

## RULE ANALYSIS

**Introduction:** THE NEW RULE IS SUBMITTED TO THE BOARD FOR CONSIDERATION AS AN ADOPTED RULE

**Short Title:** Opioid Dispensing

**Rule Numbers:** §295.14

**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 implements SB 1462, passed during the 2015 Texas Legislative Session allowing pharmacists to dispense naloxone to individuals under a standing order from a physician.

1 **CHAPTER 295. PHARMACISTS**

2 **22 TAC §295.14**

3 The Texas State Board of Pharmacy proposes new §295.14, concerning Dispensing of Opioid  
4 Antagonist by Pharmacist.

5 The proposed new rule, if adopted, implements SB 1462, passed during the 2015 Texas  
6 Legislative Session allowing pharmacists to dispense naloxone to individuals under a standing  
7 order from a physician.

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

11 Ms. Dodson has determined that, for each year of the first five-year period the rule will be in  
12 effect, the public benefit anticipated as a result of enforcing the new rule will be to ensure  
13 consumers are able to receive naloxone under a standing order.

14 Written comments on the new rule may be submitted to Allison Vordenbaumen Benz, R.Ph.,  
15 M.S., Director of Professional Services, Texas State Board of Pharmacy, 333 Guadalupe Street,  
16 Suite 3-600, Austin, Texas, 78701, FAX (512) 305-6778. Comments must be received by 5:00  
17 p.m., October 25, 2016.

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

23 The statutes affected by the new rule: Texas Pharmacy Act, Chapters 551 - 569, Texas  
24 Occupations Code.

25 **§295.14. Dispensing of Opioid Antagonist by Pharmacist.**

26 (a) Purpose. The purpose of this section is to provide standards for pharmacists engaged in the  
27 dispensing of opioid antagonists as authorized in Chapter 483 of the Health and Safety Code.

28 (b) Definitions.

29 (1) Opioid antagonist--Any drug that binds to opioid receptors and blocks or otherwise inhibits  
30 the effects of opioids acting on those receptors.

31 (2) Opioid-related drug overdose--A condition, evidenced by symptoms such as extreme physical  
32 illness, decreased level of consciousness, constriction of the pupils, respiratory depression, or

33 coma, that a layperson would reasonably believe to be the result of the consumption or use of an  
34 opioid.

35 (3) Prescriber--A person authorized by law to prescribe an opioid antagonist.

36 (c) Dispensing.

37 (1) A pharmacist may dispense an opioid antagonist under a valid prescription, including a  
38 prescription issued by a standing order, to:

39 (A) a person at risk of experiencing an opioid-related drug overdose; or

40 (B) a family member, friend, or other person in a position to assist a person described by  
41 subparagraph (A) of this paragraph.

42 (2) A prescription dispensed under this section is considered as dispensed for a legitimate  
43 medical purpose in the usual course of professional practice.

44 (3) A pharmacist who, acting in good faith and with reasonable care, dispenses or does not  
45 dispense an opioid antagonist under a valid prescription is not subject to any criminal or civil  
46 liability or any professional disciplinary action for:

47 (A) dispensing or failing to dispense the opioid antagonist; or

48 (B) if the pharmacist chooses to dispense an opioid antagonist, any outcome resulting from the  
49 eventual administration of the opioid antagonist.

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

52 Filed with the Office of the Secretary of State on September 12, 2016.

53 TRD-201604759

54 Gay Dodson, R.Ph.

55 Executive Director

56 Texas State Board of Pharmacy

57 Earliest possible date of adoption: October 23, 2016

58 For further information, please call: (512) 305-8028