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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: January 16, 2014

(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 to eliminate the specified number of drugs provided by a pharmacy to a long term care facility.

TIME, PLACE, MANNER OR PRESENTING VIEW:

Comments can be presented at the public hearing scheduled at 9:00 a.m. on February 25, 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 March 9, 2015.

FINAL DATE FOR COMMENT AND COMPLETION OF NOTICE:

March 9, 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. ~~The number of drugs provided by a pharmacy to a long term care facility shall be limited to fifty (50).~~ There shall be a limited number of doses of any medication, not to exceed a 48 hour supply, of any drug dosage form per fifty (50) beds, and 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.

Author: ~~Herb Bobo~~ Susan Alverson, P.D.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.

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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.**