

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, 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.

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

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

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14 (2) there is inadequate security or procedures to prevent the diversion of prescription drugs.
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16 (b) For the purposes of §565.002(a)(3) of the Act, it is grounds for discipline for a pharmacy
17 license when:

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19 (1) during the time an individual's license to practice pharmacy, either as a pharmacist or a
20 pharmacist-intern, or a pharmacy technician's registration has been disciplined by the Board,
21 resulting in the license or registration being revoked, canceled, retired, surrendered, denied or
22 suspended, the pharmacy employs or allows such individual access to prescription drugs;
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24 (2) the pharmacy possesses or engages in the sale, purchase, or trade or the offer to sell,
25 purchase, or trade prescription drug samples; provided however, this paragraph does not apply
26 to:

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29 for such manufacturer's outdated drugs;

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31 (B) prescription drugs provided by a manufacturer in replacement for such manufacturer's
32 drugs that were dispensed pursuant to written starter prescriptions; or
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34 (C) prescription drug samples possessed by a pharmacy of a health care entity which
35 provides health care primarily to indigent or low income patients at no or reduced cost and if:
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37 (i) the samples are possessed in compliance with the Prescription Drug Marketing Act of
38 1987;

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40 (ii) the pharmacy is owned by a charitable organization described in the Internal Revenue
41 Code of 1986, §501(c)(3), or by a city, state or county government; and
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43 (iii) the samples are for dispensing or provision at no charge to patients of such health care
44 entity;
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46 (3) the pharmacy possesses or engages in the sale, purchase, or trade or the offer to sell,
47 purchase, or trade of prescription drugs:

48 (A) sold for export use only;

49 (B) purchased by a public or private hospital or other health care entity; or
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53 (C) donated or supplied at a reduced price to a charitable organization described in the
54 Internal Revenue Code of 1986, §501(c)(3), and possessed by a pharmacy other than one
55 owned by the charitable organization;

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

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

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

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67 (iii) the sale, purchase or trade of a drug or an offer to sell, purchase, or trade a drug among
68 hospitals or other health care entities which are under common control;

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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;

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

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

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81 (A) misbranded prescription drugs; or

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

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

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

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

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95 **(8) the pharmacy waived, discounted, or reduced, or offered to waive, discount, or**
96 **reduce, a patient copayment or deductible for a compounded drug in the absence of:**

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98 **(A) a legitimate, documented financial hardship of the patient; or**

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100 **(B) evidence of a good faith effort to collect the copayment or deductible from the**
101 **patient.**

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

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107 (1) "Fraud" means an intentional perversion of truth for the purpose of inducing another in
108 reliance upon it to part with some valuable thing belonging to him, or to surrender a legal right,
109 or to issue a license; a false representation of a matter of fact, whether by words or by conduct,
110 by false or misleading allegations, or by concealment of that which should have been disclosed,
111 which deceives or is intended to deceive another;

112
113 (2) "Deceit" means the assertion, as a fact, of that which is not true by any means whatsoever
114 to deceive or defraud another; and

115
116 (3) "Misrepresentation" means a manifestation by words or other conduct which is a false
117 representation of a matter of fact.

AN ACT

relating to the licensing and regulation of pharmacists and pharmacies.

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

SECTION 1. Section 483.047, Health and Safety Code, is amended by amending Subsection (a) and adding Subsections (b-1) and (b-2) to read as follows:

(a) Except as authorized by Subsections [~~Subsection~~] (b) and (b-1), a pharmacist commits an offense if the pharmacist refills a prescription unless:

(1) the prescription contains an authorization by the practitioner for the refilling of the prescription, and the pharmacist refills the prescription in the manner provided by the authorization; or

(2) at the time of refilling the prescription, the pharmacist is authorized to do so by the practitioner who issued the prescription.

(b-1) Notwithstanding Subsection (b), in the event of a natural or manmade disaster, a pharmacist may dispense not more than a 30-day supply of a dangerous drug without the authorization of the prescribing practitioner if:

(1) failure to refill the prescription might result in an interruption of a therapeutic regimen or create patient suffering;

1 (2) the natural or manmade disaster prohibits the
2 pharmacist from being able to contact the practitioner;

3 (3) the governor has declared a state of disaster
4 under Chapter 418, Government Code; and

5 (4) the board, through the executive director, has
6 notified pharmacies in this state that pharmacists may dispense up
7 to a 30-day supply of a dangerous drug.

8 (b-2) The prescribing practitioner is not liable for an act
9 or omission by a pharmacist in dispensing a dangerous drug under
10 Subsection (b-1).

11 SECTION 2. Section 555.002(a), Occupations Code, is amended
12 to read as follows:

13 (a) The board by rule shall establish methods by which
14 consumers and service recipients are notified of the name, mailing
15 address, and telephone number of the board for the purpose of
16 directing complaints to the board. The board may provide for that
17 notice:

18 (1) on each registration form, application, or written
19 contract for services of a person regulated by the board;

20 (2) on a sign prominently displayed in the place of
21 business of each person regulated by the board; ~~[or]~~

22 (3) on an electronic messaging system in a font
23 specified by board rule prominently displayed in the place of
24 business of each person regulated by the board; or

25 (4) in a bill for service provided by a person
26 regulated by the board.

27 SECTION 3. Section 556.051, Occupations Code, is amended to

1 read as follows:

2 Sec. 556.051. AUTHORIZATION TO ENTER AND INSPECT. (a) The
3 board or a representative of the board may enter and inspect a
4 facility relative to the following:

5 (1) drug storage and security;

6 (2) equipment;

7 (3) components used in compounding, finished and
8 unfinished products, containers, and labeling of any item;

9 (4) sanitary conditions; ~~or~~

10 (5) records, reports, or other documents required to
11 be kept or made under this subtitle, Chapter 481 or 483, Health and
12 Safety Code, or the Comprehensive Drug Abuse Prevention and Control
13 Act of 1970 (21 U.S.C. Section 801 et seq.) or rules adopted under
14 one of those laws; or

15 (6) subject to Subsection (b), financial records
16 relating to the operation of the facility.

17 (b) The board or a representative of the board may inspect
18 financial records under Subsection (a) only in the course of the
19 investigation of a specific complaint. The board or representative
20 may inspect only records related to the specific complaint. The
21 inspection is subject to Section 565.055.

22 SECTION 4. Section 556.054, Occupations Code, is amended to
23 read as follows:

24 Sec. 556.054. CONFIDENTIALITY OF CERTAIN INFORMATION
25 [LIMITATION ON INSPECTION]. The following information obtained by
26 the board during an inspection of a facility is confidential and not
27 subject to disclosure under Chapter 552, Government Code [Unless

1 ~~the owner, pharmacist, or agent in charge of a facility consents in~~
2 ~~writing, an inspection of the facility authorized by this chapter~~
3 ~~may not extend to]:~~

- 4 (1) financial data;
- 5 (2) sales data, other than shipment data; and ~~[or]~~
- 6 (3) pricing data.

7 SECTION 5. Subchapter B, Chapter 556, Occupations Code, is
8 amended by adding Section 556.057 to read as follows:

9 Sec. 556.057. INSPECTION OF PHARMACIST RECORDS. A
10 pharmacist shall provide to the board, on request, records of the
11 pharmacist's practice that occurs outside of a pharmacy. The
12 pharmacist shall provide the records at a time specified by board
13 rule.

14 SECTION 6. Sections 558.055(a) and (b), Occupations Code,
15 are amended to read as follows:

16 (a) An applicant who on the applicant's first attempt fails
17 the examination may take the examination four ~~[two]~~ additional
18 times.

19 (b) Before an applicant who has failed the examination five
20 ~~[three]~~ times is allowed to retake the examination, the applicant
21 must provide documentation from a college of pharmacy that the
22 applicant has successfully completed additional college course
23 work in each examination subject area the applicant failed.

24 SECTION 7. Section 560.052(b), Occupations Code, is amended
25 to read as follows:

26 (b) To qualify for a pharmacy license, an applicant must
27 submit to the board:

1 (1) a license fee set by the board, except as provided
2 by Subsection (d); and

3 (2) a completed application that:

4 (A) is on a form prescribed by the board;

5 (B) is given under oath;

6 (C) includes proof that:

7 (i) a pharmacy license held by the
8 applicant in this state or another state, if applicable, has not
9 been restricted, suspended, revoked, or surrendered for any reason;
10 and

11 (ii) no owner of the pharmacy for which the
12 application is made has held a pharmacist license in this state or
13 another state, if applicable, that has been restricted, suspended,
14 revoked, or surrendered for any reason; and

15 (D) includes a statement of:

16 (i) the ownership;

17 (ii) the location of the pharmacy;

18 (iii) the license number of each pharmacist
19 who is employed by the pharmacy, if the pharmacy is located in this
20 state, or who is licensed to practice pharmacy in this state, if the
21 pharmacy is located in another state;

22 (iv) the pharmacist license number of the
23 pharmacist-in-charge; and

24 (v) any other information the board
25 determines necessary.

26 SECTION 8. Section 561.003(e), Occupations Code, is amended
27 to read as follows:

1 (e) If a pharmacy's license has been expired for 91 days
2 [~~one year~~] or more, the pharmacy may not renew the license. The
3 pharmacy may obtain a new license by complying with the
4 requirements and procedures for obtaining an original license.

5 SECTION 9. Sections 562.056(a) and (a-1), Occupations Code,
6 are amended to read as follows:

7 (a) Before dispensing a prescription, a pharmacist shall
8 determine, in the exercise of sound professional judgment, that the
9 prescription is a valid prescription. A pharmacist may not
10 dispense a prescription drug if the pharmacist knows or should know
11 that the prescription was issued [~~on the basis of an Internet-based~~
12 ~~or telephonic consultation~~] without a valid practitioner-patient
13 relationship.

14 (a-1) To be a valid prescription, a prescription [~~for a~~
15 ~~controlled substance~~] must be issued for a legitimate medical
16 purpose by a practitioner acting in the usual course of the
17 practitioner's professional practice. The responsibility for the
18 proper prescribing and dispensing of prescription drugs
19 [~~controlled substances~~] is on the prescribing practitioner, but a
20 corresponding responsibility rests with the pharmacist who fills
21 the prescription.

22 SECTION 10. Section 562.106, Occupations Code, is amended
23 by amending Subsection (a) and adding Subsection (a-1) to read as
24 follows:

25 (a) A pharmacy shall report in writing to the board not
26 later than the 10th day after the date of:

27 (1) a permanent closing of the pharmacy;

- 1 (2) a change of ownership of the pharmacy;
- 2 (3) [~~a change of location of the pharmacy,~~
- 3 [~~(4)~~] a change of the person designated as the
- 4 pharmacist-in-charge of the pharmacy;
- 5 (4) [~~(5)~~] a sale or transfer of any controlled
- 6 substance or dangerous drug as a result of the permanent closing or
- 7 change of ownership of the pharmacy;
- 8 (5) [~~(6)~~] any matter or occurrence that the board
- 9 requires by rule to be reported;
- 10 (6) [~~(7)~~] as determined by the board, an out-of-state
- 11 purchase of any controlled substance;
- 12 (7) [~~(8)~~] a final order against the pharmacy license
- 13 holder by the regulatory or licensing agency of the state in which
- 14 the pharmacy is located if the pharmacy is located in another state;
- 15 or
- 16 (8) [~~(9)~~] a final order against a pharmacist who is
- 17 designated as the pharmacist-in-charge of the pharmacy by the
- 18 regulatory or licensing agency of the state in which the pharmacy is
- 19 located if the pharmacy is located in another state.
- 20 (a-1) A pharmacy shall report in writing to the board not
- 21 later than the 30th day before the date of a change of location of
- 22 the pharmacy.

23 SECTION 11. Section [565.002\(a\)](#), Occupations Code, is

24 amended to read as follows:

25 (a) The board may discipline an applicant for or the holder

26 of a pharmacy license, including a Class E pharmacy license subject

27 to Section [565.003](#) [~~[565.003\(b\)](#)~~], if the board finds that the

1 applicant or license holder has:

2 (1) been convicted of or placed on deferred
3 adjudication community supervision or deferred disposition or the
4 applicable federal equivalent for:

5 (A) a misdemeanor:

6 (i) involving moral turpitude; or

7 (ii) under Chapter 481 or 483, Health and
8 Safety Code, or the Comprehensive Drug Abuse Prevention and Control
9 Act of 1970 (21 U.S.C. Section 801 et seq.); or

10 (B) a felony;

11 (2) advertised a prescription drug or device in a
12 deceitful, misleading, or fraudulent manner;

13 (3) violated any provision of this subtitle or any
14 rule adopted under this subtitle or that an owner or employee of a
15 pharmacy has violated any provision of this subtitle or any rule
16 adopted under this subtitle;

17 (4) sold without legal authorization a prescription
18 drug or device to a person other than:

19 (A) a pharmacy licensed by the board;

20 (B) a practitioner;

21 (C) a person who procures a prescription drug or
22 device for lawful research, teaching, or testing, and not for
23 resale;

24 (D) a manufacturer or wholesaler licensed by the
25 commissioner of public health as required by Chapter 431, Health
26 and Safety Code; or

27 (E) a carrier or warehouseman;

1 (5) allowed an employee who is not a pharmacist to
2 practice pharmacy;

3 (6) sold an adulterated or misbranded prescription or
4 nonprescription drug;

5 (7) failed to engage in or ceased to engage in the
6 business described in the application for a license;

7 (8) failed to maintain records as required by this
8 subtitle, Chapter 481 or 483, Health and Safety Code, the
9 Comprehensive Drug Abuse Prevention and Control Act of 1970 (21
10 U.S.C. Section 801 et seq.), or any rule adopted under this subtitle
11 or Chapter 483, Health and Safety Code;

12 (9) failed to establish and maintain effective
13 controls against diversion of prescription drugs into other than a
14 legitimate medical, scientific, or industrial channel as provided
15 by this subtitle, another state statute or rule, or a federal
16 statute or rule;

17 (10) engaged in fraud, deceit, or misrepresentation as
18 defined by board rule in operating a pharmacy or in applying for a
19 license to operate a pharmacy;

20 (11) violated a disciplinary order;

21 (12) been responsible for a drug audit shortage; ~~[or]~~

22 (13) been disciplined by the regulatory board of
23 another state for conduct substantially equivalent to conduct
24 described under this subsection; or

25 (14) waived, discounted, or reduced, or offered to
26 waive, discount, or reduce, a patient copayment or deductible for a
27 compounded drug in the absence of:

1 (A) a legitimate, documented financial hardship
2 of the patient; or

3 (B) evidence of a good faith effort to collect
4 the copayment or deductible from the patient.

5 SECTION 12. Section 565.060(d), Occupations Code, is
6 amended to read as follows:

7 (d) If a license holder complies with and successfully
8 completes the terms of a remedial plan, the board shall remove all
9 records of the remedial plan from the board's records at the end of
10 the state fiscal year in which ~~on~~ the fifth anniversary of the
11 date the board issued the terms of the remedial plan occurs.

12 SECTION 13. Section 565.061(a), Occupations Code, is
13 amended to read as follows:

14 (a) Except as provided by Chapter 564, a disciplinary action
15 taken by the board ~~[under Section 565.060 or]~~ on the basis of a
16 ground for discipline under Subchapter A is governed by Chapter
17 2001, Government Code, and the rules of practice and procedure
18 before the board.

19 SECTION 14. The following provisions of the Occupations
20 Code are repealed:

- 21 (1) Section 561.003(d);
22 (2) Section 562.009(a-1); and
23 (3) Section 562.051.

24 SECTION 15. The change in law made by this Act to Section
25 483.047, Health and Safety Code, applies only to an offense
26 committed on or after the effective date of this Act. An offense
27 committed before the effective date of this Act is governed by the

1 law in effect on the date the offense was committed, and the former
2 law is continued in effect for that purpose. For purposes of this
3 section, an offense was committed before the effective date of this
4 Act if any element of the offense occurred before that date.

5 SECTION 16. Section 560.052(b), Occupations Code, as
6 amended by this Act, applies only to an application for a pharmacy
7 license submitted on or after the effective date of this Act. An
8 application submitted before the effective date of this Act is
9 governed by the law in effect on the date the application was
10 submitted, and the former law is continued in effect for that
11 purpose.

12 SECTION 17. Section 561.003(e), Occupations Code, as
13 amended by this Act, and the repeal by this Act of Section
14 561.003(d), Occupations Code, apply only to a pharmacy license that
15 expires on or after the effective date of this Act. A pharmacy
16 license that expired before the effective date of this Act is
17 governed by the law in effect on the date the license expired, and
18 the former law is continued in effect for that purpose.

19 SECTION 18. Section 562.106(a), Occupations Code, as
20 amended by this Act, and Section 562.106(a-1), Occupations Code, as
21 added by this Act, apply only to a pharmacy that changes location on
22 or after October 1, 2015. A pharmacy that changes location before
23 that date is governed by the law in effect immediately before the
24 effective date of this Act, and the former law is continued in
25 effect for that purpose.

26 SECTION 19. The change in law made by this Act to Section
27 565.002(a), Occupations Code, applies only to conduct that occurs

1 on or after the effective date of this Act. Conduct that occurs
2 before that date is governed by the law in effect on the date the
3 conduct occurred, and the former law is continued in effect for that
4 purpose.

5 SECTION 20. The change in law made by this Act to Section
6 565.061(a), Occupations Code, is a clarification of existing law
7 and does not imply that existing law may be construed as
8 inconsistent with the law as amended by this Act.

9 SECTION 21. This Act takes effect September 1, 2015.

S.B. No. 460

President of the Senate

Speaker of the House

I hereby certify that S.B. No. 460 passed the Senate on April 14, 2015, by the following vote: Yeas 31, Nays 0.

Secretary of the Senate

I hereby certify that S.B. No. 460 passed the House on May 22, 2015, by the following vote: Yeas 137, Nays 3, two present not voting.

Chief Clerk of the House

Approved:

Date

Governor