

CERTIFICATION OF ADMINISTRATIVE RULES
FILED WITH THE LEGISLATIVE SERVICES AGENCY
OTHNI LATHRAM, DIRECTOR

(Pursuant to Code of Alabama 1975, §41-22-6, as amended).

I certify that the attached is/are correct copy/copies of rule/s as promulgated and adopted on the 16 day of November 2022 and filed with the agency secretary on the 17 day of November, 2022.

AGENCY NAME: Alabama State Board of Pharmacy

X Amendment New Repeal (Mark appropriate space)

Rule No. 680-X-2-.07
(If amended rule, give specific paragraph, subparagraphs, etc., being amended)

Rule Title: Mail Order Prescription

ACTION TAKEN: State whether the rule was adopted with or without changes from the proposal due to written or oral comments:

Adopted with change - An addition to amended paragraph (4) subsection (f)

NOTICE OF INTENDED ACTION PUBLISHED IN VOLUME XL,
ISSUE NO. 12, AAM, DATED SEPTEMBER 30,
2022.

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

(Date Filed)
(For LRS Use Only)

REC'D & FILED

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LEGISLATIVE SVC AGENCY


Certifying Officer or his or her
Deputy

(NOTE: In accordance with §41-22-6(b), as amended, a proposed rule is required to be certified within 90 days after completion of the notice.

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:** Filed September 19, 2019 effective November 15, 2019. **Amended:** Filed September 16, 2022 effective January 14, 2023