FORM APA4
Revised 1/2018

CERTIFICATION OF EMERGENCY RULES FILED WITH LEGISLATIVE SERVICES AGENCY OTHNI LATHRAM, DIRECTOR

Pursuant to Code of Alabama 1975, §§41-22-5(b) and 41-22-6(c)(2) a. and b.

I certify that the attached emergency amendment is a correct copy as promulgated and adopted on the 25th day of March 2020.

AGENCY NAME:	Alabama Department of Public Health
RULE NO. AND TITLE:	420-5-10-.16, ER Pharmacy Services
EFFECTIVE DATE OF RULE:	March 25, 2020
EXPIRATION DATE:	120 days
NATURE OF EMERGENCY:	During the Coronavirus Disease (COVID-19) emergency, in lieu of a pharmacist being required to visit a nursing facility to verify the destruction of drugs, this rule permits a nursing facility's nursing home administrator or a medical director to substitute for a pharmacist.
STATUTORY AUTHORITY:	Code of Alabama 1975, §§ 22-21-28 and 22-21-20

SUBJECT OF RULE TO BE ADOPTED ON PERMANENT BASIS _____ YES _X_ NO

NAME, ADDRESS, AND TELEPHONE NUMBER OF PERSON TO CONTACT FOR COPY OF RULE:

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MAR 25 2020
LEGISLATIVE SVC AGENCY

Signature of officer authorized to Promulgate and adopt rules and Regulations or his or her deputy

420-5-10-.16, ER, Pharmacy Services.

(1) The facility must provide routine and emergency drugs and biologicals to its residents, or obtain them under an agreement described in §483.75(h) of Title 42 Code of Federal Regulations revised 10/1/93.

(a) Procedures. A facility must provide pharmaceutical services (including procedures that assure the accurate acquiring, receiving, dispensing, and administering of all drugs and biologicals) to meet the needs of each resident.

(b) Service consultation. The facility must employ or obtain the services of a licensed pharmacist who-

1. Provides consultation on all aspects of the provision of pharmacy services in the facility;

2. Establishes a system of records of receipt and disposition of all controlled drugs in sufficient detail to enable an accurate reconciliation; and

3. Determines that drug records are in order and that an account of all controlled drugs is maintained and periodically reconciled.

(c) Drug regimen review.

1. The drug regimen of each resident must be reviewed at least once a month by a licensed pharmacist.

2. The pharmacist must report any irregularities to the attending physician and the director of nursing, and these reports must be acted upon.

(d) Storage of drugs and biologicals.

1. In accordance with State and Federal laws, the facility must store all drugs and biologicals in locked compartments under proper temperature controls and permit only authorized personnel to have access to the keys.

2. The facility must provide separately locked, permanently affixed compartments for storage of controlled drugs listed in Schedule II of the Comprehensive Drug Abuse Prevention and Control Act of 1976 and other drugs subject to abuse, except when the facility uses single unit package drug distribution

systems in which the quantity stored is minimal and a missing dose can be readily detected.

3. The facility must maintain readily traceable records of receipt and disposition of all controlled drugs.

(e) Destruction of Drugs.

1. The nursing facility develops policies and procedures for the destruction of drugs and biologicals.

2. Controlled substances and legend drugs dispensed to residents, that are unused because the medication is discontinued, or because the resident dies shall be destroyed within 30 days, except unused legend drugs may be donated to a charitable clinic pursuant to Alabama Administrative Code Chapter 420-11-11, et. seq.

3. Medications of residents transferred to a hospital may be retained until the resident is returned to the facility. Upon return of the resident to the facility, the physician's order will dictate whether or not the resident is to continue the same drug regimen as previously ordered. Medications not reordered by the physician must be destroyed.

4. Medications ordered to be used on an "as needed" basis shall be destroyed after 90 days if they have not been used during that period of time. Medications shall be destroyed upon expiration of the drug.

5. Both controlled substances and non-controlled substances may be destroyed on the premises or may be picked up by an environmental agency that provides such service. Drugs to be destroyed shall not be returned to the drug store for destruction.

6. Records must be completed and maintained by the facility that include:

(i) Name and address of the facility

(ii) Date of destruction/date drugs picked up

(iii) Method used in destruction (If picked up by an environmental agency, the record/receipt must indicate the proposed date and method of destruction.

(iv) Prescription number, name of drug store from which the medicine was dispensed, resident's name, name and strength of drug destroyed, amount destroyed and reason for destruction.

7. The pharmacist, administrator or medical director will verify that the list of drugs to be destroyed is accurate and with a Registered Nurse, will carry out destruction. Both will sign the destruction form indicating amounts listed are correct and have been destroyed. For destruction of controlled substances there shall be a third witness who may be a law enforcement official, management or supervisory personnel, i.e., administrator, LPN charge nurse, etc. If medications are to be picked up and destroyed by an environmental agency, the RN should verify the list of drugs to be destroyed and should obtain a signed copy of the destruction form as a receipt.

8. If records of destruction are maintained in resident's medical record, they must be retained for as long as the medical record is kept. If a separate file of destruction records is to be maintained, they must be retained for a period of not less than two years.

(f) Labeling of Drugs and Biologicals.

1. All containers of medicines and drugs shall be properly and plainly labeled, including name and strength of drug, resident's name, ordering physician, date of filling, directions for administration, prescription number, expiration date, number of tablets or capsules sent and any necessary auxiliary labels. The prescription label shall conform with any additional federal, state and local requirements.

2. Use of and labeling of generic drugs shall comply with State Board of Pharmacy requirements.

3. When authorized substitution of a drug takes place, there will be established policies and procedures to provide accurate identification.

4. Over-the-counter (non-prescription) medicines shall be plainly labeled with the name and strength of the drug. Additional labeling information may be at the discretion of the facility as related in its policies and procedures except that manufacturer's labeling information must be present in the absence of prescription labeling.

5. The contents of all individual prescriptions shall be kept in the original dispensed container bearing the original prescription label.

6. Procedures shall be developed to assure proper control and labeling for medications provided a resident upon leaving the facility on a temporary absence.

7. Unit dose medications shall be packaged according to an acceptable format to include product name, strength, control number, and expiration date. Procedures for utilization of the system used are developed and approved by administration, nursing and pharmacy personnel and must comply with federal and state regulations.

(g) Emergency medication kits will be kept in accordance with Chapter 680-x-2 of the Alabama State Board of Pharmacy Rules and Regulations governing institutional pharmacies.

1. Emergency kits may contain controlled substances utilizing the following conditions:

(i) The source from which a long term care facility may obtain controlled substances must be a DEA registered pharmacy or practitioner.

(ii) There shall be a maximum three day supply of any controlled substance stocked in the emergency kit.

(iii) The responsibility for proper control and accountability of the emergency kit shall rest with both the nursing facility and the DEA registrant providing the drug. The facility and the drug provider shall maintain complete and accurate records of the controlled substances placed in the emergency kit including receipt and disposition of the drugs as well as destruction of unused or outdated drugs where appropriate.

(iv) Adequate security measures shall be provided for the emergency kit (if the controlled drugs are to be maintained within the kit) or the drugs (if they are to be maintained in a separate area) to include double locks. Access to emergency drugs shall be limited to those with an actual need, i.e., medication nurse and/or director of nurses and the pharmacist.

(v) Controlled drugs maintained for emergency use may be used only upon the written or telephone orders of the attending physician, who must sign a telephone order as soon as possible after giving it.

(vi) Violations in these rules and regulations may result in the revocation, denial or suspension of the privilege of maintaining controlled substance drugs in the emergency kit.

(h) "Stat" Medicine Cabinets

1. Each nursing 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 State Board of Health. The following rules apply to such a cabinet:

(i) There shall be a minimum number of doses of any medication in the "stat" cabinet based upon the established needs of the facility.

(ii) There must be a list of contents, approved by the nursing facility, giving the name and strength of the drug and the quantity of each.

(iii) 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.

(iv) There shall be written procedures for utilization of the "stat" medicine cabinet with provisions for prompt replacement of used items.

(v) 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.

Author: Patricia E. Ivie, Dennis Blair
Statutory Authority: Code of Ala. 1975, §§22-21-20, et seq.
History: Repealed and Replaced: Filed July 19, 1996; effective August 23, 1996. **Amended:** Filed June 23, 2004; effective July 28, 2004. Filed July 19, 1996. **Amended:** Emergency Rule Filed March 25, 2020; effective March 25, 2020.