



TO: Health and Human Services Commission
Executive Council

DATE: February 22, 2018

FROM: Manda Hall, M.D., Associate Commissioner
Community Health Improvement Division

AGENDA ITEM: 2.c

SUBJECT: Epinephrine Auto-Injector Policies in Schools

BACKGROUND: Federal Legislative Other: Program Initiative

The proposed new rules implement Senate Bill (SB) 66 of the 84th Legislature, Regular Session, 2015, and SB 579 of the 85th Legislature, Regular Session, 2017. These laws require the adoption of rules for the maintenance, administration, and disposal of epinephrine auto-injectors in school districts, open-enrollment charter schools, and private schools who voluntarily adopt epinephrine auto-injector policies.

The law also requires the establishment of the Stock Epinephrine Advisory Committee (committee). The committee is tasked with advising DSHS on the storage and maintenance of epinephrine auto-injectors on school campuses; the training of school personnel and school volunteers in the administration of an epinephrine auto-injector; and a plan for one or more school personnel members or school volunteers trained in the administration of an epinephrine auto-injector to be on each school campus. Based on the recommendations of the committee, DSHS is proposing §§37.601 - 37.611 in Texas Administrative Code, Title 25.

ISSUES AND ALTERNATIVES:

There are no outstanding issues or concerns with implementation of the proposed new rules.

STAKEHOLDER INVOLVEMENT:

On October 17, 2017, the proposed rules were published on the Health and Human Services Rulemaking webpage for external stakeholder review.

Stakeholders were asked to submit written comments by Friday, November 3, 2017. Comments received from stakeholders were reviewed by program and taken into consideration. External stakeholders included the Texas Association of School Boards, Texas School Nurses Organization, Texas School Alliance – Health Services, Texas School Health Advisory Council, and Texas School Nurse Administrators Association.

Feedback on the proposed rules was positive. Changes were made in response to the comments, which included clarifying rule language and changing that the school principal may select school personnel and volunteers to administer epinephrine auto-injectors and seek school volunteers.

FISCAL IMPACT:

None

SERVICES IMPACT STATEMENT:

The public will benefit from this proposal because the proposal will allow school districts, open-enrollment charter schools, and private schools to voluntarily adopt unassigned epinephrine auto-injector policies, allowing trained individuals to administer epinephrine auto-injectors to persons suspected of experiencing anaphylaxis.

RULE DEVELOPMENT SCHEDULE:

| | |
|-------------------|---|
| February 22, 2018 | Present to HHSC Executive Council |
| March 2018 | Publish proposed rules in <i>Texas Register</i> |
| July 2018 | Publish adopted rules in <i>Texas Register</i> |
| July 2018 | Effective date |

PROPOSED PREAMBLE

The Executive Commissioner of the Health and Human Services Commission, on behalf of the Department of State Health Services (DSHS), proposes new §§37.601 – 37.611, concerning Epinephrine Auto-Injector Policies in Schools.

BACKGROUND AND PURPOSE

The purpose of the proposed new sections is to implement Senate Bill (SB) 66, 84th Legislature, Regular Session, 2015, and SB 579, 85th Legislature, Regular Session, 2017. The new laws require the adoption of rules for the maintenance, administration, and disposal of epinephrine auto-injectors in school districts, open-enrollment charter schools, and private schools who voluntarily adopt epinephrine auto-injector policies. The law requires the establishment of the Stock Epinephrine Advisory Committee to advise DSHS on the storage and maintenance of epinephrine auto-injectors on school campuses; the training of school personnel and school volunteers in the administration of an epinephrine auto-injector; and a plan for one or more school personnel members or school volunteers trained in the administration of an epinephrine auto-injector to be on each school campus.

The proposed new rules set the minimum standards for schools to follow in adopting an epinephrine auto-injector policy. Schools who adopt an unassigned epinephrine auto-injector policy are encouraged to stock additional epinephrine auto-injectors based on the needs of the populations served on each campus, including acquiring pediatric epinephrine auto-injectors for younger students. School personnel and school volunteers who are trained to administer unassigned epinephrine auto-injectors may administer an epinephrine auto-injector to a person suspected of experiencing anaphylaxis, including students, school personnel, school volunteers, and visitors. The proposed new rules allow flexibility so that local school boards or governing bodies may develop policies that address issues specific to each campus. Students with known allergies and assigned epinephrine auto-injectors should be managed according to the school's medication administration policy. Online resources are available on the DSHS School Health Program website to provide guidance and suggested best practices for policy implementation.

SECTION-BY-SECTION SUMMARY

Proposed new §37.601 states the purpose of the subchapter which is to establish minimum standards for administering, maintaining, and disposing

of epinephrine auto-injectors in school districts, open-enrollment charter schools, and private schools who adopt epinephrine auto-injector policies.

Proposed new §37.602 addresses schools voluntarily adopting epinephrine auto-injector policies. Subsection (a) states that school districts, open-enrollment charter schools, and private schools may adopt and implement written epinephrine auto-injector policies. Subsection (b) states that the epinephrine auto-injector policy must comply with Texas Education Code, §38.208 and this subchapter. Subsection (c) states that schools who adopt written epinephrine auto-injector policies do not have to create an additional policy for the care of certain students at risk for anaphylaxis, per Texas Education Code, §38.0151.

Proposed new §37.603 defines terms and phrases used in the rules relating to the maintenance, administration, and disposal of epinephrine auto-injectors in school districts, open-enrollment charter schools, and private schools.

Proposed new §37.604 states that the proposed rules apply to any school district, open-enrollment charter school, or private school that chooses to adopt and implement a written policy regarding the maintenance, administration, and disposal of epinephrine auto-injectors on each school campus.

Proposed new §37.605 presents the minimum standards regarding the maintenance, administration, and disposal of unassigned epinephrine auto-injectors in public school districts, open-enrollment charter schools, and private schools. Subsection (a) addresses obtaining a prescription for at least one adult epinephrine auto-injector pack (two doses) for each school campus. Subsection (a)(1) addresses schools obtaining pediatric epinephrine auto-injectors, if they so choose. Subsection (a)(2) addresses obtaining additional epinephrine auto-injectors for off-campus events and travel. Subsection (b) addresses designating school personnel to coordinate and manage the implementation of the epinephrine auto-injector policy. The designated school personnel must also coordinate with each campus to ensure that the unassigned epinephrine auto-injectors are checked monthly for usage and expiration. Subsection (c) addresses having at least one trained school personnel or school volunteer on campus during all hours the campus is open. Subsection (d) states that the trained school personnel or school volunteer may administer an epinephrine auto-injector to a person reasonably suspected of experiencing anaphylaxis. Subsection (e) addresses promptly contacting emergency medical services. Subsection (f) addresses promptly notifying the parent, legal guardian, or emergency contact when an epinephrine auto-injector is administered to their child. Subsection (g)

addresses storage of unassigned epinephrine auto-injectors. It is recommended that the location of the unassigned epinephrine auto-injectors be indicated on a campus map as well as the location of the automated external defibrillator. Subsection (h) addresses replacing expired and used unassigned epinephrine auto-injectors as soon as reasonably possible. Subsection (i) addresses disposal of epinephrine auto-injectors per the school's bloodborne pathogen control policy. Subsection (j) addresses disposing of expired epinephrine auto-injectors per the manufacturer's guidelines.

Proposed new §37.606 addresses the recruitment process in order to identify the school personnel or school volunteers who will be trained to administer an epinephrine auto-injector. Subsection (a)(1) states the school principal may assign school personnel or school volunteers to be trained. Subsection (a)(2) states the school principal may seek volunteers to be trained. Subsection (b) addresses distributing a notice about the unassigned epinephrine auto-injector volunteer position. Subsection (b)(1) addresses including a description of the volunteer position. Subsection (b)(2) addresses including a description of the required training. Subsection (c) states that the individual who volunteers for the epinephrine auto-injector volunteer position must submit a signed form stating that the volunteer agrees to perform the required duties.

Proposed new §37.607 addresses the minimum training requirements for school personnel or school volunteers responsible for the administration of an epinephrine auto-injector. Paragraph (1) states that the training may be provided in a formal face-to-face training session or through an online education course. Paragraph (2) states that the training must meet the requirements found in Texas Education Code, §38.210, and include information about inspecting the epinephrine auto-injector for usage and expiration. Paragraph (3) states that the initial training must include a hands-on skills demonstration. Paragraph (4) states that the annual refresher course must include a hands-on demonstration. Paragraph (5) addresses that the training includes information to promptly notify emergency medical services. Paragraph (6) addresses maintaining training records and maintaining a list of epinephrine auto-injector school personnel or volunteer names.

Proposed new §37.608 addresses the required reporting on the administration of epinephrine auto-injectors. Subsection (a) addresses the timeframe in which the report must be submitted and to whom. Subsection (b) addresses the format for submission to the commissioner of DSHS.

Proposed new §37.609 addresses the requirements for notifying parents or guardians of the epinephrine auto-injector policy. Subsection (a) addresses the written notice to parents or guardians required in Texas Education Code, §38.212. Subsection (b) addresses notifying parents or guardians within 15 calendar days if the epinephrine auto-injector policy changes or is discontinued.

Proposed new §37.610 references gifts, grants, and donations as outlined in Texas Education Code, §38.213.

Proposed new §37.611 references immunity from liability as outlined in Texas Education Code, §38.215.

FISCAL NOTE

Donna Sheppard, Chief Financial Officer has determined that for each year of the first five years that the sections will be in effect, there will be no fiscal implications to state or local governments as a result of enforcing and administering the sections as proposed.

GOVERNMENT GROWTH IMPACT STATEMENT

DSHS has determined that during the first five years that the sections will be in effect:

- (1) the proposed rules will not create or eliminate a government program;
- (2) implementation of the proposed rules will not affect the number of employee positions;
- (3) implementation of the proposed rules will not require an increase or decrease in future legislative appropriations;
- (4) the proposed rules will not affect fees paid to the agency;
- (5) the proposed rules will create a new rule;
- (6) the proposed rules will not expand, limit, or repeal an existing rule;
- (7) the proposed rules will increase the number of individual's subject to the rule; and
- (8) the proposed rules will not affect the state's economy.

SMALL BUSINESS, MICRO-BUSINESS, AND RURAL COMMUNITY IMPACT ANALYSIS

Dr. Manda Hall, Associate Commissioner, has determined that there will be an impact on small or micro-businesses and rural communities who voluntarily comply with the sections as proposed. Based on the definition for small business and micro-business, private and open-enrollment charter

schools may be classified as small or micro-businesses. The only adverse impact will be the cost to comply with the proposed new sections for the schools that elect to adopt epinephrine auto-injector policies. There will be a cost to purchase the packs of unassigned epinephrine auto-injectors, and there will be a cost to train the school personnel or school volunteer. DSHS is unable to estimate the number of private and open-enrollment charter schools that may fall under the small or micro-business umbrella, as DSHS and the Texas Education Agency (TEA) do not maintain data on the number of employees employed at private and open-enrollment charter schools. Alternative methods were not considered to implement the proposed rules because the proposal is legislatively directed. School districts, open-enrollment charter schools, and private schools may accept gifts, grants, donations, and federal and local funds to implement the proposed new sections, per Texas Education Code §38.213.

ECONOMIC COSTS TO PERSONS AND IMPACT ON LOCAL EMPLOYMENT

There is an anticipated economic cost to schools who comply with the sections as proposed. Based on data from TEA, there are 8,685 public and charter school campuses in Texas. According to the Texas Private School Accreditation Commission, there are approximately 1,579 accredited private schools in Texas. The cost of the epinephrine auto-injector pack ranges from \$300-600 per pack. Assuming each school or campus purchased one adult pack of epinephrine auto-injectors for \$300, the total cost for all public, private, and open-enrollment charter schools to purchase one pack of epinephrine auto-injectors will be \$3,079,200. If the price of each pack is \$600, the total cost will be \$6,158,400. Assuming each campus purchases one adult epinephrine auto-injector pack at the beginning of the pack's (12 - 18 month) shelf life during the start of fiscal year 1, each campus will have to replace the pack within the following year (within 18 months). DSHS is assuming that the cost for the hands-on training with an epinephrine auto-injector trainer will cost \$20 per person. Assuming each school or campus trains at least one person to administer the epinephrine auto-injector, the total cost to train one person per campus or school will be \$205,280 each year. Therefore, depending on the cost of the epinephrine auto-injector pack, the total cost of compliance of all schools is between \$3,284,480 and \$6,363,680 per year (\$320-620 per school per year). Because participation is voluntary, the overall cost could be less. This estimate does not include the cost to replace an auto-injector that is used nor does it include the costs if a school chooses to purchase more than one pack.

There is no anticipated negative impact on local employment.

COSTS TO REGULATED PERSONS

Texas Government Code, §2001.0045 does not apply to these rules because the rules do not impose a cost on regulated persons and are necessary to implement legislation that does not specifically state that §2001.0045 applies to the rules.

PUBLIC BENEFIT

In addition, Dr. Hall has determined that for each year of the first five years the sections are in effect, the public will benefit from adoption of the sections. The public will benefit as a result of administering the sections because school districts, private schools, and open-enrollment charter schools who choose to adopt epinephrine auto-injector policies will be able to administer epinephrine auto-injectors to individuals suspected of experiencing anaphylaxis. By administering epinephrine auto-injectors to people suspected of anaphylaxis, many lives may be saved.

REGULATORY ANALYSIS

DSHS has determined that this proposal is not a "major environmental rule" as defined by Government Code, §2001.0225. "Major environmental rule" is defined to mean a rule the specific intent of which is to protect the environment or reduce risk to human health from environmental exposure and that may adversely affect, in a material way, the economy, a sector of the economy, productivity, competition, jobs, the environment or the public health and safety of a state or a sector of the state. This proposal is not specifically intended to protect the environment or reduce risks to human health from environmental exposure.

TAKINGS IMPACT ASSESSMENT

DSHS has determined that the proposal does not restrict or limit an owner's right to his or her property that would otherwise exist in the absence of government action and, therefore, does not constitute a taking under Government Code, §2007.043.

PUBLIC COMMENT

Questions about the content of this proposal may be directed to Anita Wheeler, Department of State Health Services, Community Health Improvement Division, School Health Program, (512) 776-7279.

Written comments on the proposal may be submitted to School Health Program, P.O. Box 149347, Austin, Texas 78714-9347, or 1100 West 49th Street, Austin, Texas 78756; faxed (512) 776-7555, or e-mail to Schoolhealth@dshs.texas.gov.

To be considered, comments must be submitted no later than 30 days following publication of the proposal in the *Texas Register*. The last day to submit comments falls on a Sunday; however, comments postmarked, shipped, faxed, or emailed before midnight on the following Monday will be accepted.

STATUTORY AUTHORITY

The new sections are required to comply with Texas Education Code, Chapter 38, Subchapter E. The new sections are also authorized by Texas Government Code, §531.0055, and Texas Health and Safety Code, §1001.075, which authorize the Executive Commissioner of the Health and Human Services Commission to adopt rules and policies necessary for the operation and provision of health and human services by DSHS and for the administration of Texas Health and Safety Code, Chapter 1001.

The sections affect Texas Government Code, Chapter 531; Texas Education Code, Chapter 38; and Health and Safety Code, Chapter 1001.

The agency certifies that legal counsel has reviewed the proposal and found it to be within the state agency's legal authority to adopt.

For further information, please call: (512) 776-7279.

TITLE 25 HEALTH SERVICES
PART 1 DEPARTMENT OF STATE HEALTH SERVICES
CHAPTER 37 MATERNAL AND INFANT HEALTH SERVICES
SUBCHAPTER U EPINEPHRINE AUTO-INJECTOR POLICIES IN SCHOOLS

§37.601. Purpose.

The purpose of this subchapter is to establish minimum standards for administering, maintaining, and disposing of epinephrine auto-injectors in school districts, open-enrollment charter schools, and private schools who adopt unassigned epinephrine auto-injector policies. These standards are implemented under Texas Education Code, Chapter 38, Subchapter E.

§37.602. Voluntary Unassigned Epinephrine Auto-injector Policies for School Districts, Open-enrollment Charter schools, and Private Schools.

(a) A school district, open-enrollment charter school, or private school may adopt and implement a written policy regarding the maintenance, administration, and disposal of unassigned epinephrine auto-injectors at each school campus.

(b) If a written policy is adopted under this subchapter, the policy must comply with Texas Education Code, §38.208 and this subchapter.

(c) A school district or open-enrollment charter school that chooses to adopt and implement a written unassigned epinephrine auto-injector policy under Texas Education Code, Chapter 38, Subchapter E, and this subchapter, is not required to create an additional policy for care of certain students at risk for anaphylaxis under Texas Education Code, §38.0151.

§37.603. Definitions.

The following terms and phrases, when used in this subchapter, shall have the following meanings, unless the context clearly indicates otherwise:

(1) All hours the campus is open--At a minimum, during regular on-campus school hours, when school personnel are physically on site.

(2) Anaphylaxis--As defined in Texas Education Code, §38.201.

(3) Authorized healthcare provider--A physician or person who has been delegated prescriptive authority under Occupations Code Chapter 157.

(4) Campus--A unit of a school district, open-enrollment charter school, or private school that has an assigned administrator, has enrolled students who are counted for average daily attendance, has assigned instructional staff, provides instructional services to students, has one or more grades in the range from early childhood education through grade 12 or is ungraded, and complies with relevant Texas laws.

(5) Private School--As defined in Texas Education Code, §38.201.

(6) School Nurse--As defined in Title 19, Texas Administrative Code, §153.1022.

(7) School Personnel--As defined in Texas Education Code, §38.201.

(8) School Volunteer--As defined in Texas Education Code, §22.053.

(9) Unassigned epinephrine auto-injector--An epinephrine auto-injector prescribed in the name of the school issued with a non-patient-specific standing delegation order for the administration of an epinephrine auto-injector, issued by a physician or person who has been delegated prescriptive authority under Occupations Code, Chapter 157.

§37.604. Applicability.

This subchapter applies to any school district, open-enrollment charter school, or private school who voluntarily chooses to adopt and implement a written policy regarding the maintenance, administration and disposal of unassigned epinephrine auto-injectors on each school campus.

§37.605. Maintenance, Administration, and Disposal of Unassigned Epinephrine Auto-injectors.

(a) A school district, open-enrollment charter school, or private school shall obtain a prescription from an authorized healthcare provider each year, to stock, possess, and maintain at least one unassigned adult epinephrine auto-injector pack (two doses) on each school campus as described in Texas Education Code, §38.211.

(1) A school may choose to stock unassigned pediatric epinephrine auto-injector packs, based on the need of the school's population.

(2) A school district or the governing body of an open-enrollment charter school or private school may develop, as part of the policy, provisions for

additional doses to be stocked and utilized at off campus school events, or in transit to or from school events.

(b) Each school district superintendent, open-enrollment charter school administrator, or private school administrator will designate appropriate school personnel to coordinate and manage policy implementation, including training of school personnel, and the acquisition or purchase, usage, expiration, and disposal of unassigned epinephrine auto-injectors. Throughout the school calendar year, the designated school personnel shall coordinate with each campus to ensure that the unassigned epinephrine auto-injectors are checked monthly for expiration and usage and the findings are documented.

(c) At least one school personnel or one school volunteer who is authorized and trained to administer an unassigned epinephrine auto-injector must be present on campus during all hours the campus is open.

(d) School personnel or school volunteers who are trained and authorized may administer an unassigned epinephrine auto-injector to a person who is reasonably believed to be experiencing anaphylaxis on a school campus.

(e) Local emergency medical services must be promptly notified when an individual is suspected of experiencing an anaphylactic reaction and when an epinephrine auto-injector is administered. If the trained school personnel or school volunteer is the only individual available to notify emergency medical services, the trained individual should administer the unassigned epinephrine auto-injector before notifying emergency medical services.

(f) The parent, legal guardian, or emergency contact must be promptly notified when an unassigned epinephrine auto-injector is utilized on their child as soon as is feasible during the emergency response to suspected anaphylaxis. School records of the administration of the unassigned epinephrine auto-injector and suspected anaphylactic reaction must be provided to the parent or guardian upon request.

(g) Unassigned epinephrine auto-injectors shall be stored in a secure, easily accessible area for an emergency, in accordance with the manufacturer's guidelines. It is recommended that the school administrator develop a map to be placed in high traffic areas that indicates the location of the unassigned epinephrine auto-injectors on each school campus. It is recommended that the map also indicates the locations of the automated external defibrillator (AED).

(h) The school district, open-enrollment charter school, or private school shall develop a plan to replace, as soon as reasonably possible, any unassigned epinephrine auto-injector that is used or close to expiration.

(i) Used unassigned epinephrine auto-injectors shall be considered infectious waste and shall be disposed of according to the school's bloodborne pathogen control policy.

(j) Expired unassigned epinephrine auto-injectors shall be disposed of according to the manufacturer's guidelines.

§37.606. Assignment and Recruitment of School Personnel and School Volunteers to be Trained to Administer Epinephrine Auto-Injectors.

(a) At each school campus in which a school adopts an unassigned epinephrine auto-injector policy, the school principal may:

(1) assign school personnel or school volunteers to be trained to administer unassigned epinephrine auto-injectors; or

(2) seek school personnel or school volunteers who volunteer to be trained to administer unassigned epinephrine auto-injectors.

(b) In order to increase the number of trained individuals in the administration of unassigned epinephrine auto-injectors, schools may distribute to school personnel and school volunteers in the school district, open-enrollment charter school, or private school, at least once per school year, a notice that includes:

(1) a description of the request seeking volunteers to be trained to administer an epinephrine auto-injector to a person believed to be experiencing an anaphylactic reaction; and

(2) a description of the training that the school personnel or school volunteers will receive in the administration of epinephrine with an auto-injector.

(c) Trained school personnel or school volunteers who administer the unassigned epinephrine auto-injector must submit a signed statement indicating that they agree to perform the service of administering an unassigned epinephrine auto-injector to a student or individual that may be experiencing an anaphylactic reaction.

§37.607. Training.

Each school district, open-enrollment charter school, or private school that adopts an unassigned epinephrine auto-injector written policy under this subchapter is responsible for training school personnel and school volunteers in the recognizing of anaphylaxis signs and symptoms and administration of an unassigned epinephrine auto-injector. Each assigned school personnel or school volunteer shall receive initial training and an annual refresher training. Training shall be consistent with the most recent Voluntary Guidelines for Managing Food Allergies in Schools and Early Care and Education Programs published by the federal Centers for Disease Control and Prevention.

(1) Training may be provided in a formal face-to-face training session or through an online education course.

(2) Training required under this subchapter must meet the requirements found in Texas Education Code, §38.210 and include information on properly inspecting unassigned epinephrine auto-injectors for usage and expiration.

(3) The initial training must include hands-on training with an epinephrine auto-injector trainer.

(4) The annual refresher training must include a hands-on demonstration of administration skills.

(5) The training must also include information about promptly notifying local emergency medical services.

(6) Each school campus shall maintain training records and make available upon request a list of those school personnel or school volunteers trained and authorized to administer the unassigned epinephrine auto-injector on the campus.

§37.608. Report on Administering Epinephrine Auto-injectors.

(a) A report shall be submitted no later than the 10th business day after the date school personnel or a school volunteer administers an epinephrine auto-injector in accordance with the unassigned epinephrine auto-injector policy adopted under this section. The report shall be submitted to the individuals and entities identified in Texas Education Code, §38.209, including the commissioner of the Texas Education Agency and the commissioner of the Department of State Health Services (DSHS).

(b) Notifications to the commissioner of DSHS shall be submitted on the designated electronic form available on the DSHS School Health Program website.

§37.609. Notice to Parents Regarding Unassigned Epinephrine Auto-Injector Policies in Schools.

(a) If a school district, open-enrollment charter school, or private school implements an unassigned epinephrine auto-injector policy under this subchapter, the district or school shall provide written or electronic notice to a parent or guardian of each student in accordance with Texas Education Code, §38.212.

(b) If a school district, open-enrollment charter school, or private school changes or discontinues the policy under this subchapter, written or electronic notice detailing the change or discontinuation must be provided to a parent or guardian of each student within 15 calendar days.

§37.610. Gifts, Grants, and Donations.

A school district, open-enrollment charter school, or private school may accept gifts, grants, donations, and federal and local funds to implement the unassigned epinephrine auto-injector policy in accordance with Texas Education Code, §38.213.

§37.611. Immunity from liability.

A person who in good faith takes, or fails to take, any action under this subchapter or Texas Education Code, Chapter 38, Subchapter E is immune from civil or criminal liability or disciplinary action resulting from that action or failure to act in accordance with the Texas Education Code, §38.215.