

## RULE ANALYSIS

**Introduction:** THE AMENDMENTS ARE SUBMITTED TO THE BOARD FOR CONSIDERATION AS A PROPOSED RULE

**Short Title:** Administration of Epinephrine

**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 amendments, if adopted, update the definition of auto-injectors.

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 epinephrine  
8 through an auto-injector device to a patient in an emergency situation as authorized in Chapter  
9 562 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 (1) Act--The Texas Pharmacy Act, Chapter 551 - 569, Occupations Code, as amended.

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

16 (3) Anaphylaxis--A sudden, severe, and potentially life-threatening allergic reaction that occurs  
17 when a person is exposed to an allergen. Symptoms may include shortness of breath,  
18 wheezing, difficulty breathing, difficulty talking or swallowing, hives, itching, swelling, shock, or  
19 asthma. Causes may include, but are not limited to, an insect sting, food allergy, drug reaction,  
20 and exercise.

21 (4) Epinephrine auto-injector--A disposable drug delivery system [~~with a spring-activated~~  
22 ~~needle~~] that **contains a premeasured single dose of epinephrine that is used to treat**  
23 **anaphylaxis in an emergency situation** [~~is designed for emergency administration of~~  
24 ~~epinephrine to provide rapid, convenient first aid for persons suffering a potentially fatal~~  
25 ~~anaphylactic reaction~~].

26  
27 (c) Administration requirements.

28 (1) Pharmacists may administer epinephrine through an auto-injector to a patient in an  
29 emergency situation.

30 (2) The authority of a pharmacist to administer epinephrine through an auto-injector may not  
31 be delegated.

32 (3) Epinephrine administered by a pharmacist under the provisions of this section shall be in  
33 the legal possession of a pharmacist or the legal possession of a pharmacy which shall be the  
34 pharmacy responsible for drug accountability, including the maintenance of records of  
35 administration of the epinephrine.

36  
37 (d) Limitation on liability.

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

41 (2) A pharmacist may not receive remuneration for the administration of epinephrine through  
42 an auto-injector but may seek reimbursement for the cost of the epinephrine auto-injector.

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

46  
47 (e) Notifications.

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

51 (2) Immediately, after administering the epinephrine auto-injector, the pharmacist shall ensure  
52 that 911 is called and the patient is evaluated by emergency personnel for possible transfer to  
53 the nearest emergency department for additional evaluation, monitoring, and treatment.

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

55 (A) name of the patient;

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

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

58 (D) date the epinephrine was administered;

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

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

61

62 (f) Records.

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

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

69 (A) the records maintained in the alternative system contain all of the information required on  
70 the manual record; and

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