

RULE ANALYSIS

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

Short Title: Grounds for Discipline

Rule Numbers: §281.8

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, implement provisions of SB 460 which amends the Texas Pharmacy Act to include waiving, discounting, reducing, or offering to waive, discount, or reduce a patient copayment or deductible for a compounded drug.

The Board reviewed and voted to propose the amendments during the May 3, 2016, meeting. The proposed amendments were published in the June 24, 2016, issue of the *Texas Register* at 41 TexReg 4588.

1 **PART 15. TEXAS STATE BOARD OF PHARMACY**

2 **CHAPTER 281. ADMINISTRATIVE PRACTICE AND PROCEDURES**

3 **SUBCHAPTER A. GENERAL PROVISIONS**

4 **22 TAC §281.8**

5 The Texas State Board of Pharmacy proposes amendments to §281.8, concerning Grounds for
6 Discipline for a Pharmacy License. The amendments to §281.8, if adopted, implement provisions
7 of SB 460 which amends the Texas Pharmacy Act to include waiving, discounting, reducing, or
8 offering to waive, discount, or reduce a patient copayment or deductible for a compounded drug.

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

12 Ms. Dodson has determined that, for each year of the first five-year period the rule will be in
13 effect, the public benefit anticipated as a result of enforcing the amendments will ensure patients
14 receive appropriate compounded prescriptions. There is no fiscal impact for individuals, small or
15 large businesses, or to other entities which are required to comply with this section.

16 Written comments on the amendments may be submitted to Allison Vordenbaumen Benz, R.Ph.,
17 M.S., Director of Professional Services, Texas State Board of Pharmacy, 333 Guadalupe Street,
18 Suite 3-600, Austin, Texas 78701, FAX (512) 305-6778. Comments must be received by 5:00
19 p.m., August 1, 2016.

20 The amendments are proposed under §§551.002, 554.051, and 565.002 of the Texas Pharmacy
21 Act (Chapters 551 - 569, Texas Occupations Code). The Board interprets §551.002 as
22 authorizing the agency to protect the public through the effective control and regulation of the
23 practice of pharmacy. The Board interprets §554.051(a) as authorizing the agency to adopt rules
24 for the proper administration and enforcement of the Act. The Board interprets §565.002 as
25 authorizing the agency to discipline the holder of a pharmacy license.

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

28 ***§281.8. Grounds for Discipline for a Pharmacy License.***

29 (a) For the purposes of §565.002(a)(9) of the Act, a pharmacy fails to establish and maintain
30 effective controls against diversion of prescription drugs when:

31 (1) there is inadequate security or procedures to prevent unauthorized access to prescription
32 drugs; or

33 (2) there is inadequate security or procedures to prevent the diversion of prescription drugs.

34 (b) For the purposes of §565.002(a)(3) of the Act, it is grounds for discipline for a pharmacy
35 license when:

36 (1) during the time an individual's license to practice pharmacy, either as a pharmacist or a
37 pharmacist-intern, or a pharmacy technician's registration has been disciplined by the Board,
38 resulting in the license or registration being revoked, canceled, retired, surrendered, denied or
39 suspended, the pharmacy employs or allows such individual access to prescription drugs;

40 (2) the pharmacy possesses or engages in the sale, purchase, or trade or the offer to sell,
41 purchase, or trade prescription drug samples; provided however, this paragraph does not apply
42 to:

43 (A) prescription drugs provided by a manufacturer as starter prescriptions or as replacement for
44 such manufacturer's outdated drugs;

45 (B) prescription drugs provided by a manufacturer in replacement for such manufacturer's drugs
46 that were dispensed pursuant to written starter prescriptions; or

47 (C) prescription drug samples possessed by a pharmacy of a health care entity which provides
48 health care primarily to indigent or low income patients at no or reduced cost and if:

49 (i) the samples are possessed in compliance with the Prescription Drug Marketing Act of 1987;

50 (ii) the pharmacy is owned by a charitable organization described in the Internal Revenue Code
51 of 1986, §501(c)(3), or by a city, state or county government; and

52 (iii) the samples are for dispensing or provision at no charge to patients of such health care
53 entity;

54 (3) the pharmacy possesses or engages in the sale, purchase, or trade or the offer to sell,
55 purchase, or trade of prescription drugs:

56 (A) sold for export use only;

57 (B) purchased by a public or private hospital or other health care entity; or

58 (C) donated or supplied at a reduced price to a charitable organization described in the Internal
59 Revenue Code of 1986, §501(c)(3), and possessed by a pharmacy other than one owned by the
60 charitable organization;

61 (D) provided that subparagraphs (A) - (C) of this paragraph do not apply to:

62 (i) the purchase or other acquisition by a hospital or other health care entity which is a member
63 of a group purchasing organization or from other hospitals or health care entities which are
64 members of such organization;

- 65 (ii) the sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug by an
66 organization described in paragraph (2)(C)(ii) of this subsection to a nonprofit affiliate of the
67 organization to the extent otherwise permitted by law;
- 68 (iii) the sale, purchase or trade of a drug or an offer to sell, purchase, or trade a drug among
69 hospitals or other health care entities which are under common control;
- 70 (iv) the sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug for
71 emergency medical reasons including the transfer of a drug between pharmacies to alleviate
72 temporary shortages of the drug arising from delays in or interruptions of regular distribution
73 schedules;
- 74 (v) the dispensing of a prescription drug pursuant to a valid prescription drug order to the extent
75 otherwise permitted by law;
- 76 (4) the pharmacy engages in the sale, purchase, or trade or the offer to sell, purchase, or trade of:
- 77 (A) misbranded prescription drugs; or
- 78 (B) prescription drugs beyond the manufacturer's expiration date.
- 79 (5) the owner or managing officer has previously been disciplined by the board; or
- 80 (6) a non-resident pharmacy fails to reimburse the board or its designee for all expenses,
81 including travel, incurred by the board in inspecting the non-resident pharmacy as specified in
82 §556.0551 of the Act; ~~or~~
- 83 (7) the owner, managing officer(s), or other pharmacy employee(s) displays abusive,
84 intimidating, or threatening behavior toward a board member or employee during the
85 performance of such member's or employee's lawful duties; or[-]
- 86 (8) the pharmacy waived, discounted, or reduced, or offered to waive, discount, or reduce, a
87 patient copayment or deductible for a compounded drug in the absence of:
- 88 (A) a legitimate, documented financial hardship of the patient; or
- 89 (B) evidence of a good faith effort to collect the copayment or deductible from the patient.
- 90 (c) For the purposes of §565.002(a)(10) of the Act, the terms "fraud," "deceit," or
91 "misrepresentation" in operating a pharmacy or in seeking a license to operate shall be defined as
92 follows:
- 93 (1) "Fraud" means an intentional perversion of truth for the purpose of inducing another in
94 reliance upon it to part with some valuable thing belonging to him, or to surrender a legal right,
95 or to issue a license; a false representation of a matter of fact, whether by words or by conduct,

96 by false or misleading allegations, or by concealment of that which should have been disclosed,
97 which deceives or is intended to deceive another;

98 (2) "Deceit" means the assertion, as a fact, of that which is not true by any means whatsoever to
99 deceive or defraud another; and

100 (3) "Misrepresentation" means a manifestation by words or other conduct which is a false
101 representation of a matter of fact.

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