

**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 Wednesday, March 26, 2025, and filed with the agency secretary on Friday, March 28, 2025.

AGENCY NAME: Alabama State Board of Pharmacy

INTENDED ACTION: Amend

RULE NO.: 680-X-2-.39

(If amended rule, give specific paragraph, subparagraphs, etc., being amended) **(1) through (13)**

RULE TITLE: Pharmacy Off Site Order Entry

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

Adopted without changes. Six comments were received alongside the amendment to Rule 680-X-2-.49 Remote Work for Pharmacists. Four comments received in opposition, 2 in support. There were also three additional stakeholders in opposition who provided comments verbally during the public hearing.

NOTICE OF INTENDED ACTION PUBLISHED IN VOLUME XLIII, ISSUE NO. 4, AAM, DATED FRIDAY, JANUARY 31, 2025.

STATUTORY RULEMAKING AUTHORITY: 34-23-92

REC'D & FILED
Date Filed)
(For IRS Use Only)
MAR 28, 2025
LEGISLATIVE SVC AGENCY

Anne Marie Nolen

Anne Nolen

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.)

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.