

APA-1  
11/96

**TRANSMITTAL SHEET FOR  
NOTICE OF INTENDED ACTION**

Control 680 Department of Agency: Alabama State Board of Pharmacy

Rule No. 680-X-2-.18

Rule Title: **INSTITUTIONAL PHARMACIES**

     New      xx Amend           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 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 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 Reference Service.

Signature of certifying officer   
Mitzi G. Ellenburg, Director of Operations

Date: May 14, 2015

(DATE FILED)  
(STAMP)

**ALABAMA STATE BOARD OF PHARMACY  
NOTICE OF INTENDED ACTION**

**AGENCY NAME:** ALABAMA STATE BOARD OF PHARMACY

**RULE NO. AND TITLE:** 680-X-2-.18 INSTITUTIONAL PHARMACIES

**INTENDED ACTION:** AMENDED

**SUBSTANCE OF PROPOSED ACTION:**

The Alabama State Board of Pharmacy proposes to amend this rule in accordance with Act 2013-106 to allow for the use and operation of automated dispensing systems in skilled nursing facilities under certain circumstances.

**TIME, PLACE, MANNER OR PRESENTING VIEW:**

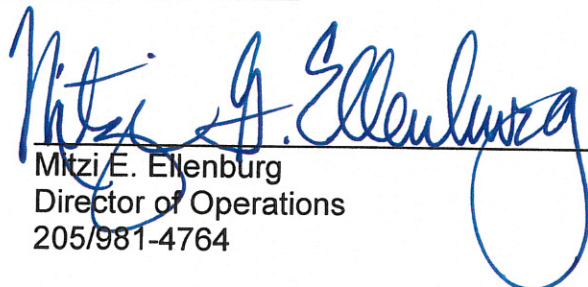
Comments can be presented at the public hearing scheduled at 9:00 a.m. on June 17, 2015 at the Alabama State Board of Pharmacy located at 111 Village Street, Birmingham, Alabama 35242. Additionally, written comments may be addressed to Mitzi Ellenburg, Director of Operations, Alabama State Board of Pharmacy, at the same address. Written comments must be received in the Board Office no later than 4:00 p.m. on July 6, 2015.

**FINAL DATE FOR COMMENT AND COMPLETION OF NOTICE:**

July 6, 2015

**CONTACT PERSON AT AGENCY:**

Mitzi Ellenburg  
Director of Operations  
205/981-4764

  
Mitzi E. Ellenburg  
Director of Operations  
205/981-4764

**680-X-2-.18. INSTITUTIONAL PHARMACIES.**

(1) **APPLICABILITY:** In addition to existing State and Federal Regulations, the following Rules are applicable to all Institutions and Institutional Pharmacies as defined in Section 2 below.

(2) **DEFINITIONS.**

(a) "Institutional Facility" means any organization whose primary purpose is to provide a physical environment for inpatients to obtain health care services, including but not limited to a:

1. Hospital;
2. Convalescent Home;
3. Nursing Home;
4. Extended Care Facility;
5. Mental Health Facility;
6. Rehabilitation Center;
7. Psychiatric Center;
8. Developmental Disability Center;
9. Drug Abuse Treatment Center;
10. Family Planning Clinic;
11. Penal Institution;
12. Hospice;
13. Public Health Facility;
14. Athletic Facility.

(b) "Institutional Pharmacy" means that physical portion of an Institutional Facility that is engaged in the compounding, dispensing, and distribution of drugs, devices, and other materials used in the diagnosis and treatment of injury, illness, and disease (hereinafter referred to as "Drugs"); and which is registered with the State Board of Pharmacy.

(3) **PERSONNEL:**

(a) Each Institutional Pharmacy shall be directed by a pharmacist, hereinafter referred to as the Supervising Pharmacist, who is licensed to engage in the practice of pharmacy in this State.

(4) **ABSENCE OF PHARMACIST:**

(a) During such times as 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 Institutional Facility by use of a locked 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 the absence of a pharmacist, Drugs shall be stored in a

cabinet/enclosure constructed and located outside of the Pharmacy area, to which only specifically authorized personnel may obtain access by key or combination, and which is sufficiently secure to deny access to unauthorized persons. The Supervising Pharmacist shall, in conjunction with the appropriate committee of the Institutional Facility, develop inventory listings of those Drugs to be included in such cabinet/enclosure and determine who may have access, and shall 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/enclosure 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/enclosure is conducted no less than once per month; and
6. Written policies and procedures are established to implement the requirements of this Section 4.

(c) Whenever any Drug is not available from floor supplies or cabinet/enclosure, 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 4. 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 Institutional 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, room number, name of Drug, strength, amount, date, and time and signature of designee. The form shall be left with the container from which the drug was removed.

(d) For an Institutional Facility that does not have an Institutional Pharmacy, Drugs may be provided for use by authorized personnel by emergency kits located at such Facility, provided, however, such kits meet the following requirements:

1. The contents of the Emergency kit shall consist of those Drugs needed to effectively manage a critical care incident or need of a patient. 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 Institutional Facility shall jointly determine the Drugs, by identity and quantity, to be included in emergency kits;
4. Emergency kits shall be stored in secured areas to prevent unauthorized access, and to ensure a proper environment for preservation of the Drugs within them;

5. The exterior of 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 written 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 a reasonable time but 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.

(e) For an institutional Facility that does not have an institutional pharmacy, Drugs may be stored in a cabinet/enclosure to which only authorized personnel may obtain access by key, combination, or access code and which is sufficiently secure to deny access to unauthorized persons, provided, however, such cabinet/enclosure meet the following requirements:

1. Definition of Stat Cabinet - A Stat Cabinet 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 patient by delay resulting from attaining such Drugs from other sources.

2. Each facility may maintain one "stat" cabinet/enclosure 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" cabinet/enclosure, it must be approved by the Alabama State Board of Health and the Alabama State Board of Pharmacy.

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

4. 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" cabinet shall be properly labeled with name, strength and expiration date.

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

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

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

**(5) DRUG DISTRIBUTION AND CONTROL:**

(a) The Supervising Pharmacist shall establish written procedures for the

safe and efficient distribution of Drugs and for the provision of pharmaceutical care. An annual updated copy of such procedures shall be on hand for inspection by the Board of Pharmacy.

(b) All of the activities and operations of each Institutional Pharmacy shall be personally and directly supervised by its Supervising Pharmacist or a designated pharmacist. All functions and activities of technicians shall be personally and directly supervised by a registered pharmacist to insure that all functions and activities are performed competently, safely, and without risk of harm to patients. There shall be not more than three (3) technicians, at least one of which shall be certified by any credentialing organization approved by the Board, on duty in the prescription area for each full time licensed pharmacist on duty. Nothing in this rule shall prevent an institutional pharmacy from employing technicians to perform supervised tasks not requiring professional judgment.

(c) Whenever patients bring drugs into an Institutional 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 Institution or follow written policy provided by the Supervising Pharmacist.

(d) 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) The Supervising Pharmacist shall develop and implement a recall procedure that can be readily activated to assure the medical staff of the Institutional Facility and the Pharmacy staff that all drugs included on the recall intended for use within the facility are returned to the Pharmacy for proper disposition.

#### (6) AUTOMATED DISPENSING SYSTEMS

(a) Definitions: For purposes of this section only, the terms defined in this subdivision have the meanings set forth below:

1. "Automated dispensing system" means a mechanical system approved by the Board of Pharmacy that performs operations or activities related to the storage and dispensing of emergency medications; other than compounding, packaging, or labeling. Approved systems must collect, control, and maintain all required transaction information and records.

2. "Emergency Medication" means any medication ordered by a licensed prescriber that meets the patient's needs for up to 72 hours or until the managing pharmacy can provide on-going therapy to continue maintenance of patient.

3. "Packaging" means the preparation of medication from bulk containers to devices for individual patient administration containers.

4. "Managing pharmacy" means a pharmacy physically located in Alabama and licensed by the Board of Pharmacy that controls and is responsible for the operation of the facility's automated dispensing system.

5. "Positive identification" means identification of a caregiver using a password combined with a personal identifier such as a fingerprint, personal ID badge, iris pattern, or other biometric or unique identifier.

(b) Authorization:

1. A managing pharmacy may use an automated dispensing system to meet the prescription needs of residents in skilled nursing facilities. The automated dispensing system must be located in a skilled nursing facility that holds a valid contract with a managing pharmacy to provide pharmacy services. The approved automated dispensing system is to be considered an extension of the managing pharmacy provider. Medications remain the property of the managing pharmacy until dispensed.

(c) Approval/Notification to Board of Pharmacy:

1. All automated dispensing technology must be approved by the Board of Pharmacy.

2. The managing pharmacy shall submit a written request for approval to utilize automated dispensing technology a minimum of 30 days prior to the Board of Pharmacy meeting at which the managing pharmacy seeks Board approval. The request shall be accompanied by a policy and procedures manual for the automated dispensing system specific to the managing pharmacy and skilled nursing facility. The application for approval shall also include the name of the manufacturer and model of the automated dispensing system.

3. Thirty days prior to use of approved automated dispensing system - the managing pharmacy must provide written notification to the Board of Pharmacy. This notification shall include:

(i) A copy of the managing pharmacy's initial approval for automated dispensing technology by the Board of Pharmacy.

(ii) The manufacturer and model of the approved automated dispensing system

(iii) The address at which the approved automated dispensing system will be located.

4. In the event the automated dispensing system is to be removed from the skilled nursing facility, the managing pharmacy must provide written notification to the Board of Pharmacy within 30 days after removal.

(d) General Requirements for Automated Dispensing Systems. A managing pharmacy may utilize automated dispensing systems provided:

1. The managing pharmacy and the supervising pharmacist are responsible for the operation of the automated dispensing system. The automated dispensing system must be under the supervision of a licensed Alabama pharmacist. The pharmacist is not required to be physically present at the site of the automated

dispensing system; however, the managing pharmacy must have appropriate technology allowing access to necessary information.

2. Access to the drugs contained within the automated dispensing system must be secured through the use of positive identification.

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

(a) Licensed nurses

(b) Licensed pharmacists

(c) Registered pharmacy technicians

(d) Authorized field service personnel for maintenance purposes only.

Service personnel must be supervised by a pharmacist or nurse while the device is open.

4. Restocking or reloading the automated dispensing system may be performed by a licensed pharmacist, a registered pharmacy technician, or a licensed facility nurse approved by the Board of Pharmacy if the automated system utilizes technology to ensure accurate restock and reloading. Medications delivered to the skilled nursing facility for the purpose of restocking the automated dispensing system must be stored in a secure manner compliant with the skilled nursing facility's regulations for both legend and controlled drugs. The facility should sign for receipt of delivered medications..

5. The managing pharmacy shall conduct an on-site inventory of the contents of the automated dispensing system no less than quarterly. Security measures shall be implemented so that the same personnel do not stock and inventory consecutively.

6. A pharmacist employed by the managing pharmacy must review, interpret, and approve all prescription medication orders prior to removal from the automated dispensing system. Emergency access to medications when a pharmacist has not reviewed and approved the prescription medication order is permitted by formal written policies and procedures which have been agreed upon by the managing pharmacy, the Medical Director, the designated facility pharmacist and appropriate nursing facility staff.

7. The number and quantity of medications and products kept in the automated dispensing unit shall be determined jointly by the managing pharmacy, the designated facility pharmacist, the Medical Director and appropriate nursing facility staff.

8. Nothing in this rule shall be interpreted to amend, alter or modify the provisions of Code of Alabama (1975) Title 34, Chapter 23 or supporting regulations.

9. The Board of Pharmacy shall not approve an automated dispensing system for use in a skilled nursing facility for the purpose of compounding, packaging, or labeling of medications.

10. The Board of Pharmacy approved policy and procedures manual shall be maintained at the location of the automated dispensing system and at the managing pharmacy and be available for inspection.

(e) Reports:



1. The managing pharmacy shall retain records of the transactions performed by the automated dispensing system for the same period of time as required for retention of prescription records. These records shall be readily retrievable and copies of such records shall be produced in a printed format if requested by authorities within two business days. A policy specifying time access parameters , including timeouts, logoffs, and lockouts must be in place.

Author: Susan Alverson, P. D.P. A., R.Ph., Secretary  
Statutory Authority: §34-23-92, Code of Alabama 1975  
Adopted: 04 November 1987; Effective 01 January 1988;  
Amended 6 July 1993; Effective 1 January 1994; Amended 4 February 1997;  
Effective 4 April 1997; Amended 4 September 1999; Effective 1 November 1999;  
Amended 3 March 2003; Effective 7 May 2003; Amended September 4, 2009;  
Effective November 1, 2009; Amended January 19, 2012; Effective March 5, 2012;  
Amended March 25, 2015; Effective May 13, 2015; Amended .

APA-6

**ECONOMIC IMPACT STATEMENT  
FOR APA RULE  
(Section 41-22-23(f))**

Control No. 680 Department of Agency: Alabama State Board of Pharmacy

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

Rule Title: **INSTITUTIONAL PHARMACIES.**

       New   XX   Amend        Repeal        Adopt by Reference

  X   This rule has no economic impact.

       This rule has an economic impact, as explained below:

1. NEED/EXPECTED BENEFIT OF RULE:
  
2. COSTS/BENEFITS OF RULE AND WHY RULE IS THE MOST EFFECTIVE, EFFICIENT, AND FEASIBLE MEANS FOR ALLOCATING RESOURCES AND ACHIEVING THE STATED PURPOSE:
  
3. EFFECT OF THIS RULE ON COMPETITION:
  
4. EFFECT OF THIS RULE ON COST-OF-LIVING AND DOING BUSINESS IN THE GEOGRAPHICAL AREA WHERE THE RULE IS TO BE IMPLEMENTED:
  
5. EFFECT OF THIS RULE ON EMPLOYMENT IN THE GEOGRAPHICAL AREA WHERE THE RULE IS TO BE IMPLEMENTED:
  
6. SOURCE OF REVENUE TO BE USED FOR IMPLEMENTING AND ENFORCING THIS RULE:
  
7. THE SHORT-TERM/LONG-TERM ECONOMIC IMPACT OF THIS RULE ON AFFECTED PERSONS, INCLUDING ANALYSIS OF PERSONS WHO WILL BEAR THE COSTS AND THOSE WHO WILL BENEFIT FROM THE RULE:

8. UNCERTAINTIES ASSOCIATED WITH THE ESTIMATED BENEFITS AND BURDENS OF THE RULE, INCLUDING QUALITATIVE/QUANTITATIVE BENEFITS AND BURDEN COMPARISON:
9. THE EFFECT OF THIS RULE ON THE ENVIRONMENT AND PUBLIC HEALTH:
10. DETRIMENTAL EFFECT ON THE ENVIRONMENT AND PUBLIC HEALTH IF THE RULE IS NOT IMPLEMENTED:

**\*\* Additional pages may be used if needed.**