

## RULE ANALYSIS

**Introduction:** THE NEW RULE IS SUBMITTED TO THE BOARD FOR CONSIDERATION AS A PROPOSED 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 **§295.14 Dispensing of Opioid Antagonist by Pharmacist**

2  
3 (a) Purpose. The purpose of this section is to provide standards for pharmacists  
4 engaged in the dispensing of opioid antagonists as authorized in Chapter 483 of the  
5 Health and Safety Code.

6  
7 (b) Definitions.

8  
9 (1) Opioid antagonist - Any drug that binds to opioid receptors and blocks or otherwise  
10 inhibits the effects of opioids acting on those receptors.

11 (2) Opioid-related drug overdose - A condition, evidenced by symptoms such as  
12 extreme physical illness, decreased level of consciousness, constriction of the pupils,  
13 respiratory depression, or coma, that a layperson would reasonably believe to be the  
14 result of the consumption or use of an opioid.

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

16  
17 (c) Dispensing.

18  
19 (1) A pharmacist may dispense an opioid antagonist under a valid prescription,  
20 including a prescription issued by a standing order, to:

21  
22 (A) a person at risk of experiencing an opioid-related drug overdose; or

23  
24 (B) a family member, friend, or other person in a position to assist a person described  
25 by subparagraph (A) of this paragraph.

26  
27 (2) A prescription dispensed under this section is considered as dispensed for a  
28 legitimate medical purpose in the usual course of professional practice.

29  
30 (3) A pharmacist who, acting in good faith and with reasonable care, dispenses or does  
31 not dispense an opioid antagonist under a valid prescription is not subject to any  
32 criminal or civil liability or any professional disciplinary action for:

33  
34 (A) dispensing or failing to dispense the opioid antagonist; or

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

AN ACT

relating to the prescription, administration, and possession of certain opioid antagonists for the treatment of suspected opioid overdoses.

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

SECTION 1. Chapter 483, Health and Safety Code, is amended by adding Subchapter E to read as follows:

SUBCHAPTER E. OPIOID ANTAGONISTS

Sec. 483.101. DEFINITIONS. In this subchapter:

(1) "Emergency services personnel" includes firefighters, emergency medical services personnel as defined by Section 773.003, emergency room personnel, and other individuals who, in the course and scope of employment or as a volunteer, provide services for the benefit of the general public during emergency situations.

(2) "Opioid antagonist" means any drug that binds to opioid receptors and blocks or otherwise inhibits the effects of opioids acting on those receptors.

(3) "Opioid-related drug overdose" means a condition, evidenced by symptoms such as extreme physical illness, decreased level of consciousness, constriction of the pupils, respiratory depression, or coma, that a layperson would reasonably believe to be the result of the consumption or use of an opioid.

(4) "Prescriber" means a person authorized by law to

1 prescribe an opioid antagonist.

2 Sec. 483.102. PRESCRIPTION OF OPIOID ANTAGONIST; STANDING  
3 ORDER. (a) A prescriber may, directly or by standing order,  
4 prescribe an opioid antagonist to:

5 (1) a person at risk of experiencing an opioid-related  
6 drug overdose; or

7 (2) a family member, friend, or other person in a  
8 position to assist a person described by Subdivision (1).

9 (b) A prescription issued under this section is considered  
10 as issued for a legitimate medical purpose in the usual course of  
11 professional practice.

12 (c) A prescriber who, acting in good faith with reasonable  
13 care, prescribes or does not prescribe an opioid antagonist is not  
14 subject to any criminal or civil liability or any professional  
15 disciplinary action for:

16 (1) prescribing or failing to prescribe the opioid  
17 antagonist; or

18 (2) if the prescriber chooses to prescribe an opioid  
19 antagonist, any outcome resulting from the eventual administration  
20 of the opioid antagonist.

21 Sec. 483.103. DISPENSING OF OPIOID ANTAGONIST. (a) A  
22 pharmacist may dispense an opioid antagonist under a valid  
23 prescription to:

24 (1) a person at risk of experiencing an opioid-related  
25 drug overdose; or

26 (2) a family member, friend, or other person in a  
27 position to assist a person described by Subdivision (1).

1       (b) A prescription filled under this section is considered  
2 as filled for a legitimate medical purpose in the usual course of  
3 professional practice.

4       (c) A pharmacist who, acting in good faith and with  
5 reasonable care, dispenses or does not dispense an opioid  
6 antagonist under a valid prescription is not subject to any  
7 criminal or civil liability or any professional disciplinary action  
8 for:

9           (1) dispensing or failing to dispense the opioid  
10 antagonist; or

11           (2) if the pharmacist chooses to dispense an opioid  
12 antagonist, any outcome resulting from the eventual administration  
13 of the opioid antagonist.

14       Sec. 483.104. DISTRIBUTION OF OPIOID ANTAGONIST; STANDING  
15 ORDER. A person or organization acting under a standing order  
16 issued by a prescriber may store an opioid antagonist and may  
17 distribute an opioid antagonist, provided the person or  
18 organization does not request or receive compensation for storage  
19 or distribution.

20       Sec. 483.105. POSSESSION OF OPIOID ANTAGONIST. Any person  
21 may possess an opioid antagonist, regardless of whether the person  
22 holds a prescription for the opioid antagonist.

23       Sec. 483.106. ADMINISTRATION OF OPIOID ANTAGONIST. (a) A  
24 person who, acting in good faith and with reasonable care,  
25 administers or does not administer an opioid antagonist to another  
26 person whom the person believes is suffering an opioid-related drug  
27 overdose is not subject to criminal prosecution, sanction under any

1 professional licensing statute, or civil liability, for an act or  
2 omission resulting from the administration of or failure to  
3 administer the opioid antagonist.

4 (b) Emergency services personnel are authorized to  
5 administer an opioid antagonist to a person who appears to be  
6 suffering an opioid-related drug overdose, as clinically  
7 indicated.

8 Sec. 483.107. CONFLICT OF LAW. To the extent of a conflict  
9 between this subchapter and another law, this subchapter controls.

10 SECTION 2. The change in law made by this Act relating to  
11 conduct that is grounds for imposition of a disciplinary sanction  
12 applies only to conduct that occurs on or after September 1, 2015.  
13 Conduct that occurs before September 1, 2015, is governed by the law  
14 in effect on the date the conduct occurred, and the former law is  
15 continued in effect for that purpose.

16 SECTION 3. The change in law made by this Act relating to  
17 conduct that is the basis for civil liability applies only to  
18 conduct that occurs on or after September 1, 2015. Conduct that  
19 occurs before September 1, 2015, is governed by the law in effect on  
20 the date the conduct occurred, and the former law is continued in  
21 effect for that purpose.

22 SECTION 4. The change in law made by this Act relating to  
23 conduct that constitutes a criminal offense applies only to an  
24 offense committed on or after September 1, 2015. For purposes of  
25 this section, an offense is committed before September 1, 2015, if  
26 any element of the offense occurs before that date. An offense  
27 committed before September 1, 2015, is governed by the law in effect

1 on the date the offense was committed, and the former law is  
2 continued in effect for that purpose.

3 SECTION 5. This Act takes effect September 1, 2015.

\_\_\_\_\_  
President of the Senate

\_\_\_\_\_  
Speaker of the House

I hereby certify that S.B. No. 1462 passed the Senate on April 22, 2015, by the following vote: Yeas 30, Nays 0; and that the Senate concurred in House amendment on May 29, 2015, by the following vote: Yeas 31, Nays 0.

\_\_\_\_\_  
Secretary of the Senate

I hereby certify that S.B. No. 1462 passed the House, with amendment, on May 26, 2015, by the following vote: Yeas 146, Nays 0, two present not voting.

\_\_\_\_\_  
Chief Clerk of the House

Approved:

\_\_\_\_\_  
Date

\_\_\_\_\_  
Governor