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

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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.

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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

Mitzi G. Ellenburg, Director of Operations

Date: October 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 November 10, 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 December 7, 2015.

FINAL DATE FOR COMMENT AND COMPLETION OF NOTICE:

December 7, 2015

CONTACT PERSON AT AGENCY:
Mitzi Ellenburg
Director of Operations
205/981-4764

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

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.**

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 IN SKILLED NURSING FACILITIES

(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 an electromechanical system that performs operations or activities related to the storage and dispensing of medications and which is capable of collecting, controlling, and maintaining all required transaction information and records.

2. "Emergency Medication" means any medication, including controlled substances, ordered by a licensed prescriber in response to a critical patient need.

3. "STAT medication" means any medication, excluding controlled substances, ordered and added to the drug regimen of a newly admitted patient or an existing patient that is not available from the Managing Pharmacy in sufficient time to

prevent risk of harm to the patient that might result from a delay in obtaining such drug.

4. "Packaging" means the preparation of medication from bulk containers to unit-dose or unit-of-use containers intended for individual patient administration.

5. "Managing Pharmacy" means a pharmacy physically located in Alabama, holding a current pharmacy permit issued by the Alabama Board of Pharmacy, and which is responsible for supplying prescribed medications for patients in a skilled nursing facility and for the safe operation of any automated dispensing system used in the facility.

6. "Positive identification" means the method by which access to the medications and information contained in an automated dispensing system in a skilled nursing 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.

(b) Authorization: A Managing Pharmacy may use an automated dispensing system to meet the emergency medication needs and the STAT medication needs of residents in skilled nursing facilities. The automated dispensing system must be located in a skilled nursing facility that 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.

(c) Notifying the Board of Pharmacy:

1. The Managing Pharmacy shall submit a written request to the Board of Pharmacy for approval to use an automated dispensing system. The Board of Pharmacy shall determine at which future meeting the request shall be considered. Requests must be submitted no less than 30 days prior to the Board of Pharmacy meeting at which the request will be considered.

2. The request for approval to use an automated dispensing system shall include:

(a) written policies and procedures for the automated dispensing system specific to the automation to be used,

(b) the name and address of the facility in which the automation will be used,

(c) the name and permit number of the Managing Pharmacy,

(d) a description of the automation (type, manufacturer, and model) along with a description of how the system is to be used,

(e) The specific location(s) within the facility where the automated dispensing system will be placed, and

(f) The date the automation will be placed into operation. The Board of Pharmacy must be notified at least 30 days prior to use.

3. If the automated dispensing system is removed from the skilled nursing facility, the Managing Pharmacy must notify the Board of Pharmacy in writing at any time prior to removal but no more than 30 days after removal.

(d) General Requirements for Automated Dispensing Systems: A Managing Pharmacy may utilize an automated dispensing system provided:

1. The Supervising Pharmacist of the Managing Pharmacy is responsible for the operation of the automated dispensing system. There is no requirement that a pharmacist be physically present at the site of the automated dispensing system. However, a pharmacist of the Managing Pharmacy must have access to the equipment and all transaction information at all times.

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 Managing Pharmacy and shall be limited to:

(i) Licensed nurses

(ii) Licensed pharmacists

(iii) Registered pharmacy technicians

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

4. Medications delivered to the skilled nursing 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 Managing 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 the Managing Pharmacy, a licensed nurse of the facility, or other licensed healthcare personnel approved by the Board of Pharmacy.

6. A pharmacist of the Managing Pharmacy conducts an on-site physical inventory of the contents of the automated dispensing system at least quarterly.

7. A pharmacist employed by the 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 Managing Pharmacy, the facility's Medical Director, and appropriate nursing leadership of the facility.

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

(e) According to the Institute for Safe Medication Practices, topics to consider for the safe use of automated dispensing systems include:

1. Choose a location with good lighting, temperature control, sufficient space, and which minimizes distractions and errors.

2. Address security related issues such as access, assigning of passwords, prohibition of password sharing or recycling, blind counts, and resolution of discrepancies.

3. Electronic patient profiles and electronic medication administration record should be used to minimize the risk of medication errors.

4. Information on the computer monitor for use by the caregiver should include the patient's name, a second identifier, allergies, drug interactions, brand and generic drug names, TALLman lettering, and the location of the drug within the cabinet.

5. Address inventory issues, such as criteria to add or delete drugs, the avoidance of bulk drug containers, setting of minimum and maximum quantities to be stocked, and frequency of audits.

6. When stocking or restocking an automated dispensing system barcode verification, if available, should be used or a second person should verify accuracy.

7. Withdrawals should be limited to profiled drugs, except in case of an emergency.

8. An override policy should be developed and followed. Overrides (emergency withdrawals when a profile withdrawal is not possible) should be minimized. The inclusion of a rationale statement for each override should be required. Two-person checks for overrides of high alert medications should be required.

9. Medications being transported after withdrawal from an automated dispensing system should remain in their unit dose package until just prior to administration.

10. If medications for more than one patient are being removed from the automated dispensing system at the same time, each patient's medications should be segregated and clearly labeled by individual patient.

11. Staff using the automated dispensing system is educated and can demonstrate competency for the proper use of the cabinet, including downtime procedures.

12. Steps to take in case of unexpected malfunctions, including trouble shooting and repairs, should be addressed.

13. A timeframe should be specified within which discrepancies will be resolved.

14. Address the mechanism by which and the timeframe within which a user's access will be removed when the user should no longer have access to contents or information in the automated dispensing system.

(f) Reports: Records of automated drug system transactions shall be retained by the Managing Pharmacy for the same period of time as required for retention of prescription records. These records shall be readily retrievable and printed copies of such records shall be available within two business days upon request by the Board of Pharmacy or its representatives.

(g) The Board of Pharmacy must approve policies and procedures for the operation of the automated drug system. A copy of the policies and procedures shall be maintained at the location of the automated dispensing system and at the Managing Pharmacy and shall be available for inspection at all times.

(h) 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.

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

Author: ~~Herb Bobo, R.Ph., Secretary~~ Dr. Timothy Martin PharmD, Vice-President
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 .