

ALABAMA STATE BOARD OF PHARMACY
ADMINISTRATIVE CODECHAPTER 680-X-2
PRACTICE OF PHARMACY

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(Repealed)

Author: James W. McLane

Statutory Authority: Code of Ala. 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 **Repealed:** Filed August 23, 1994; effective September 27, 1994.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 Ala. 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 investigators, with respect to any violations of law, except in or to a court of justice.

Author: James W. McLane

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

History: Filed June 1, 1982. **Amended:** Published August 31, 2021; effective October 15, 2021.

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; and hot and cold running water in the prescription area.

(2) Every satellite pharmacy of licensed institutional pharmacies shall have all of the above. 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: Donna C. Yeatman, R.Ph., Executive Secretary

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

History: Filed June 1, 1982. **Amended:** Filed May 11, 1987.
Amended: Filed September 20, 1999; effective October 25, 1999.
Amended: Published August 31, 2020; effective October 15, 2020.

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 Ala. 1975, §34-23-92.

History: 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 alternative 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 30 minutes following a request for his appearance.

Author: James W. McLane

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

History: 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 Ala. 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 Ala. 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 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 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. This plan shall not exceed ninety (90) days before the permit holder is in violation of operating a pharmacy without a supervising pharmacist at which time the board may require closure of the pharmacy until such time as a supervising pharmacist assumes his/her duties.

(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 time;

(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.

(e) All the statutory and regulatory requirements of the Alabama Practice Act. (34-23-1, et seq)

Author: Donna C, Yeatman, R.Ph, Executive Secretary

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

History: Filed June 1, 1982. **Amended:** Filed March 12, 1986; April 17, 1991. **Amended:** Filed January 6, 2005; effective February 10, 2005. **Amended:** Filed May 6, 2014; effective June 10, 2014. **Amended:** Filed February 24, 2016; effective April 9, 2016. **Amended:** Published September 30, 2019; effective November 14, 2019. **Amended:** Published November 30, 2022; effective January 14, 2023.

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 manage 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 ensure 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. 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 an eight (8) 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.

5. 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 eight (8) live hours that have been previously approved by the Board each renewal cycle.

Author: Brenda Denson, Pharm.D., BCPPS, FASHP, Board President

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

History: Filed June 1, 1982. **Amended:** Filed September 2, 1994; effective January 1, 1995. **Amended:** Filed July 24, 2012; effective August 28, 2012. **Amended:** Published January 29, 2021; effective March 15, 2021.

680-X-2-.09 Training For Preceptors.

In accordance with Section 34-23-73, Title 34, Chapter 23, Code of Ala. 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 and complete an initial two (2) hour board approved preceptor training program. All Pharmacists who have been approved by the Alabama State Board of Pharmacy as Preceptors must complete a two (2) hour training seminar for preceptors each renewal cycle or be approved by the School of Pharmacy for curriculum hours. Such training seminar shall have prior approval of the Board.

Author: Donna C. Yeatman, R.Ph., Executive Secretary

Statutory Authority: Code of Ala. 1985, §34-23-92.

History: Filed June 1, 1982. **Amended:** Filed July 17, 1995; operative August 21, 1995, effective January 1, 1996. **Amended:** Filed December 2, 1998; effective January 6, 1999. **Amended:** Filed July 24, 2012; effective August 28, 2012. **Amended:** Published December 31, 2020; effective February 14, 2021.

680-X-2-.10 Reporting Place Of Employment, Interns And Externs..

In accordance with §27(a) of Code of Ala. 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 Ala. 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 Ala. 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 storerooms 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 of 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 Hobo, R.Ph., Secretary

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

History: Filed June 1, 1982. **Amended:** 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 Ala. 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) Whenever a registered Pharmacist terminates his/her the duties as 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.

(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. In addition, it is a violation of this rule for any person to subvert the authority of the supervising pharmacist by impeding the management of any pharmacy in relation to compliance with federal and state drug or pharmacy laws and regulations. Any such act(s) may result in charges being filed against the permit holder.

(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's supervising pharmacist will be or is no longer employed or no longer desires to act as a supervising pharmacist, the permit holder shall notify the Board within ten (10) days by the submission of an action plan for the designation of another supervising pharmacist. This plan shall not exceed ninety (90) days before the permit holder is in violation of operating a pharmacy without a supervising pharmacist at which time the Board may require closure of the pharmacy until such time as a supervising pharmacist assumes his/her duties.

(9) In the event of a temporary absence by supervising pharmacist of greater than 30 days, the permit holder shall designate a temporary supervising pharmacist with notification to the Board of the name of the temporary supervising pharmacist and the

period of time during which he/she shall act as such. The permit holder must notify the Board of the assignment of the temporary supervising pharmacist prior to the time the temporary supervising pharmacist begins to act as such. The permit holder will inform the board of the date of the original supervising pharmacist's return from his/her absence.

Author: Donna C., Yeatman, R.Ph., Executive Secretary

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

History: Filed June 1, 1982. **Amended:** Filed June 8, 1989; effective July 31, 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. **Amended:** Filed January 22, 2019; effective March 8, 2019. **Amended:** Filed June 20, 2019; effective August 4, 2019. **Amended:** Published August 31, 2021; effective October 15, 2021.

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 in-patients. 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 Ala. 1975, §34-23-92.

History: Filed June 1, 1982.

680-X-2-.14 The Role Of Technicians In Pharmacies.

(1) Title 34, Chapter 23, Code of Ala. 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 hold an assistant's license.

(3) It is ruled by the Board of Pharmacy that the following ratio(s) of technicians on duty are sufficient in the prescription area of a retail pharmacy or an institutional pharmacy for each full-time licensed pharmacist on duty.

(a) Four (4) technicians, two of which shall be certified by any credentialing organization approved by the Board; or,

(b) Three (3) technicians, one of which shall be certified by any credentialing organization approved by the Board; or

(c) Two (2) technicians, neither of which is required to be certified by any credentialing organization approved by the Board

(d) 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 nametag, 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 dollars

(§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 registrants to renewal of their registrations 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 Twenty Dollars (\$20.00) for each lapsed year and all lapsed fees for each lapsed year, up to a maximum of 5 years of total penalties and lapsed fees.

(a) All technicians receiving their initial registration on or after January 1, 2020, shall complete a Board-approved training program within the first six months after their registration and submit evidence of completion to the board within 10 days of completion. The technician and the employing pharmacy shall keep documentation of this training for a period of two years from the completion of the training. The passage of a Board-recognized pharmacy technician certification examination shall be accepted as a training program. The training program shall be the responsibility of the technician and the pharmacy employing the technician. The Board may impose allowable sanctions for violation of this Rule against the employing pharmacy permit holder, the Supervising Pharmacist of the employing pharmacy and/or the pharmacy technician.

(b) Every pharmacy technician registered by the Alabama State Board of Pharmacy shall, prior to reregistration, complete six (6) hours of continuing education, two (2) hours of which shall be 'live' presentation, within the renewal periods.

(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 Ala. 1975, §34-24-1 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 Ala. 1975, §34-24-1 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 of 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 a 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.

(12) In addition to all other applicable requirements for registration or reinstatement as a pharmacy technician and a

prerequisite for consideration of an application for registration or reinstatement as a pharmacy technician, each individual seeking registration or reinstatement of registration as a pharmacy technician shall consent and be subject to a Board approved criminal background check, the cost of which to be paid by the applicant. The information received as a result of the background check shall be relied upon in determining whether the applicant meets the applicable qualifications to obtain the referenced registration.

Author: Donna C. Yeatman R.Ph., Executive Secretary

Statutory Authority: Code of Ala. 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; refiled 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. **Amended:** Filed March 21, 2016; effective May 5, 2016. **Amended:** Filed July 25, 2016; effective September 8, 2016. **Amended:** Filed August 23, 2019; effective October 7, 2019. **Amended:** Published August 31, 2020; effective October 15, 2020. **Amended:** Published August 31, 2021; effective October 15, 2021. **Amended:** Published September 30, 2022; effective November 14, 2022.

680-X-2-.15**Use Of Computers For Recordkeeping In Pharmacies In Alabama.**

(1) Title 34, Chapter 23, Code of Ala. 1975, 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 pharmacists 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 72 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 recordkeeping 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 requests 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 downtime, the pharmacy must have an auxiliary procedure which will be used for documentation of refills of Schedules III, IV, and V controlled substance prescription orders. This auxiliary procedure must ensure 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 prescribes' 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

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

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) All interns/externs shall apply for a permit with the Alabama State Board of Pharmacy. The permit shall expire on December 31 of odd numbered years. Initial permit fee and renewal fee shall be fifty dollars (\$50). All interns/externs shall pay the renewal fee biennially with this fee being due on October 31 and delinquent after December 31 of odd numbered years. If any intern/extern shall fail to pay a renewal fee on or before December 31 of any year, such registration shall become null and void.

(3) An extern/intern permit 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. Any person, working as an extern/intern, must obtain a permit from the Board before assuming duties in a pharmacy.

(4) In addition to all other statutory requirements for the issuance of a permit, upon initial application, the applicant shall consent to and be subject to a Board approved criminal background check, the cost of which to be paid by the applicant. The information received as a result of the background check shall be relied upon in determining whether the applicant meet the applicable qualifications to obtain the referenced permit.

(5) 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 nonstructured 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. Externs/Interns shall submit to the Board of Pharmacy adequate documentation

demonstrating compliance with the traditional hour 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 of completion of required hours to the Board.

(6) 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 required 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.

(7) 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.

(8) 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.

(9) 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.

(10) 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.

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

Author: Donna C. Yeatman, R.Ph., Executive Secretary

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

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. **Amended:** Published July 29, 2022; effective September 12, 2022.

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 Ala. 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 patients 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 and the provision of services used in the prevention, diagnosis, and treatment of injury, illness, and disease (hereafter referred to as "Institutional Pharmacy Services") 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. All medications 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 IN INSTITUTIONAL PHARMACY:

(a) The Supervising Pharmacist shall establish written procedures for the safe and efficient distribution of Drugs and for the provision of Institutional Pharmacy Services. 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 ensure that all functions and activities are performed competently, safely, and without risk of harm to patients.

(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.

(6) OFF-SITE INSTITUTIONAL PHARMACY

(a) Issuance and Maintenance of Permit

1. A hospital may file a separate application for an off-site pharmacy permit within a separate facility bearing the same hospital license number issued by the Alabama Department of Public Health or the facility possessing a pharmacy permit issued by the Board. Any such application shall comply with all requirements of the Alabama Pharmacy Practice Act or applicable rule.

(7) AUTOMATED DISPENSING SYSTEMS IN SKILLED NURSING FACILITIES

(a) Definitions: For purposes of this section only, the terms defined in this subdivision have the meanings set forth below: 1. "Automated dispensing system" means an electromechanical system that performs operations or activities related to the storage and dispensing of medications and which is capable of collecting, controlling, and maintaining all required transaction information and records. 2. "Emergency Medication" means any medication, including controlled substances, ordered by a licensed prescriber in response to a critical patient need. 3. "STAT medication" means any medication, excluding controlled substances, ordered and added to the drug regimen of a newly admitted patient or an existing patient that is not available from the Managing Pharmacy in sufficient time to prevent risk of harm to the patient that might result from a delay in obtaining such drug. 4. "Packaging" means the preparation of medication from bulk containers to unit-dose or unit-of-use containers intended for individual patient administration. 5. "Managing Pharmacy" means a pharmacy physically located in Alabama, holding a current pharmacy permit issued by the Alabama Board of Pharmacy, and which is responsible for supplying prescribed medications for patients in a skilled nursing facility and for the safe operation of any automated dispensing system used in the facility. 6. "Positive

identification" means the method by which access to the medications and information contained in an automated dispensing system in a skilled nursing facility is limited to only authorized individuals, and which includes the use of a user-specific password combined with a user-specific personal identifier such as a fingerprint, personal ID badge, retinal pattern, or other unique identifier.

(b) Authorization: A Managing Pharmacy may use an automated dispensing system to meet the emergency medication needs and the STAT medication needs of residents in skilled nursing facilities. The automated dispensing system must be located in a skilled nursing facility that holds a valid and current contract with a Managing Pharmacy to provide pharmacy services to that facility. The automated dispensing system shall be considered an extension of the Managing Pharmacy.

(c) Notifying the Board of Pharmacy:

1. The Managing Pharmacy shall submit a written request to the Board of Pharmacy for approval to use an automated dispensing system. The Board of Pharmacy shall determine at which future meeting the request shall be considered. Requests must be submitted no less than 30 days prior to the Board of Pharmacy meeting at which the request will be considered.

2. The request for approval to use an automated dispensing system shall include:

- (i) written policies and procedures for the automated dispensing system specific to the automation to be used,

- (ii) the name and address of the facility in which the automation will be used,

- (iii) the name and permit number of the Managing Pharmacy,

- (iv) a description of the automation (type, manufacturer, and model) along with a description of how the system is to be used,

- (v) The specific location(s) within the facility where the automated dispensing system will be placed, and

- (vi) The date the automation will be placed into operation. The Board of Pharmacy must be notified at least 30 days prior to use.

3. After the Managing Pharmacy has received Board approval for utilizing an automated dispensing system, expansion of the system in the skilled nursing home or the addition of automated dispensing technology to an additional facility or facilities, the Managing Pharmacy need only notify the Board of Pharmacy of such expansion and addition. The notification to the Board shall be submitted at least 30 days prior to use. The Board may require additional information related to the expansion and/or addition and, upon reviewing the notification may, at its discretion, require approval for the expansion and/or addition.

(d) General Requirements for Automated Dispensing Systems: A Managing Pharmacy may utilize an automated dispensing system provided:

1. The Supervising Pharmacist of the Managing Pharmacy is responsible for the operation of the automated dispensing system. There is no requirement that a pharmacist be physically present at the site of the automated dispensing system. However, a pharmacist of the Managing Pharmacy must have access to the equipment and all transaction information at all times.

2. Access to the drugs and information contained within the automated dispensing system is secured through the use of positive identification.

3. Access to the automated dispensing system shall be controlled by the Managing Pharmacy and shall be limited to:

(i) Licensed nurses

(ii) Licensed pharmacists

(iii) Registered pharmacy technicians

(iv) Authorized field service personnel for maintenance purposes and only while under direct observation of a licensed nurse, a licensed pharmacist, or a registered pharmacy technician.

4. Medications delivered to the skilled nursing facility but not yet stocked into the automated dispensing system are stored in a secure manner and in compliance with the policies and procedures agreed upon by the Managing Pharmacy and the leadership of the facility.

5. Restocking of the automated dispensing system shall be limited to a licensed pharmacist or a registered pharmacy technician of the Managing Pharmacy, a licensed nurse of

the facility, or other licensed healthcare personnel approved by the Board of Pharmacy.

6. A pharmacist of the Managing Pharmacy conducts an on-site physical inventory of the contents of the automated dispensing system at least quarterly.

7. A pharmacist employed by the Managing Pharmacy reviews, interprets, and approves all prescription medication orders prior to removal of a drug from the automated dispensing system. When a medication is ordered and needed but the order has not been reviewed, interpreted and approved by the pharmacist, emergency access to the medication by authorized users is allowed if such access is permitted by written policies and procedures agreed upon by the Managing Pharmacy, the facility's Medical Director, and appropriate nursing leadership of the facility.

8. The name and quantity of medications and products kept in the automated dispensing unit shall be agreed upon by the Managing Pharmacy, the facility's Medical Director, and appropriate nursing leadership of the facility.

(e) According to the Institute for Safe Medication Practices, topics to consider for the safe use of automated dispensing systems include:

1. Choose a location with good lighting, temperature control, sufficient space, and which minimizes distractions and errors.

2. Address security related issues such as access, assigning of passwords, prohibition of password sharing or recycling, blind counts, and resolution of discrepancies.

3. Electronic patient profiles and electronic medication administration record should be used to minimize the risk of medication errors.

4. Information on the computer monitor for use by the caregiver should include the patient's name, a second identifier, allergies, drug interactions, brand and generic drug names, TALLman lettering, and the location of the drug within the cabinet.

5. Address inventory issues, such as criteria to add or delete drugs, the avoidance of bulk drug containers, setting of minimum and maximum quantities to be stocked, and frequency of audits.

6. When stocking or restocking an automated dispensing system barcode verification, if available, should be used or a second person should verify accuracy.
 7. Withdrawals should be limited to profiled drugs, except in case of an emergency.
 8. An override policy should be developed and followed. Overrides (emergency withdrawals when a profile withdrawal is not possible) should be minimized. The inclusion of a rationale statement for each override should be required. Two-person checks for overrides of high alert medications should be required.
 9. Medications being transported after withdrawal from an automated dispensing system should remain in their unit dose package until just prior to administration.
 10. If medications for more than one patient are being removed from the automated dispensing system at the same time, each patient's medications should be segregated and clearly labeled by individual patient.
 11. Staff using the automated dispensing system is educated and can demonstrate competency for the proper use of the cabinet, including downtime procedures.
 12. Steps to take in case of unexpected malfunctions, including trouble shooting and repairs, should be addressed,
 13. A timeframe should be specified within which discrepancies will be resolved.
 14. Address the mechanism by which and the timeframe within which a user's access will be removed when the user should no longer have access to contents or information in the automated dispensing system.
- (f) Reports: Records of automated drug system transactions shall be retained by the Managing Pharmacy for the same period of time as required for retention of prescription records. These records shall be readily retrievable and printed copies of such records shall be available within two business days upon request by the Board of Pharmacy or its representatives.
- (g) The Board of Pharmacy must approve policies and procedures for the operation of the automated drug system. A copy of the policies and procedures shall be maintained at the location of the automated dispensing system and at the Managing Pharmacy and shall be available for inspection at all times.

(h) The Board of Pharmacy shall not approve an automated dispensing system for use in a skilled nursing facility for the purpose of compounding, packaging, or labeling of medications.

(i) Nothing in this rule shall be interpreted to amend, alter, or modify the provisions of Alabama Code Section 34, Chapter 23 or supporting regulations.

(8) Dispensing for Institutional Facilities

(a) "Emergency dispensing" is defined as prescribing/ providing necessary medications to patients being treated by institutional facilities within the physical institutional facility or to be taken with the patient upon discharge.

(b) Requirements for "Emergency Dispensing" labeling must include, but is not limited to:

1. The name and address of the facility from which the prescription was dispensed
2. The directions for use
3. The name of the drug as it is dispensed
4. The strength per dosage unit.
5. 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.

(c) "Emergency Dispensing" may be utilized for the following medications:

1. Bulk medications for single patient use
2. Medications deemed necessary with Board approval

Author: James S. Ward, Board Attorney

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

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680-X-2-.19 Parenteral Sterile 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 Alabama consumer 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 products which should be sterile shall be registered with the Alabama State Board of Pharmacy biennially which shall expire on December 31 of even-numbered years and Alabama pharmacies shall receive a permit in accordance with Code of Ala. 1975, §34-23-30. Such pharmacies shall be certified, further, by the Alabama State Board of Pharmacy as a parenteral sterile compounding pharmacy.

(3) Registration and Certification, Pharmacists: All pharmacists, permitted and practicing in Alabama, engaged in compounding and dispensing of product which should be sterile, including cytotoxic agents, shall register each renewal cycle with the Board of Pharmacy in accordance with Code of Ala. 1975, §§34-23-51, 34-23-52. After January 1, 1994, pharmacists who have not successfully completed a certifying course for sterile compounding approved by the Board, will not be registered as sterile compounding pharmacists until they have completed said certifying course. Programs submitted for certification shall be a minimum of eight (8) 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. Pharmacists performing high risk sterile compounding shall complete an additional four (4) hour board approved high risk program. All pharmacists approved by the Alabama State Board of Pharmacy as sterile compounding pharmacists must successfully complete two (2) continuing education hours approved by the Board including didactic and hands on training each renewal cycle.

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

Author: Donna C. Yeatman, R.Ph., Executive Secretary

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

History: Filed July 18, 1989. **Amended:** March 19, 1993.

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

Amended: Filed July 24, 2012; effective August 28, 2012.
Amended: Filed July 25, 2018; effective September 8, 2018.
Amended: Published December 31, 2020; effective February 14, 2021.

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 pharmacy 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, recordkeeping or disposal of radiopharmaceuticals.

(d) Radiopharmaceutical -Any substance defined as a drug in Code of Ala. 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. Recertification 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. Application and recertification 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 recertification earned in the previous calendar year related to nuclear pharmacy shall be required.

(5) General Requirement: 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.

* "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.

(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."
 3. The name of the procedure.
 4. The prescription number of the radio-pharmaceutical 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 ensure 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 State 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 hazards, and the applicable regulations of the U.S.

Nuclear Regulatory Commission. 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. Lead 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 radio pharmacy internship is 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 Bob, R. Ph., Secretary

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

History: Filed June 8, 1989. **Amended:** Filed July 24, 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 Ala. 1975, §34-23-92.

History: Filed April 17, 1991. **Amended:** 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 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 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 pharmacy shall provide an environment that allows for the proper exercise of professional judgment and skill by pharmacists.

(h) A pharmacy shall not allow an environment that may cause a deterioration of the quality of professional services, or that require unethical conduct, including, but not limited to:

1. Any deviation from safe pharmacy practices
2. Any other conditions or practices which may adversely affect the public health, safety, or welfare

(i) 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.

(j) 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: Chris Phung, R.Ph.

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

History: Filed May 30, 1990. **Amended:** Filed May 9, 2011; effective June 13, 2011. **Amended:** Filed December 16, 2011; effective January 20, 2012. **Amended:** Published October 31, 2022; effective December 15, 2022.

Ed. Note: This 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 Ala. 1975, §§41-22-23, 41-22-24.)

680-X-2-.23

Drug Manufacturers; Wholesale Distributors; Private Label Distributors, Repackagers, Third-Party Logistics, 503B Outsourcer; Reverse Distributor; Retail Medical Oxygen Supplier.

(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, 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) Medical Oxygen - Oxygen USP is liquid or gaseous form intended for human consumption.

(h) Wholesale Drug Distributor -Every person engaged in the business of distributing drugs and medicines, to include medical oxygen, 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, (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.

(i) Private Label Distributor - A firm that does not participate in the manufacture or processing of a drug but instead markets and distributes under its own trade name, and labels a drug product made by someone else. A private label distributor is responsible for the products it introduces into interstate commerce and for compliance with federal Food, Drug and Cosmetic Act requirements and Current Good Manufacturing Practices regulations.

(j) 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 and drug to a patient.

(k) Third Party Logistics Provider - (abbreviated as 3PL, or TPL) an entity that provides or coordinates warehousing or other logistics services of a product in interstate commerce on behalf of a manufacturer, wholesale distributor, or dispenser of a product, that does not take ownership of the product, nor have responsibility to direct the sale or disposition of the product.

(l) Outsourcing Facility - A facility at one geographic location or address that is engaged in the compounding of sterile drugs, which as elected to register with the federal Food and Drug Administration as an outsourcing facility and complies with the requirements of Section 503B(d) (4) (A) of the federal Food, Drug, and Cosmetic Act.

(m) Reverse Distributor - An entity that acts as an agent for pharmacies, drug wholesalers, third party logistics providers, manufacturers and others by receiving, inventorying, warehousing and managing the disposition of outdated or nonsaleable drugs or devices.

(n) Retail Medical Oxygen Supplier - any person, agency, business, or entity of any kind which sells or provides medical oxygen to patients or consumers and which bill the patient or consumer or their insurance, Medicare, Medicaid, or other third-party payor.

(o) Charge Back -A process whereby a wholesale drug distributor is reimbursed for preferential pricing.

(p) Blood -Whole blood collected from a single donor and processed either for transfusion or further manufacturing.

(q) Blood Component -That part of blood separated by physical or mechanical means.

(r) Drug Sample -A unit of a drug that is not intended to be sold and is intended to promote the sale of the drug.

(s) 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 medicine 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 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, to include medical oxygen, 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 permitted entities shall be secure from unauthorized entry.

2. All permitted entities must be equipped with an alarm system to detect entry after hours.

3. All permitted entities 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) Recordkeeping:

1. All permitted entities 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.

6. The recordkeeping requirements of this Rule shall be followed for all incoming and outgoing shipments in compliance with the Drug Supply Chain Security Act (DSCSA) standards.

(e) Inspections:

1. All permitted entities shall allow 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. Such officials shall be required to show appropriate identification prior to being granted access to permitted premises and delivery vehicles.

2. The Board may contract inspections for out of state facilities to other state boards, NABP, or other inspection entities.

3. Costs for out of state inspections will be the responsibility of the permit holder.

(f) Written Policies and Procedures:

1. Wholesale drug distributors and private label 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 and private label distributors shall include in their written policies and procedures the following:

(i) A procedure to ensure that wholesale drug distributors and private label distributors prepare 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. The procedure shall include the following:

(I) 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.

(II) 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.

(III) 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. 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 and private label 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.

(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 for examination of drugs and medicines:

(I) 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.

(II) 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.

(v) 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 approved product or new package design.

2. Repackagers 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. Repackagers shall include in their written policies and procedures the following:

(i) A procedure to ensure that repackagers prepare 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 for examination of drugs and medicines:

(I) 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.

(II) 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.

(v) 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 approved product or new package design.

3. Third-party logistics providers shall establish, maintain, and adhere to written policies and procedures, which shall be followed for the documentation of 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.

(i) A procedure to ensure that third-party logistics providers prepare for, protect against, and handle any crisis that affects security or operation in the event of strike, fire, flood, or other natural disaster or any other situation of local, state, or national emergency.

4. Outsourcing facilities shall establish, maintain, and adhere to written policies and procedures, which shall be followed for the 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. Outsourcing facilities shall include in their written policies and procedures the following:

(i) A procedure to ensure that outsourcing facilities prepare 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; or

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

5. Reverse Distributors shall establish, maintain, and adhere to written policies and procedures, which shall be followed for the 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. Reverse distributors shall include in their written policies and procedures the following:

(i) A procedure to ensure that reverse distributors prepare 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.

6. Retail Medical Oxygen Suppliers shall establish, maintain, and adhere to written policies and procedures, which shall be followed for the security, storage, inventory and distribution of medical oxygen, including policies and procedures for identifying, recording and reporting losses or thefts, and for correcting all errors and inaccuracies in inventories.

(i) Retail Medical Oxygen Suppliers shall include in their written policies and procedures the following:

(I) A procedure to ensure employment of adequate, trained personnel for the delivery and supplying of medical oxygen so that they can safely and properly deliver and supply the same; and

(II) A designated person to ensure compliance with all USP, FDA, DOT and OSHA requirements, any other applicable requirements of state or federal law and any rules or regulations promulgated thereunder regarding the storage, packaging, labeling, shipping, dispensing, transfilling, and repackaging of medical oxygen; and

(III) A procedure to supply patients information for obtaining medical oxygen on a twenty-four (24) hour, seven (7) day a week basis when essential to the maintenance of life or when lack of services might reasonably cause harm; and

(IV) A written procedure at each location for handling complaints and problems and resolution of the complaint and problems; and

(V) A procedure to ensure that all medical oxygen stored and available for sale is properly

identified by a tag or label to its current status of use; and

(VI) A procedure to ensure that lot numbers are affixed to each cylinder delivered; and

(VII) A procedure to maintain a tracking system for all medical oxygen delivered.

(ii) Nothing in this section shall prohibit the non-hospital emergency administration of medical oxygen by licensed health care providers, emergency medical technicians, first responders, fire fighters, law enforcement officers and other emergency personnel trained in the proper use of emergency oxygen.

(iii) Prescription Requirements. I. Retail medical oxygen suppliers shall not provide any medical oxygen to a patient without a valid prescription issued by a person authorized to prescribe medical oxygen in the course of that person's professional practice. II. Retail medical oxygen suppliers shall make a record at the time of dispensing. The record of dispensing shall be maintained for two (2) years from the date of dispensing and shall include: A. Name and address of patient; B. Name and address of prescriber; C. Item dispensed and quantity; D. Date of dispensing. III. Retail medical oxygen suppliers will instruct the patient about emergency and routine contact procedures. IV. Retail medical oxygen suppliers will develop, implement, and document a written plan of service in the patient record for the purpose of ensuring that patients and/or caregivers are properly instructed in the safe and effective use of medical oxygen, and in compliance with physician prescriptions and orders. V. The requirements of this section do not apply to licensed pharmacies or pharmacists.

(g) Responsibility for Operation:

1. All permitted entities 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 entities permitted for operation 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 with pharmaceutical activities including, but not limited to, those described in this rule;

(iv) The furnishing by the applicant of false or fraudulent material in any application made in connection with pharmaceutical activities including, but not limited to, those described in this rule;

(v) Any discipline by any Federal, State, Municipal government or entity thereof, of any license, permit, registration, etc. currently or previously held by the applicant;

(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; 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.

5. A transfer of ownership requires filing of an application for a permit.

6. Any change in the control of ownership of an entity shall be reported to the board in writing within 10 days of such occurrence.

(h) Personnel:

1. The Alabama State Board of Pharmacy shall require that manufacturers, wholesale drug distributors, private label distributors, repackagers, and third-party logistics providers have a designated representative that has appropriate education and/or experience to assume responsibility for positions related to compliance with State licensing requirements.

(i) The designated representative must:

(I) Be at least 21 years of age.

(II) 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 for the federal government.

(III) Be employed by the entity full-time in a position of authority.

(IV) Be actively involved in and aware of the actual daily operation of the entity.

(V) Be physically present at the entity during regular business hours.

(VI) Serve as a designated representative for only one entity at any one time.

(VII) Not have been convicted of a violation of any federal, state, or local law relating to any drug offense.

(VIII) Not have been convicted, received adjudication, community supervision, or deferred prosecution of any felony offense or any crime related to fraud, violence, sexual violations or related to the practice of pharmacy.

(ii) If the permit holder's Designated Representative will be or is no longer employed or no longer desires to act as a designated representative, the permit holder shall notify the Board within ten (10) days of the change in designated representative by completing the "Notice of Change of Designated Representative" form provided by the Board.

2. The Alabama State Board of Pharmacy shall require that outsourcing facilities have an Alabama licensed supervising pharmacist for the individual location and comply with 680-X-2-.12.

(i) Violations:

1. It shall be a violation of these rules any permitted entity 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 entities described herein 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. Permitted entities shall operate in compliance with applicable Federal, State and Municipal laws and regulations.

Author: Donna C. Yeatman, R.Ph., Executive Secretary

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

History: Filed May 30, 1990. **Amended:** Filed October 18, 1991; August 10, 1992. **Amended:** May 20, 1996; effective June 24, 1996; operative August 15, 1996. **Amended:** Published August 31, 2020; effective October 15, 2020. **Amended:** Published March 31, 2022; effective May 15, 2022. **Amended:** Published July 29, 2022; effective September 12, 2022. **Amended:** Published November 30, 2022; effective January 14, 2023.

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 Ala. 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 Ala. 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 any holder of such a license fails to pay the renewal fee on or before the due date, the license may be reinstated only upon payment of a penalty of ten dollars (\$10) for each lapsed month as prescribed by rule of the board.

(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: Donna Yeatman, R.Ph.

Statutory Authority: Code of Ala. 1975, §§20-2-180 et. seq.; 34-23-92.

History: Filed October 18, 1991, Adopted October 7, 1991; effective January 1, 1992; Filed September 15, 1992. **Amended:** Filed September 20, 1999; effective October 25, 1999. **Amended:** Filed January 13, 2006; 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. **Amended:** Filed July 25, 2016; effective September 8, 2016.

680-X-2-.25

Drug Manufacturers; Wholesale Drug Distributors; Private Label Distributors, Repackager, Third Party Logistics, 503B Outsourcer; Reverse Distributor Permit Fees. Retail Medical Oxygen..

(1) PERMIT

(a) An annual permit must be obtained from the Alabama State Board of Pharmacy by any manufacturer, Wholesale Drug Distributor, Private Label Distributer, Repackager, Third Party Logistic, 503B Outsourcer or Reverse 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 annual permit, with the exception of retail medical oxygen, shall be in the amount of \$750.00. The fee for the annual permit for the retail medical oxygen shall be \$400.00.

(c) The fee for any renewal permit, with the exception of retail medical oxygen, shall be in the amount of \$500.00. The fee for any renewal permit for retail medical oxygen shall be in the amount of \$250.00.

(d) The fee to transfer ownership of the permit shall be in the amount of \$750.00.

(e) 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 every year. Each application for the renewal of the permit shall be made on or before December 31 of every year, at which time the previous permit shall become null and void. A penalty of one hundred dollars (\$100.00) for each overdue month shall be assessed in addition to the permit fee for renewal of delinquent permits.

Author: Donna C. Yeatman, R.Ph., Executive Director

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

History: Filed October 18, 1991. **Amended:** Filed January 6, 2005; effective February 10, 2005. **Amended:** Filed September 5, 2018; effective October 20, 2018. **Amended:** Filed June 20, 2019; effective August 4, 2019. **Amended:** Published March 31, 2021; effective May 15, 2021. **Amended:** Published September 30, 2022; effective November 14, 2022.

680-X-2-.26

Emergency Prescription Refills.

(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

(ii) 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

- (vii) 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) Diuretics 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

I. Pediatric

(VI) Decongestant, Antihistamine and
Anticholinergic

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. Antitussive 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 Anagenic Combinations

(III) Narcotic Agonist-Antagonist Analgesics

(IV) Central Analgesics

(V) Acetaminophen

(VI) Salicylates

(VII) Nonnarcotic Analgesic Combinations

(VIII) Nonsteroid 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
 - (vii) GI Stimulants
 - (I) Metoclopramide
 - (II) Dexpanthenol
 - (viii) Digestive Enzymes
 - (ix) Gastric Acidifiers
 - (x) Cholagogues
 - (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 Subsalcylate
 - (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. Streptococci
- (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 Ala. 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 areas 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 Ala. 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 pharmacies 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 Ala. 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 Multi-State 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: Code of Ala. 1975, §34-23-92.

History: 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 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 Alabama Pharmacy Practice Act, Code of Ala. 1975, §34-23-1, et seq. and the Alabama Uniform Controlled Substances Act, Code of Ala. 1975, §20-2-1, et seq.

(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 pharmacy may outsource a prescription drug order filling to another 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 temperate 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.

(iii) The filling pharmacy shall comply with the provisions of the Act.

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) The Board shall approve based on a presentation before the Board any pharmacy(ies) who intend on utilizing central prescription filling.

(5) 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 the sign in the pharmacy.

(6) 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 or Rules.

(7) 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 annual record; and

2. 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.

3. 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.

4. 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).

(8) Policies and Procedures. A policy and procedure manual as it relates to centralized filing 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 Rules;
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: James S. Ward, Board Attorney

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

History: New Rule: Filed February 13, 2003; effective March 20, 2003. **Amended:** Filed June 20, 2019; effective August 4, 2019.

Amended: Filed June 20, 2019; effective August 4, 2019.

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 Ala. 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 Ala. 1975, §34-23-1(25), 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 included 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 recordkeeping and prescription information mandated by the provisions of the Alabama Pharmacy Practice Act or Board Rule now existing or later amended.

(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: Timothy Martin PharmD, President

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

History: New Rule: Filed January 13, 2006; effective February 17, 2006. **Amended:** Filed July 21, 2006; effective August 25, 2006. **Amended:** Filed April 29, 2016; effective June 13, 2016.

Amended: Published August 31, 2021; effective October 15, 2021.

680-X-2-.33 Internet Pharmacies.

Before dispensing a prescription, 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 and pursuant to a valid patient-practitioner relationship.

Author: James S. Ward, J.D.

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

History: New Rule: Filed March 17, 2006; effective April 21, 2006. **Amended:** Published December 31, 2019; effective February 14, 2020.

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).

(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 Ala. 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 for a resident pharmacy or a resident pharmacy services permit shall be \$200.00. The application fee for a new pharmacy permit for a non-resident pharmacy or for a non-resident pharmacy services permit shall be \$750.00.

(2) The fee for biennial renewal of a pharmacy or pharmacy services permit shall be \$100.00. The fee for biennial renewal of a non-resident pharmacy permit or pharmacy services permit shall be \$400.00.

(3) The fee for transfer of ownership of a pharmacy permit shall be \$250.00.

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

(5) Penalties for late renewal of a pharmacy permit or pharmacy services permit shall be governed by the provisions of the Alabama Pharmacy Practice Act.

Author: Susan Alverson, R.Ph., Executive Director

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

History: **New Rule:** Filed March 17, 2006; effective April 21, 2006. **New Rule:** Filed September 5, 2018; effective October 20, 2018. **Amended:** Published August 31, 2021; effective October 15, 2021.

680-X-2-.36**Continuing Education For Pharmacists.**

(1) Pharmacists shall complete thirty (30) hours of continuing education each renewal cycle 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 renewal cycle.

(2) Section (1) shall not apply to pharmacists applying for the first renewal of their license. If a pharmacist has only been licensed for one full calendar year, they shall complete fifteen (15) hours of continuing education for the first renewal of their license. If a pharmacist has been licensed for less than one full calendar year, no continuing education is required for the first renewal of their license.

(3) 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 or ACCME approved continuing education courses for which a program number is available.

(4) Continuing Education may be completed by either attendance or by distance-based program, video or by publications; however, a pharmacist must complete at least six (6) hours of live continuing education through attendance at a course(s), within the renewal cycle. If a pharmacist has only been licensed for one full calendar year, they must complete at least three (3) hours of live continuing education.

(5) 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.

(6) 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, on the first violation to a non-disciplinary administrative penalty authorized by Code of Ala. 1975, §34-23-33(b) an amount not less than one hundred dollars (\$100.00) or more than two hundred fifty dollars (\$250.00) as determined by the board.

(7) 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.

(8) 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 Ala. 1975, §34-23-52, the Board may require as a condition for reinstatement any amount of continuing education deemed appropriate.

Author: Donna C. Yeatman, R.Ph., Executive Secretary

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

History: New Rule: Filed July 6, 2006; effective August 10, 2006. **Amended:** Filed January 22, 2019; effective March 8, 2019. **Amended:** Published October 31, 2019; effective December 15, 2019. **Amended:** Published September 30, 2022; effective November 14, 2022.

680-X-2-.37

Continuing Education For Pharmacy Technicians.

(1) Pharmacy Technicians shall complete six (6) hours of continuing education within the renewal period, 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 renewal cycle.

(2) Section (1) shall not apply to pharmacy technicians applying for the first renewal of their registration. If a pharmacy technician has only been registered for one full calendar year, they shall complete three (3) hours of continuing education for the first renewal of their license. If a pharmacy technician has been licensed for less than one full calendar year, no continuing education is required for the first renewal of their license.

(3) 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.

(4) 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 two (2) hours of live continuing education through attendance at a course(s), within each renewal cycle. If a pharmacy technician has only been registered for one full calendar year, they must complete at least one (1) hour of live continuing education.

(5) 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 renewal cycle 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.

(6) 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, on the first violation to a non-disciplinary administrative penalty authorized by Code of Ala. 1975, §34-23-132 an amount not less than twenty five dollars (\$25.00) or more than one hundred dollars (\$100.0) as determined by the board.

(7) 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.

(8) Any pharmacy technician who allows their registration 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 three (3) hours of continuing education in the manner described above for each lapsed calendar year. If a registration is lapsed for more than five (5) calendar years, the Board may require as a condition for reinstatement any amount of continuing education deemed appropriate.

Author: Donna C. Yeatman, R.Ph., Executive Secretary

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

History: New Rule: Filed July 6, 2006; effective August 10, 2006. **Amended:** Filed January 22, 2019; effective March 8, 2019. **Amended:** Published August 31, 2020; effective October 15, 2020. **Amended:** Published September 30, 2022; effective November 14, 2022.

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 Ala. 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 Director

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

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

680-X-2-.39

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 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 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 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 entity's initiation of off-site order entry.

(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;
 - (iv) Each pharmacist involved in the off-site order process is responsible for ensuring compliance and may incur disciplinary actions for failing to do so.

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.

(4) 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.

(5) 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.

(6) Off-site order entry shall be approved only if performed by pharmacies to whom a permit has been issued by the Board and which permit is in good standing when under the following circumstances:

(a) Retail pharmacies must be located within 25 miles of each other

(b) Institutional facility must have no more than an average daily census of seventy-five (75) beds and be without an inhouse 24-hour pharmacy available seven days a week.

(c) Any technician function must be verified by the onsite pharmacist prior to transfer to other pharmacy or dispensing to the patient.

(d) The Board shall approve based on a presentation before the Board any pharmacies who intent on utilizing off-site order entry outside the above parameters.

(e) Any modifications to the policies, procedures, or activities as contained in the previously approved off-site order entry process requires Board approval.

(7) Prescription Labeling.

(a) The data entry and dispensing pharmacists' initials must be on the label.

(b) Comply with all other labeling requirements of federal and state statutes or rules.

(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 handheld 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.

(13) Institutional pharmacies may institute off-site order entry to occur in emergency situations provided:

(a) Emergency policies and procedures are provided to the Board for approval, which must include the following:

1. "Emergency" must be defined in the policy and procedure.
2. Identify processes and security measures for off-site order entry outside the physical location of the institution.
3. Procedures for ensuring HIPAA compliance.

(b) Notification is given to the Board within 72 hours of the institutional pharmacy initiating the emergency plan and anticipated duration of the emergency actions.

(c) Notification is given to the Board of the termination of the emergency actions.

Author: Ralph E. Sorrell, R.Ph., Board President

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

History: **New Rule:** Filed October 8, 2009; effective November 12, 2009. **Amended:** Filed June 20, 2019; effective August 4, 2019. **Amended:** Published February 26, 2021; effective April 12, 2021.

**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 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 and activities requiring renewal were ongoing, a non-disciplinary administrative penalty as indicated below shall be received in the Board Office within fourteen (14) days of the Board's receipt of the renewal and if not, the opportunity to avoid discipline shall no longer be available, rather the Board shall initiate appropriate disciplinary actions. This penalty shall be in addition to the prevailing renewal fee.

(a) Pharmacy permits to include retail, institutional, non-resident pharmacies, and pharmacy services permits - \$1,000.00.

(b) Pharmacist license - \$1,000.00

(c) Technician Registration - \$250.00

(d) Pharmacist controlled substance permits - \$500.00

(e) Pharmacy controlled substance permits to include retail, institutional, and non-resident pharmacies - \$500.00

(f) Drug manufacturers; Wholesale Distributors; Private Label Distributors, Repackagers, Third-Party Logistics, 503B Outsourcers, Retail Oxygen Supplier, Oxygen Manufacturer, and any entities which may be regulated in the future - \$1,000.00.

(g) Controlled Substance permits for Drug manufacturers; Wholesale Distributors; Private Label Distributors, Repackagers, Third-Party Logistics, 503B Outsourcers - \$500

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

Author: Donna Yeatman, R.Ph., Executive Secretary

Statutory Authority: Code of Ala. 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.

Amended: Filed July 6, 2016; effective August 20, 2016.

Amended: Published May 28, 2021; effective July 12, 2021.

Amended: Published October 29, 2021; effective December 13, 2021. **Amended:** Published March 31, 2022; effective May 15, 2022.

680-X-2-.41 Pharmacy Services Permit.

(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, 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 Ala. 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 the Code of Ala. 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 difference 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 followed 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 Ala. 1975, §34-23-92.

History: New Rule: Filed October 1, 2012; effective November 5, 2012; **Amended:** Filed November 25, 2013; effective December 30, 2013.

680-X-2-.42

**Requirements For The Disposal Of Prescription
Drug By Pharmacies Collected From Ultimate
User(s) Or Person(s) Entitled To Dispose Of
Drugs.**

(1) This Rule shall apply only to the collection and disposal of prescription drugs by pharmacies returned or received from an ultimate user or a person entitled to dispose of prescription drugs.

(2) An ultimate user is a person who has lawfully obtained and who possesses the controlled substance for his own use or for the use of a member of his/her household or an animal owned by him/her or a member of his/her household.

(3) A person entitled to dispose of prescription drugs is one lawfully entitled to dispose of a decedent's property if that decedent was an ultimate user who died while in possession of prescription drugs (hereinafter referred to as Other Person(s)).

(4) Any pharmacy which intends to receive, collect and dispose of controlled substances from an ultimate user(s) or Other Person(s) shall comply with the applicable provisions of any existing rule or regulation or any amendment or revision thereto adopted pursuant to the Secure and Responsible Drug Disposal Act of 2010. Each such pharmacy shall submit to the Board the necessary authorization to be a collector issued by the DEA within ten (10) days of the receipt thereof. In the event any such pharmacy ceases activities as a collector the Board shall be notified in the same manner as required by the applicable Federal rule or regulation.

(5) Any pharmacy who also intends to receive, collect and dispose of non-controlled prescription drugs from ultimate user(s) or from Other Person(s) shall also comply with the same requirements relating to controlled substances with the exception of any requirement for authorization from the DEA. Each such pharmacy shall notify the Board at the same time of the submission of the Authorization referenced in Paragraph 3 above as well as the notification at the same time if such pharmacy ceases activities as a collector referenced in Paragraph 3 above.

Author: James S. Ward, J.D

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

History: **New Rule:** Filed November 25, 2013; effective December 30, 2013. **Repealed and New Rule:** Filed September 20, 2018; effective November 4, 2013

680-X-2-.43 Requirements For Compounding.

All pharmacies that engage in the compounding of drugs or drug products shall comply with all applicable and current regulations of United States Pharmacopeia-National Formulary (USP)-NF. Section 34-23-11 applies.

Author: Susan Alverson, R.Ph., Executive Secretary

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

History: **New Rule:** Filed July 25, 2018; effective September 8, 2018.

680-X-2-.44 Collaborative Practice.

(1) **Definitions:** The following definitions are applicable to collaborative drug therapy management:

(a) "Agreement" means the Collaborative Drug Therapy Management Agreement.

(b) "Board of Medical Examiners" means the State Board of Medical Examiners established pursuant to Code of Ala. 1975, §34-24-53.

(c) "Board of Pharmacy" means the State Board of Pharmacy established pursuant to Code of Ala. 1975, §34-23-90.

(d) "Collaborative Drug Therapy Management" means the practice of pharmacy whereby an individual pharmacist licensed in this state jointly and voluntarily works with an individual physician licensed in this state under a Collaborative Drug Therapy Management Agreement to provide a range of services to a patient of the Collaborating Physician and the Collaborating Pharmacist intended to optimize therapeutic outcomes; detect and prevent adverse medication interactions and side effects; provide education on the patient's medications used to treat the disease state so that medications are taken correctly; monitor, modify, and discontinue drug therapy as directed by the physician; provide education on managing medication side effects; communicate with third party payors and insurers regarding prior authorization for prescription medications; and any other activity or service specified in a protocol approved by both the Board of Medical Examiners and the Board of Pharmacy, or otherwise authorized by this Rule.

(e) "Collaborating Pharmacist" means a pharmacist who is licensed to practice pharmacy in Alabama, who is a party to a Collaborative Drug Therapy Management Agreement, and who has a direct pharmacist-patient relationship with the patient served by the Agreement.

(f) "Collaborating Physician" means a doctor of medicine or a doctor of osteopathy licensed to practice medicine in Alabama who is a party to a Collaborative Drug Therapy Management Agreement, who has a direct physician-patient relationship, or otherwise authorized by this Rule, with the patient served by the Agreement, and who has prepared the patient-specific, drug or drug class-specific, disease-specific, and condition-specific plan of care based on a physical examination of the patient where required under this Rule.

(g) "Covering Pharmacist" means a pharmacist licensed to practice pharmacy in Alabama who agrees in writing to be readily available to fulfill the duties of a Collaborating Pharmacist pursuant to a Collaborative Drug Therapy Management Agreement during the absence of the Collaborating Pharmacist. The Covering Pharmacist shall be an employee of the same pharmacy practice as the Collaborating Pharmacist, demonstrate the ability to provide the services listed in the Agreement, and abide by the rules and regulations of the Board of Medical Examiners and Board of Pharmacy.

(h) "Covering Physician" means a doctor of medicine or a doctor of osteopathy licensed to practice medicine in Alabama who agrees in writing to be readily available to fulfill the duties of a Collaborating Physician pursuant to a Collaborative Drug Therapy Management Agreement during the absence of the Collaborating Physician. The covering physician shall be either a member of the same medical practice, practice group, or multidisciplinary medical team, or of the same or similar practice specialty as the Collaborating Physician and shall abide by the rules and regulations adopted by the Board of Medical Examiners and Board of Pharmacy.

(i) "Formulary" means a list of legend drugs or drug classes that may be utilized under a Collaborative Drug Therapy Management Agreement.

(j) "Joint Committee" means the Joint Committee on Pharmacy Collaborative Practice established for the purpose of enabling a mechanism for the exchange of information between the Board of Medical Examiners and the Board of Pharmacy on matters related to physician-pharmacist collaboration.

(k) "Licensed Healthcare Facility" means a hospital, as defined in Code of Ala. 1975, §22-21-20(1), licensed by the Alabama Department of Public Health, or a Federally Qualified

Health Center, as defined by ALA. ADMIN. CODE r. 560-X-48-.01(1).

(l) "Patient Care Services" means services rendered by Collaborating Physicians and Collaborating Pharmacists for the benefit of the patient and which must be within the professional training and experience of the Collaborating Physician and Collaborating Pharmacist and be covered by the Collaborative Drug Therapy Management Agreement.

(m) "Protocol" means a document approved by the Board of Medical Examiners and Board of Pharmacy establishing the permissible functions and activities to be performed by a Collaborating Pharmacist and signed by the parties to the Collaborative Drug Therapy Management Agreement.

(n) "Quality Assurance" means documented evaluation by the Collaborating Physician of the parties' adherence to the Agreement and patient outcomes against defined quality outcome measures, using a selected, meaningful sample of patient records, which will identify outcomes needing improvement, set performance goals, and assess progress towards meeting established goals, with a summary of findings, conclusions, and, if indicated, recommendations for change. The physician's signature on the patient record does not constitute quality assurance monitoring.

(o) "Routine Scope of Practice and Services" means any patient care service provided by the Collaborating Physician and his or her practice in compliance with his or her medical education, training, experience, and the Board of Medical Examiners' laws, rules, policies and procedures, and that of the collaborating pharmacist and his or her practice in compliance with his or her pharmacy education, training, experience, and the Board of Pharmacy's laws, rules, policies, and procedures.

(p) "Unrestricted" for the purpose of this Rule, means an active pharmacy permit, pharmacy Drug Enforcement Administration (DEA) registration, pharmacist license, medical license, and Alabama Controlled Substances Certificate that is not revoked, suspended, or on probation at the time of application and is not subject to any conditions, restrictions, or limitations imposed by the applicable licensing board which relate directly to the delivery of health care services. A condition, restriction, or limitation directly relates to the delivery of health care services when it prevents a provider from treating certain types of patients or certain types of ailments or injuries, or otherwise limits a provider from fully engaging in the practice which would otherwise be authorized pursuant to his or her license.

(2) Collaborative Drug Therapy Management Agreement Required.

(a) Physicians and pharmacists may only engage in Collaborative Drug Therapy Management when:

1. An Agreement has been appropriately executed and a written attestation has been filed with and approved by the Board of Pharmacy and the Board of Medical Examiners; and
2. The patient or the patient's authorized representative has signed an Agreement-specific consent that the patient is to receive services from a healthcare team, including a Collaborating Pharmacist.

(b) The patient's consent to treatment under a Collaborative Drug Therapy Management Agreement shall be made part of the patient record.

(c) The written attestation shall include the names of the Collaborating Pharmacist, Collaborating Physician, and any Covering Physician or Covering Pharmacist, if applicable, participating in the Agreement, the date of the Agreement, and a description of the scope of the services covered by the Agreement.

(d) The written attestation shall include a formulary and a list of services authorized by the Agreement.

(e) The Agreement and written attestation must be provided to the Board of Pharmacy and the Board of Medical Examiners no later than ten (10) days after the Agreement is signed by the parties.

(f) A copy of the Agreement, including any addendum, modification, or termination shall be accessible at each practice site and shall be made available to the Board of Pharmacy and Board of Medical Examiners for review upon request.

(3) Eligibility Requirements

(a) No physician or pharmacist may engage in a Collaborative Drug Therapy Management Agreement unless each Collaborating Physician and Collaborating Pharmacist who is a party to the Agreement holds an active, unrestricted license in Alabama.

(b) No physician may enter into an Agreement with a Collaborating Pharmacist who is not licensed by the Board of Pharmacy, does not have an active unrestricted license, is not employed by a pharmacy with an unrestricted permit (where applicable), and does not comply with each term and

requirement of the Board of Pharmacy's rule(s) regarding Collaborative Drug Therapy Management.

(c) No pharmacist may enter into an Agreement with a Collaborating Physician who is not licensed by the Board of Medical Examiners, does not have an active unrestricted license, and does not comply with each term and requirement of the Board of Medical Examiners' rule(s) regarding Collaborative Drug Therapy Management.

(d) A physician or pharmacist engaged in an Agreement shall have:

1. An active unrestricted license to practice medicine or pharmacy in the State of Alabama;
2. An active unrestricted Alabama Controlled Substances Certificate issued by the Board of Medical Examiners or Board of Pharmacy;
3. As to pharmacists provide services in a facility permitted pursuant to §34-23-30 only, the pharmacy must maintain an active unrestricted pharmacy permit and DEA registration;
4. As to physicians only, shall have practiced medicine for at least three years, or have practiced medicine for at least one year, if the physician is certified by a specialty board approved by the American Board of Medical Specialties (ABMS) or American Osteopathic Association Bureau of Osteopathic Specialists (AOABOS); and
5. Paid all collaborative practice fees due to the Board of Medical Examiners and the Board of Pharmacy.

(4) Collaborative Drug Therapy Management Agreement: Required Terms

(a) Each Agreement shall contain the following elements, at a minimum:

1. Names and Titles of Collaborating Providers. The Agreement must contain identification of the Collaborating Pharmacist, the Collaborating Physician, Covering Physician(s), and Covering Pharmacist(s) who are parties ("collaborating providers") to the Agreement. The Agreement shall state the procedure to be followed to indicate changes in the collaborating providers participating in the Agreement. Unless expressly stated in the Agreement, changes to the list of collaborating providers bound by the Agreement shall not automatically void the Agreement. Signatures may be handwritten,

electronic, or any other method authorized by the Board of Pharmacy and the Board of Medical Examiners.

2. Authorized Care and Services. The Agreement must contain an "Authorized Care and Services" section defining the nature and scope of patient care services and activities, including screening, prevention, assessment, management, and care, authorized or restricted, to be provided by the Collaborating Pharmacist pursuant to approved Protocol(s) under the Agreement. All care and services to be provided shall be within the routine scope of practice and services delivered by the Collaborating Physician; provided, however, that the authorized care and services may not be broader in scope than the permissible functions and activities authorized under the Collaborating Pharmacist's license, training, experience, and Board of Pharmacy's laws, rules, policies, and procedures. All care and services provided, with the exception of immunizations, opioid antagonists, and screening or testing which do not require such patient-specific plans, must be pursuant to a diagnosis appropriately made and documented by the Collaborating Physician. An Agreement which includes a Protocol authorizing the Collaborating Pharmacist to modify or discontinue drug therapy must include specific authorization in the authorized care and services portion of the Agreement and must contain a Formulary that may be modified or discontinued by the Collaborating Pharmacist under the terms of the Agreement.

3. Documentation and Communication. The Collaborating Physician shall be responsible for documenting the communication in the patient medical record maintained by the Collaborating Physician. The Collaborating Physician shall, within 24 hours, communicate to the Collaborating Pharmacist any changes initiated to a patient's drug therapy that is subject to an Agreement; a written, telephonic, or electronic prescription which contains specific dosage information may satisfy this requirement. The collaborating pharmacist shall, within 24 hours, communicate to the collaborating physician any changes to a patient's drug therapy and/or individual patient care services as set out in the Agreement. The Agreement shall describe the methods for documenting the patient medical record by the Collaborating Pharmacist and the Collaborating Physician, for documentation of services performed pursuant to the Agreement, and for communication and feedback between the Collaborating Pharmacist and the Collaborating Physician. All such records shall be maintained by the Collaborating Physician for a period of not less than six (6) years from the date of the last patient contact, or if the

patient is a minor, the record shall be maintained for a period of not less than eight (8) years from the date of the last patient contact. All such records shall be maintained by the Collaborating Pharmacist within the employing pharmacy for a period of not less than two (2) years from the date of the last patient contact.

4. Override Clause. A provision must be included in the Agreement providing for the Collaborating Physician to override the actions taken by the Collaborating Pharmacist specific to services provided under the Agreement. This provision must state how such overrides shall be documented and communicated to the Collaborating Pharmacist and the patient in a timely manner, as defined in the Agreement.

5. Expiration, Modification, and Termination. The effective date of the Agreement shall be stated in the Agreement. Each Agreement must contain a term or expiration date upon which the Agreement will expire if not renewed; however, in any event, all Agreements must be reviewed, updated where applicable, and renewed by December 31 at least every two (2) years as evidenced by signatures of the parties. Every Agreement must contain a provision stating the process for modification or termination of the Agreement by any of the parties. An Agreement may be amended upon mutual approval by the Collaborating Physician and Collaborating Pharmacist who have been duly authorized to execute, modify, or change the Agreement. Such amendments shall include, at a minimum, a description of the desired change and the effective date of the change. Any amendment executed shall not automatically void the terms and conditions of the existing Agreement unless expressly stated. Amendments to the authorized care and services which establish substantive additions or reductions to the scope of patient care services provided under the Agreement, including new therapeutic classes of drugs added to the authorized Formulary, must be provided to the Board of Pharmacy and Board of Medical Examiners no later than ten (10) days from the date the amendment is signed by the parties.

6. Automatic Exclusions. Agreements must have a provision that identifies any terms under which a provider will be automatically excluded from participation in the Agreement, which shall include, but are not limited to: death; the suspension, surrender, revocation, or retirement of license; loss or restriction of prescriptive authority; the suspension, surrender, or revocation of a Drug Enforcement Administration registration or Alabama Controlled Substances

Certificate; or exclusion from any federally-funded health programs.

7. Quality Assurance. The Collaborating Physician and Collaborating Pharmacist shall engage in a quality assurance review of the care provided for patients pursuant to the Agreement on a quarterly basis. Quality Assurance shall include, and the Agreement shall provide for, a quarterly review by the Collaborating Physician of a meaningful sample of patient records. A "meaningful sample" shall consist of:

- (i) Not less than twenty-five percent (25%) of the patients treated pursuant to the Agreement for the first two years of the Agreement;

- (ii) Not less than ten percent (10%) of the patients treated pursuant to the Agreement after the Agreement has been in effect for two years; and

- (iii) All adverse outcomes of the patients treated pursuant to the Agreement.

The quality assurance review shall be properly documented, retained by the participating parties of the Agreement, and available for review by representatives of the Board of Medical Examiners for at least five (5) years and the Board of Pharmacy for at least two (2) years.

8. All Agreements shall require the Collaborating Pharmacist to use an area for in-person or other approved consultations with patients that ensures the confidentiality of the communication and complies with the requirements and standards set forth by the Board of Pharmacy in Board Rule 680-X-2-.27.

9. Notice. All Agreements shall include a provision stating which party or parties shall bear the costs and responsibility of promptly notifying affected individuals in the event that an Agreement expires or is terminated. All Agreements shall specify when patients served by an Agreement are to be notified of changes to the Agreement. Any provision of the Agreement notwithstanding, the patients served by an Agreement shall be promptly notified when a Collaborating Physician or Collaborating Pharmacist departs from or is terminated from an Agreement, and said notice shall include the Collaborating Physician's or Collaborating Pharmacist's contact information as well as instructions for how patients may obtain copies of their records or have them forwarded to the physician or pharmacist of their choice.

(5) Limitations

(a) The scope of an Agreement shall NOT include:

1. Any person or patient of a Collaborating Physician for whom such Collaborating Physician has not prepared a patient- specific, drug- or drug class-specific, disease-specific, or condition-specific plan of care based on a physical examination of the patient by the Collaborating Physician within the past twelve (12) months, with the exception of immunizations and screening or testing which do not require such patient-specific plans, as well as the dispensing of opioid antagonists as defined in Code of Ala. 1975, §20-2-280; or
2. The prescribing of controlled substances listed or to be listed in the schedules under federal law and in Code of Ala. 1975, §§20-2-23, 20-2-25, 20-2-27, 20-2-29, and 20-2-31 and/or Board Rule 420-7-2 and its Appendix.

(b) No retail pharmacy may employ a physician for the purpose of maintaining, establishing, or entering into a collaborative practice agreement. Nothing shall prohibit a retail pharmacy from hiring a physician or licensed medical practitioner for the purpose of conducting quality assurance reviews of its pharmacists that are engaged in the practice of collaborative drug therapy.

(6) Standards for Physicians

(a) Physicians engaged in an Agreement shall:

1. Provide professional medical oversight and instruction to the Collaborating Pharmacist;
2. Establish and maintain a physician-patient relationship with each patient receiving services under the Agreement;
3. Be readily available to the Collaborating Pharmacist through direct telecommunication for consultation, assistance, and direction, or shall make arrangements for a substitute physician to be readily available who is pre-approved by the Board of Medical Examiners, who practices in a specialty substantially similar to that of the Collaborating Physician, and who is familiar with these rules; and
4. Collaborate with pharmacist(s) who agree to be readily available to the physician through direct telecommunication for consultation, assistance, and collaboration.

(b) In the event the Collaborating Physician is not readily available, provisions shall be made for professional medical oversight and direction by a Covering Physician who is readily available, who is pre-approved by the Board of Medical Examiners, and who is familiar with these rules. The Collaborating Physician shall certify to the Board of Medical Examiners at least annually that any approved Covering Physician continues to agree to serve in that capacity and shall inform the Board of Medical Examiners of the termination of a Covering Physician within ten (10) days of the termination.

(c) In the event of an unanticipated, permanent absence of a Collaborating Physician, a previously approved Covering Physician may be designated as a temporary Collaborating Physician for a period of up to sixty (60) days. During the sixty (60) daytime period, a new Agreement designating a new Collaborating Physician should be submitted for approval.

(7) Standards for Pharmacists

(a) Pharmacists engaged in an Agreement shall:

1. Establish and maintain a pharmacist-patient relationship with each patient receiving services under the Agreement;

2. Be readily available to the Collaborating Physician through direct telecommunication for consultation, assistance, and direction; and

3. Collaborate with physician(s) who agree to be readily available to the pharmacist through direct telecommunication for consultation, assistance, and collaboration.

(b) In the event the Collaborating Pharmacist is not readily available, provisions shall be made for a Covering Pharmacist who is readily available, who is pre-approved by the Board of Pharmacy, and who is familiar with these rules. The Collaborating Pharmacist shall certify to the Board of Pharmacy at least annually that any approved Covering Pharmacist continues to agree to serve in that capacity and shall inform the Board of Pharmacy of the termination of a Covering Pharmacist within ten (10) days of the termination.

(c) In the event of an unanticipated, permanent absence of a Collaborating Pharmacist, a Covering Pharmacist may be designated as a temporary Collaborating Pharmacist for a period of up to sixty (60) days. During the sixty (60) daytime period, a new Agreement designating a new Collaborating Pharmacist should be submitted for approval.

(8) Approval of the Collaborative Drug Therapy Management Agreement

(a) A physician and pharmacist shall not engage in Collaborative Drug Therapy Management until the Agreement is approved by both the Board of Medical Examiners and the Board of Pharmacy.

(b) Agreements must be submitted to the Board of Medical Examiners and the Board of Pharmacy within ten (10) days after the Agreement is signed by all parties.

(c) Any amendment or addendum to an Agreement must be submitted to the Board of Medical Examiners and the Board of Pharmacy within ten (10) days after the amendment is signed by all parties.

(d) No Agreement, nor any amendment or addendum thereto, shall be effective until it is approved by both the Board of Pharmacy and the Board of Medical Examiners.

(e) Each Agreement submitted to the Board of Medical Examiners shall be accompanied by a fee of three hundred dollars (\$300), except those Agreements submitted by a physician who is engaging in Collaborative Drug Therapy Management at an indigent clinic, in which case the fee may be \$1. Each application requesting the nominal fee will be placed before the Joint Committee for individual review. This fee is due and payable concurrently with the submission of an application for a Collaborative Drug Therapy Management Agreement. The fee is not refundable.

(f) Each Agreement submitted to the Board of Pharmacy shall be accompanied by a fee of one hundred dollars (\$100) except those Agreements submitted by a pharmacist who is engaging in Collaborative Drug Therapy Management at an indigent clinic, in which case the fee may be \$1. Each application requesting the nominal fee will be placed before the Joint Committee for individual review. This fee is due and payable concurrently with the submission of an application for a Collaborative Drug Therapy Management Agreement. The fee is not refundable.

(9) Denial of an Application for a Collaborative Drug Therapy Management Agreement

(a) The Board of Medical Examiners or Board of Pharmacy may deny approval of any Agreement based on any of the grounds specified in this Rule.

(b) Before denying an Agreement on any of the grounds specified in this Rule, the Board of Medical Examiners and/or Board of Pharmacy shall conduct a hearing in accordance with Chapter 6 of the Rules of the Board of Medical Examiners, or

pursuant to any applicable provisions of the Alabama Pharmacy Practice Act, respectively, and the Alabama Administrative Procedure Act.

(c) The following acts shall constitute grounds for the denial of approval of an Agreement:

1. Failure of a Collaborating Physician or a Collaborating Pharmacist to submit an application or Agreement that complies with the terms and requirements of this Rule;
2. A finding by the Board of Medical Examiners or Board of Pharmacy that a Collaborating Physician or Collaborating Pharmacist has submitted or caused to be submitted false, misleading, or untruthful information in connection with an application or Agreement;
3. A finding by the Board of Medical Examiners that a Collaborating or Covering Physician has committed any of the acts or offenses constituting grounds to discipline the license to practice medicine in this state pursuant to Code of Ala. 1975, §34-24-360, or any of the acts or offenses constituting grounds to discipline the controlled substances registration of a physician under Code of Ala. 1975, §20-2-54, or that the Collaborating or Covering Physician is unable to practice Collaborative Drug Therapy Management with reasonable skill or safety to patients;
4. A finding by the Board of Pharmacy that a Collaborating or Covering Pharmacist has committed any of the acts or offenses constituting grounds to discipline the license to practice pharmacy in this state pursuant to Code of Ala. 1975, §34-23-33, or any of the acts or offenses constituting grounds to discipline the controlled substances registration of the pharmacist under Code of Ala. 1975, §20-2-54, or that the Collaborating or Covering Pharmacist is unable to practice Collaborative Drug Therapy Management with reasonable skill or safety to patients;
5. A finding by the Board of Pharmacy that a Collaborating or Covering Pharmacist has violated the Alabama Pharmacy Practice Act, the laws that regulate the sale and/or dispensing of prescription or legend drugs and/or narcotics or any rules and regulations of the Board of Pharmacy or the pharmacy law or rules of the Board of Pharmacy of another state or any other applicable laws;
6. A finding by the Board of Medical Examiners and/or the Board of Pharmacy that a party to the Agreement is under

any state or federal restriction, probation, discipline, or indictment related to the provision of medical services, the practice of medicine or pharmacy, or fraud;

7. Failure on the part of a Collaborating or Covering Physician to maintain an active, unrestricted license to practice medicine, an active, unrestricted Drug Enforcement Administration (DEA) registration, or an active, unrestricted Alabama Controlled Substances Certificate; or

8. Failure on the part of a Collaborating or Covering Pharmacist to maintain an active, unrestricted license to practice pharmacy, an active, unrestricted Alabama Controlled Substances Certificate, or (where applicable), an active, unrestricted Drug Enforcement Administration (DEA) registration issued to the pharmacy which is the location for the services to be provided pursuant to the Agreement.

(10) Grounds for Modification, Restriction, or Termination of a Collaborative Drug Therapy Management Agreement

(a) The Board of Medical Examiners and/or Board of Pharmacy on its own motion may investigate any evidence which appears to show that its respective licensee is or may be guilty of a violation of any of the acts, offenses, or conditions set out in this Rule. A violation of this Rule is grounds for disciplinary action and sanctions against a Collaborating Physician, Collaborating Pharmacist, Covering Physician, Covering Pharmacist, or pharmacy permit, and shall be prosecuted against and in the name of the Collaborating Physician, Collaborating Pharmacist, Covering Physician, or Covering Pharmacist participating in the alleged violation.

(b) A violation of this Rule may be sanctioned by termination, modification, or restriction of the Agreement, disciplinary action against the license of the Collaborating Physician, Collaborating Pharmacist, Covering Physician, or Covering Pharmacist, or pharmacy permit, the assessment of a fine, or any combination thereof.

(c) Before modifying, restricting, or terminating an Agreement, disciplining a license or permit, or assessing a fine, the Board of Medical Examiners and/or Board of Pharmacy shall conduct a hearing in accordance with Chapter 6 of the rules of the Board of Medical Examiners, or pursuant to any applicable provisions of the Alabama Pharmacy Practice Act, respectively, and the Alabama Administrative Procedure Act.

(d) Pursuant to the requirements of Code of Ala. 1975, § 41-22-19(d), the Board of Medical Examiners or the Board of Pharmacy may order the emergency suspension of the Agreement

for any of the reasons stated in this Chapter/Rule if the Board of Medical Examiners and/or Board of Pharmacy finds that danger to the public health, safety, or welfare necessitates the emergency suspension of the Agreement.

(e) An order of emergency suspension of the Agreement shall become effective immediately, unless otherwise stated in the order. Simultaneously with the issuance of an order of emergency suspension, there shall be service of a statement of charges and notice of hearing. The suspension shall be effective for a period of not longer than one hundred and twenty (120) days.

(f) The following acts shall constitute violations of this Rule:

1. Failure of a Collaborating or Covering Physician to comply with any term or requirement of this Rule or the terms of the Agreement;
2. A finding by the Board of Medical Examiners that an Agreement contains false, misleading, or untruthful information, or that a Collaborating or Covering Physician has submitted or caused to be submitted false, misleading, or untruthful information to the Board of Medical Examiners in connection with an Agreement;
3. A finding by the Board of Medical Examiners that a Collaborating or Covering Physician has committed any of the acts or offenses constituting grounds to discipline the license to practice medicine in this state pursuant to Code of Ala. 1975, §34-24-360, or any of the acts or offenses constituting grounds to discipline the controlled substances registration of the physician under Code of Ala. 1975, §20-2-54;
4. A finding by the Board of Pharmacy that a Collaborating or Covering Pharmacist has committed any of the acts or offenses constituting grounds to discipline the license to practice pharmacy in this state pursuant to Code of Ala. 1975, §34-23-33, or any of the acts or offenses constituting grounds to discipline the controlled substances registration of the pharmacist under Code of Ala. 1975, §20-2-54;
5. A finding by the Board of Pharmacy that a Collaborating or Covering Pharmacist has violated the Alabama Pharmacy Practice Act, the laws that regulate the sale and/or dispensing of prescription or legend drugs and/or narcotics or any rules and regulations of the Board of Pharmacy or the pharmacy law or rules of the Board of Pharmacy of another state or any other applicable laws;

6. A finding by the Board of Medical Examiners and/or the Board of Pharmacy that a party to the Agreement is under any state or federal restriction, probation, discipline, or indictment related to the provision of medical services or fraud;

7. Failure on the part of a Collaborating or Covering Physician to maintain an active, unrestricted license to practice medicine, an active, unrestricted Drug Enforcement Administration (DEA) registration, or an active, unrestricted Alabama Controlled Substances Certificate; or

8. Failure on the part of a Collaborating or Covering Pharmacist to maintain an active, unrestricted license to practice pharmacy, an active, unrestricted Alabama Controlled Substances Certificate, or, where applicable, an active, unrestricted Drug Enforcement Administration (DEA) registration issued to the pharmacy which is the location for the services to be provided pursuant to the Agreement.

(11) Reporting Requirement

(a) Any physician engaging in a Collaborative Drug Therapy Management Agreement shall be subject to disciplinary action by the Board of Medical Examiners if he or she violates the terms of this Rule or the terms of the Agreement. The Board of Medical Examiners shall report to the Board of Pharmacy the initiation of any proceeding against the physician or any conduct which it believes to be in violation of any such Agreement.

(b) Any pharmacist engaging in a Collaborative Drug Therapy Management Agreement shall be subject to disciplinary action by the Board of Pharmacy if he or she violates the terms of this Rule or the terms of the Agreement. The Board of Pharmacy shall report to the Board of Medical Examiners the initiation of any proceeding against the pharmacist or any conduct which it believes to be in violation of any such Agreement.

(c) Any party to an Agreement which is voluntarily terminated shall, within ten (10) days of the termination, notify their respective board.

(d) If the Alabama medical license of a Collaborating Physician becomes inactive, revoked, suspended, restricted, or placed on probation, then that physician's participation in any and all Agreements shall be administratively terminated by operation of law. The Board of Medical Examiners shall notify the Board of Pharmacy whenever disciplinary action is taken against a Collaborating

Physician's license or when a Collaborating Physician's participation in an Agreement is terminated by operation of law.

(e) If the Alabama pharmacy license of a Collaborating Pharmacist becomes inactive, revoked, suspended, restricted, or placed on probation, then that pharmacist's participation in any and all Agreements shall be administratively terminated by operation of law. The Board of Pharmacy shall notify the Board of Medical Examiners whenever disciplinary action is taken against a Collaborating Pharmacist's license or when a Collaborating Pharmacist's participation in an Agreement is terminated by operation of law.

(f) A Collaborating Physician whose Alabama medical license becomes inactive, revoked, suspended, restricted, or placed on probation, or who is administratively terminated from an Agreement shall be required to notify each party to the Agreement of said action. The Collaborating Physician shall additionally be responsible for notifying each patient served by the Agreement and shall bear the costs of such notice.

(12) Renewal

(a) Agreements shall be renewed by December 31 every two (2) years.

(b) Each Collaborating Physician and Collaborating Pharmacist renewing an Agreement shall review the terms, conditions, protocols, parties, and content of the Agreement and shall certify that the information is accurate and complies with this Rule.

(c) The fee for renewing an Agreement with the Board of Medical Examiners shall be two hundred dollars (\$200).

(d) The fee for renewing an Agreement with the Board of Pharmacy shall be fifty dollars (\$50).

(13) Joint Committee

(a) There shall be established a Joint Committee on Pharmacy Collaborative Practice for the purpose of enabling a mechanism for the exchange of information between the Board of Medical Examiners and the Board of Pharmacy on matters related to physician-pharmacist collaboration.

(b) The Joint Committee shall be composed of the following:

1. Two (2) voting members of the Board of Medical Examiners appointed by the Chairman of the Board of Medical Examiners. For the initial term, one member shall be appointed to a term concluding on December 31, 2022,

and one member shall be appointed to a term concluding on December 31, 2023. Thereafter, each appointee shall serve a term of two (2) years.

2. The President and Vice-President of the Board of Pharmacy, or his or her appointee, the terms of which shall coincide with their term as President or Vice-President of the Board of Pharmacy.

(c) Members of the Joint Committee shall be eligible for reappointment. Should a vacancy occur on the Joint Committee, a successor shall be appointed by the original appointing authority to serve the unexpired term. The committee shall select one of its members to serve as chairperson for a one-year term. The chairperson shall alternate between a physician member of the committee and a pharmacist member of the committee.

(d) The Joint Committee shall not meet without the consent of both the Board of Medical Examiners and Board of Pharmacy unless all four (4) Joint Committee Members are present. The Chairman of the Board of Medical Examiners and the President of the Board of Pharmacy may appoint a proxy when necessary to ensure that each board is represented by two (2) Joint Committee members.

(e) The Joint Committee shall meet at least on a quarterly basis, or more or less frequently pursuant to a joint resolution by the Board of Medical Examiners and Board of Pharmacy.

(f) A member's participation in a Joint Committee meeting shall constitute official functions of and the performance of the duties of the boards and shall be eligible for the compensation, per diem, and travel allowance allowed to members of the Board of Medical Examiners under Code of Ala. 1975, §34-24-54, and members of the Board of Pharmacy under Code of Ala. 1975, §34-23-91. The Board of Medical Examiners and Board of Pharmacy shall pay compensation, per diem, and travel allowance of their respective members and shall furnish necessary clerical, legal, and administrative support for operation of the committee.

(g) The Joint Committee may exercise the following functions and responsibilities:

1. Review and/or recommend changes to the current rules and regulations for physician-pharmacist collaboration.

2. Discuss and/or make recommendations regarding changes to the standard protocol(s) adopted pursuant to Rule 680-X-2-.44(14) (a)

3. Discuss and/or make recommendations regarding changes to the standard formulary(ies) adopted pursuant to Board Rule 680-X-2-.44(15) (a) .

4. Review and/or make recommendations regarding any expanded protocol requests made pursuant to Board Rule 680-X-2-.44(14) (b) .

5. Review and/or make recommendations regarding any expanded formulary requests made pursuant to Board Rule 680-X-2-.44(15) (b) .

6. Serve in an advisory role regarding issues related to applications for Collaborative Drug Therapy Management Agreements, required education, renewal, and other matters concerning the implementation of physician-pharmacist collaborative practice.

(h) Notwithstanding any other provision of this Rule, the Joint Committee shall serve in an advisory capacity only and any recommendation made by the Committee shall be subject to approval by both the Board of Medical Examiners and the Board of Pharmacy.

(14) Protocols

(a) The Board of Medical Examiners and the Board of Pharmacy shall promulgate standard protocols consistent with the recommendation of the Joint Committee establishing the patient care services that may be rendered under an Agreement.

(b) Protocols deviating from the standard protocols shall be submitted to the Joint Committee for recommendation for approval. When evaluating whether to recommend the approval or denial of a non-standard Protocol, the Joint Committee shall consider certain factors, including, but not limited to:

1. The Collaborating Physician's and Collaborating Pharmacist's education, training, experience, and specialty;

2. The Collaborating Physician's and Collaborating Pharmacist's disciplinary history and any licensure restrictions;

3. FDA approved usages and recommendations;

4. Whether a proposed Protocol is within the current standard of care for treatment of the disease or condition specified in the Protocol, including usages

known as "off- label," and whether the use is supported by evidence-based research;

5. Whether the proposed Protocol creates an undue risk of harm to patients; and

6. The routine scope of practice and services provided by the Collaborating Physician and Collaborating Pharmacist.

(c) After consideration of the factors listed herein, the Joint Committee may recommend approval or denial of a non-standard Protocol in whole or in part.

(15) Formulary

(a) The Board of Medical Examiners and the Board of Pharmacy shall promulgate a standard formulary of legend drugs and/or drug classes consistent with the recommendations of the Joint Committee that may be utilized under an Agreement.

(b) Any Formulary that includes prescription drugs and/or drug classes additional to the standard Formulary shall be submitted to the Joint Committee for recommendation for approval. When evaluating whether to recommend the approval or denial of the addition of a drug or drug class to a Formulary, the Joint Committee shall consider certain factors, including, but not limited to:

1. The Collaborating Physician's and Collaborating Pharmacist's education, training, experience, and specialty;

2. The Collaborating Physician's and Collaborating Pharmacist's disciplinary history and any licensure restrictions;

3. FDA approved usages and recommendations;

4. Whether the usage of the proposed drug(s) or drug class(es) is within the current standard of care for treatment of the disease or condition specified in the Protocol, including usages known as "off-label, and whether the use is supported by evidence-based research;

5. Whether the use of the proposed drug(s) or drug class(es) creates an undue risk of harm to patients; and

6. The routine scope of practice and services provided by the Collaborating Physician and Collaborating Pharmacist.

(c) After consideration of the factors listed herein, the Joint Committee may recommend approval or denial of the addition of a drug or drug class to a Formulary.

(16) Exclusion

(a) The foregoing provisions of this Rule shall not apply to a pharmacist licensed by the Alabama State Board of Pharmacy who is employed by a Licensed Healthcare Facility.

(b) The Board of Medical Examiners and/or the Board of Pharmacy shall each have the authority to identify those licensees who are exempt under this Rule.

(c) The Board of Medical Examiners or the Board of Pharmacy may investigate or request additional documentation or information from their respective licensee(s) to determine those who qualify for the exemption under this Rule.

(17) Implementation

(a) Any physician and/or pharmacist currently participating in any activities described by this Rule must be in full compliance with these rules no later than April 30, 2022. The provisions of this Rule shall become enforceable by the Board of Medical Examiners and Board of Pharmacy on May 1, 2022.

Author: Donna C. Yeatman R.Ph. Executive Secretary

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

History: **New Rule:** Published December 31, 2019; effective February 14, 2020. **Repealed and New Rule:** Published August 31, 2021; effective October 15, 2021. **Amended:** Published February 28, 2022; effective April 14, 2022. **Amended:** Published April 28, 2023; effective June 12, 2023.

680-X-2-.45**Noncontrolled Prescription Requirements.**

(1) Original prescriptions for noncontrolled substances shall contain the following:

- (a) Name of the patient;
- (b) Date the original prescription was issued;
- (c) Name, strength and, if needed, dosage form of drug to be dispensed;
- (d) Directions for use by the patient;
- (e) Total number of refills authorized by the prescriber, if any;
- (f) Prescribing practitioner's name;
- (g) A prescription number assigned by the pharmacist;

(h) Any additional information as deemed essential for proper communication of the prescription.

(2) The transfer of prescription information for a noncontrolled substance for the purpose of dispensing is permissible between pharmacies. Transfer prescriptions are subject to the following requirements:

(a) Transfers received orally must be communicated between licensed pharmacists or intern/externs under direct supervision of licensed pharmacists.

1. The transferring pharmacist/intern/extern must record:

(i) Date of the transfer

(ii) Name of the pharmacist/intern/extern transferring the information

(iii) Name and address of the pharmacy to where the prescription was transferred

(iv) Name of the pharmacist/intern/extern receiving the information

2. The pharmacist/intern/extern receiving the transfer must document the following:

(i) Date of the transfer

(ii) Name of the pharmacist/intern/extern transferring the information

(iii) Name and address of the pharmacy from where the prescription was transferred

(iv) Name of the patient

(v) Date the original prescription was issued

(vi) Name and strength of drug to be dispensed

(vii) Directions for use

(viii) Total number of refills and/or quantity remaining

(ix) Prescribing practitioner's name

(x) Date of last fill by transferring pharmacy

(xi) Any additional information as deemed essential for proper communication of the prescription.

(b) Transfers may be performed electronically when the following conditions are met:

1. The transferring pharmacy must provide the receiving pharmacy with the following information in addition to the original prescription data:

(i) Total number of refills and/or quantity remaining

(ii) Name and address of the pharmacy from which the prescription was transferred.

2. The pharmacy receiving the transfer must create an electronic record for the prescription that includes the transferring pharmacy's name and the original prescription data.

Author: Donna C. Yeatman, R.Ph., Executive Secretary

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

History: New Rule: Published August 31, 2020; effective October 15, 2020. 6

680-X-2-.46

Immunization Training.

(1) Purpose: The Alabama State Board of Pharmacy (Board) is charged with the duty and responsibility to maintain standards of professional conduct and to regulate professional practice and is further charged to protect the health, safety, and welfare of the citizens of the State of Alabama. In conformity with this purpose, this rule shall provide guidelines for administering vaccinations by Alabama licensed pharmacists and/or registered interns, externs, and technicians.

(2) In order to administer immunizations, a pharmacist, intern, or extern must be licensed and/or registered by the Alabama Board of Pharmacy and comply with the following requirements:

(a) The pharmacist, intern, and/or extern must have and maintain a current certificate in basic cardiopulmonary resuscitation.

(b) The intern and/or extern must be under the direct supervision of an Alabama licensed pharmacist.

(3) Technicians must be registered by the Alabama Board of Pharmacy, in good standing, acting under the direct supervision of an Alabama licensed pharmacist and in order to administer vaccines, shall comply with the following requirements:

(a) The registered pharmacy technician must complete a minimum two (2) hours of Accreditation Council for

Pharmacy Education (ACPE) approved practical training program to include hands-on injection technique training, the recognition and treatment of emergency reactions to vaccines and successful examination to assure sufficient knowledge of vaccines;

(b) The registered technician must have a current certificate in basic cardiopulmonary resuscitation;

(c) The vaccine must be ordered by an Alabama licensed pharmacist or pursuant to a valid prescription;

(d) The Alabama licensed pharmacist must be readily and immediately available to the immunizing registered pharmacy technician;

(e) The registered technician shall submit to the Board of Pharmacy documentation of the satisfactory completion of the requirements of (3)(a) within 10 days of completion.

(f) For each submission of the documentation referenced in paragraph e. above, the Secretary of the Board shall issue to the registered technician a certificate for immunization authority, which shall be displayed in a conspicuous place.

(4) The pharmacist, in his or her capacity and as part of their supervision of intern, extern, and/or technician shall report any adverse event required by the Vaccine Adverse Event Reporting System (VAERS), including but not limited to:

(a) Any adverse event listed in the VAERS table of Reporting Events Following Vaccination within the listed specified time period.

(b) Any adverse event listed by the vaccine manufacturer as a contraindication to further doses of the vaccine.

(5) The pharmacist is further responsible to ensure, the following:

(a) The vaccine must be FDA-authorized or FDA-licensed;

(b) In the case of a designated emergency vaccine, the vaccine must be ordered and administered according to the Advisory Committee on Immunization Practices (ACIP) vaccine recommendation(s);

(c) A childhood vaccine must be ordered and administered according to ACIP's standard immunization schedule;

(d) Storage, use and administration of any sterile product used in the administration of immunizations meets the United States Pharmacopeia (USP) requirements, as well as those of

the Centers for Disease Control and any applicable provision of the Alabama Pharmacy Practice Act and/or any rules of the Board now in effect or which may become effective in the future;

(e) The pharmacy must have available an epinephrine kit (epinephrine in lmg/ml aqueous solution) or an epinephrine autoinjector;

(f) Compliance with blood borne pathogen requirements, including, but not limited to medical waste disposal, and FDA-cleared sharps disposal containers;

(g) Compliance with all record keeping and reporting requirements, which are now in effect or may become required in the future.

(6) The licensed pharmacist must complete a minimum of two hours of Board approved, immunization-related continuing pharmacy education each renewal cycle.

(7) The supervising pharmacist shall ensure any pharmacists, interns, externs, and registered technicians prior to providing immunizations completion of the immunization training set out above and is acting in compliance with all requirements of the rule.

(8) Any pharmacist, intern, extern, or technician performing immunizations without complying with this rule shall be subject to discipline by the Board.

Author: Donna C. Yeatman, R.Ph., Executive Secretary

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

History: Published August 31, 2021; effective October 15, 2021.

680-X-2-.47

Off Site Vaccine Order Entry Processing.

(1) The purpose of this Rule is to provide standards for off-site vaccine order entry processing for immunizations by any pharmacy in the state of Alabama to which a permit has been issued by the Alabama State Board of Pharmacy.

(2) "Off-site vaccine order entry processing" is a means by which a licensed pharmacist, registered technician and/or intern under the direct supervision of a licensed pharmacist, may remotely access their own pharmacy's electronic database from outside the pharmacy in order to process vaccinations provided that the pharmacy establishes controls to protect the privacy and security of patient records or any other confidential records. This processing shall be limited to:

- (a) Interpreting or clarifying vaccine orders;
 - (b) Data entry of the vaccine order information;
 - (c) Performing drug regimen review; and
 - (d) Providing clinical vaccine information concerning a patient's immunizations. "Off-site vaccine processing" does not include the order entry or dispensing of any legend or controlled substance prescriptions.
- (3) Off-site vaccine order entry processing of vaccinations shall be completed in real time at the remote site where the vaccine is being administered, after which the technology used to complete the vaccine processing is returned to the pharmacy for secure storage within the permitted pharmacy.
- (4) Any records generated in this process whether in a hard copy or electronic format shall be maintained at the pharmacy for a minimum period of two years from the date of entry.
- Author:** Donna Yeatman, R.Ph., Executive Secretary
Statutory Authority: Code of Ala. 1975, §34-23-92.
History: New Rule: Published October 29, 2021; effective December 13, 2021.

680-X-2-.48**State Of Emergency Provisions.**

- (1) Whenever the Governor duly proclaims the existence of a State of Emergency defined in Code of Ala. 1975, §31-9-3(5) pursuant to the authority and power given to the Governor by Code of Ala. 1975, §31-9-6, a pharmacy technician(s) holding a current and valid Registration, shall be allowed to enter a pharmacy where he/she is employed without the necessity of a pharmacist's presence for only the purpose of providing properly filled, checked and approved prescriptions ready for pickup by the ultimate user of his/her agent who shall be provided a contact number for a pharmacist for the purpose of counseling.
- (2) The ability of a technician(s) to perform the functions described above are authorized only for the duration of the Governor's proclamation.
- (3) The Supervising Pharmacist of any pharmacy allowing a technician(s) to engage in the activities described above shall notify the Board within 48 hours of the initiation of this activity.
- Author:** Donna C. Yeatman, R.Ph., Executive Secretary
Statutory Authority: Code of Ala. 1975, §34-23-92.
History: New Rule: Published September 30, 2022; effective November 14, 2022.