

RULE ANALYSIS

Introduction: THE AMENDMENTS ARE SUBMITTED TO THE BOARD FOR CONSIDERATION AS AN ADOPTED 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 **22 TAC §295.16**

2 The Texas State Board of Pharmacy proposes amendments to §295.16, concerning
3 Administration of Epinephrine by a Pharmacist.

4 The proposed amendments, if adopted, update the definition of auto-injectors.

5 Gay Dodson, R.Ph., Executive Director/Secretary, has determined that, for the first five-year
6 period the rule is in effect, there will be no fiscal implications for state or local government as a
7 result of enforcing or administering the rule.

8 Ms. Dodson has determined that, for each year of the first five-year period the rule will be in
9 effect, the public benefit anticipated as a result of enforcing the amendments will ensure
10 pharmacists are able to appropriately administer epinephrine to consumers in emergency
11 situations.

12 Written comments on the amendments may be submitted to Allison Vordenbaumen Benz, R.Ph.,
13 M.S., Director of Professional Services, Texas State Board of Pharmacy, 333 Guadalupe Street,
14 Suite 3-600, Austin, Texas 78701, FAX (512) 305-6778. Comments must be received by 5 p.m.,
15 October 25, 2016.

16 The amendments are proposed under §551.002 and §554.051 of the Texas Pharmacy Act
17 (Chapters 551 - 569, Texas Occupations Code). The Board interprets §551.002 as authorizing the
18 agency to protect the public through the effective control and regulation of the practice of
19 pharmacy. The Board interprets §554.051(a) as authorizing the agency to adopt rules for the
20 proper administration and enforcement of the Act.

21 The statutes affected by these amendments: Texas Pharmacy Act, Chapters 551 - 569, Texas
22 Occupations Code.

23 ***§295.16.Administration of Epinephrine by a Pharmacist.***

24 (a) Purpose. The purpose of this section is to allow pharmacists to administer epinephrine
25 through an auto-injector device to a patient in an emergency situation as authorized in Chapter
26 562 of the Act.

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

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

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

32 (3) Anaphylaxis--A sudden, severe, and potentially life-threatening allergic reaction that occurs
33 when a person is exposed to an allergen. Symptoms may include shortness of breath, wheezing,

34 difficulty breathing, difficulty talking or swallowing, hives, itching, swelling, shock, or asthma.
35 Causes may include, but are not limited to, an insect sting, food allergy, drug reaction, and
36 exercise.

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

41 (c) Administration requirements.

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

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

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

50 (d) Limitation on liability.

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

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

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

59 (e) Notifications.

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

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

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

- 67 (A) name of the patient;
- 68 (B) age of the patient if under 8 years of age;
- 69 (C) name and manufacturer of the epinephrine auto-injector;
- 70 (D) date the epinephrine was administered;
- 71 (E) name and title of the person administering the epinephrine; and
- 72 (F) name, address, and telephone number of the pharmacy.
- 73 (f) Records.
- 74 (1) The notification required to be made under this section shall be kept by the pharmacy and
75 such records shall be available for at least two years from the date of such record, for inspecting
76 and copying by the board or its representative and to other authorized local, state, or federal law
77 enforcement or regulatory agencies.
- 78 (2) The notification may be maintained in an alternative data retention system, such as a data
79 processing system or direct imaging system provided:
- 80 (A) the records maintained in the alternative system contain all of the information required on
81 the manual record; and
- 82 (B) the data processing system is capable of producing a hard copy of the record upon request of
83 the board, its representative, or other authorized local, state, or federal law enforcement or
84 regulatory agencies.
- 85 The agency certifies that legal counsel has reviewed the proposal and found it to be within the
86 state agency's legal authority to adopt.
- 87 Filed with the Office of the Secretary of State on September 12, 2016.
- 88 TRD-201604754
- 89 Gay Dodson, R.Ph.
- 90 Executive Director
- 91 Texas State Board of Pharmacy
- 92 Earliest possible date of adoption: October 23, 2016
- 93 For further information, please call: (512) 305-8028