

## RULE ANALYSIS

**Introduction:** THE NEW RULE IS SUBMITTED TO THE BOARD FOR CONSIDERATION AS A PROPOSED RULE

**Short Title:** Administration of Epinephrine by a Pharmacist

**Rule Numbers:** §295.16

**Statutory Authority:** Texas Pharmacy Act, Chapter 551-569, Occupations Code:

- (1) Section 551.002 specifies that the purpose of the Act is to protect the public through the effective control and regulation of the practice of pharmacy; and
- (2) Section 554.051 gives the Board the authority to adopt rules for the proper administration and enforcement of the Act.

**Purpose:** The new rule, if adopted, implements the provisions of HB 1550 regarding the administration of epinephrine by a pharmacist.

1 TITLE 22 EXAMINING BOARDS  
2 PART 15 TEXAS STATE BOARD OF PHARMACY  
3 CHAPTER 295 PHARMACISTS  
4

5 **§295.16 Administration of Epinephrine by a Pharmacist**  
6

7 **(a) Purpose. The purpose of this section is to allow pharmacists to administer**  
8 **epinephrine through an auto-injector device to a patient in an emergency situation as**  
9 **authorized in Chapter 562 of the Act.**  
10

11 **(b) Definitions. The following words and terms, when used in this section, shall have the**  
12 **following meanings, unless the context clearly indicates otherwise.**  
13

14 **(1) Act--The Texas Pharmacy Act, Chapter 551- 569, Occupations Code, as amended.**  
15

16 **(2) Administer--The direct application of a prescription drug to the body of an individual**  
17 **by any means, including injection, by a pharmacist.**  
18

19 **(3) Anaphylaxis - a potentially life-threatening hypersensitivity to a substance.**  
20 **Symptoms may include shortness of breath, wheezing, difficulty breathing, difficulty**  
21 **talking or swallowing, hives, itching, swelling, shock, or asthma. Causes may include,**  
22 **but are not limited to, an insect sting, food allergy, drug reaction, and exercise.**  
23

24 **(4) Epinephrine auto-injector - a disposable drug delivery system with a spring-activated**  
25 **needle that is designed for emergency administration of epinephrine to provide rapid,**  
26 **convenient first aid for persons suffering a potentially fatal reaction to anaphylaxis.**  
27

28 **(c) Administration requirements.**  
29

30 **(1) Pharmacists may administer epinephrine through an auto-injector to a patient in an**  
31 **emergency situation.**  
32

33 **(2) The authority of a pharmacist to epinephrine through an auto-injector may not be**  
34 **delegated.**  
35

36 **(3) Epinephrine administered by a pharmacist under the provisions of this section shall**  
37 **be in the legal possession of a pharmacy, which shall be the pharmacy responsible for**  
38 **drug accountability, including the maintenance of records of administration of the**  
39 **epinephrine.**  
40

41 **(d) Limitation on liability.**  
42

43 **(1) A pharmacist who in good faith administers epinephrine through an auto-injector in**  
44 **accordance with this section and Chapter 562 of the Act is not liable for civil damages for**  
45 **an act performed in the administration unless the act is willfully or wantonly negligent.**  
46

47 **(2) A pharmacist may not receive remuneration for the administration of epinephrine**  
48 **through an auto-injector but may seek reimbursement for the cost of the epinephrine**  
49 **auto-injector.**  
50

51 (3) The administration of epinephrine through an auto-injector to a patient in accordance  
52 with the requirements of this section and Chapter 562 of the Act does not constitute the  
53 unlawful practice of any health care profession.

54  
55 (e) Notifications.

56  
57 (1) A pharmacist who administers epinephrine through an auto-injector to a patient shall  
58 report the use to the patient's primary care physician, as identified by the patient, as  
59 soon as practical, but in no event more than 72 hours from the time of administering the  
60 epinephrine.

61  
62 (2) Immediately, after administering the epinephrine auto-injector, the pharmacist shall  
63 ensure that 911 is called and the patient is evaluated by emergency personnel for  
64 possible transferred to the nearest emergency department for additional evaluation,  
65 monitoring, and treatment.

66  
67 (3) The notifications required in paragraph (1) of this subsection shall include the:

68  
69 (A) name of the patient;

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71 (B) age of the patient if under 8 years of age;

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73 (C) name and manufacturer of the epinephrine auto-injector;

74  
75 (D) date the epinephrine was administered;

76  
77 (E) name and title of the person administering the epinephrine; and

78  
79 (F) name, address, and telephone number of the pharmacy.

80  
81 (f) Records.

82  
83 (1) The notification required to be made under this section shall be kept by the pharmacy  
84 and such records shall be available for at least two years from the date of such record,  
85 for inspecting and copying by the board or its representative and to other authorized  
86 local, state, or federal law enforcement or regulatory agencies.

87  
88 (2) The notification may be maintained in an alternative data retention system, such as  
89 a data processing system or direct imaging system provided:

90  
91 (A) the records maintained in the alternative system contain all of the information  
92 required on the manual record; and

93  
94 (B) the data processing system is capable of producing a hard copy of the record  
95 upon request of the board, its representative, or other authorized local, state, or federal  
96 law enforcement or regulatory agencies.

AN ACT

relating to the administration of epinephrine by pharmacists.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF TEXAS:

SECTION 1. Subchapter B, Chapter 562, Occupations Code, is amended by adding Section 562.057 to read as follows:

Sec. 562.057. ADMINISTRATION OF EPINEPHRINE. (a) A pharmacist may administer epinephrine through an auto-injector device in accordance with this section.

(b) The board shall adopt rules designed to protect the public health and safety to implement this section. The rules must provide that a pharmacist may administer epinephrine through an auto-injector device to a patient in an emergency situation.

(c) A pharmacist may maintain, administer, and dispose of epinephrine auto-injector devices only in accordance with rules adopted by the board under this section.

(d) A pharmacist who administers epinephrine through an auto-injector device to a patient shall report the use to the patient's primary care physician, as identified by the patient, if the patient has a primary care physician.

(e) A pharmacist who in good faith administers epinephrine through an auto-injector device in accordance with the requirements of this section is not liable for civil damages for an act performed in the administration unless the act is wilfully or wantonly negligent. A pharmacist may not receive remuneration for the

1 administration of epinephrine through an auto-injector device but  
2 may seek reimbursement for the cost of the epinephrine  
3 auto-injector device.

4 (f) The administration of epinephrine through an  
5 auto-injector device to a patient in accordance with the  
6 requirements of this section does not constitute the unlawful  
7 practice of any health care profession.

8 SECTION 2. Before January 1, 2016, pharmacists may  
9 administer epinephrine through an auto-injector device to the  
10 extent allowed under the law that exists before September 1, 2015.

11 SECTION 3. (a) Except as provided by Subsection (b) of  
12 this section, this Act takes effect September 1, 2015.

13 (b) Section 562.057, Occupations Code, as added by this Act,  
14 takes effect January 1, 2016, except that Section 562.057 takes  
15 effect September 1, 2015, for the limited purpose of allowing the  
16 Texas State Board of Pharmacy to adopt rules under that law that may  
17 take effect before January 1, 2016.

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President of the Senate

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Speaker of the House

I certify that H.B. No. 1550 was passed by the House on April 29, 2015, by the following vote: Yeas 145, Nays 0, 1 present, not voting.

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Chief Clerk of the House

I certify that H.B. No. 1550 was passed by the Senate on May 22, 2015, by the following vote: Yeas 31, Nays 0.

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Secretary of the Senate

APPROVED: \_\_\_\_\_

Date

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Governor