ARKANSAS REGISTER

Transmittal Sheet

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Effective Date _____ Code Number _____

Name of Agency Arkansas Department of Health

Department Center for Health Protection/Pharmacy Services

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Statutory Authority for Promulgating Rules A.C.A. 20-13-403--408

Rule Title: Rules and Regulations Pertaining to Public Access to Auto-Injectable Epinephrine

Intended Effective Date
(Check One)

- ☐ Emergency (ACA 25-15-204)
- ☐ 10 Days After Filing (ACA 25-15-204)
- ☑ Other November 15, 2016 (Must be more than 10 days after filing date.)

	Date
Legal Notice Published	April 20, 2016
Final Date for Public Comment	May 24, 2016
Reviewed by Legislative Council	August 16, 2016
Adopted by State Agency	October 20, 2016

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

S. Elizabeth Harris — elizabeth.harris@arkansas.gov — 10/28/16

Contact Person | E-mail Address | Date

FILED
ARKANSAS REGISTER DIV.
2016 OCT 28 AM 10:18
MARK MARTIN
SECRETARY OF STATE
STATE OF ARKANSAS

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

501-661-28789 — robert.brech@arkansas.gov

Phone Number | E-mail Address

General Counsel

Title

October 27, 2016

Date

RECEIVED
OCT 28 2016
BUREAU OF LEGISLATIVE RESEARCH

Revised 7/2015 to reflect new legislation passed in the 2015 Regular Session (Act 1258). This act changed the effective date from 30 days to 10 days after filing the rule.

RULES AND REGULATIONS PERTAINING TO PUBLIC ACCESSS TO AUTO-INJECTABLE EPINEPHRINE

CENTER FOR HEALTH PROTECTION

Effective November 15, 2016

By the Arkansas State Board of Health
Arkansas Department of Health
Little Rock, Arkansas
Nathaniel Smith, MD, MPH

Rules and Regulations Pertaining to
Public Access to Auto-Injectable Epinephrine

Table of Contents

SECTION I – Authority

The following regulations have been hereby promulgated pursuant to Act 1108 of 2015, codified at Arkansas Code §§ 20-13-403 and 20-13-408.

SECTION II – Purpose

The purpose of these regulations is to expand public access to auto-injectable epinephrine and to expand immunity to include an authorized entity that provides prescribed auto-injectable epinephrine.

SECTION III – Definitions

As used in this section:

(1) "Authorized entity" means an entity or organization at which or in connection with which allergens capable of causing an anaphylactic reaction may be present, including without limitation:

(A) A restaurant;

(B) An amusement park;

(C) A sports arena;

(D) Day Care;

(E) Colleges and Universities;

(F) Before and After School programs; and

(G) Summer and recreational camps

(2) "Auto-injectable epinephrine" means a single-use device used for the automatic injection of a premeasured dose of epinephrine into the human body;

(3) "Certificate" means a certificate issued under this subchapter to authorize the receipt, possession, and administration of prescribed auto-injectable epinephrine;

(4) "Expected user" means an authorized entity's employee or agent who is responsible for the storage, maintenance, and general supervision of auto-injectable epinephrine acquired by the authorized entity;

(5) "Healthcare professional" means a licensed physician, chiropractor, dentist, optometrist, podiatrist, or other licensed healthcare professional;

(6) "Physician" means an individual licensed to practice medicine in the State of Arkansas under the Arkansas Medical Practices Act, § 17-95-201 et seq., § 17-95-301 et seq., and § 17-95-401 et seq.; and

(7) "Self-administration" means a person's discretionary use of auto-injectable epinephrine pursuant to a prescription or written direction from a healthcare professional.

SECTION IV – Eligibility for Certificate

A person may receive a certificate under this subchapter only if the person:

(1) Is eighteen (18) years of age or older;

(2) Has, or reasonably expects to have, regular contact with at least one (1) other person as a result of the person's relationship or occupational or volunteer status, including without limitation:

(A) A parent;
(B) A camp counselor;
(C) A scout leader;
(D) A school nurse, school teacher, or other school employee;
(E) A forest ranger;
(F) A tour guide;
(G) A chaperone; or
(H) An authorized entity; and

(3) Has been properly instructed by a physician or has completed an anaphylaxis training program conducted by a nationally recognized organization experienced in training laypersons in emergency health treatment or other person approved by the Department of Health. The instruction shall minimally include recognition of the symptoms of systemic reactions to insect stings and other allergic reactions and the proper administration of an injection of epinephrine.

(4) A certificate issued pursuant to these Rules and Regulations expires two (2) years after the date of issuance. A new certificate may be issued to the individual upon proof of completion of the knowledge and skills course described in Section VIII of these Rules.

SECTION V – Authority of Certificate Holder

The certificate also shall authorize the certificate holder to possess, provide, and administer in an emergency situation when a physician is not immediately available - the prescribed epinephrine to a person who:

(1) Has contact with the certificate holder as a result of the certificate holder's relationship or occupational or volunteer status under § 20-13-404(2); and

(2) Appears to be suffering a severe adverse reaction to an insect sting or other allergic reaction.

SECTION VI – Immunity

(A) A person or entity that in good faith renders emergency care or treatment by the use of auto-injectable epinephrine is immune from civil liability resulting from:

(1) The emergency care or treatment; and

(2) Any good faith act or omission to provide or arrange for further medical treatment.

(B) A person or entity granted immunity under subsection (a) of this section includes without limitation:

(1) A physician or medical facility that distributes auto- injectable epinephrine or issues a certificate under this subchapter;

(2) A person or entity that provides auto-injectable epinephrine training to an expected user or authorized entity;

(3) A person or entity responsible for the location where the auto-injectable epinephrine is located or used; and

(4) A certificate holder.

(C) The immunity under subsection (a) of this section does not apply if the cause of action results from gross negligence or willful or wanton misconduct.

(D) Immunity under this section is in addition to the immunity provided to an individual acting as a "Good Samaritan" under the provisions of § 17-95-101.

SECTION VII – Administration of Act

(A) The Department of Health shall prepare a certificate form for use by a physician as authorized under this subchapter.

(1) A copy of a certificate issued under this subchapter shall be forwarded by the issuing physician to the department.

(2) The department shall maintain the copy on file and make it available for public inspection.

(B) Certificates of training issued pursuant to Section IV (3) will be accepted and kept on file by the Arkansas Department of Health.

SECTION VIII - Auto-injectable epinephrine use by an authorized entity

(A) In order to ensure the public health and safety, an authorized entity that acquires auto-injectable epinephrine shall ensure that:

(1) An expected user:

(a) Completes appropriate knowledge and skills courses at least one (1) time every two (2) years in anaphylaxis and auto-injectable epinephrine use; and

(b) Obtains a certificate under this subchapter;

(2) The auto-injectable epinephrine is maintained according to the manufacturer's operational guidelines and instructions in a locked, secure location; and

(3) A person who renders emergency care or treatment to a person having an anaphylactic reaction by using auto-injectable epinephrine activates the emergency medical services system as soon as possible and immediately reports the use of auto-injectable epinephrine to the medical provider responding to the emergency.

(B) An authorized entity and its expected users may:

(1) Obtain a prescription in the name of the authorized entity for epinephrine auto-injectors and acquire epinephrine auto-injectors under the prescription;

(2) Provide auto-injectable epinephrine for immediate self-administration to an individual who the authorized entity or expected user believes in good faith is experiencing anaphylaxis, regardless of whether the individual has a prescription for auto-injectable epinephrine or has previously been diagnosed with an allergy;

(3) Administer auto-injectable epinephrine directly to an individual who the authorized entity or expected user believes in good faith is experiencing anaphylaxis, regardless of whether the individual has a prescription for auto-injectable epinephrine or has been previously diagnosed with an allergy.

(C) An authorized entity that possesses and makes available auto- injectable epinephrine shall:

(1) Submit to the Department of Health a report of each incident on the authorized entity's premises in which the authorized entity provides or administers auto-injectable epinephrine. The report shall include the following:

(a) the name and address of the authorized entity;
(b) the name and certificate number of the person administering auto-injectable epinephrine;
(c) the age of the person receiving the injection; and
(d) the name of the emergency medical service contacted after the injection was administered.

The department shall annually publish a report that summarizes and analyzes the reports submitted under this subdivision; and

(2) Notify an agent of emergency communications, 911, or vehicle dispatch center of the existence, location, and type of auto-injectable epinephrine.

CERTIFICATION

I hereby certify that the foregoing Rules and Regulations Pertaining to Public Access to Auto-Injectable Epinephrine were duly adopted by the Arkansas State Board of Health on the 20th day of October, 2016.

(*Original signed on October 20, 2016*)
Nathaniel Smith, MD, MPH
Secretary, State Board of Health

FINANCIAL IMPACT STATEMENT

PLEASE ANSWER ALL QUESTIONS COMPLETELY

DEPARTMENT Arkansas Department of Health
DIVISION Center for Health Protection
PERSON COMPLETING THIS STATEMENT Elizabeth Harris
TELEPHONE NO. (501) 280-4034 **FAX NO.** (501) 661-2357 **EMAIL:** sarah.harris@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 Rules and Regulations Pertaining to Public Access to Auto-Injectable Epinephrine

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		**Next Fiscal Year**	
General Revenue	0	General Revenue	0
Federal Funds	0	Federal Funds	0
Cash Funds	0	Cash Funds	0
Special Revenue	0	Special Revenue	0
Other (Identify)	0	Other (Identify)	0

Total	0	Total	0

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

Current Fiscal Year		Next Fiscal Year	
General Revenue	0	General Revenue	0
Federal Funds	0	Federal Funds	0
Cash Funds	0	Cash Funds	0
Special Revenue	0	Special Revenue	0
Other (Identify)	0	Other (Identify)	0
Total	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	Next Fiscal Year
$ 0	$ 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	Next Fiscal Year
$ 0	$ 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.