APA-1

TRANSMITTAL SHEET FOR NOTICE OF INTENDED ACTION

Control: 680

Department or Agency: Alabama State Board of Pharmacy

Rule No.: 680-X-2-.18

Rule Title: Institutional Pharmacies

Intended Action: Amend

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?	No

To what degree?: N/A

Is the increase in cost more harmful to the public than the harm that might result from the absence of the proposed rule?	NA
Are all facets of the rule-making 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

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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: Anne Marie Nolen

Anne Nolen

Date: Wednesday, April 9, 2025

REC'D & FILED

APR 9, 2025

LEGISLATIVE SVC AGENCY

APA-2

ALABAMA STATE BOARD OF PHARMACY

NOTICE OF INTENDED ACTION

AGENCY NAME: Alabama State Board of Pharmacy

RULE NO. & TITLE: 680-X-2-.18 Institutional Pharmacies

INTENDED ACTION: Amend

SUBSTANCE OF PROPOSED ACTION:
The following amendment is proposed to clarify which entities shall obtain an institutional pharmacy permit, as well as to allow for institutional pharmacies to utilize a centralized services model.

TIME, PLACE AND MANNER OF PRESENTING VIEWS:
The public hearing will be June 25, 2025 during the Business meeting beginning at 9:00 am CDT. Comments may be submitted to Anne Marie Nolen via email to anolen@albop.com by no later than June 20, 2025 at 4:00 pm CDT.

FINAL DATE FOR COMMENT AND COMPLETION OF NOTICE:
Friday, June 20, 2025

CONTACT PERSON AT AGENCY:
Anne Marie Nolen
anolen@albop.com

Anne Marie Nolen
Anne Nolen

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

680-X-2-.18 Institutional Pharmacies.

(1) Definitions.

(a) "Automated dispensing system" means an electromechanical system that performs operations or activities related to the storage and dispensing of medications and can collect, control, and maintain required transaction information and records.

(b) "Emergency dispensing" is defined as prescribing/ providing necessary medications to patients being treated by institutional facilities within the physical institutional facility or to be taken with the patient upon discharge.

(c) "Emergency kit" is a kit consisting of drugs, including controlled substances, needed to effectively manage a critical care incident or need of a patient.

(d) "~~Institutional pharmacy" means a physical portion of a licensed healthcare facility that is engaged in the compounding, dispensing, and distribution of drugs, devices, and other materials and the provision of services used in the prevention, diagnosis, and treatment of injury, illness, and disease (hereafter referred to as "institutional pharmacy services") and which is permitted with the Alabama State Board of Pharmacy.~~

~~(e) "~~Licensed healthcare facility" means a hospital, as defined in Code of Ala. 1975, §22–21–20(1) licensed by the Alabama Department of Public Health~~, or a Federally Qualified Health Center, as defined by ALA. ADMIN. CODE r. 560-X-48-.01(1).~~

~~(f)~~(e) "Managing pharmacy" means a pharmacy responsible for supplying prescribed medications for patients in a licensed healthcare facility and the safe operation of any automated dispensing system used in the facility. A managing pharmacy may be one of the following:

1. A pharmacy physically located in Alabama, not within a licensed healthcare facility, holding a current pharmacy permit issued by the Alabama Board of Pharmacy

2. An institutional pharmacy serving as the managing pharmacy for a facility operating as a department of the licensed healthcare facility upon approval by the Board.

~~(g)~~(f) "Stat medicine cabinet" is a cabinet or enclosure that consists of non–controlled drugs needed to effectively manage

a patient's drug regimen which are not available from any other authorized source in sufficient time to prevent risk of harm to patients.

~~(h)~~ (g) "Positive identification" means the method by which access to the medications and information contained in an automated dispensing system in a licensed healthcare facility is limited to only authorized individuals, and which includes the use of a user—specific password combined with a user—specific personal identifier such as a fingerprint, personal ID badge, retinal pattern, or other unique identifier.

(2) Drug Distribution and Control in Institutional Pharmacies

(a) The following locations shall obtain an institutional pharmacy permit from the Board:

1. A pharmacy that is a physical portion of a licensed healthcare facility

2. A pharmacy that is a physical portion of a healthcare facility located outside Alabama;

3. A pharmacy that is not a physical portion of a licensed healthcare facility but provides centralized services to an institutional pharmacy;

4. A pharmacy providing services for patients who receive care through an integrated correctional health care system

(b) The supervising pharmacist shall establish written procedures for the safe and efficient distribution of drugs and for the provision of institutional pharmacy services. A current updated copy of such procedures shall be on hand for inspection by the Board of Pharmacy.

~~(b)~~ (c) All of the activities and operations of each institutional pharmacy shall be personally and directly supervised by its supervising pharmacist or a designated pharmacist.

~~(c)~~ (d) When patients bring drugs into a licensed healthcare facility, such drugs shall not be administered unless they can be precisely identified. Administration shall be pursuant to a practitioner's order only. If such drugs are not to be administered, they shall be given to an adult member of the patient's immediate family for removal from the facility, or follow written policy provided by the supervising pharmacist.

~~(d)~~ (e) Investigational drugs for inpatient use shall be stored in and dispensed from the pharmacy only. Complete information on all investigational drugs stored or dispensed shall be maintained in the pharmacy.

~~(e)~~ (f) The supervising pharmacist shall develop a recall procedure that can be readily implemented to assure the medical and pharmacy staff of the licensed healthcare facility that all drugs included on the recall intended for use within the facility are returned to the pharmacy for proper disposal.

(3) Stat Medicine Cabinets

(a) During such times an institutional pharmacy may be unattended by a pharmacist, arrangements shall be made in advance by the supervising pharmacist for provision of drugs to the medical staff and other authorized personnel of the licensed healthcare facility by use of a stat medicine cabinet or other enclosure constructed and located outside of the pharmacy area and, in emergency circumstances, by access to the pharmacy. A pharmacist shall be available after hours in accordance with established institutional policy.

(b) In licensed healthcare facilities utilizing a managing pharmacy, drugs shall be stored in a stat medicine cabinet to which only specifically authorized personnel may obtain access by key or combination, and which is sufficiently secure to deny access to unauthorized persons, provided, however, such cabinet meets the following requirements:

1. Each facility may maintain one stat medicine cabinet for the purpose of keeping a minimum amount of stock medications that may be needed quickly or after regular duty hours. If a facility wants more than one stat medicine cabinet, it must be approved by the Alabama State Board of Health pursuant to Chapter 420-5-10.

2. All medications shall be packaged in an appropriate manner in the stat medicine cabinet based on the established needs of the facility. Need for such medications shall be reviewed by the pharmacist annually.

3. There must be a list of contents, approved by the appropriate committee and a pharmacist, giving the name and strength of the drug and the quantity of each. Contents of the stat medicine cabinet shall be properly labeled with name, strength, and expiration date.

4. There shall be records available to show amount received, name of patient and amount used, prescribing physician, time of administration, name of individual removing and using the medication, and the balance on hand.

5. There shall be written procedures for utilization of the stat medicine cabinet with provisions for prompt replacement of used items.

6. The pharmacist shall inspect the stat medicine cabinet at least monthly replacing outdated drugs and reconciliation of its prior usage. Information obtained shall be included in a monthly report.

(c) The supervising pharmacist of either the institutional pharmacy or the managing pharmacy shall, in conjunction with the appropriate committee of the licensed healthcare facility, develop inventory listings of those drugs to be included in a stat medicine cabinet, determine who may have access, and have written policies and procedures to ensure that:

1. The drugs are properly labeled;

2. Only prepackaged drugs are available, in amounts sufficient for immediate therapeutic requirements;

3. Whenever access to the cabinet occurs, written orders of an authorized practitioner and proofs of use are provided;

4. All drugs therein are inventoried regularly based on institutional policy, but no less than every thirty (30) days;

5. A complete audit of all activity concerning such cabinet is conducted no less than once per month.

(d) Whenever any drug is not available from floor supplies or cabinet, and such drug is required to treat the immediate needs of a patient whose health would otherwise be jeopardized, such drug may be obtained from the pharmacy in accordance with the requirements of this Section 3. One supervisory nurse or physician in any given shift is responsible for obtaining drugs from the pharmacy. The responsible person shall be designated in writing by the appropriate committee of the licensed healthcare facility. Removal of any drug from the pharmacy by an authorized designee must be pursuant to written orders of an authorized

practitioner and must be recorded on a suitable form showing patient name, patient date of birth, room number, name of drug, strength, amount, date, time, and signature of designee. The form shall be left with the container from which the drug was removed.

(4) Emergency Kits

(a) Drugs may also be provided in a licensed healthcare facility for use by authorized personnel by emergency kits located at such facility, provided, however, such kits meet the following requirements:

1. A copy of the list of the contents of the emergency kit shall be maintained both at the institution and the pharmacy supplying the drugs;

2. All emergency kit drugs shall be provided and sealed by a pharmacist who is licensed to engage in the practice of pharmacy in this state;

3. The supplying pharmacist and the medical staff of the licensed healthcare facility shall jointly determine the drugs, by identity and quantity, to be included in emergency kits;

4. Emergency kits shall be securely stored in areas to prevent unauthorized access, and to ensure a proper environment for preservation of the drugs within them;

5. Each emergency kit shall be labeled so as to clearly indicate that it is an emergency drug kit and that it is for use in emergencies only. The label shall contain a listing of the drugs contained in the kit, including name, strength, quantity, and expiration date of the contents, and the name, address(es) and telephone number(s) of the supplying pharmacist;

6. Drugs shall be removed from emergency kits only pursuant to a valid order of an authorized practitioner;

7. Whenever an emergency kit is opened, the supplying pharmacist shall be notified, and the pharmacist shall stock and reseal the kit within not more than 72 hours, so as to prevent risk of harm to patients; and

8. The expiration date of an emergency kit shall be the earliest date of expiration of any drugs supplied in the kit. Upon the occurrence of the expiration date, the supplying pharmacist shall replace the expired drug.

(5) Automated Dispensing Systems

(a) Automated dispensing systems may be used to meet the needs of patients in licensed healthcare facilities. The automated dispensing system must be located in a licensed healthcare facility that either:

1. Has an Alabama Board of Pharmacy institutional pharmacy permit; or

2. Holds a valid and current contract with a Managing Pharmacy to provide pharmacy services to that facility. The automated dispensing system shall be considered an extension of the managing pharmacy.

(b) General requirements for automated dispensing systems include:

1. The supervising pharmacist of either the facility or managing pharmacy is responsible for the operation of the automated dispensing system. A pharmacist of either the facility or managing pharmacy must always have access to the equipment and all transaction information.

2. Access to the drugs and information contained within the automated dispensing system is secured through the use of positive identification.

3. Access to the automated dispensing system shall be controlled by the pharmacy and shall be limited to:

i. Licensed nurses

ii. Licensed pharmacists

iii. Registered pharmacy technicians

iv. Respiratory therapy

v. Other licensed healthcare professionals as approved by the supervising pharmacist or medical staff

vi. Authorized field service personnel for maintenance purposes and only while under direct observation of a licensed nurse, a licensed pharmacist, or a registered pharmacy technician.

4. If the automated dispensing system is managed by a managing pharmacy, medications delivered to the licensed

healthcare facility but not yet stocked into the automated dispensing system are stored in a secure manner and in compliance with the policies and procedures agreed upon by the pharmacy and the leadership of the facility.

5. Restocking of the automated dispensing system shall be limited to a licensed pharmacist or a registered pharmacy technician of either the facility or managing pharmacy, a licensed nurse of the facility, or other licensed healthcare personnel approved by the Board of Pharmacy.

6. If the facility is utilizing a managing pharmacy, a pharmacist of the managing pharmacy shall conduct an on—site physical inventory of the contents of the automated dispensing system at least quarterly.

7. A pharmacist employed by either the facility or managing pharmacy reviews, interprets, and approves all prescription medication orders prior to removal of a drug from the automated dispensing system. When a medication is ordered and needed but the order has not been reviewed, interpreted, and approved by the pharmacist, emergency access to the medication by authorized users is allowed if such access is permitted by written policies and procedures agreed upon by the pharmacy and appropriate leadership of the facility.

8. The name and quantity of medications and products kept in the automated dispensing system shall be agreed upon by the pharmacy, the facility's Medical Director, and appropriate nursing leadership of the facility.

(c) Nothing in this rule shall be interpreted to amend, alter, or modify the provisions of Alabama Code Section 34, Chapter 23 or supporting regulations.

(6) Dispensing For Institutional Facilities

(a) Requirements for emergency dispensing labeling must include, but is not limited to:

1. The name and address of the facility from which the prescription was dispensed

2. The directions for use

3. The name of the drug as it is dispensed

4. The strength per dosage unit

5. Any additional information that is a true statement of fact may be included as deemed essential for proper storage, handling, safety, and/or usage of the prescription.

(b) Emergency dispensing may be utilized for the following medications:

1. Bulk medications for single patient use

2. Medications deemed necessary with Board approval

(7) Centralized Services

(a) The purpose of this Rule is to provide standards for an institutional pharmacy to perform Centralized Services.

(b) An institutional pharmacy may perform the following centralized services:

1. Preparing unit dose packages for single administration to patients from bulk containers

2. Preparing non-sterile or sterile compounded unit dose drugs for administration to patients

3. Warehouse bulk supply medications and supplies

4. Perform off-site order entry in compliance with requirements of the Pharmacy Practice Act and any other applicable state and federal statutes and regulations

5. Additional functions as approved by the Board

(c) The pharmacies must notify the Board before utilizing centralized services.

(d) Regardless of whether located within or outside this State, the following requirements apply to any pharmacy involved in centralized services:

1. The pharmacies must be permitted by the Board before providing any centralized services

2. The pharmacies must either:

i. be owned by the same person or entity; or

ii. have a written contract with the originating pharmacy outlining the services to be provided and

the responsibilities of each pharmacy in fulfilling the terms of the contract; and

iii. share a common electronic file or have appropriate technology to allow access to sufficient information necessary to process medication orders

3. The institutional pharmacy performing centralized services shall maintain a record of all pharmacies, including name, address, and DEA number to which services are provided.

4. The pharmacies and all pharmacy personnel must comply with all provisions of the Pharmacy Practice Act, and all other State and federal statutes, rules, and regulations.

(e) The pharmacies utilizing centralized services shall maintain a policy and procedure manual which includes the following:

1. appropriate records to identify the responsible pharmacists in performing centralized services;

2. mechanism for tracking the prescription drug order during each step in all processes;

3. description of adequate security to protect the integrity and prevent the illegal use or disclosure of protected health information;

4. description of drug storage and security in compliance with all applicable federal and state statutory and regulatory requirements;

5. a continuous quality improvement program; and

6. documented annual review.

Author: Alabama State Board of Pharmacy
Statutory Authority: Code of Ala. 1975, §34-23-74.
History: Filed November 6, 1987; effective January 1, 1988. **Amended:** July 6, 1993; effective January 1, 1994. **Amended:** Filed August 6, 1993. **Amended:** Filed February 13, 1997; effective March 20, 1997. **Amended:** Filed September 20, 1999; effective October 25, 1999. **Amended:** Filed April 3, 2003; effective May 8, 2003. **Amended:** Filed September 22, 2009; effective October 27, 2009. **Amended:** Filed January 30, 2012; effective March 5, 2012. **Amended:** Filed April 14, 2015; effective May 19, 2015. **Amended:** Filed June 8, 2016; effective July 23, 2016. **Amended:** Filed August 23, 2019, effective October 7, 2019. **Amended:** Published September 30, 2022; effective November 14, 2022. **Repealed and**

New Rule: Published September 29, 2023, effective November 13, 2023. **Amended:** Published _____; effective _____.