

RULE ANALYSIS

Introduction: THE AMENDMENTS ARE SUBMITTED TO THE BOARD FOR CONSIDERATION AS A PROPOSED 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, add abusive, intimidating, or threatening behavior toward a board member or employee during the performance of such member's or employee's lawful duties by the owner, managing officer(s), or other pharmacy employee(s) as grounds for discipline of a pharmacy license.

1 **TITLE 22 EXAMINING BOARDS**
2 **PART 15 TEXAS STATE BOARD OF PHARMACY**
3 **CHAPTER 281 ADMINISTRATIVE PRACTICE AND PROCEDURES**
4 **SUBCHAPTER A GENERAL PROVISIONS**

5
6 **§281.8 Grounds for Discipline for a Pharmacy License**
7

8
9 (a) For the purposes of §565.002(a)(9) of the Act, a pharmacy fails to establish and maintain
10 effective controls against diversion of prescription drugs when:

11
12 (1) there is inadequate security or procedures to prevent unauthorized access to prescription
13 drugs; or

14
15 (2) there is inadequate security or procedures to prevent the diversion of prescription drugs.
16

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

19
20 (1) during the time an individual's license to practice pharmacy, either as a pharmacist or a
21 pharmacist-intern, or a pharmacy technician's registration has been disciplined by the Board,
22 resulting in the license or registration being revoked, canceled, retired, surrendered, denied or
23 suspended, the pharmacy employs or allows such individual access to prescription drugs;
24

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

28
29 (A) prescription drugs provided by a manufacturer as starter prescriptions or as replacement
30 for such manufacturer's outdated drugs;

31
32 (B) prescription drugs provided by a manufacturer in replacement for such manufacturer's
33 drugs that were dispensed pursuant to written starter prescriptions; or
34

35 (C) prescription drug samples possessed by a pharmacy of a health care entity which
36 provides health care primarily to indigent or low income patients at no or reduced cost and if:
37

38 (i) the samples are possessed in compliance with the Prescription Drug Marketing Act of
39 1987;

40
41 (ii) the pharmacy is owned by a charitable organization described in the Internal Revenue
42 Code of 1986, §501(c)(3), or by a city, state or county government; and
43

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

46
47 (3) the pharmacy possesses or engages in the sale, purchase, or trade or the offer to sell,
48 purchase, or trade of prescription drugs:

49 (A) sold for export use only;
50
51

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

53
54 (C) donated or supplied at a reduced price to a charitable organization described in the
55 Internal Revenue Code of 1986, §501(c)(3), and possessed by a pharmacy other than one
56 owned by the charitable organization;

57
58 (D) provided that subparagraphs (A) - (C) of this paragraph do not apply to:

59
60 (i) the purchase or other acquisition by a hospital or other health care entity which is a
61 member of a group purchasing organization or from other hospitals or health care entities which
62 are members of such organization;

63
64 (ii) the sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug by an
65 organization described in paragraph (2)(C)(ii) of this subsection to a nonprofit affiliate of the
66 organization to the extent otherwise permitted by law;

67
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
71 (iv) the sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug for
72 emergency medical reasons including the transfer of a drug between pharmacies to alleviate
73 temporary shortages of the drug arising from delays in or interruptions of regular distribution
74 schedules;

75
76 (v) the dispensing of a prescription drug pursuant to a valid prescription drug order to the
77 extent otherwise permitted by law;

78
79 (4) the pharmacy engages in the sale, purchase, or trade or the offer to sell, purchase, or trade
80 of:

81
82 (A) misbranded prescription drugs; or

83
84 (B) prescription drugs beyond the manufacturer's expiration date.

85
86 (5) the owner or managing officer has previously been disciplined by the board; ~~[or]~~

87
88 (6) a non-resident pharmacy fails to reimburse the board or its designee for all expenses,
89 including travel, incurred by the board in inspecting the non-resident pharmacy as specified in
90 §556.0551 of the Act; or

91
92 **(7) the owner, managing officer(s), or other pharmacy employee(s) displays abusive,**
93 **intimidating, or threatening behavior toward a board member or employee during the**
94 **performance of such member's or employee's lawful duties .**

95
96 (c) For the purposes of §565.002(a)(10) of the Act, the terms "fraud," "deceit," or
97 "misrepresentation" in operating a pharmacy or in seeking a license to operate shall be defined
98 as follows:

99
100 (1) "Fraud" means an intentional perversion of truth for the purpose of inducing another in
101 reliance upon it to part with some valuable thing belonging to him, or to surrender a legal right,
102 or to issue a license; a false representation of a matter of fact, whether by words or by conduct,

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

105

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

108

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