APA-4
Revised 1/2018

CERTIFICATION OF EMERGENCY RULES
FILED WITH LEGISLATIVE SERVICES AGENCY
OTHNI LATHRAM, INTERIM DIRECTOR

Pursuant to Code of Alabama 1975, §§41-22-5(b) and 41-22-6(c)(2)a. and b.

I certify that the attached emergency (amendment, new rule, new chapter, repeal or adoption by reference) is a correct copy as promulgated and adopted on the 20 day of **MARCH 2020**.

AGENCY NAME: **Alabama State Board of Pharmacy**

RULE NO. AND TITLE: **680-X-2-.39 .01ER Pharmacy Off Site Order Entry.**

EFFECTIVE DATE OF RULE: **March 20, 2020**

EXPIRATION DATE (If less than 120 days): **July 18, 2020 or until date authorized by Governor**

NATURE OF EMERGENCY: **COVID - 19 State of Emergency**

STATUTORY AUTHORITY: Code of Ala 1975 §34-23-92

SUBJECT OF RULE TO BE ADOPTED ON PERMANENT BASIS ____ YES **X** NO

NAME, ADDRESS, AND TELEPHONE NUMBER OF PERSON TO CONTACT FOR COPY OF RULE:

Wendy Passmore, Operations Manager
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Donna C Yeatman
Signature of officer authorized to promulgate and adopt rules and regulations or his or her deputy

FILING DATE
(For APA Use Only)

REC'D & FILED
MAR 20 2020
LEGISLATIVE SVC AGENCY

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 for State of Emergency

SUBSTANCE OF PROPOSED ACTION:

The Alabama State Board of Pharmacy proposes to amend rule 680-X-2-.39 to maintain continuity of care during COVID 19 State of Emergency.

TIME, PLACE, MANNER OF PRESENTING VIEWS:

Not Applicable - Emergency Submission

FINAL DATE FOR COMMENT AND COMPLETION OF NOTICE:

Not Applicable - Emergency Submission

CONTACT PERSON AT AGENCY:

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Donna C. Yeatman, R.Ph. Executive Secretary

680-X-2-.39 .01ER 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 intent on utilizing off-site order entry.

(4) 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 Board approval.

(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;

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) 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) 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) Off-site order entry may only be performed by pharmacies to whom a permit has been issued by the Board and which permit is in good standing.

(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) Only during the State of Emergency as declared by the Governor of the State of Alabama relating to the COVID-19 virus and in the event of reduced pharmacist staffing, the following may occur with Board approval:

(a) Remote order verification from a location outside the facility through a safe, secure and established technology to allow access to sufficient information necessary or required to process a non-dispensing function and perform the following:

a. Interpreting or clarifying prescription drug orders;

b. Data entering and transferring of prescription drug order information;

c. Performing drug utilization review;

d. Obtaining refill and substitution authorizations;

e. Performing therapeutic interventions: and

f. Providing clinical drug information concerning a patient's prescription

(b) Supervising Pharmacists of the facilities are responsible for ensuring:

a. Compliance with all HIPPA standards and patient confidentiality;

b. Compliance with quality standards for remote activities by individuals authorized by their facilities;

c. Ensure pharmacist holds a current license in good standing with Alabama Board of Pharmacy.

(c) Final verification of medication preparations and orders to be delivered or administered to a patient must be done by a pharmacist ONSITE.

Author: ~~James S. Ward, Board Attorney~~ Donna C. Yeatman, Executive Secretary
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.