

TRANSMITTAL SHEET FOR
NOTICE OF INTENDED ACTION

Control 680 Department or Agency: Alabama State Board of Pharmacy
Rule No. 680-X-2-.30
Rule Title: Central Prescription Filling
 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 *Donna C. Decker*

Date 4/18/19

REC'D & FILED
2019 APR 18 (DATE FILED)
(STAMP)
LEGISLATIVE SVC AGENCY

ALABAMA STATE BOARD OF PHARMACY
NOTICE OF INTENDED ACTION

AGENCY NAME: ALABAMA STATE BOARD OF PHARMACY
RULE NO. AND TITLE: 680-X-2-.30 : Central Prescription Filling
INTENDED ACTION: AMEND AN EXCISTING RULE

SUBSTANCE OF PROPOSED ACTION:

To delete references to retail pharmacy only, so rule applies to all pharmacies. Also, to require appearance before the Board for approval before utilizing central prescription filling.

TIME, PLACE, MANNER OR PRESENTING VIEW:

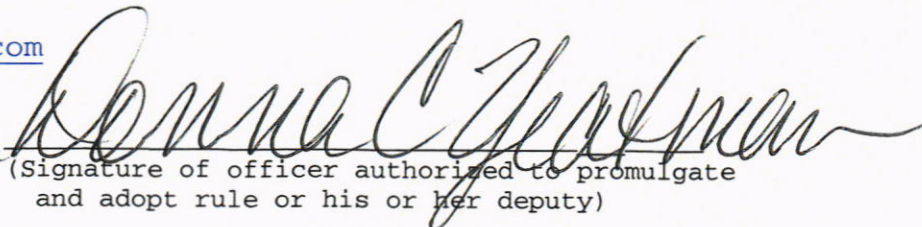
Oppositions can be directed to Wendy Passmore at the Alabama Board of Pharmacy from May 1, 2019 until June 14, 2019. Please present your views in writing, fax or email.

FINAL DATE FOR COMMENT AND COMPLETION OF NOTICE:

Final date to present your views will be June 14, 2019
Public Hearing will be held on June 19, 2019 at 9:00am
Location will be the Board Office, 111 Village Street,
Birmingham Alabama, 35242

CONTACT PERSON AT AGENCY:

Wendy Passmore
Operations Manager
111 Village Street
Birmingham, Al 35242
Phone 205-981-4764
Fax 205-803-6481
Email - wpassmore@albop.com


(Signature of officer authorized to promulgate
and adopt rule or his or her deputy)

680-X-2-.30 Central Prescription Filling

(1) Purpose. The purpose of this section is to provide standards for centralized prescription filling by a ~~retail~~ 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 Code of Ala. 1975, Title 34, Chapter 23, Practice of Pharmacy Act 205 and the Code of Ala. 1975, Title 20 Chapter 2, Alabama Uniform Controlled Substances Act 1407.~~ **The Alabama Pharmacy Practice Act, Code of Alabama (1975), § 34-23-1, et seq. and the Alabama Uniform Controlled Substances Act, Code of Alabama (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 ~~retail~~ pharmacy may outsource a prescription drug order filling to another ~~retail~~ 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 ~~Code of Ala. 1975, Title 34 Chapter 23, Practice of Pharmacy Act 205 and the Code of Ala. 1975, Title 20 Chapter 2, Alabama Uniform Controlled Substances Act 1407~~ **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.

~~(4)~~ (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.

~~(5)~~ (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.

~~(6)~~ (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. The State Board of Pharmacy and its drug inspectors shall enforce all provisions of this rule. Prescriptions, orders and records required by this chapter and stocks of controlled substances enumerated in Schedules I, II, III, IV, and V shall be open for inspection only to federal, state, county and municipal officers whose duty it is to enforce the laws of this state or of the United States relating to controlled substances. No officer having knowledge by virtue of his/her office of any such prescription, order or record shall divulge such knowledge, except in connection with a prosecution or proceeding in court or before a licensing board or officer, to which prosecution or proceeding the person to whom such prescriptions, orders or records relate is a party.~~

~~3~~ 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.

~~4~~ 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.

~~5~~ 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).

~~(7)~~ (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 ~~regulations~~ **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: ~~Jerry Moore, R.Ph., J.D., Executive Director~~ **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**