

APA-1
Revised 4/2018

TRANSMITTAL SHEET FOR
NOTICE OF INTENDED ACTION

Control 680 Department or Agency: Alabama State Board of Pharmacy
Rule No. 680-X-2-.39
Rule Title: Pharmacy Off Site Order Entry

 New X Amendment Repeal Adopt by Reference

Would the absence of the proposed rule significantly harm or endanger the public health, welfare, or safety? Yes

Is there a reasonable relationship between the state's police power and the protection of the public health, safety, or welfare? Yes

Is there another, less restrictive method of regulation available that could adequately protect the public? No

Does the proposed rule have the effect of directly or indirectly increasing the costs of any goods or services involved and, if so, to what degree? No

Is the increase in cost, if any, more harmful to the public than the harm that might result from the absence of the proposed rule? No

Are all facets of the rulemaking process designed solely for the purpose of, and so they have, as their primary effect, the protection of the public? Yes

Does the proposed action relate to or affect in any manner any litigation which the agency is a party to concerning the subject matter of the proposed rule? No

Does the proposed rule have an economic impact? No

If the proposed rule has an economic impact, the proposed rule is required to be accompanied by a fiscal note prepared in accordance with subsection (f) of Section 41-22-23, Code of Alabama 1975.

Certification of Authorized Official

I certify that the attached proposed rule has been proposed in full compliance with the requirements of Chapter 22, Title 41, Code of Alabama 1975, and that it conforms to all applicable filing requirements of the Administrative Procedure Division of the Legislative Services Agency.

Signature of certifying officer *Ronna C. Gentryman*

Date 11/18/2020

REC'D & FILED
NOV 18 2020
LEGISLATIVE SVC AGENCY

APA-2

Alabama State Board of Pharmacy

NOTICE OF INTENDED ACTION

AGENCY NAME: Alabama Board of Pharmacy

RULE NO. & TITLE:

680-X-2-.39 Pharmacy Off Site Order Entry.

INTENDED ACTION:

Amend Rule

SUBSTANCE OF PROPOSED ACTION:

The Alabama State Board of Pharmacy proposes to amend Rule No.680-X-2.39 - Pharmacy Off Site Order Entry to provide clearer guidelines to ensure the public's safety.

TIME, PLACE, MANNER OF PRESENTING VIEWS:

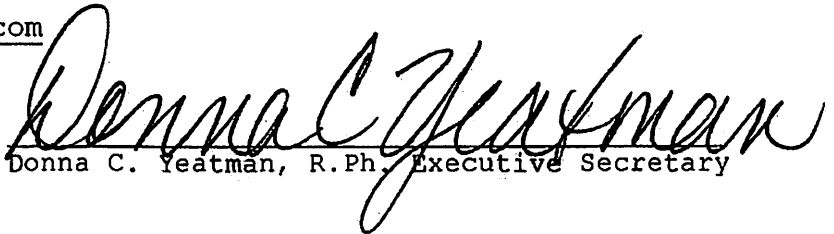
Oppositions can be submitted to the Alabama State Board of Pharmacy office. Business hours are 8:00am - 4:00pm Monday through Friday. Please present your views in writing, fax or email. Public hearing will be held February 17, 2021 at 9:00am

FINAL DATE FOR COMMENT AND COMPLETION OF NOTICE:

Comments concerning this change must be received by the Alabama State Board of Pharmacy no later than February 6th, 2020

CONTACT PERSON AT AGENCY:

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Donna C. Yeatman, R.Ph. Executive Secretary

680-X-2-.39 Pharmacy Off Site Order Entry.

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

(2) Definitions

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

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

1. Interpreting or clarifying prescription drug orders;
2. Data entering and transferring of prescription drug order information;
3. Performing drug regimen review;
4. Obtaining refill and substitution authorizations;
5. Performing therapeutic interventions; and
6. Providing clinical drug information concerning a patient's prescription.

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

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

~~(3) The Board shall approve based on a presentation before the Board any pharmacy(ies) who intend on utilizing off site order entry.~~

~~(4)~~ (3) The supervising pharmacist or the permit holder of the pharmacy shall submit a written request for off-site order entry a minimum of 30 days prior to the Board meeting at which the pharmacy seeks approval entity's initiation of off-site order entry.

(a) The request shall be accompanied by a policy and procedure manual for off-site order entry which shall be maintained at all pharmacies involved in off-site order entry and be available for inspection. Each pharmacy is required to

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

1. Outline the responsibilities of each of the pharmacies;
2. Include a list of the name, address, and telephone numbers of the pharmacies involved in off-site prescription order entry; and
3. Include policies and procedures for:
 - (i) Patient confidentiality and full compliance with HIPAA requirements;
 - (ii) Maintenance of appropriate records to identify the name(s), initials, or identification code(s) and specific activity(ies) of each pharmacist or pharmacy technician who performed any processing and the store it was processed in;
 - (iii) Mechanism for tracking the prescription drug order during each step of the dispensing process;
 - (iv) Each pharmacist involved in the off-site order process is responsible for ensuring compliance and may incur disciplinary actions for failing to do so.

4. Specify that a pharmacist holding a current license in good standing or a pharmacy technician working under the direct supervision of a pharmacist shall enter prescription drug orders at a location that is a duly licensed pharmacy.

5. Comply with federal and state laws and regulations; and 6. Include procedures for annually reviewing the written policies and procedures for needed modification with documentation of such review.

~~(5)~~ (4) General requirements.

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

1. Share a common electronic file or have appropriate technology to allow access to sufficient information necessary or required to process a non-dispensing function; and have;
2. The same owner; or
3. Entered into a written contract or agreement which outlines the services to be provided and the responsibilities and accountabilities of each pharmacy in compliance with federal and state laws and regulations.

~~(6)~~ (5) All pharmacies involved in off-site order entry approved by the Board shall comply with all applicable provisions of the Alabama Pharmacy Practice Act and/or Board Rule. Nothing in this Rule shall expand allowable duties of pharmacy technicians as set forth in Board Rule 680-X-2.14.

~~(7)~~ (6) Off-site order entry may only be shall be approved only if performed by pharmacies to whom a permit has been issued by the Board and which permit is in good standing when under the following circumstances:

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

(b) Institutional facility must have no more than an average daily census of 100 beds and be without an inhouse 24 hour pharmacy available seven days a week.

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

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

(7) Prescription Labeling.

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

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

(8) Notifications to patients.

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

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

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

(9) Records.

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

1. Separately by each pharmacy and pharmacist; or

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

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

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

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

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

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

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

1. "Emergency" must be defined in the policy and procedure.

2. Identify processes and security measures for off-site order entry outside the physical location of the institution.

3. Procedures for ensuring HIPAA compliance.

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

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

Author: James S. Ward, Board Attorney Ralph E. Sorrell, R.Ph.,
Board President.

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

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

Amended : Filed December 18, 2020