

RULE ANALYSIS

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

Short Title: Administrative Penalties

Rule Numbers: §281.65

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 an administrative penalty for failing to operate a pharmacy within six months of the date of issuance of the pharmacy license and make minor corrections.

1 TITLE 22 EXAMINING BOARDS
2 PART 15 TEXAS STATE BOARD OF PHARMACY
3 CHAPTER 281 ADMINISTRATIVE PRACTICE AND PROCEDURES
4 SUBCHAPTER C DISCIPLINARY GUIDELINES

5
6 **§281.65. Schedule of Administrative Penalties.**
7

8 The board has determined that the assessment of an administrative penalty promotes the intent
9 of §551.002 of the Act. In disciplinary matters, the board may assess an administrative penalty
10 in addition to any other disciplinary action in the circumstances and amounts as follows:

11 (1) The following violations by a pharmacist may be appropriate for disposition with an
12 administrative penalty with or without additional sanctions or restrictions:

13 (A) **failing** [failure] to provide patient counseling: \$1,000;

14 (B) **failing** [failure] to conduct a drug regimen review or inappropriate drug regimen reviews
15 provided by §291.33(c)(2)(A): \$1,000;

16 (C) **failing** [failure] to clarify a prescription with the prescriber: \$1,000;

17 (D) **failing** [failure] to properly supervise or improperly delegating a duty to a pharmacy
18 technician: \$1,000;

19 (E) **failing** [failure] to identify the dispensing pharmacist on required pharmacy records:
20 \$500;

21 (F) **failing** [failure] to maintain records of prescriptions: \$500;

22 (G) **failing** [failure] to respond or **failing** [failure] to provide all requested records within the
23 time specified in a board audit of continuing education records: \$100 per hour of continuing
24 education credit not provided;

25 (H) **failing** [failure] to provide or providing false or fraudulent information on any application,
26 notification, or other document required under this Act, the Dangerous Drug Act, or Controlled
27 Substances Act, or rules adopted pursuant to those Acts: \$1,000;

28 (I) ~~[shortages of prescription drugs]~~ following an accountability audit, **shortages of**
29 **prescription drugs**: up to \$5,000;

30 (J) dispensing a prescription drug pursuant to a forged, altered, or fraudulent prescription: up
31 to \$5,000;

32 (K) dispensing unauthorized prescriptions: up to \$5,000;

33 (L) dispensing controlled substances or dangerous drugs to an individual or individuals in
34 quantities, dosages, or for periods of time which grossly exceed standards of practice, approved
35 labeling of the federal Food and Drug Administration, or the guidelines published in professional
36 literature: up to \$5,000;

37 (M) violating a disciplinary order of the Board or a contract under the program to aid impaired
38 pharmacists or pharmacy students under Chapter 564 of the Act: \$500 - \$1,000;

39 (N) **failing** [failure] to report or to assure the report of a malpractice claim: up to \$1,000;

40 (O) **failing** [failure] to respond within the time specified on a warning notice to such warning
41 notice issued as a result of a compliance inspection or responding to a warning notice as a
42 result of a compliance inspection in a manner that is false or misleading: up to \$1,000;

43 (P) practicing pharmacy with a delinquent license: \$250 - \$1,000;

44 (Q) operating a pharmacy with a delinquent license: \$1,000 - \$5,000;

45 (R) allowing an individual to perform the duties of a pharmacy technician without a valid
46 registration: \$500 - \$2,000;

47 (S) **failing** [failure] to comply with the requirements of the Official Prescription Program: up to
48 \$1,000;

49 (T) aiding and abetting the unlicensed practice of pharmacy, if the pharmacist knew or
50 reasonably should have known that the person was unlicensed at the time: up to \$5,000;

- 51 (U) **receiving** a conviction or deferred adjudication for a misdemeanor or felony, which
52 serves as a ground for discipline under the Act: up to \$5,000;
- 53 (V) unauthorized substitutions: \$1,000;
- 54 (W) **submitting** false or fraudulent claims to third parties for reimbursement of pharmacy
55 services: up to \$5,000;
- 56 (X) **selling, purchasing, or trading, or offering** [~~sale, purchase, or trade or offer~~] to sell,
57 purchase, or trade of misbranded prescription drugs or prescription drugs beyond the
58 manufacturer's expiration date: up to \$1,000;
- 59 (Y) **selling, purchasing, or trading, or offering** [~~sale, purchase, or trade or offer~~] to sell,
60 purchase, or trade of prescription drug samples as provided by §281.7(a)(27) of this title
61 (relating to Grounds for Discipline for a Pharmacist License): up to \$1,000;
- 62 (Z) **failing** [~~failure~~] to keep, maintain or furnish an annual inventory as required by §291.17:
63 \$1,000;
- 64 (AA) **failing** [~~failure~~] to obtain training on the preparation of sterile pharmaceutical
65 compounding: \$1,000;
- 66 (BB) **failing** [~~failure~~] to maintain the confidentiality of prescription records: \$1,000 - \$5,000;
- 67 (CC) **failing** [~~failure~~] to inform the board of any notification or information required to be
68 reported by the Act or rules: \$250 - \$500; **and**
- 69 **(DD) failing to operate a pharmacy within six months of the date of issuance of the**
70 **license: \$2,000.**
- 71
- 72 (2) The following violations by a pharmacy may be appropriate for disposition with an
73 administrative penalty with or without additional sanctions or restrictions:
- 74 (A) **failing** [~~failure~~] to provide patient counseling: \$1,500;
- 75 (B) **failing** [~~failure~~] to conduct a drug regimen review or inappropriate drug regimen reviews
76 provided by §291.33(c)(2)(A) of this title (relating to Operational Standards): \$1,500;
- 77 (C) **failing** [~~failure~~] to clarify a prescription with the prescriber: \$1,500;
- 78 (D) **failing** [~~failure~~] to properly supervise or improperly delegating a duty to a pharmacy
79 technician: \$1,500;
- 80 (E) **failing** [~~failure~~] to identify the dispensing pharmacist on required pharmacy records:
81 \$500;
- 82 (F) **failing** [~~failure~~] to maintain records of prescriptions: \$500;
- 83 (G) **failing** [~~failure~~] to provide or providing false or fraudulent information on any application,
84 notification, or other document required under this Act, the Dangerous Drug Act, or Controlled
85 Substances Act, or rules adopted pursuant to those Acts: \$1,000;
- 86 (H) [~~shortages of prescription drugs~~] following an accountability audit, **shortages of**
87 **prescription drugs**: up to \$5,000;
- 88 (I) dispensing a prescription drug pursuant to a forged, altered, or fraudulent prescription: up
89 to \$5,000;
- 90 (J) dispensing unauthorized prescriptions: up to \$5,000;
- 91 (K) dispensing controlled substances or dangerous drugs to an individual or individuals in
92 quantities, dosages, or for periods of time which grossly exceed standards of practice, approved
93 labeling of the federal Food and Drug Administration, or the guidelines published in professional
94 literature: up to \$5,000;
- 95 (L) violating a disciplinary order of the Board: \$1,000 - \$5,000;
- 96 (M) **failing** [~~failure~~] to report or to assure the report of a malpractice claim: up to \$1,000;
- 97 (N) **failing** [~~failure~~] to respond within the time specified on a warning notice to such warning
98 notice issued as a result of a compliance inspection or responding to a warning notice as a
99 result of a compliance inspection in a manner that is false or misleading: up to \$1,000;
- 100 (O) allowing a pharmacist to practicing pharmacy with a delinquent license: \$250 - \$1,000;
- 101 (P) operating a pharmacy with a delinquent license: \$1,000 - \$5,000;

- 102 (Q) allowing an individual to perform the duties of a pharmacy technician without a valid
103 registration: \$500 - \$3,000;
- 104 (R) **failing** [failure] to comply with the requirements of the Official Prescription Program: up to
105 \$1,000;
- 106 (S) aiding and abetting the unlicensed practice of pharmacy, if an employee of the pharmacy
107 knew or reasonably should have known that the person engaging in the practice of pharmacy
108 was unlicensed at the time: up to \$5,000;
- 109 (T) **receiving** a conviction or deferred adjudication for a misdemeanor or felony which serves
110 as a ground for discipline under the Act: up to \$5,000;
- 111 (U) unauthorized substitutions: \$1,000;
- 112 (V) **submitting** false or fraudulent claims to third parties for reimbursement of pharmacy
113 services: up to \$5,000;
- 114 (W) possessing or engaging in the sale, purchase, or trade or the offer to sell, purchase, or
115 trade of misbranded prescription drugs or prescription drugs beyond the manufacturer's
116 expiration date: up to \$1,000;
- 117 (X) possessing or engaging in the sale, purchase, or trade or the offer to sell, purchase, or
118 trade of prescription drug samples as provided by §281.8(b)(2) of this title (relating to Grounds
119 for Discipline for a Pharmacy License): up to \$1,000;
- 120 (Y) **failing** [failure] to keep, maintain or furnish an annual inventory as required by §291.17 of
121 this title (relating to Inventory Requirements): \$1,000;
- 122 (Z) **failing** [failure] to obtain training on the preparation of sterile pharmaceutical
123 compounding: \$1,500;
- 124 (AA) **failing** [failure] to maintain the confidentiality of prescription records: \$1,000 - \$5,000;
- 125 (BB) **failing** [failure] to inform the board of any notification or information required to be
126 reported by the Act or rules: \$250 - \$500; **and**
- 127 **(CC) failing to operate a pharmacy within six months of the date of issuance of the**
128 **license: \$3,000.**
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- 130 (3) The following violations by a pharmacy technician may be appropriate for disposition with
131 an administrative penalty with or without additional sanctions or restrictions:
- 132 (A) **failing** [failure] to respond or **failing** [failure] to provide all requested records within the
133 time specified in a board audit of continuing education records: \$30 per hour of continuing
134 education credit not provided;
- 135 (B) **failing** [failure] to provide or providing false or fraudulent information on any application,
136 notification, or other document required under this Act, the Dangerous Drug Act, or Controlled
137 Substances Act, or rules adopted pursuant to those Acts: \$500;
- 138 (C) ~~shortages of prescription drugs~~ following an accountability audit, **shortages of**
139 **prescription drugs**: up to \$5,000;
- 140 (D) violating a disciplinary Order of the Board: \$250 - \$500;
- 141 (E) **failing** [failure] to report or to assure the report of a malpractice claim: up to \$500;
- 142 (F) performing the duties of a pharmacy technician without a valid registration: \$250 -
143 \$1,000;
- 144 (G) **receiving** a conviction or deferred adjudication for a misdemeanor or felony, which
145 serves as a ground for discipline under the Act: up to \$5,000;
- 146 (H) **submitting** false or fraudulent claims to third parties for reimbursement of pharmacy
147 services: up to \$5,000;
- 148 (I) **failing** [failure] to obtain training on the preparation of sterile pharmaceutical
149 compounding: \$1,000;
- 150 (J) **failing** [failure] to maintain the confidentiality of prescription records: \$1,000 - \$5,000;
- 151 (K) **failing** [failure] to inform the board of any notification or information required to be
152 reported by the Act or rules: \$100 - \$250.

153 (4) Any of the violations listed in this section may be appropriate for disposition by the
154 administrative penalties in this section in conjunction with any other penalties in §281.61 of this
155 chapter.

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157 (5) Each day a violation continues or occurs is a separate violation for purposes of imposing a
158 penalty or fine.

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160 (6) The amount, to the extent possible, shall be based on:

161 (A) the seriousness of the violation, including the nature, circumstances, extent, and gravity of
162 any prohibited act, and the hazard or potential hazard created to the health, safety, or economic
163 welfare of the public;

164 (B) the economic harm to property or the environment caused by the violation;

165 (C) the history of previous violations;

166 (D) the amount necessary to deter a future violation;

167 (E) efforts to correct the violation; and

168 (F) and other matter that justice may require.