

RULE ANALYSIS

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

Short Title: Immunizations

Rule Numbers: §295.15

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, add requirements regarding hand sanitation for pharmacists administering immunizations.

The Board reviewed and voted to propose the amendments during the August 4, 2015, meeting. The proposed amendments were published in the September 25, 2015, issue of the *Texas Register* at 40 TexReg 6542.

1 **CHAPTER 295. PHARMACISTS**

2 **22 TAC §295.15, §295.16**

3 The Texas State Board of Pharmacy proposes amendments to §295.15 concerning
4 Administration of Immunizations or Vaccinations by a Pharmacist under Written Protocol of a
5 Physician and new §295.16 concerning Administration of Epinephrine by a Pharmacist. The
6 amendments to §295.15, if adopted, add requirements regarding hand sanitization for
7 pharmacists administering immunizations. New §295.16, if adopted, implements the provisions
8 of HB 1550 regarding the administration of epinephrine by a pharmacist.

9 Gay Dodson, R.Ph., Executive Director/Secretary, has determined that, for the first five-year
10 period the rules are in effect, there will be no fiscal implications for state or local government as
11 a result of enforcing or administering the rules.

12 Ms. Dodson has determined that, for each year of the first five-year period the rules will be in
13 effect, the public benefit anticipated as a result of enforcing the amendments to §295.15 will
14 ensure patient safety when receiving immunizations or vaccinations from a pharmacist; and new
15 §295.16 will allow pharmacists to provide epinephrine through an auto-injector in emergency
16 situations. There is no fiscal impact for individuals, small or large businesses, or to other entities
17 which are required to comply with these sections.

18 Written comments on the amendments and new section may be submitted to Allison Benz, R.Ph.,
19 M.S., Director of Professional Services, Texas State Board of Pharmacy, 333 Guadalupe Street,
20 Suite 3-600, Austin, Texas 78701, FAX (512) 305-6778. Comments must be received by 5:00
21 p.m., October 30, 2015.

22 The amendments and new section are proposed under §§551.002, 554.051, 554.052, and 562.057
23 of the Texas Pharmacy Act (Chapters 551 - 569, Texas Occupations Code). The Board interprets
24 §551.002 as authorizing the agency to protect the public through the effective control and
25 regulation of the practice of pharmacy. The Board interprets §554.051(a) as authorizing the
26 agency to adopt rules for the proper administration and enforcement of the Act. The Board
27 interprets §554.052 as authorizing the agency to adopt rules regarding the administration of
28 immunizations and vaccinations. The Board interprets §562.057 as authorizing the agency to
29 adopt rules designed to protect the public health and safety of patients by allowing pharmacists
30 to administer epinephrine through an auto-injector device to a patient in an emergency situation.

31 The statutes affected by the amendments and new section: Texas Pharmacy Act, Chapters 551 -
32 569, Texas Occupations Code.

33 *§295.15. Administration of Immunizations or Vaccinations by a Pharmacist under Written*
34 *Protocol of Physician.*

35 (a) - (d) (No change.)

36 (e) Special Provisions. Pharmacists involved in the administration of immunizations or
37 vaccinations under their license to practice pharmacy shall meet the following restrictions and
38 requirements.

39 (1) Pharmacists may only administer immunizations or vaccinations pursuant to a written
40 protocol from a physician authorizing the administration.

41 (2) Pharmacists may administer immunizations or vaccinations to a patient under 14 years of age
42 only upon a referral from a physician who has an established physician-patient relationship with
43 each patient. However, a pharmacist may administer an influenza vaccination to a patient over
44 seven years of age without an established physician-patient relationship.

45 (3) Pharmacists may administer immunizations or vaccinations under written protocol of a
46 physician within a pharmacy or at any other location specifically identified in the written
47 protocol. Such other location may not include where the patient resides, except for a licensed
48 nursing home or hospital.

49 (4) The authority of a pharmacist to administer immunizations or vaccinations may not be
50 delegated.

51 (5) Pharmacists may administer immunizations and vaccinations only when a licensed health-
52 care provider authorized to administer the medication is not reasonably available to administer
53 the medication. For the purpose of this section, "reasonably available" means those times when
54 the licensed health-care provider is immediately available to administer the immunization or
55 vaccine and is specifically tasked to do so.

56 (6) Under the provisions of the National Vaccine Injury Compensation Program (NVICP), the
57 health-care provider under whose authority a covered vaccine is administered (i.e., the physician
58 issuing the written protocol) must maintain certain information in the patient's permanent record.
59 In order for the physician to comply with the provisions of the NVICP, the pharmacist shall
60 provide the physician with the information specified in subsection (g) of this section.

61 (7) Before preparing an immunization or vaccine and between each patient contact, the
62 pharmacist shall cleanse his or her hands with an alcohol-based waterless antiseptic hand rub or
63 shall wash his or her hands with soap and water. If gloves are worn, the pharmacist shall change
64 gloves between patients.

65 (8) [(7)] The pharmacist shall comply with all other state and federal requirements regarding
66 immunizations or vaccinations.

67 (f) - (i) (No change.) §295.16.Administration of Epinephrine by a Pharmacist.

68 (a) Purpose. The purpose of this section is to allow pharmacists to administer epinephrine
69 through an auto-injector device to a patient in an emergency situation as authorized in Chapter
70 562 of the Act.

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

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

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

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

80 (4) Epinephrine auto-injector--A disposable drug delivery system with a spring-activated needle
81 that is designed for emergency administration of epinephrine to provide rapid, convenient first
82 aid for persons suffering a potentially fatal anaphylactic reaction.

83 (c) Administration requirements.

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

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

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

92 (d) Limitation on liability.

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

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

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

101 (e) Notifications.

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

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

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

109 (A) name of the patient;

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

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

112 (D) date the epinephrine was administered;

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

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

115 (f) Records.

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

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

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

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

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

129 Filed with the Office of the Secretary of State on September 14, 2015.

130 TRD-201503757

131 Gay Dodson, R.Ph.
132 Executive Director
133 Texas State Board of Pharmacy
134 Earliest possible date of adoption: October 25, 2015
135 For further information, please call: (512) 305-8028
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