34-23-92.
History: New Rule: Filed October 1, 2012; effective November 5, 2012. Amended 23 October 2013; Effective 1 January 2014.

680-X-2.42 REQUIREMENTS FOR RETURN AND DESTRUCTION OF DRUGS BY PHARMACIES

(1) This rule shall apply only to unused or expired non-controlled legend drugs. The return of controlled drugs shall not be authorized until the adoption of applicable regulations pursuant to the Secure and Responsible Drug Disposal Act of 2010, at which time there must be compliance with the provisions of any such regulation(s) or any subsequent amendments thereto.

(2) The following requirements shall apply whenever an individual desires to return unused or expired drugs to a pharmacy and if the pharmacy agrees to accept the return.

- (a) Drugs may only be returned for the sole purpose of destruction.
- (b) It shall be the pharmacist(s) responsibility to ensure compliance with the requirements of this Rule.

(c) The pharmacy shall maintain a separate log of all returned drugs which shall include the following information.

1. General description of returned drugs.
2. Date of return.
3. Date and method of destruction of drugs.
4. The above referenced log shall be available for inspection in the same manner as set forth in the Code of Alabama 1975, § 34-23-70(k).

(3) Any returned drug must be maintained and stored in an area within the pharmacy which is separate and apart from the regular inventory of the pharmacy.

(4) No returned drugs shall be dispensed for any purpose.

(5) Any returned drugs shall be destroyed within 180 days of their return to the pharmacy.

Author: Kenny Sanders, R.Ph., President

Statutory Authority: Code of Alabama 1975, §34-23-92.

History: Adopted: 20 November 2013; 1 January 2014

Revised May 2, 2014

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