ALABAMA STATE BOARD OF PHARMACY
ADMINISTRATIVE CODE

CHAPTER 680-X-2
PRACTICE OF PHARMACY

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680-X-2-.01 Statewide Circulation For Rules And Regulations (Repealed 9-27-94).

(Repealed)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 **Repealed:** Filed August 23, 1994; effective September 27, 1994.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 Pharmacies.

(1) Consistent with the definition of "pharmacy" set forth in §34-23-1, the Board further classifies pharmacies into the following subtypes: independent, chain, non-resident, institutional, and retail medical oxygen.

(a) An independent pharmacy is a community pharmacy providing dispensing services as a component of their practice that:

1. Is not owned, operated, or controlled by a chain pharmacy corporation;

2. Employs fewer than forty (40) full-time equivalent pharmacists that work in a dispensing role; and

3. Meets all licensing and permit requirements of the Board

(b) A chain pharmacy is a pharmacy providing dispensing services as a component of their practice that:

1. Is owned, operated, or controlled by a chain pharmacy corporation;

2. Employs at least forty (40) full-time equivalent pharmacists that work in a dispensing role across all its pharmacy locations collectively; and

3. Meets all licensing and permit requirements of the Board

Author: Alabama Board of Pharmacy
Statutory Authority: Code of Ala. 1975, §34-23-92.
History: Filed June 1, 1982. **Repealed and New Rule:** Published May 29, 2026; effective July 13, 2026.

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 permitted intern or extern as defined in Code of Ala. §34-23-1

(3) A registered pharmacy technician may assist in the above tasks under direct supervision; however, a technician 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.

(4) In order to be registered as a pharmacy technician in this state, an applicant shall:

(a) Have submitted an application in a manner provided by the Board of Pharmacy.

(b) Have attained the age of seventeen (17).

(5) 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.

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

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

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

(9) All pharmacy technicians shall register with the Alabama State Board of Pharmacy. This registration shall expire on December 31 of odd numbered years. The initial registration fee and renewal fee shall be sixty dollars ($60). The registration shall only be considered successfully renewed once payment has been received and the renewal has been approved by the Board. If any pharmacy technician fails to pay a renewal fee on or before December 31 of any odd-numbered 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 five dollars ($5) for each lapsed month, and all lapsed fees for each lapsed month, up to a maximum of 2 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 obtaining their registration. Board administrative staff may grant a request to extend the training period for up to six (6) months. Proof of training shall be submitted to the board within 30 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 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, by December 31 of odd-numbered years, complete six (6) hours of continuing education, two (2) hours of which shall be 'live' presentation.

(10) The Alabama State Board of Pharmacy may 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.

(11) 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: Alabama State Board of Pharmacy
Statutory Authority: Code of Ala. 1975, §34-23-131.
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. **Amended:** Published December 31, 2024; effective February 14, 2025. **Amended:** Published October 31, 2025; effective December 15, 2025. **Amended:** Published February 27, 2026; effective April 13, 2026.

680-X-2-.15 Record-keeping Requirements.

(1) A pharmacy's computer system shall provide for the storage and retrieval of original prescription orders and their refill histories. It must include:

(a) The original prescription number

(b) The prescribing practitioner's name, DEA registration number (if applicable), and Alabama controlled substance number (if applicable)

(c) Full name of the patient

(d) Date the original prescription was issued and dispensed

(e) Drug name, strength, dosage form, and directions

(f) Total number of refills authorized by the prescriber

(g) Quantity dispensed originally and on each refill

(h) Dates of all refills

(i) Identification of the dispensing pharmacist for the original prescription and each refill

(2) A pharmacist refilling a Schedule III-V prescription must verify the accuracy of the entered refill information using one of two methods:

(a) 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

(b) 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.

(3) Any system shall be capable of 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). The pharmacy must be capable of producing the printout within two business days. If an investigator of the Board or compliance investigator requests a copy of such printout from the pharmacy, it must verify the transmittal capability of its system by documentation (e.g., postmark).

(4) During system downtime, the pharmacy must have a backup procedure to document Schedule III-V refills, ensuring authorization, compliance with refill limits, and data retention for later online entry.

(5) Each pharmacy shall maintain its own series of consecutive numbered prescriptions. A series of numbers cannot be shared with another pharmacy.

(6) In addition to the controlled substances printout referred to in (3), a printout shall be obtained at least weekly of all new and refill prescription activity of the pharmacy for this period.

(7) All documentation required under this rule shall be retained for two years.

(8) 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. The institution shall provide sufficient alternate records to maintain adequate controls and accountability.

Author: Alabama State Board of Pharmacy
Statutory Authority: Code of Ala. 1975, §34-23-70.
History: Filed June 1, 1982. **Amended:** Filed February 13, 1997; effective March 20, 1997. **Amended:** Published July 31, 2025; effective September 14, 2025.

680-X-2-.16 Interns and Externs.

(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, and the holder of such permit may be reinstated as an intern/extern only upon payment of a penalty of five dollars ($5) for each lapsed month and all lapsed fees for each lapsed month, up to a maximum of 2 years of total penalties and lapsed fees.

(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 appr oved 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: Alabama State Board of Pharmacy
Statutory Authority: Code of Ala. 1975, §34-23-50.
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. **Amended:** Published February 27, 2026; effective April 13, 2026.

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) Definitions

(a) "Automated dispensing system" means an electromechanical system that performs operations or activities related to the storage and dispensing of medications and can collect, control, and maintain required transaction information and records.

(b) "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.

(c) "Emergency kit" is a kit consisting of drugs, including controlled substances, needed to effectively manage a critical care incident or need of a patient.

(d) "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.

(e) "Managing pharmacy" means a pharmacy responsible for supplying prescribed medications for patients in a licensed healthcare facility and the safe operation of any automated dispensing system used in the facility. A managing pharmacy may be one of the following:

1. A pharmacy physically located in Alabama, not within a licensed healthcare facility, holding a current pharmacy permit issued by the Alabama Board of Pharmacy

2. An institutional pharmacy serving as the managing pharmacy for a facility operating as a department of the licensed healthcare facility upon approval by the Board.

(f) "Stat medicine cabinet" is a cabinet or enclosure that 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 patients.

(g) "Positive identification" means the method by which access to the medications and information contained in an automated dispensing system in a licensed healthcare 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.

(2) Drug Distribution and Control in Institutional Pharmacies

(a) The following locations shall obtain an institutional pharmacy permit from the Board:

1. A pharmacy that is a physical portion of a licensed healthcare facility

2. A pharmacy that is a physical portion of a healthcare facility located outside Alabama;

3. A pharmacy that is not a physical portion of a licensed healthcare facility but provides centralized services to an institutional pharmacy;

4. A pharmacy providing services for patients who receive care through an integrated correctional health care system

(b) The supervising pharmacist shall establish written procedures for the safe and efficient distribution of drugs and for the provision of institutional pharmacy services. A current updated copy of such procedures shall be on hand for inspection by the Board of Pharmacy.

(c) All of the activities and operations of each institutional pharmacy shall be personally and directly supervised by its supervising pharmacist or a designated pharmacist.

(d) When patients bring drugs into a licensed healthcare 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 facility, or follow written policy provided by the supervising pharmacist.

(e) 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.

(f) The supervising pharmacist shall develop a recall procedure that can be readily implemented to assure the medical and pharmacy staff of the licensed healthcare facility that all drugs included on the recall intended for use within the facility are returned to the pharmacy for proper disposal.

(3) Stat Medicine Cabinets

(a) During such times 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 licensed healthcare facility by use of a stat medicine 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 licensed healthcare facilities utilizing a managing pharmacy, drugs shall be stored in a stat medicine cabinet to which only specifically authorized personnel may obtain access by key or combination, and which is sufficiently secure to deny access to unauthorized persons, provided, however, such cabinet meets the following requirements:

1. Each facility may maintain one stat medicine cabinet 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 medicine cabinet, it must be approved by the Alabama State Board of Health pursuant to Chapter 420-5-10.

2. All medications shall be packaged in an appropriate manner in the stat medicine cabinet based on the established needs of the facility. Need for such medications shall be reviewed by the pharmacist annually.

3. 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 medicine cabinet shall be properly labeled with name, strength, and expiration date.

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

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

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

(c) The supervising pharmacist of either the institutional pharmacy or the managing pharmacy shall, in conjunction with the appropriate committee of the licensed healthcare facility, develop inventory listings of those drugs to be included in a stat medicine cabinet, determine who may have access, and have written policies and procedures to 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 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 is conducted no less than once per month.

(d) Whenever any drug is not available from floor supplies or cabinet, 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 3. 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 licensed healthcare 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, patient date of birth, room number, name of drug, strength, amount, date, time, and signature of designee.

The form shall be left with the container from which the drug was removed.

(4) Emergency Kits

(a) Drugs may also be provided in a licensed healthcare facility for use by authorized personnel by emergency kits located at such facility, provided, however, such kits meet the following requirements:

1. 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 licensed healthcare facility shall jointly determine the drugs, by identity and quantity, to be included in emergency kits;

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

5. 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 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 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.

(5) Automated Dispensing Systems

(a) Automated dispensing systems may be used to meet the needs of patients in licensed healthcare facilities. The automated

dispensing system must be located in a licensed healthcare facility that either:

1. Has an Alabama Board of Pharmacy institutional pharmacy permit; or

2. 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.

(b) General requirements for automated dispensing systems include:

1. The supervising pharmacist of either the facility or managing pharmacy is responsible for the operation of the automated dispensing system. A pharmacist of either the facility or managing pharmacy must always have access to the equipment and all transaction information.

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 pharmacy and shall be limited to:

i. Licensed nurses

ii. Licensed pharmacists

iii. Registered pharmacy technicians

iv. Respiratory therapy

v. Other licensed healthcare professionals as approved by the supervising pharmacist or medical staff

vi. 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. If the automated dispensing system is managed by a managing pharmacy, medications delivered to the licensed healthcare 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 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 either the facility or managing pharmacy, a licensed nurse of the facility, or other licensed healthcare personnel approved by the Board of Pharmacy.

6. If the facility is utilizing a managing pharmacy, a pharmacist of the managing pharmacy shall conduct an on—site physical inventory of the contents of the automated dispensing system at least quarterly.

7. A pharmacist employed by either the facility or 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 pharmacy and appropriate leadership of the facility.

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

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

(6) Dispensing For Institutional Facilities

(a) 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.

(b) Emergency dispensing may be utilized for the following medications:

1. Bulk medications for single patient use

2. Medications deemed necessary with Board approval

(7) Centralized Services

(a) The purpose of this Rule is to provide standards for an institutional pharmacy to perform Centralized Services.

(b) An institutional pharmacy may perform the following centralized services:

1. Preparing unit dose packages for single administration to patients from bulk containers

2. Preparing non-sterile or sterile compounded unit dose drugs for administration to patients

3. Warehouse bulk supply medications and supplies

4. Perform off-site order entry in compliance with requirements of the Pharmacy Practice Act and any other applicable state and federal statutes and regulations

5. Additional functions as approved by the Board

(c) The pharmacies must notify the Board before utilizing centralized services.

(d) Regardless of whether located within or outside this State, the following requirements apply to any pharmacy involved in centralized services:

1. The pharmacies must be permitted by the Board before providing any centralized services

2. The pharmacies must either:

i. be owned by the same person or entity; or

ii. have a written contract with the originating pharmacy outlining the services to be provided and the responsibilities of each pharmacy in fulfilling the terms of the contract; and

iii. share a common electronic file or have appropriate technology to allow access to sufficient information necessary to process medication orders

3. The institutional pharmacy performing centralized services shall maintain a record of all pharmacies, including name, address, and DEA number to which services are provided.

4. The pharmacies and all pharmacy personnel must comply with all provisions of the Pharmacy Practice Act, and all other State and federal statutes, rules, and regulations.

(e) The pharmacies utilizing centralized services shall maintain a policy and procedure manual which includes the following:

1. appropriate records to identify the responsible pharmacists in performing centralized services;

2. mechanism for tracking the prescription drug order during each step in all processes;

3. description of adequate security to protect the integrity and prevent the illegal use or disclosure of protected health information;

4. description of drug storage and security in compliance with all applicable federal and state statutory and regulatory requirements;

5. a continuous quality improvement program; and

6. documented annual review.

Author: Alabama State Board of Pharmacy
Statutory Authority: Code of Ala. 1975, §34-23-74.
History: Filed November 6, 1987; effective January 1, 1988. **Amended:** July 6, 1993; effective January 1, 1994. **Amended:** Filed August 6, 1993. **Amended:** Filed February 13, 1997; effective March 20, 1997. **Amended:** Filed September 20, 1999; effective October 25, 1999. **Amended:** Filed April 3, 2003; effective May 8, 2003. **Amended:** Filed September 22, 2009; effective October 27, 2009. **Amended:** Filed January 30, 2012; effective March 5, 2012. **Amended:** Filed April 14, 2015; effective May 19, 2015. **Amended:** Filed June 8, 2016; effective July 23, 2016. **Amended:** Filed August 23, 2019, effective October 7, 2019. **Amended:** Published September 30, 2022; effective November 14, 2022. **Repealed and New Rule:** Published September 29, 2023, effective November 13, 2023. **Amended:** Published July 31, 2025; effective September 14, 2025.

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 who prepare compounded sterile products from one or more non-sterile starting components shall complete an additional four (4) hour board approved 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: Alabama State Board of Pharmacy
Statutory Authority: Code of Ala. 1975, §34-23-162.
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. **Amended:** Published March 31, 2025; effective May 15, 2025.

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. Leaded glass syringe and vial shields

11. Personnel radiation detection devices

12. Radioactive storage container and/or storage vault for waste materials

(c) Supplies:

1. Syringes and vials required to perform practice

2. Disposable gloves and protective lab coats

3. Appropriate supplies to ensure aseptic technique

4. Appropriate supplies to perform thin layer chromatography

5. Lead transport shields for syringes and vials

6. D. O. T. Type 7A approved transport containers and other labels and supplies for shipping radioactive materials.

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

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

1. Radiation physics and instrumentation

2. Radiation protection

3. Mathematics pertaining to the use and measurement of radioactivity

4. Radiation biology

5. Radiopharmaceutical chemistry

(b) The minimum on-the-job training which shall be included in a 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 a 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 Providers, Outsourcing Facilities; Reverse Distributors; Retail Medical Oxygen Suppliers.**

(1) Definitions.

(a) Drug Manufacturer -Every facility, except a pharmacy, that prepares, derives, produces, compounds, or packages any drug, chemical or poison.

(b) Principals -Officers, directors and primary stockholders of a business entity or corporation.

(c) 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.

(d) Medical Oxygen – Oxygen USP is liquid or gaseous form intended for human consumption.

(e) Wholesale distributor -Every facility engaged in the business of distributing drugs, to include medical oxygen, for resale to pharmacies, hospitals, practitioners, government agencies, or other lawful outlets permitted to sell drugs. 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.

(f) Private Label Distributor – A firm that does not participate in the manufacturing 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.

(g) Repackager – A facility that purchases or acquires from a manufacturer or distributor, a drug, 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.

(h) 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 or wholesale distributor of a product that neither takes ownership of the product nor has responsibility to direct the sale or disposition of the product.

(i) 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 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.

(j) Reverse Distributor – A facility that acts as an agent for pharmacies, wholesalers, third party logistics providers, drug manufacturers and others by receiving, inventorying,

warehousing, and managing the disposition of outdated or nonsaleable drugs or devices.

(k) 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.

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

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

(n) 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) Storage Conditions.

(a) Storage Conditions:

1. All facilities at which drugs 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, 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 drug 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 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.

(3) Facilities.

(a) All buildings in which drugs, and/or 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.

(4) Security.

(a) All permitted facilities shall be secure from unauthorized entry.

(b) All permitted facilities shall be equipped with an alarm system to detect entry after hours.

(c) All permitted facilities shall 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.

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

(e) Entry into areas where drugs are held shall be limited to authorized personnel.

(5) Recordkeeping.

(a) All permitted facilities 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:

1. 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;

2. The identity and quantity of the drugs received and distributed or disposed of; and

3. The dates of receipt and distribution or other disposition of the drugs.

(b) 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.

(c) 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.

(d) All charge back transactions shall be maintained separately from all other records.

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

(f) The recordkeeping requirements of this Rule shall be followed for all incoming and outgoing shipments in compliance with all state and federal laws and regulations.

(6) Inspections.

(a) All permitted facilities shall allow the Board of Pharmacy and authorized federal, 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.

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

(c) Costs for out of state inspections will be the responsibility of the permit holder.

(7) Written Policies and Procedures.

(a) Drug manufacturers, wholesale distributors, private label distributors, repackagers, third party logistics providers, outsourcing facilities, and reverse 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. All facilities shall include a procedure to 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.

(b) In addition to (a), drug manufacturers, wholesale distributors, private label distributors, repackagers, third party logistics providers, and outsourcing facilities shall also include in their written policies and procedures the following:

1. 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.

2. A procedure for examination of drugs:

(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 has been damaged in storage or held under improper conditions.

3. 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.

(c) 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.

1. 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 area fixed to each cylinder delivered; and

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

2. 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.

3. 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:

(I) Name and address of patient;

(II) Name and address of prescriber;

(III) Item dispensed and quantity;

(IV) 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.

(8) Responsibility for Operation:

(a) All permitted facilities should maintain a list of principals and persons in charge (including officers, directors, or primary stockholders) including a list of their duties and qualifications.

(b) All applicants for a controlled substance permit shall be permitted with the Board of Pharmacy and with the U.S. Drug Enforcement Administration and comply with all DEA regulations.

(c) The Board of Pharmacy shall consider, at a minimum, the following factors in reviewing the qualifications of the applicant, including the applicant's owners, partners, officers, stockholders, members, and designated representatives:

1. 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;

2. Any felony convictions under federal, state, or municipal laws;

3. Past experience with pharmaceutical activities including, but not limited to, those described in this rule;

4. The furnishing of false or fraudulent material in any application made in connection with pharmaceutical activities including, but not limited to, those described in this rule;

5. Any discipline by any federal, state, municipal government or entity thereof, of any license, permit, registration, etc. currently or previously held by the applicant;

6. Compliance with licensing requirements under previously granted licenses, if any;

7. 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

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

(d) 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.

(e) A transfer of ownership requires filing of an application for a permit.

(f) Any change in the control of ownership of an entity shall be reported to the board by completing the "Change in Ownership" form provided by the Board within 10 days of such occurrence.

(9) Personnel.

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

1. All designated representatives shall register with the Alabama State Board of Pharmacy. The initial registration fee and renewal fee shall be one hundred dollars ($100). All designated representatives shall pay the renewal fee annually with this fee being due on October 31 and delinquent after December 31 annually. All designated representative registrations shall expire on December 31 annually. If the renewal is not timely received by the board, the applicant shall pay a penalty of fifty dollars ($50) for each month the renewal is late, not to exceed one thousand dollars ($1,000).

2. The designated representative shall:

(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 facility full-time in a position of authority and be physically present at the facility for a minimum of 50% of the hours the facility is in operation or at least thirty (30) hours per week, whichever is less.

(iv) Be actively involved in and aware of the actual daily operation of the facility.

(v) Serve as a designated representative for only one physical location for a permitted facility at any one time.

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

vii. 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.

3. 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 by completing the "Notice of Change of Designated Representative" form provided by the Board.

4. If the permit holder is unable to maintain a designated representative, the permit holder shall notify the Board within ten (10) days with an action plan to designate another designated representative. This plan shall not exceed ninety (90) days before the permit holder is in violation of operating a facility without a designated representative, at which time the Board may require closure of the facility until a designated representative assumes his/her duties.

5. In addition to all other applicable requirements for registration as a designated representative and a prerequisite for consideration of registration as a designated representative, each individual seeking registration 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.

(b) 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.

(10) Violations:

(a) It shall be a violation of these rules any permitted facility to operate in such a manner as to endanger the public health.

(b) Permitted facilities shall operate in compliance with applicable federal, state and municipal laws and regulations.

(11) Permit Fees

(a) An annual permit must be obtained from the Alabama State Board of Pharmacy by any drug manufacturer, wholesale distributor, private label distributor, repackager, third party logistics provider, outsourcing facility, or reverse distributor of drugs, chemicals, or poisons for medicinal purposes. A biannual permit must be obtained by any retail medical oxygen supplier. All permits 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 initial fee for the annual permit, with the exception of retail medical oxygen, shall be in the amount of $750.00. The initial retail medical oxygen permit fee 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 $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 the applicable year. Each application for the renewal of the permit shall be made on or before December 31 of the applicable 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: Alabama Board of Pharmacy
Statutory Authority: Code of Ala. 1975, §34-23-32.
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. **Amended:** Published November 30, 2023; effective January 14, 2024. **Amended:** Published October 31, 2025; effective December 15, 2025. **Amended:** Published February 27, 2026; effective April 13, 2026. **Amended:** Published April 30, 2026; effective June 14, 2026.

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. (Repealed 1/14/2024).

(Repealed)
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. **Repealed:** Published November 30, 2023; effective January 14, 2024.

680-X-2-.26 Emergency Prescription Refills.

(1) If a pharmacist receives a request for a prescription refill, and the pharmacist is unable to readily obtain refill authorization from the prescriber, the pharmacist may dispense a one-time emergency refill of up to a 72-hour supply of the prescribed medication or the smallest dispensable package size if a 72 hour supply is not readily available, under the following conditions:

(a) The prescription is not a medicinal agent listed in Schedule I or II pursuant to Title 20, Chapter 2, or the controlled substance list for Schedule I or II maintained by the State Board of Health.

(b) The medication is essential to the maintenance of life or the continuation of therapy and in the pharmacist's professional judgement, the interruption of therapy might reasonably produce undesirable health consequences or may cause physical or mental discomfort.

(c) The pharmacist has a record of a prescription at the pharmacy or has been presented proof of a prescription filled within the last 90 days in the name of the patient for whom the request of the emergency supply is being made.

(d) A pharmacist or pharmacy shall not dispense or sell the same drug to the same patient, as provided in this section, more than one time in any 12-month period.

(e) The pharmacist must inform the patient or the patient's representative at the time of dispensing that the refill is being provided without the practitioner's authorization, and that practitioner authorization is required for any future refill.

(f) The dispensing pharmacist shall create a written prescription order containing all of the prescription information required by federal and state statutes, rules and regulations and shall also include the statement "Emergency Fill".

(g) The dispensing pharmacist shall notify the prescriber orally or in writing of the emergency dispensing within twenty-four (24) hours after such dispensing.

(2) This rule is adopted jointly by the Board of Pharmacy and Board of Medical Examiners.
Author: Alabama Board of Pharmacy
Statutory Authority: Code of Ala. 1975, §34-23-75.

History: Adopted: October 5, 1993; effective November 25, 1993.
Amended: Published November 30, 2023; effective January 14, 2024.

680-X-2-.27 Private Consultation Areas For Pharmacies.

(1) All pharmacies and facilities, as defined in Code of Ala. §34-23-1, that are open to the public shall have a private consultation area.

(2) The private consultation area shall:

(a) be large enough to accommodate the participants

(b) be devoted to enhancing patient outcomes

(c) be accessible by the patient from outside the pharmacy area without traversing the pharmacy or stock room

(d) be private to both viewing and sound by unauthorized parties

(3) The private consultation area shall not be used for storage or other non-related items.
Author: Alabama State Board of Pharmacy
Statutory Authority: Code of Ala. 1975, §34-23-92.
History: **New Rule:** Filed August 1, 1995; operative September 5, 1995, effective January 1, 1996. **Repealed and New Rule:** Published September 30, 2024; effective November 14, 2024.

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 $125.00.

(3) The fee for biennial renewal of a pharmacist license will be $125.00. Upon verification of fifty (50) years of licensure in this state the renewal fee shall be 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: Alabama State Board of Pharmacy
Statutory Authority: Code of Ala. 1975, §34-23-52.
History: **New Rule:** Filed March 17, 2006; effective April 21, 2006. **Amended:** Filed July 23, 2013; effective August 27, 2013. **Amended:** Published December 31, 2024; effective February 14, 2025. **Amended:** Published April 30, 2026; effective June 14, 2026.

680-X-2-.35 Licensing Fees for Pharmacies.

(1) The application fee for a new pharmacy permit for a resident pharmacy or a resident pharmacy services permit shall be $250.00. The application fee for a new pharmacy permit for a non-resident pharmacy or for a non-resident pharmacy services permit shall be $1,000.00.

(2) The fee for biennial renewal of a pharmacy permit shall be $150.00. The fee for biennial renewal of a pharmacy services permit shall be $100.00. The fee for biennial renewal of a non-resident pharmacy permit or pharmacy services permit shall be $600.00.

(3) The fee for transfer of ownership of a pharmacy permit shall be $350.00.

(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: Alabama State Board of Pharmacy
Statutory Authority: Code of Ala. 1975, §34-23-30.
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. **Amended:** Published April 30, 2026; effective June 14, 2026.

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 to either administrative fines as described in Rule 680-X-2-.40 or civil penalties as described in Rule 680-X-2-.50.

(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: Alabama State Board of Pharmacy
Statutory Authority: Code of Ala. 1975, §34-23-33; Code of Ala. 1975 §34-23-52.
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. **Amended:** Published December 31, 2024; effective February 14, 2025. **Amended:** Published April 30, 2026; effective June 14, 2026.

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 registration. If a pharmacy technician has been registered for less than one full calendar year, no continuing education is required for the first renewal of their registration.

(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 within each renewal cycle. If a pharmacy technician has only been registered for one full calendar year, they shall complete at least one (1) hour of live continuing education.

(5) It is the responsibility of each pharmacy technician to maintain accurate records relating to all continuing education courses they have completed for a period of two (2) years. 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 to assure compliance with these rules. Failure to maintain the documentation or information set forth in these rules, 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 to either administrative fines as described in Rule 680-X-2-.40 or civil penalties as described in Rule 680-X-2-.50.

(7) Upon written request to the Board of Pharmacy, and upon the demonstration of sufficient cause, the Board of Pharmacy may grant a waiver or extension of time for the completion of the 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.

(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: Alabama State Board of Pharmacy
Statutory Authority: Code of Ala. 1975, §34-23-131.
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. **Amended:** Published June 28, 2024; effective August 12, 2024. **Amended:** Published December 31, 2024; effective February 14, 2025. **Amended:** Published April 30, 2026; effective June 14, 2026.

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 off-site order entry in any pharmacy to which a permit has been issued by the Alabama State Board of Pharmacy ("the Board"). A pharmacy participating in off-site order entry shall notify the Board on their initial application and on each renewal application.

(2) Off-site order entry occurs when an Alabama-permitted pharmacy remotely accesses another pharmacy's electronic database to process prescription drug orders, provided the pharmacy establishes controls to protect the privacy and security of confidential records.

(3) Off-site order entry does not include the dispensing of a prescription drug order but includes any of the following:

(a) Interpreting or clarifying prescription drug orders;

(b) Data entering and transferring of prescription drug order information;

(c) Performing drug regimen review;

(d) Obtaining refill and substitution authorizations;

(e) Performing therapeutic interventions;

(f) Providing clinical drug information concerning a patient's prescription; and

(g) Final verification of medication

(4) Off-site order entry is permissible, provided the pharmacies:

(a) Have the same owner and share a common electronic file or have appropriate technology to allow access to sufficient information necessary or required to process a non-dispensing function; or

(b) 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.

(5) The supervising pharmacist or the permit holder of the pharmacy shall develop, implement, and comply with a policy and procedure manual for off-site order entry which shall be maintained at all pharmacies involved and 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 pharmacy;

(b) Include a list of the name, address, and telephone numbers of each pharmacy involved;

(c) Comply with federal and state laws and regulations; and

(d) Include policies and procedures for:

1. Patient confidentiality and full compliance with HIPAA requirements;

2. Tracking the prescription drug order during each step of the off-site order entry process, including which individual performed each step and in which location; and

3. A documented annual review of this manual

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

(7) All pharmacies involved in off-site order entry 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 and 680-X-2-.49.

(8) Prescription labeling shall comply with labeling requirements of federal and state statutes and rules.

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

(a) Notify patients that prescription processing may be outsourced to another pharmacy; and

(b) 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.

(10) All pharmacies shall maintain appropriate records that identify, by prescription drug order, the names, initials or identification codes of each individual 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:

(a) Separately by each pharmacy; or

(b) In a common electronic file, provided the system can produce a printout listing the functions performed by each pharmacy and individual.

(11) Patient confidentiality and full compliance with HIPAA requirements shall be observed at all times.
Author: Alabama State Board of Pharmacy
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. **Amended:** Published April 30, 2025; effective June 14, 2025.

680-X-2-.40 Non-Disciplinary Penalties.

(1) Pursuant to the requirements set forth in Code of Ala. 1975, §34-23-33(b), this Rule adopts an administrative fine penalty schedule for non-disciplinary violations.

(2) The Board has the discretion to impose an administrative fine for any violation listed in the non-disciplinary penalty schedule. If the Board elects to issue an administrative fine, that individual or permittee may not receive another administrative fine for the same violation within a five (5) year period. Any

subsequent occurrence of that same violation within five (5) years shall be treated as a disciplinary matter, unless otherwise specified in the schedule.

(3) The procedure for imposition of an administrative fine pursuant to this Rule shall be as follows:

(a) The decision to initiate imposition of an administrative fine, and the amount of the proposed administrative fine, shall be made by the Board in a public meeting.

(b) When considering the amount of an administrative fine for a specific violation, the Board shall consider the statutorily prescribed factors of (i) the level and scope of misconduct, (ii) the level of risk to public health and safety, and (iii) the compliance history of the violator.

(c) Upon direction by the Board, the Executive Secretary shall issue a written "Notice of Proposed Administrative Fine" to the licensee, which shall include at least the following information:

(i) An identification of the statute or rule allegedly violated by the licensee;

(ii) A short and plain statement of the facts substantiating the alleged violation;

(iii) The proposed dollar amount of the administrative fine;

(iv) A notice that, if the licensee wishes to contest the administrative fine, the licensee may request a public hearing before the Board, including instructions on how to contest the administrative fine;

(v) A notice that, if the licensee does not contest the proposed administrative fine within thirty (30) days of service, then the proposed administrative fine will be assessed and will be deemed final and non-appealable; and

(vi) A notice to the license holder to review this Rule 680-X-2-.40.

(d) If the licensee does not contest the proposed administrative fine within thirty (30) days of services of the Notice of Proposed Administrative Fine, then the proposed administrative fine will be assessed and will be deemed final and non-appealable.

(e) If the licensee contests the administrative fine within thirty (30) days of service of the Notice of Proposed Administrative Fine, then the matter shall be heard in a

public hearing as a contested case before the Board, including the right of judicial review. Provided, however, that if the matter is heard and determined by the Board as a contested case hearing, that shall not change the administrative and non-disciplinary character of the fine, and the amount of the administrative fine imposed after the hearing shall not exceed the amount initially proposed by the Board in the Notice of Proposed Administrative Fine.

(4) The Board's classification of the violations scheduled below is designed and intended to correspond generally to the categories of non-reportable administrative citations described on page E-64 of the National Practitioner Data Bank ("NPDB") Guidebook. Accordingly, administrative fines assessed under this Rule are generally regarded as non-reportable to the NPDB. Practitioners are advised, however, that other factors may cause an administrative fine to be reportable. In all cases, the Board will follow the requirements of federal law with respect to NPDB reporting.

(5) If a non-disciplinary violation occurs alongside a disciplinary violation, the disciplinary violation shall proceed through the formal disciplinary process, while the non-disciplinary violation will be addressed pursuant to this Rule.

(6) The tables below set forth each non-disciplinary violation, the individual or permittee eligible for a non-disciplinary penalty, and the associated administrative fine. For the purposes of the table below, the term "license" refers to any license, permit, certificate, or registration issued by the Board.

Administrative Fines for Pharmacy Technicians

Description	Fine
Failure to Complete Required Continuing Education	First violation: $0-$100 Second violation: $0-$100 + $10/hr short of requirement
Failure to complete technician training program in compliance with Rule 680-X-2-.14	$0-$200
Failure to Submit Documentation of Training Within 10 Days	$0-$25
Failure to Report Employment Within 10 Days	First violation: Warning Letter, no fine Second violation: $0-$500

Failure to wear name tag	$0-$25

Administrative Fines for Interns/Externs

Description	Fine
Failure to Report Employment Within 10 Days	First violation: Warning Letter, no fine Second violation: $0-$500

Administrative Fines for Pharmacists

Description	Fine
Failure to Complete Required Continuing Education	First violation: $0-$250 Second violation: $0-$250 + $25/hr short of requirement
Failure to Report Employment Within 10 Days	First violation: Warning Letter, no fine Second violation: $0-$1,000
Unauthorized Presence Inside the Pharmacy excluding: 1. Cashiers 2. Shadowing in compliance with Board Policy 23-006 3. Individuals authorized under applicable statue, rule, or policy	$0-250
Failure to Renew Collaborative Practice Agreement	$0-$100
Exceeding Technician to Pharmacist or Intern to Pharmacist Ratio	$0-$250 per technician or intern over ratio
Violation of Code of Professional Conduct where, in the Board's judgement, the violation does not: • Impact public safety or direct patient care, and • Cause the Board to expend Board resources to evaluate and/or correct	$0-$2,000

Administrative Fines for Supervising Pharmacists

Description	Fine
Allowing a technician to work without completing training	$0-$100
Failure to provide notice of change of Supervising Pharmacist within 10 days for incoming and/or outgoing Supervising Pharmacist	$0-$1,000
Failure to maintain required records	$0-$500
Failure to display all required licenses	$0-$500
Exceeding Technician to Pharmacist or Intern to Pharmacist Ratio	$0-$250 per technician or intern over ratio

Administrative Fines for Chain Pharmacies

Description	Fine
Allowing a technician to work without completing training	$0-$100
Failure to Submit Action Plan Within 10 Days of Outgoing Supervising Pharmacist Departure (No Incoming Supervising Pharmacist)	$0-$1,000
Failure to Identify New Supervising Pharmacist Within 90 Days of Initiating an Action Plan	< 30 days: $0-$500 30-100 days: $500-$750 >100 days: $750-$1,000
Failure to Provide Notice of Change of Ownership Within 10 Days	< 30 days: $0-$500 30-100 days: $500-$750 >100 days: $750-$1,000
Unauthorized Presence Inside the Pharmacy excluding: 1. Cashiers 2. Shadowing in compliance with Board Policy 23-006 3. Individuals authorized under applicable statue, rule, or policy	First violation: Warning Letter, no fine Second violation: $0-$500

Failure to Maintain Required Records	$0-$500
Failure to display all required licenses	$0-$500
Failure to Notify Board of Authorization to be a DEA Drug Collector	$0-$250
Violation of Code of Professional Conduct where, in the Board's judgement, the violation does not: 1. Impact public safety or direct patient care, and 2. Cause the Board to expend Board resources to evaluate and/or correct	$0-$2,000

Administrative Fines for Independent Pharmacies

Description	Fine
Allowing a technician to work without completing training	$0-$100
Failure to Submit Action Plan Within 10 Days of Outgoing Supervising Pharmacist Departure (No Incoming Supervising Pharmacist)	$0-$1,000
Failure to Identify New Supervising Pharmacist Within 90 Days of Initiating an Action Plan	< 30 days: $0-$500 30-100 days: $500-$750 >100 days: $750-$1,000
Failure to Provide Notice of Change of Ownership Within 10 Days	< 30 days: $0-$500 30-100 days: $500-$750 >100 days: $750-$1,000
Unauthorized Presence Inside the Pharmacy excluding: 1. Cashiers 2. Shadowing in compliance with Board Policy 23-006 3. Individuals authorized under applicable statue, rule, or policy	First violation: Warning Letter, no fine Second violation: $0-$500

Failure to Maintain Required Records	$0-$500
Failure to display all required licenses	$0-$500
Failure to Notify Board of Authorization to be a DEA Drug Collector	$0-$250
Violation of Code of Professional Conduct where, in the Board's judgement, the violation does not: 1. Impact public safety or direct patient care, and 2. Cause the Board to expend Board resources to evaluate and/or correct	$0-$2,000

Administrative Fines for Institutional Pharmacies

Description	Fine
Allowing a technician to work without completing training	$0-$100
Failure to Submit Action Plan Within 10 Days of Outgoing Supervising Pharmacist Departure (No Incoming Supervising Pharmacist)	$0-$1,000
Failure to Identify New Supervising Pharmacist Within 90 Days of Initiating an Action Plan	< 30 days: $0-$500 30-100 days: $500-$750 >100 days: $750-$1,000
Failure to Provide Notice of Change of Ownership Within 10 Days	< 30 days: $0-$500 30-100 days: $500-$750 >100 days: $750-$1,000
Unauthorized Presence Inside the Pharmacy excluding: 1. Cashiers 2. Shadowing in compliance with Board Policy 23-006 3. Individuals authorized under applicable statue, rule, or policy	First violation: Warning Letter, no fine Second violation: $0-$500

Failure to Maintain Required Records	$0-$500
Failure to display all required licenses	$0-$500
Failure to Notify Board of Authorization to be a DEA Drug Collector	$0-$250
Violation of Code of Professional Conduct where, in the Board's judgement, the violation does not: 1. Impact public safety or direct patient care, and 2. Cause the Board to expend Board resources to evaluate and/or correct	$0-$2,000

Administrative Fines for Non-Resident Pharmacies

Description	Fine
Failure to Submit Action Plan Within 10 Days of Outgoing Supervising Pharmacist Departure (No Incoming Supervising Pharmacist)	$0-$1,000
Failure to Identify New Supervising Pharmacist Within 90 Days of Initiating an Action Plan	< 30 days: $0-$500 30-100 days: $500-$750 >100 days: $750-$1,000
Failure to Provide Notice of Change of Ownership Within 10 Days	< 30 days: $0-$500 30-100 days: $500-$750 >100 days: $750-$1,000
Unauthorized Presence Inside the Pharmacy excluding: 1. Cashiers 2. Shadowing in compliance with Board Policy 23-006 3. Individuals authorized under applicable statue, rule, or policy	First violation: Warning Letter, no fine Second violation: $0-$500
Failure to Maintain Required Records	$0-$500

Failure to display all required licenses	$0-$500
Failure to Notify Board of Authorization to be a DEA Drug Collector	$0-$250
Violation of Code of Professional Conduct where, in the Board's judgement, the violation does not: 1. Impact public safety or direct patient care, and 2. Cause the Board to expend Board resources to evaluate and/or correct	$0-$2,000

Administrative Fines for Pharmacy Services Permits

Description	Fine
Allowing a technician to work without completing training	$0-$100
Failure to Submit Action Plan Within 10 Days of Outgoing Supervising Pharmacist Departure (No Incoming Supervising Pharmacist)	$0-$1,000
Failure to Identify New Supervising Pharmacist Within 90 Days of Initiating an Action Plan	< 30 days: $0-$500 30-100 days: $500-$750 >100 days: $750-$1,000
Failure to Provide Notice of Change of Ownership Within 10 Days	< 30 days: $0-$500 30-100 days: $500-$750 >100 days: $750-$1,000
Unauthorized Presence Inside the Pharmacy excluding: 1. Cashiers 2. Shadowing in compliance with Board Policy 23-006 3. Individuals authorized under applicable statue, rule, or policy	First violation: Warning Letter, no fine Second violation: $0-$500
Failure to Maintain Required Records	$0-$500

Failure to display all required licenses	$0-$500
Violation of Code of Professional Conduct where the violation does not: 1. In the Board's judgement does not impact public safety or direct patient care, and 2. Cause the Board to expend Board resources to evaluate and/or correct	$0-$2,000

Administrative Fines for Retail Medical Oxygen Suppliers

Description	Fine
Failure to Provide Notice of Change of Ownership Within 10 Days	< 30 days: $0-$500 30-100 days: $500-$750 >100 days: $750-$1,000
Failure to Maintain Required Records	$0-$500
Failure to display all required licenses	$0-$500

Administrative Fines for Medical Oxygen Manufacturers and Wholesalers

Description	Fine
Failure to Provide Notice of Change of Ownership Within 10 Days	< 30 days: $0-$500 30-100 days: $500-$750 >100 days: $750-$1,000
Failure to Maintain Required Records	$0-$500
Failure to display all required licenses	$0-$500

Administrative Fines for 503B Outsourcing Facilities

Description	Fine
Failure to Provide Notice of Change of Ownership Within 10 Days	< 30 days: $0-$500 30-100 days: $500-$750 >100 days: $750-$1,000

Failure to Maintain Required Records	$0-$500
Failure to Display the License	$0-$500

Administrative Fines for Third Party Logistics Providers

Description	Fine
Failure to Provide Notice of Change of Ownership Within 10 Days	< 30 days: $0-$500 30-100 days: $500-$750 >100 days: $750-$1,000
Failure to Provide Notice of New Designated Representative Within 10 Days	< 30 days: $0-$500 30-100 days: $500-$750 >100 days: $750-$1,000
Failure to submit an action plan Within 10 Days of outgoing Designated Representative (no incoming DR)	< 30 days: $0-$500 30-100 days: $500-$750 >100 days: $750-$1,000
Failure to Identify Incoming Designated Representative Within 90 Days of Initiating an Action Plan	< 30 days: $0-$500 30-100 days: $500-$750 >100 days: $750-$1,000
Failure to Maintain Required Records	$0-$500
Failure to Display the License	$0-$500

Administrative Fines for Precursors

Description	Fine
Failure to Provide Notice of Change of Ownership Within 10 Days	< 30 days: $0-$500 30-100 days: $500-$750 >100 days: $750-$1,000
Failure to Maintain Required Records	$0-$500
Failure to Display the License	$0-$500

Administrative Fines for Manufacturers

Description	Fine
Failure to Provide Notice of Change of Ownership Within 10 Days	< 30 days: $0-$500 30-100 days: $500-$750 >100 days: $750-$1,000
Failure to Provide Notice of New Designated Representative Within 10 Days	< 30 days: $0-$500 30-100 days: $500-$750 >100 days: $750-$1,000
Failure to submit an action plan Within 10 Days of outgoing Designated Representative (no incoming DR)	< 30 days: $0-$500 30-100 days: $500-$750 >100 days: $750-$1,000
Failure to Identify Incoming Designated Representative Within 90 Days of Initiating an Action Plan	< 30 days: $0-$500 30-100 days: $500-$750 >100 days: $750-$1,000
Failure to Maintain Required Records	$0-$500
Failure to Display the License	$0-$500

Administrative Fines for Distributors

Description	Fine
Failure to Provide Notice of Change of Ownership Within 10 Days	< 30 days: $0-$500 30-100 days: $500-$750 >100 days: $750-$1,000
Failure to Provide Notice of New Designated Representative Within 10 Days	< 30 days: $0-$500 30-100 days: $500-$750 >100 days: $750-$1,000
Failure to submit an action plan Within 10 Days of outgoing Designated Representative (no incoming DR)	< 30 days: $0-$500 30-100 days: $500-$750

	>100 days: $750-$1,000
Failure to Identify Incoming Designated Representative Within 90 Days of Initiating an Action Plan	< 30 days: $0-$500 30-100 days: $500-$750 >100 days: $750-$1,000
Failure to Maintain Required Records	$0-$500
Failure to Display the License	$0-$500

Administrative Fines for ALL Other Drug Facility Permit Holders

Description	Fine
Failure to Provide Notice of Change of Ownership Within 10 Days	< 30 days: $0-$500 30-100 days: $500-$750 >100 days: $750-$1,000
Failure to Provide Notice of New Designated Representative Within 10 Days	< 30 days: $0-$500 30-100 days: $500-$750 >100 days: $750-$1,000
Failure to submit an action plan Within 10 Days of outgoing Designated Representative (no incoming DR)	< 30 days: $0-$500 30-100 days: $500-$750 >100 days: $750-$1,000
Failure to Identify Incoming Designated Representative Within 90 Days of Initiating an Action Plan	< 30 days: $0-$500 30-100 days: $500-$750 >100 days: $750-$1,000
Failure to Maintain Required Records	$0-$500
Failure to Display the License	$0-$500

Author: Alabama State Board of Pharmacy
Statutory Authority: Code of Ala. 1975, §34-23-33.
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. **Amended:** Published December 31, 2024; effective February 14, 2025. **Amended:** Published February 27, 2026; effective April 13, 2026. **Amended:** Published July 31, 2026; effective September 14, 2026.

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 io 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.

(q) "Acute, uncomplicated illness or injury" means a recent or new short-term problem with low risk of morbidity for which treatment is considered and full recovery without functional

impairment is expected. For the purposes of this section, an acute, uncomplicated illness or injury includes:

1. Influenza

2. Streptococcus

3. Any other condition as recommended by the Joint Committee

Under this definition, a pharmacist may use any tests which the Centers for Medicare and Medicaid Services has determined qualifies for a waiver under the federal Clinical Laboratory Improvement Amendments of 1988, or the federal rules adopted thereunder, or any established screening procedures that can safely be performed by a pharmacist.

(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 acute, uncomplicated illness or injury, 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.

(i) 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 and any physician(s) designated by the patient 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.

(ii) A pharmacist performing testing or screening for and treatment of acute, uncomplicated illness or injury conditions shall also:

(I) Provide each patient with written information to advise the patient to seek follow-up care from either a physician with whom the patient has a pre-existing relationship, or, if no pre-existing relationship exists, to seek follow-up care from the collaborating physician.

(II) Provide the patient with a consent form allowing any changes to a patient's drug therapy and/or individual patient care services as set out in the Agreement to be provided to the collaborating physician and the physician with whom the patient has a pre-existing relationship.

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.

(b) Agreements that include the testing or screening for and treatment of acute, uncomplicated illness or injury shall also include:

1. Patient selection criteria, which shall include the physician's instructions for obtaining relevant patient medical history for the purpose of identifying disqualifying health conditions, adverse reactions, and contraindications to the approved course of treatment.

2. Treatment protocols, which shall include the physician's instructions for the treatment of acute, uncomplicated illness or injury based on the patient's age, symptoms, and test results, including negative results.

3. Any other requirements as established by the Board of Pharmacy and Board of Medical Examiners.

(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 acute, uncomplicated illness or injury, 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.

(c) A collaborating physician may collaborate with a maximum of three collaborating pharmacists for testing or screening for and treatment of acute, uncomplicated illness or injury.

(d) A collaborating pharmacist may collaborate with a maximum of three collaborating physicians for testing or screening for and treatment of acute, uncomplicated illness or injury.

(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/or maintain a physician-patient relationship with each patient receiving services under the Agreement, with the exception of immunizations and opioid antagonists;

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; and

5. Contact each patient receiving treatment by a pharmacist for an acute, uncomplicated illness or injury not later than five (5) days following the first day of treatment to discuss follow-up care or refer the patient for care from a physician with whom the patient has a pre-existing relationship.

(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.

(d) If performing testing or screening for and treatment of acute, uncomplicated illness or injury, a pharmacist shall also:

1. Provide each patient with written information to advise the patient to seek follow-up care from either a physician with whom the patient has a pre-existing relationship, or, if no pre-existing relationship exists, to seek follow-up care from the collaborating physician.

2. Upon request of a patient, furnish patient records to a physician designated by the patient.

(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 sha11 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-1abel, 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: Alabama Board of Pharmacy
Statutory Authority: Code of Ala. 1975, §34-23-77.
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. **Amended:** Published November 30, 2023; effective January 14, 2024. **Amended:** Published September 30, 2024; effective November 14, 2024.

680-X-2-.45 Transferring Prescriptions.

(1) 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: Alabama State Board of Pharmacy
Statutory Authority: Code of Ala. 1975, §34-23-70.
History: **New Rule:** Published August 31, 2020; effective October 15, 2020. 6 **Amended:** Published July 31, 2025; effective September 14, 2025.

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.

680-X-2-.49 Remote Work by Pharmacists.

(1) Definitions

(a) "Remote pharmacy work" means performing the practice of pharmacy while not physically located within a permitted pharmacy or facility

(b) "Physical acts in the dispensing process" means the storing, packaging, and/or labeling of prescription drugs

(2) General Requirements

(a) Remote pharmacy work may be performed by a pharmacist who is an employee of one of the following:

1. A pharmacy or facility permitted by the Alabama Board of Pharmacy;

2. A facility regulated by the Alabama Department of Public Health;

3. A facility regulated by the Alabama Department of Insurance; or

4. A physician's office

(b) Pharmacists are allowed to perform remote pharmacy work in a location, with the United States, that is equipped with secure access to the above entity's information system, provided:

1. The pharmacy or facility shall provide the remote pharmacist with a desktop/laptop computer and the hardware/software needed to ensure a secure network.

2. Hardware/software - the computer should be directly connected to a router and/or a software platform that provides security monitoring and firewalls to ensure a secure network.

3. User ID - each user receives a unique user ID and should establish a complex password for identification and audit tracking

4. Lock out process - If no activity is detected, the system should automatically sign off the user until they go through the sign-on process to re-establish connection

(c) Remote pharmacists shall establish controls to protect the confidentiality and integrity of protected health information by complying with both the Health Insurance Portability and Accountability Act (HIPAA) and Health Information Technology for Economic and Clinical Health (HITECH) Act

(d) Remote pharmacists shall ensure that they are able to perform at the same level of competence, attention, and proficiency as if they were physically present in the above entity and comply with all applicable state and federal laws, rules, and regulations.

(e) If a pharmacist is no longer an employee of the entity as listed in subsection 2(a), he/she shall no longer have access to the entity's information system or be able to perform remote pharmacy work for that employer.

(3) Prohibited Activities

(a) Nothing in this subsection shall be construed to authorize dispensing of a prescription from a location outside of or other than a permitted pharmacy with the exception of immunizations.

(b) Nothing in this subsection shall be construed to authorize a pharmacist to perform physical acts in the dispensing process from a location outside of or other than a permitted pharmacy.

(c) Nothing in this subsection permits hard copy prescriptions to be received outside of the premises of a permitted pharmacy.

(d) No part of the facility's database may be physically or electronically duplicated, downloaded, transferred, or removed from the electronic database.

(e) Nothing in this subsection shall permit a pharmacist to perform remote pharmacy work for more than one location of a permitted pharmacy, facility, or entity without prior compliance with Board Rule 680-X-2-.39.

Author: Alabama State Board of Pharmacy
Statutory Authority: Code of Ala. 1975, §34-23-30.
History: **New Rule:** Published September 29, 2023, effective November 13, 2023. **Amended:** Published September 30, 2025; effective November 14, 2025.

680-X-2-.50 Civil Penalties.

(1) In accordance with Ala. Code §34-23-33(b), this Rule establishes the civil penalty fine schedule for disciplinary violations for chain pharmacies, independent pharmacies, all other pharmacy types, manufacturers, distributors, all other facility types, pharmacists, pharmacy technicians, and all other license types.

(2) The following provisions apply to civil penalties:

(a) The process for imposing civil penalties shall be in accordance with the contested case provisions of the Alabama Administrative Procedures Act.

(b) Civil penalties imposed pursuant to this rule shall be reported to the National Practitioner Data Bank or other national reporting systems when required by applicable state or federal law.

(c) If a non-disciplinary violation occurs alongside a disciplinary violation, both violations will be reviewed together. The disciplinary violation shall proceed through the formal disciplinary process, while the non-disciplinary violation may be included in the disciplinary case or addressed separately depending on whether it directly relates to the underlying conduct. The Board shall determine the most effective approach based on the nature and severity of the violations.

(d) When determining the amount of a civil penalty for a specific violation, the Board shall consider the level and scope of misconduct, the level of risk to public health and safety, and the compliance history of the violator, utilizing the advisory lodestar calculation methodology described below in subsection (e). The Board shall not consider whether the violator is a natural person or a legal entity, the size of the business, nor the violator's annual revenues. The Board recognizes and declares that the central purpose of imposing a civil penalty is to protect the public by incentivizing compliance with Alabama law and to deter wrongdoing.

(e) The Board shall determine an advisory lodestar civil penalty amount by scoring each case on a scale of 0-100, with 30 points allocated to the level and scope of misconduct, 50 points allocated to the level of risk to public health and safety, and 20 points allocated to the compliance history of the violator.

(i) Level and Scope of Misconduct: The Board shall utilize the following advisory anchors and guideline ranges to score the level and scope of misconduct applicable to the individual case:

Advisory Anchors	Guideline Range
Isolated Occurrence Unintentional Oversight Minimal Culpability	0-10 Points
Repeated Occurrence Negligent Oversight Moderate Culpability	11-20 Points
Systematic Occurrence Intentional Violation High Culpability	21-30 Points

(ii) Level of Risk to Public Health and Safety: The Board shall utilize the following advisory anchors and guideline ranges to score the level of risk to public health and safety applicable to the individual case:

Advisory Anchors	Guideline Range
Risk of Harm is Nonexistent, Remote, or Theoretical	0 Points
Risk of Harm is Real, but Low to Moderate in Severity	1-20 Points
Risk of Harm is Real, Meaningful, Significant	21-44 Points
Demonstrated Patient Harm	45-50 Points

(iii) Compliance History of the Violator. The Board shall utilize the following advisory anchors and guideline ranges to score the compliance history of the violator applicable to the individual case:

Advisory Anchors	Guideline Range

No Previous Discipline or Administrative Fines	0 Points
Previous Disciplines or Administrative Fines (One or Two Previous Cases)	1-14 Points
Three or More Previous Disciplines or Administrative Fines Any Repeated Occurrence of Same Violation	15-20 Points

(iv) The sum of the individual scores as determined above for the level and scope of misconduct, the level of risk to public health and safety, and the compliance history of the violator, shall be applied as a percentage to the applicable schedule range to determine the advisory lodestar civil penalty amount.

(v) The Board may depart downward in any amount, and may depart upward by up to 15% from the advisory lodestar civil penalty amount without providing any written explanation. If the Board departs upward from the advisory lodestar civil penalty amount by more than 15%, the Board, in its written order imposing the civil penalty, shall provide a brief written statement of its reasons for doing so. In no event, however, shall the Board impose a civil penalty amount in excess of the maximum applicable range set forth in the Appendix.

(f) When a Statement of Charges and Notice of Hearing alleges legal violations based on substantially the same underlying conduct, transaction, series of transactions, occurrence, or series of occurrences, the Board in its final order shall determine the civil penalties for each legal violation separately, but shall impose those civil penalties concurrently and not cumulatively.

(g) When a Statement of Charges and Notice of Hearing alleges legal violations that are not based on the same underlying conduct, transaction, series of transactions, occurrence, or series of occurrences, the Board shall impose the civil penalties for the separate legal violations separately and cumulatively.

(3) The civil penalty schedules set forth each disciplinary violation, the monetary amount of the civil penalty, and any possible corrective action. Civil penalty schedules are listed as individual appendices in Rule 680-X-A. Nothing in this Rule and

the related appendices shall affect the Board's discretion to impose non-monetary sanctions, including license revocation, suspension, probation, reprimand, corrective action plans, remedial continuing education requirements, additional inspection requirements, and other non-monetary corrective actions, as the Board deems appropriate based on the particular facts of each case.

Author: Alabama State Board of Pharmacy

Statutory Authority: Code of Ala. 1975, §34-23-33.

History: **New Rule:** Published April 30, 2026; effective June 14, 2026. **Amended:** Published August 31, 2026; effective October 15, 2026.