

ARKANSAS REGISTER

Transmittal Sheet

* Use only for **FINAL** and **EMERGENCY RULES**



Secretary of State

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For Office

Use Only:

Effective Date _____ Code Number _____

Name of Agency Arkansas State Board of Pharmacy

Department _____

Contact John Kirtley-Executive Director E-mail john.kirtley@arkansas.gov Phone (501)-682-0192

Statutory Authority for Promulgating Rules 17-92-205 (A)

Rule Title: Regulation 5- Long Term care Facilities

Intended Effective Date

(Check One)

☐ Emergency (ACA 25-15-204)

☐ 30 Days After Filing (ACA 25-15-204)

☒ Other 7/22/15 pend Leg Approval
(Must be more than 30 days after filing date.)

Legal Notice Published

Final Date for Public Comment

Reviewed by Legislative Council

Adopted by State Agency

Date

May 10, 2015

Jun 9, 2015

Pending

6/9/2015

Electronic Copy of Rule e-mailed from: (Required under ACA 25-15-218)

John Kirtley john.kirtley@arkansas.gov

6/15/2015

Contact Person

E-mail Address

Date

CERTIFICATION OF AUTHORIZED OFFICER

I Hereby Certify That The Attached Rules Were Adopted
In Compliance with the Arkansas Administrative Act. (ACA 25-15-201 et. seq.)

Signature

(501) 682-0190

Phone Number

john.kirtley@arkansas.gov

E-mail Address

Executive Director

Title

Jun 15, 2015

Date

FINANCIAL IMPACT STATEMENT

PLEASE ANSWER ALL QUESTIONS COMPLETELY

DEPARTMENT Arkansas State Board of Pharmacy

DIVISION _____

PERSON COMPLETING THIS STATEMENT John Clay Kirtley, PharmD, Executive Director

TELEPHONE NO. 501-682-0190` **FAX NO.** 501-682-0195 **EMAIL:** john.kirtley@arkansas.gov

To comply with Ark. Code Ann. § 25-15-204(e), please complete the following Financial Impact Statement and file two copies with the questionnaire and proposed rules.

SHORT TITLE OF THIS RULE Regulation 5- Long Term Care Facilities

1. Does this proposed, amended, or repealed rule have a financial impact? Yes ☐ No ☒
2. Is the rule based on the best reasonably obtainable scientific, technical, economic, or other evidence and information available concerning the need for, consequences of, and alternatives to the rule? Yes ☒ No ☐
3. In consideration of the alternatives to this rule, was this rule determined by the agency to be the least costly rule considered? Yes ☒ No ☐

If an agency is proposing a more costly rule, please state the following:

- (a) How the additional benefits of the more costly rule justify its additional cost;

- (b) The reason for adoption of the more costly rule;

- (c) Whether the more costly rule is based on the interests of public health, safety, or welfare, and if so, please explain; and;

- (d) Whether the reason is within the scope of the agency's statutory authority; and if so, please explain.

4. If the purpose of this rule is to implement a federal rule or regulation, please state the following:

- (a) What is the cost to implement the federal rule or regulation?

Current Fiscal Year

General Revenue	<u>0</u>
Federal Funds	<u>0</u>
Cash Funds	<u>0</u>
Special Revenue	<u>0</u>
Other (Identify)	<u>0</u>

Next Fiscal Year

General Revenue	<u>0</u>
Federal Funds	<u>0</u>
Cash Funds	<u>0</u>
Special Revenue	<u>0</u>
Other (Identify)	<u>0</u>

Total 0 _____

Total 0 _____

(b) What is the additional cost of the state rule?

Current Fiscal Year

General Revenue	0
Federal Funds	0
Cash Funds	0
Special Revenue	0
Other (Identify)	0
Total	0

Next Fiscal Year

General Revenue	0
Federal Funds	0
Cash Funds	0
Special Revenue	0
Other (Identify)	0
Total	0

5. What is the total estimated cost by fiscal year to any private individual, entity and business subject to the proposed, amended, or repealed rule? Identify the entity(ies) subject to the proposed rule and explain how they are affected.

Current Fiscal Year

\$ 0 _____

Next Fiscal Year

\$ 0 _____

6. What is the total estimated cost by fiscal year to state, county, and municipal government to implement this rule? Is this the cost of the program or grant? Please explain how the government is affected.

Current Fiscal Year

\$ 0 _____

Next Fiscal Year

\$ 0 _____

7. With respect to the agency's answers to Questions #5 and #6 above, is there a new or increased cost or obligation of at least one hundred thousand dollars (\$100,000) per year to a private individual, private entity, private business, state government, county government, municipal government, or to two (2) or more of those entities combined?

Yes ☐ No ☒

If YES, the agency is required by Ark. Code Ann. § 25-15-204(e)(4) to file written findings at the time of filing the financial impact statement. The written findings shall be filed simultaneously with the financial impact statement and shall include, without limitation, the following:

- (1) a statement of the rule's basis and purpose;
- (2) the problem the agency seeks to address with the proposed rule, including a statement of whether a rule is required by statute;
- (3) a description of the factual evidence that:
 - (a) justifies the agency's need for the proposed rule; and

- (b) describes how the benefits of the rule meet the relevant statutory objectives and justify the rule's costs;
- (4) a list of less costly alternatives to the proposed rule and the reasons why the alternatives do not adequately address the problem to be solved by the proposed rule;
 - (5) a list of alternatives to the proposed rule that were suggested as a result of public comment and the reasons why the alternatives do not adequately address the problem to be solved by the proposed rule;
 - (6) a statement of whether existing rules have created or contributed to the problem the agency seeks to address with the proposed rule and, if existing rules have created or contributed to the problem, an explanation of why amendment or repeal of the rule creating or contributing to the problem is not a sufficient response; and
 - (7) an agency plan for review of the rule no less than every ten (10) years to determine whether, based upon the evidence, there remains a need for the rule including, without limitation, whether:
 - (a) the rule is achieving the statutory objectives;
 - (b) the benefits of the rule continue to justify its costs; and
 - (c) the rule can be amended or repealed to reduce costs while continuing to achieve the statutory objectives.

REGULATION 5 - LONG-TERM-CARE FACILITIES

05-00—NURSING HOME CONSULTANTS

05-00-0001—DEFINITIONS

(a) Consultant pharmacist in charge

A nursing home consultant pharmacist in charge, means a pharmacist who assumes the ultimate responsibility to ensure adherence to all laws and regulations concerning pharmacy services in a nursing home.

The consultant pharmacist in charge is required to perform a majority of the consultative services provided in the nursing home and must abide by, pharmacy law and regulations, and the policy and procedures of the nursing home.

(b) Consultant pharmacist at large

A nursing home consultant pharmacist at large is a pharmacist who practices as a consultant in one or more homes to assist the consultant pharmacist in charge.

(c) Consultant pharmacist shall mean consultant pharmacist in charge and consultant pharmacist at large collectively. (Reg. Revised 02/11/2003 and 7/10/2009)

05-00-0002— GENERAL REQUIREMENTS

(a) Any pharmacist desiring to serve as a consultant pharmacist for a nursing home shall submit an application on a form provided by the Board of Pharmacy and secure a nursing home consultant permit which shall be posted in the home(s) for which he or she is consulting.

(b) Before a pharmacist can be licensed as a consultant pharmacist, he or she must satisfactorily complete a test on requirements developed by the Board to measure the knowledge of pharmaceutical duties and responsibilities in a nursing home and certify that he or she has read and understands these regulations and will abide by them.

(c) For renewal of a nursing home consultant pharmacist permit, it is required that, in addition to the continuing education required for all pharmacists, consultant pharmacists shall annually obtain three (3) hours of continuing education specifically related to his/her role as a consultant in a nursing home. Each consultant pharmacist shall report this continuing education on the renewal form approved by the Board. (Reg. Revised 02/11/2003, 11/1/2007 and 7/10/2009)

05-00-0003—RESPONSIBILITIES

Consultant pharmacists in a nursing home are involved in the following areas of pharmaceutical care which include drug storage, distribution and utilization in that nursing home:

(a) Supervision of Services

(1) The consultant pharmacist(s) shall develop, coordinate, and supervise all pharmaceutical services. The consultant pharmacist for the nursing home must ensure that pharmacist consultation is available on a 24-hours-per-day, 7-days-per-week basis. Consultant pharmacists shall devote a sufficient number of hours based upon the needs of the facility, during regularly scheduled visits to carry out these responsibilities.

(2) Consultant pharmacists shall assist the nursing home in developing procedures to ensure the provision of emergency drugs, and shall report to the Board of Pharmacy any pharmacy refusing to provide medication for the pharmacy's regular patients in the nursing home on a 24-hours-per-day, 7-days-per-week basis.

- (3) The consultant pharmacist(s) shall provide written consultation on compliance with federal and state laws governing legend drugs (including controlled substances).
 - (4) The consultant pharmacist(s) shall be knowledgeable of all laws and regulations pertaining to nursing homes and shall communicate with the state agencies involved with enforcement and regulation of nursing homes.
 - (5) The consultant pharmacist(s) shall spend sufficient time to evaluate discontinued or other unused medication for destruction or donation, destroy unused medication not intended for donation, check entries in a bound, numbered controlled drugs book, process unused medication for donation as provided in ACA § 17-92-1101 et seq. and Board Regulation 04-07-0006, and make general observations at the nursing stations.
 - (6) An individualized resident record shall indicate the day the consultant pharmacist(s) visited the home, a brief statement of purpose, finding, and actions.
- (b) Control and accountability of all legend drugs (including controlled substance)
- (1) The consultant pharmacist develops written procedures for control and accountability of all drugs and biologicals throughout the facility and supervises the implementation of these procedures.
 - (2) Only approved drugs and biologicals are used in the facility and shall be dispensed in compliance with federal and state laws. Records of receipt and disposition of all controlled drugs shall be maintained in sufficient detail to enable an accurate reconciliation. The consultant pharmacist shall determine that drug records are in order and that an account of all controlled drugs is maintained and reconciled.
 - (3) The consultant pharmacist(s) shall establish procedures to ensure that:
 - (A) All legend drugs and controlled substances must be stored in a secured location and appropriately locked.
 - (B) Proper records of receipt and administration of controlled drugs must be maintained for review by the consultant pharmacist.
 - (C) Non-controlled legend drugs.
 - (i) Drugs to be destroyed. The consultant pharmacist shall cause a designated nurse to record all discontinued and outdated non-controlled legend drugs in a bound and numbered drug destruction book when the drug is discontinued or becomes outdated. The consultant pharmacist(s) and a designated nurse shall jointly inventory and destroy the drugs and each shall sign the drug destruction book to document the destruction of these drugs.
 - (ii) Drugs to be donated. The consultant pharmacist shall cause all drugs that are designated for donation to charitable clinics licensed by the Board under Regulation 04-03-0004 and ACA § 17-92-1101 et seq., to be processed in accordance with Board Regulation 04-07-0006.
 - (D) Controlled drugs. All discontinued and outdated controlled drugs shall be signed out of narcotic inventory at the time of discontinuation or at the point of becoming outdated and shall be entered on the Arkansas Department of Health's *Report of Drugs Surrendered* form by a designated nurse and the director of nurses. Said outdated or discontinued drugs shall be secured in the office of the director of nurses pursuant to paragraph 3(A) of this section until sent to the Department of Health. The consultant pharmacist shall confirm the quantity of drugs segregated for shipment to the Arkansas Department of Health is accurately entered on the inventory of controlled substances recorded on the *Report of Drugs Surrendered* form.

- (E) The controlled drugs shall be sent to the Arkansas Department of Health by licensed facility personnel, to be designated by the administrator, at least quarterly. The Arkansas Department of Health's receipt of drugs destroyed shall be reconciled with the nurse/pharmacist inventory. The consultant pharmacist shall make recommendations ensuring that the facility conforms to the policies and procedures established by the Division of Pharmacy Services and Drug Control, Arkansas Department of Health.
- (c) Patient Drug Regimen Review
 - (1) The primary duty of the consultant pharmacist(s) to the patients' concerns is to apply his or her expertise on drugs to the patient's specific situation.
 - (2) State and federal regulations shall be the minimum standards for an adequate drug regimen review.
 - (3) Additionally, the consultant pharmacist shall routinely review each patient's chart and:
 - (A) Ascertain that patient history and drug utilization is being properly recorded.
 - (B) Review drug usage (including O.T.C. and prescriptions).
 - (C) Review patient compliance with drug regimen.
 - (D) Review drug allergies or sensitivities.
 - (E) Determine whether the patient is predisposed to side effects due to disease, illness, or age.
 - (F) Determine whether potential exists for significant drug interaction.
 - (G) Develop procedures to monitor patients' records for signs that indicate abuse or misuse of drugs by the patient or individuals.
 - (H) Make recommendations regarding drug therapy to the physician, nurse or other persons involved in the patient's care.
 - (I) Communicate to the facility, procedures that ensure adequate pharmacy services are available for emergencies that might develop in the nursing home for a specific patient.
 - (J) Promote pharmacists' ability and knowledge to all persons involved in patient care and to offer assistance in solving specific problems relating to patient drug regimen.
 - (4) A consultant pharmacist(s) shall quarterly in ICF/MR and assisted living (level II) facilities and monthly in nursing homes, review each patient's medication record, consult with and provide a written report of findings to the director of nursing or the patient's physician
- (d) Labeling of drugs and biologicals and proper storage
 - (1) All legend drugs (including controlled substances) on the premises of a nursing home except for the emergency kit maintained pursuant to Board regulations 05-00-0004 and 05-00-0005, shall be stored under lock pursuant to Arkansas Department of Health regulations, and always be in a properly labeled container as dispensed upon a prescription by the pharmacy of the patient's choice.
 - (2) It is the duty of the consultant pharmacist(s) to ascertain that medications are properly labeled, properly stored, refrigerated when needed, expiration dates routinely checked, and that appropriate accessory and cautionary instructions are on all medications when required.
- (e) Quality assurance and patient assessment committee
 - (1) A consultant pharmacist(s) shall be a member of the quality assurance and patient assessment committee (or its equivalent) and make official reports to this committee as often as needed to ensure quality pharmaceutical care.
 - (2) The consultant pharmacist shall ensure that there are written policies and procedures for safe and effective drug therapy, distribution, control, and use.
 - (3) The policies and procedures shall include and are not limited to:

- (A) Stop order policies or other methods to ensure appropriateness of continued drug therapy.
- (B) Maintaining the contents of the emergency kit in compliance with Board regulation 05-00-0005.
- (C) Policies for the safe procurement, storage, distribution, and use of drugs and biologicals. (10/9/80, Reg. Revised 2/17/82, 6/25/83, 10/12/93, 02/11/2003, 6/23/05 and 7/10/2009)

05-00-0004—EMERGENCY KITS FOR LONG-TERM-CARE FACILITIES

- (a) With recognition of D.E.A.'s statement of policy regarding emergency kits for long-term-care facilities and other law applicable to non-controlled legend drugs, the following regulation is adopted to permit controlled substances and non-controlled legend drugs to be stored in emergency kits in long-term-care facilities in Arkansas.

Requirements

- (1) All contents of the emergency kit will be provided by one pharmacy designated by the long-term-care facility. This pharmacy must be properly registered with D.E.A.
- (2) The emergency kit shall be properly sealed, stored, and accessible only to authorized personnel.
- (3) The emergency kit contents shall only be administered by authorized personnel acting on order of a physician in compliance with 21 CFR 1306.11 and 21 CFR 1306.21.
- (4) The categories of drugs that may be contained in an emergency kit are identified in Board regulation 05-00-0005. The contents of the kit shall be determined by the medical director, director of nurses and consultant pharmacist at the long-term-care facility. Any exceptions to the established standard categories must be approved by the Board of Pharmacy. A list of contents shall be kept in the kit.
- (5) The facility's licensed consultant pharmacist shall be responsible for maintaining the nursing home's emergency kit contents in compliance with Board regulation 05-00-0005 and the facility's licensed consultant pharmacist shall check the kit monthly for outdated drugs, etc.
- (6) All drugs administered from the kit will be replaced within 72 hours by the designated provider pharmacy based on a prescription for the patient to whom the drugs were administered.
- (7) Violation of this regulation 05-00-0001 through 05-00-0005 shall be just cause for the Board to impose appropriate disciplinary action.
- (8) Emergency kit drugs shall be of such a nature that the absence of such drugs would detrimentally affect the health of the patient.
- (9) Before an out of state pharmacy may supply an emergency kit to an Arkansas long-term care facility, it must provide an affidavit on a form supplied by the Board that it will comply with Arkansas law regarding emergency kits. If applicable, an out of state pharmacy will also be subject to reciprocal restrictions as are imposed by its home state on out of state pharmacies. (10/14/1981 and 7/27/2011)
- (b) Recognizing the emergency and or unanticipated need for certain legend (non-controlled) drugs to be available to nurses employed by Arkansas licensed home health agencies, an Arkansas licensed pharmacy may provide certain medications under the following conditions:
 - (1) A written contract must exist between the Arkansas licensed home health agency and the Arkansas licensed pharmacy, and this must be available for review by the Board of Pharmacy upon request.

- (2) The legend drugs remain the property of, and under the responsibility of, the Arkansas licensed pharmacy.
- (3) All medications shall be administered only on physician's orders and any medication administered from the nurse's supply must be recorded as a prescription by the pharmacy prior to the pharmacy's replacement of the drug in the emergency supply.
- (4) All medication records must be maintained as required by law, and out of date drugs must be properly destroyed by the pharmacy.
- (5) The emergency supply may be carried by each nurse or an emergency kit may be provided for each patient's home.
- (6) Careful patient planning shall be a cooperative effort between the pharmacy and the nursing agency to make all medications available and this emergency supply shall only be used for emergency or unanticipated needs and shall not become a routine source or supply.
- (7) Only the following medications can be supplied for emergency use by licensed home health agencies under this paragraph by the pharmacy in sufficient but limited quantities:
 - (A) Heparin flush: pediatric (one strength)
 - (B) Heparin flush: adult (one strength)
 - (C) Sterile water for injection: small volume
 - (D) Sodium chloride for injection: small volume
 - (E) Adrenalin (epinephrine) injection: single dose only
 - (F) Benadryl (diphenhydramine) injection : single dose only

Note: For heparin, adrenaline and benadryl, all patients shall have a precalculated dose.

- (G) If a container is opened and partially used, the unused portion shall be immediately discarded.
- (8) The pharmacy is responsible to ensure compliance with this regulation, and any abuse or misuse of the intent of this regulation shall be immediately reported to the Board of Pharmacy.
- (9) The pharmacy and the agency shall develop policy and procedures to address storage conditions for medications. (Revised 10/12/93, 10/14/97, 02/11/2003, 6/23/05, and 7/10/2009)

05-00-0005—DRUG CATEGORIES FOR EMERGENCY KITS IN LONG-TERM CARE FACILITIES

The following is a list of categories of drugs which are acceptable in emergency kits in long-term-care facilities in accordance with this regulation of the Arkansas State Board of Pharmacy. In every instance where injectables are indicated, only single-dose injectables are acceptable.

- (a) Analgesics, controlled drugs
 - (1) Schedule 2:
 - Limit: two (2)
 - Maximum quantity: two (2)
 - (2) Schedule 3, 4 or 5
 - Limit: three (3)
 - Maximum quantity: if oral: six (6);
if injectable: two (2)
- (b) Antibiotics
 - (1) Oral doses:

- Limit: five (5)
- Maximum quantity: five (5)
- (2) Parenteral doses:
 - Limit: three (3)
 - Maximum quantity: one (1)
- (c) Anticoagulant
 - Limit: one (1)
 - Maximum quantity: three (3)
- (d) Antidiarrheals
 - Limit: one (1)
 - Maximum quantity: ten (10)
- (e) Antihistamine Injectables
 - Limit: two (2)
 - Maximum quantity: four (4)
- (f) Antinauseants
 - Limit: three (3)
 - Maximum quantity: four (4)
- (g) Antipsychotic injectables
 - Limit: two (2)
 - Maximum quantity: four (4)
- (h) Anxiolytics
 - Limit: one (1)
 - Maximum quantity: four (4)
- (i) Cardiac life support medications
 - (1) Injectables:

The content and quantity of injectable cardiac life support medications is to be recommended by the quality assurance and patient assessment committee at the long-term-care facility and approved by the Executive Director of the Arkansas State Board of Pharmacy.
 - (2) Hypertensive crisis medications:
 - Limit: three (3)
 - Maximum quantity: eight (8)*
- *When nitroglycerine sublingual is used: quantity –1 bottle of 25
- (j) Coagulants
 - Limit: one (1)
 - Maximum quantity: one (1)
- (k) Hypoglycemics
 - Limit: three (3)
 - Maximum quantity: two (2)
- (l) Injectable seizure control medications
 - Limit: two (2)
 - Maximum quantity: four (4)
- (m) Large volume parenterals
 - Limit: three (3)
 - Maximum quantity: two (2)
- (n) Poison control

- Limit: two (2)
 - Maximum quantity: two (2)
 - (o) Breathing Medication
 - Limit (1)
 - Maximum quantity: two (2)
 - (p) Corticosteroid
 - Limit (1)
 - Maximum quantity: two (2)
- (Revised 02/11/2003, 11/1/2007, 7/10/2009 and 7/22/2015)

05-00-0006—DRUG CATEGORIES FOR EMERGENCY KITS IN HOSPICE CARE FACILITIES.

The following is a list of categories of drugs which are acceptable in emergency kits in licensed in-patient hospice facilities in accordance with this regulation of the Arkansas State Board of Pharmacy. The Board shall set guidelines for specific quantities of approved medications which will be reviewed periodically. The provision or presence of an emergency kit in an in-patient hospice facility does not waive the requirements of board regulation 04-00-0006 which requires any pharmacy providing prescription drugs to one or more patients in a nursing home or other institution to provide emergency prescription services for those patients and to provide information to the nursing home or institution indicating how the pharmacists can be reached after pharmacy hours.

- (a) Analgesics, controlled drugs
 - (b) Antihistamine Injectables
 - (c) Antinauseants
 - (d) Antipsychotic Medications
 - (e) Anxiolytics
 - (f) Injectable seizure control medications
 - (g) Corticosteroids
 - (h) Anticholinergic medications
 - (i) Opioid antagonist
 - (j) Other medications as approved by the Board
- (5/31/2014, Revised 7/22/2015)