Proposed Rulemaking

~~Title~~Rules for Public Access to Epinephrine

Promulgated by:
Department of Health

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Title 20. Public Health and Welfare

Chapter I. Generally, Department of Health

Subchapter H. Drugs

Part 201. Public Access to ~~Auto-Injectable~~ Epinephrine

Subpart 1. Generally

20 CAR § 201-101. Purpose.

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

20 CAR § 201-102. Definitions.

As used in this part:

(1) "Advanced Practice Registered Nurse" means an individual licensed to deliver healthcare services as an advanced practice registered nurse in the state of Arkansas under Arkansas Code §17-87-101, et seq.;

~~(1)~~(2) "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; and

(H) School;

~~(2)~~(3) "Auto-injectable epinephrine" means a single-use device used for the automatic injection of a premeasured dose of epinephrine into the human body;

~~(3)~~(4) "Certificate" means a certificate issued under the Insect Sting and Other Allergic Reactions Emergency Treatment Act, Arkansas Code § 20-13-401 et seq., to authorize the receipt, possession, and administration of prescribed ~~auto-injectable~~ epinephrine;

(5) "Epinephrine" means a neuro transmitter and hormone that has been approved by the United States Food and Drug Administration for the treatment of anaphylaxis. Epinephrine shall only include auto-injectable epinephrine and epinephrine nasal spray;

~~(4)~~(6) "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)~~(7) "Healthcare professional" means a licensed physician, chiropractor, dentist, optometrist, podiatrist, or other licensed healthcare professional;

~~(6)~~(8) "Physician" means an individual licensed to practice medicine in the State of Arkansas under the Arkansas Medical Practices Act, Arkansas Code § 17-95-201 et seq., Arkansas Code § 17-95-301 et seq., and Arkansas Code § 17-95-401 et seq.; ~~and~~

(9) "Physician assistant" means an individual licensed to provide healthcare services in the State of Arkansas under Arkansas Code § 17-105-101 et seq.; and

~~(7)~~(10) "Self-administration" means a person's discretionary use of ~~auto-injectable~~ epinephrine pursuant to a prescription or written direction from a healthcare professional.

20 CAR § 201-103. Eligibility for certificate.

(a) A person may receive a certificate under the Insect Sting and Other Allergic Reactions Emergency Treatment Act, Arkansas Code § 20-13-401 et seq., 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)(A) Has been properly instructed by a physician, physician assistant, or advanced practice registered nurse, or has completed an anaphylaxis training program conducted by a nationally recognized organization experienced in training laypersons in emergency health treatment or other persons approved by the Department of Health.

(B) 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.

(b)(1) A certificate issued pursuant to this part expires two (2) years after the date of issuance.

(2) A new certificate may be issued to the individual upon proof of completion of the knowledge and skills course described in 20 CAR § 201-107.

20 CAR § 201-104. 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 Arkansas Code § 20-13-404(2); and

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

20 CAR § 201-105. 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, physician assistant, advanced practice registered nurse, or medical facility that distributes auto-injectable epinephrine or issues a certificate under the Insect Sting and Other Allergic Reactions Emergency Treatment Act, Arkansas Code § 20-13-401 et seq.;

(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 Arkansas Code § 17-95-101.

20 CAR § 201-106. Administration of act.

(a)(1) The Department of Health shall prepare a certificate form for use by a physician as authorized under the Insect Sting and Other Allergic Reactions Emergency Treatment Act, Arkansas Code § 20-13-401 et seq.

(2) A copy of a certificate issued under the Insect Sting and Other Allergic Reactions Emergency Treatment Act, shall be forwarded by the issuing physician, physician assistant, or advanced practice registered nurse to the department.

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

(b) Certificates of training issued pursuant to 20 CAR § 201-103(3) will be accepted and kept on file by the ~~Arkansas Department of Health~~department.

20 CAR § 201-107. ~~Auto-injectable epinephrine~~ 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 the Insect Sting and Other Allergic Reactions Emergency Treatment Act, Arkansas Code § 20-13-401 et seq.;

(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; and

(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)(A) 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.

(B) The report shall include the following:

(i) The name and address of the authorized entity;

(ii) The name and certificate number of the person administering ~~auto-injectable~~ epinephrine;

(iii) The age of the person receiving the ~~injection~~epinephrine; and

(iv)*(a)* The name of the emergency medical service contacted after the ~~injection~~ epinephrine was administered.

(b) The department shall annually publish a report that summarizes and analyzes the reports submitted under this subdivision (c)(1); and

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

State of Arkansas *As Engrossed: H1/30/25 H2/13/25*
95th General Assembly **A Bill**
Regular Session, 2025 HOUSE BILL 1166

By: Representatives Gramlich, L. Johnson
By: Senator C. Penzo

For An Act To Be Entitled

AN ACT TO CLARIFY THE TYPES OF EPINEPHRINE FOR USE IN ELEMENTARY AND SECONDARY SCHOOLS IN THIS STATE; AND FOR OTHER PURPOSES.

Subtitle

TO CLARIFY THE TYPES OF EPINEPHRINE FOR USE IN ELEMENTARY AND SECONDARY SCHOOLS IN THIS STATE.

BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF ARKANSAS:

SECTION 1. Arkansas Code § 6-18-707 is amended to read as follows:

6-18-707. Prescription asthma inhaler or ~~auto-injectable~~ epinephrine — Definitions.

(a) This section shall be known and may be cited as “Alex’s Law”.

(b) As used in this section:

(1)(A) "Epinephrine" means a neurotransmitter and a hormone that has been approved by the United States Food and Drug Administration for the treatment of anaphylaxis.

(B) "Epinephrine" only includes auto-injectable epinephrine and epinephrine nasal spray;

~~(1)(A)~~(2)(A) “Medication” means a drug as that term is defined in 21 U.S.C. § 321(g) of the Federal Food, Drug and Cosmetic Act as in existence on January 1, 2005.

(B) “Medication” includes inhaled bronchodilators and ~~auto-injectable~~ epinephrine; and

~~(2)~~(3) “Self-administration” means a person’s discretionary use

of a medication pursuant to a prescription or written direction from a licensed healthcare practitioner.

(c)(1) The Division of Elementary and Secondary Education shall develop guidelines for use in school districts that allow a student to carry and use an asthma inhaler or ~~auto-injectable~~ epinephrine, or both, while in school, at an on-site school-sponsored activity, or at an off-site school-sponsored activity.

(2)(A) The procedure shall include at a minimum the following provisions:

(i) The parent or guardian of a student who needs to carry an asthma inhaler or ~~auto-injectable~~ epinephrine, or both, shall provide the school with written authorization for the student to carry an asthma inhaler or ~~auto-injectable~~ epinephrine, or both, on his or her person for use while in school, at an on-site school-sponsored activity, or at an off-site school-sponsored activity; and

(ii) The authorization shall be:

(a) Valid ~~valid~~ only for the duration of the school year at the school that the student is attending at the time the authorization is provided~~.~~; and

(b) Renewed ~~The authorization must be renewed~~ for each school year or if the student changes schools in order for the student to carry an asthma inhaler or ~~auto-injectable~~ epinephrine, or both, on his or her person.

(B) The parent or guardian of a student who needs to carry an asthma inhaler or ~~auto-injectable~~ epinephrine, or both, shall provide the school with appropriate medical documentation, which shall include:

(i) Evidence that the asthma inhaler or ~~auto-injectable~~ epinephrine, or both, have been prescribed by a healthcare practitioner with prescriptive privileges;

(ii) Evidence that the student needs to carry the asthma inhaler or ~~auto-injectable~~ epinephrine, or both, on his or her person due to a medical condition; and

(iii) A copy of an individualized healthcare plan for the student.

(C) All medical documentation provided with regard to a student who carries an asthma inhaler or ~~auto-injectable~~ epinephrine, or

both, shall be kept on file at the school the student attends in a location that is readily accessible in the event of an asthma or anaphylaxis emergency.

(D) A student's asthma inhaler or ~~auto-injectable~~ epinephrine, or both, shall be supplied by the student's parent or guardian and shall be stored and transported in its original prescription-labeled container.

(E) The student shall demonstrate to the healthcare practitioner who wrote the prescription and the school nurse, if the school nurse is available, the skill level and responsibility necessary to use and administer the asthma inhaler or ~~auto-injectable~~ epinephrine, or both.

(F)(i) A student with asthma is not required by this section or any related rule or school procedure to carry the student's asthma inhaler or ~~auto-injectable~~ epinephrine, or both, on his or her person.

(ii) If a student with asthma does not carry the student's asthma inhaler or ~~auto-injectable~~ epinephrine, or both, on his or her person, then the student's parent or guardian shall provide the school with appropriate medication in the event of an asthma or anaphylaxis emergency, which shall be immediately available to the student in an emergency.

(G) A student who carries the student's asthma inhaler or ~~auto-injectable~~ epinephrine, or both, on his or her person may provide the school with appropriate medication in the event of an asthma or anaphylaxis emergency, which shall be immediately available to the student in an emergency.

(H) A student is prohibited from sharing, transferring, or in any way diverting his or her own medications to any other person.

(d)(1) A school district, school district employee, or agent of a school district is not liable for injury to a student caused by his or her use of a prescription inhaler or self-administration of medication.

(2)(A) Regardless of whether or not a student's parents have signed a waiver of liability, when a school nurse or a school district or public charter school employee who holds a certificate under subsection (f) of this section administers ~~an~~ epinephrine ~~auto-injector~~ to a student whom the school nurse or a school district or public charter school employee in good faith professionally believes is having an anaphylactic reaction or when

a school nurse or a school district or public charter school employee administers albuterol to a student who the school nurse or a school district or public charter school employee in good faith professionally believes is in perceived respiratory distress, the following persons are immune from any damage, loss, or liability as a result of an injury arising from the administration of ~~an~~ epinephrine ~~auto-injector~~ or albuterol:

(i) The school district or public charter school;

(ii) The employees and agents of the school district or public charter school; and

(iii) A physician providing a standing protocol or prescription for epinephrine ~~auto-injectors~~ or albuterol maintained at a school.

(B) This subdivision (d)(2) does not provide immunity from suit or liability for any damage, loss, injury, or liability caused by the intentional or willful and wanton misconduct of a person in administering an epinephrine ~~auto-injector~~ or albuterol to a student under this section.

(e)(1) A school district or public charter school shall adopt a policy to authorize a school nurse or a school district or public charter school employee to:

(A) Provide ~~an~~ epinephrine ~~auto-injector~~ or albuterol to a student that meets the prescription on file or any personnel who holds a certificate under subsections (f) and (g) of this section to administer an epinephrine ~~auto-injector~~ or albuterol to the student;

(B) Administer ~~an~~ epinephrine ~~auto-injector~~ or albuterol that meets the prescription on file to a student who has an individualized healthcare plan that authorizes the use of ~~an~~ epinephrine ~~auto-injector~~ or albuterol;

(C) Administer ~~an~~ epinephrine ~~auto-injector~~ to a student who the school nurse or a school district or public charter school employee who holds a certificate under subsection (f) of this section in good faith professionally believes is having an anaphylactic reaction; and

(D) Administer albuterol to a student who the school nurse or a school district or public charter school employee in good faith professionally believes is in perceived respiratory distress.

(2) A school nurse shall administer ~~an~~ epinephrine ~~auto-injector~~ or albuterol under a standing protocol from a physician licensed to practice

medicine in this state.

(3) A school nurse who receives a supply of epinephrine ~~auto-injectors~~ under § 20-13-405 for use at a public school shall maintain the supply of epinephrine ~~auto-injectors~~ at the school in a locked, secure location.

(4) Each school district and public charter school shall develop a health plan to implement a certificate from a licensed *physician, an advanced practice registered nurse, or a physician assistant* under subsections (f) and (g) of this section.

(f)(1) A licensed physician shall issue a certificate under the Insect Sting and Other Allergic Reactions Emergency Treatment Act, § 20-13-401 et seq., authorizing a school nurse or a school district or public charter school employee who is trained in the administration of epinephrine to possess and administer epinephrine.

(2) The certificate shall specify the circumstances under which epinephrine may be administered.

(g)(1) A physician who is licensed to practice medicine in this state, an advanced practice registered nurse, or a physician assistant may issue a certificate authorizing a school nurse or a school district or public charter school employee who is trained in the administration of albuterol to possess and administer albuterol.

(2) A school district or public charter school may:

(A) Acquire and stock a supply of albuterol as authorized by subdivision (g)(1) of this section; and

(B) Enter into agreements with manufacturers of albuterol to obtain the albuterol free of charge or at fair market or reduced prices.

(3) A school district or public charter school shall designate an employee trained in the possession and administration of albuterol to be responsible for the storage, maintenance, and distribution of albuterol stocked by the school.

/s/Gramlich

APPROVED: 3/6/25