

RULE ANALYSIS

Introduction: THE NEW RULE IS SUBMITTED TO THE BOARD FOR CONSIDERATION AS AN ADOPTED RULE

Short Title: Remedial Plan

Rule Numbers: §281.68

Statutory Authority: Texas Pharmacy Act, Chapter 551-566 and 568-569, 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;
- (2) Section 554.051 gives the Board the authority to adopt rules for the proper administration and enforcement of the Act; and
- (3) Section 565.060 gives the Board the authority to issue and establish the terms of a remedial plan to resolve the investigation of certain complaints.

Purpose: The new rule, if adopted, implements S.B. 404 as passed by the 83rd Texas Legislature.

Background: S.B. 404 amends §565.060 of the Texas Pharmacy Act and requires the Board to adopt rules regarding remedial plans to resolve the investigation of certain complaints.

The Board reviewed and voted to propose the new rule during the August 6, 2013, meeting. The proposed new rule was published in the September 27, 2013, issue of the *Texas Register* at 38 TexReg 6501.

1 **SUBCHAPTER C. DISCIPLINARY GUIDELINES**
2 **§281.68**

3 The Texas State Board of Pharmacy proposes new §281.68, concerning Remedial Plan. The
4 proposed new rule, if adopted, implements Senate Bill 404 as passed by the 83rd Texas
5 Legislature, amending §565.060 of the Texas Pharmacy Act, which requires the Board to adopt
6 rules regarding remedial plans.

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

10 Ms. Dodson has determined that, for each year of the first five-year period the rule will be in
11 effect, the public benefit anticipated as a result of enforcing the new rule is to provide guidelines
12 for a complaint resolved with a remedial plan. Economic cost to licensees who are required to
13 comply with the new rule will be \$1,000 to recover the cost of administering the remedial plan.
14 The effect on large, small or micro-businesses (pharmacies) will be the same as the economic
15 cost to an individual.

16 Comments on the new rule may be submitted to Allison Benz, R.Ph., M.S., Director of
17 Professional Services, Texas State Board of Pharmacy, 333 Guadalupe Street, Suite 3-600,
18 Austin, Texas 78701, fax (512) 305-8008. Comments must be received by 5:00 p.m., October 31,
19 2013.

20 The new rule is proposed under §551.002 and §554.051 of the Texas Pharmacy Act (Chapters
21 551 - 566, 568 and 569, Texas Occupations Code). The Board interprets §551.002 as authorizing
22 the agency to protect the public through the effective control and regulation of the practice of
23 pharmacy. The Board interprets §554.051(a) as authorizing the agency to adopt rules for the
24 proper administration and enforcement of the Act.

25 The statutes affected by the new rule: Texas Pharmacy Act, Chapters 551 - 566, 568 and 569,
26 Texas Occupations Code.

27 **§281.68. Remedial Plan.**

28 (a) The board may issue a remedial plan by agreement with the respondent to resolve the
29 investigation of a complaint relating to the Act unless the complaint involves:

30 (1) a death;

31 (2) a hospitalization;

32 (3) the commission of a felony;

33 (4) the unlicensed practice of a licensee or registrant;

- 34 (5) audit shortages;
- 35 (6) diversion of controlled substances;
- 36 (7) impairment by chemical abuse or mental or physical illness of a licensee or registrant;
- 37 (8) unauthorized dispensing of a prescription drug;
- 38 (9) gross immorality as defined by the board;
- 39 (10) engaging in fraud, deceit, or misrepresentation as defined by board rule;
- 40 (11) disciplinary action by another regulatory board of this state or another state; or
- 41 (12) any other matter determined by the board.
- 42 (b) The board shall not impose a remedial plan if the appropriate resolution of the complaint
43 involves a restriction on the manner in which a license holder practices pharmacy.
- 44 (c) The board may not issue a remedial plan to resolve a complaint against a license holder if the
45 license holder has entered into a remedial plan with the board in the preceding 24 months for the
46 resolution of a different complaint relating to this subtitle.
- 47 (d) If a license holder complies with and successfully completes the terms of a remedial plan, the
48 board shall remove all records of the remedial plan from the board's records on the fifth
49 anniversary of the date the board issued the terms of the remedial plan.
- 50 (e) The board may assess a fee against a license holder participating in a remedial plan in an
51 amount of \$1,000 to recover the costs of administering the plan.

AN ACT

relating to complaints filed with the Texas State Board of Pharmacy; authorizing fees.

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

SECTION 1. Section 555.005, Occupations Code, is amended to read as follows:

Sec. 555.005. RECORDS OF COMPLAINTS. For each complaint received by the board, the board shall maintain information about parties to the complaint, including the complainant's identity, the subject matter of the complaint, a summary of the results of the review or investigation of the complaint, and the [~~its~~] disposition of the complaint.

SECTION 2. Section 555.007, Occupations Code, is amended by adding Subsection (d) to read as follows:

(d) The board may not consider or act on a complaint involving a violation alleged to have occurred more than seven years before the date the complaint is received by the board.

SECTION 3. Section 565.056, Occupations Code, is amended by amending Subsection (b) and adding Subsections (d) and (e) to read as follows:

(b) A rule adopted under this section must:

(1) provide the complainant, if applicable and permitted by law, and the license holder an opportunity to be heard; ~~and~~

(2) require the presence of an attorney to advise the board or a board employee; and

(3) if an informal meeting will be held, require notice of the time and place of the informal meeting to be given to the license holder not later than the 45th day before the date the informal meeting is held.

(d) The notice required by Subsection (b)(3) must be accompanied by a written statement of the nature of the allegations against the license holder and the information the board intends to use at the informal meeting. If the board does not provide the statement or information when the notice is provided, the license holder may use that failure as grounds for rescheduling the informal meeting. The license holder must provide to the board the license holder's rebuttal not later than the 15th day before the date of the meeting in order for that information to be considered at the meeting.

(e) On request by a license holder under review, the board shall make a recording of the informal meeting. The recording is a part of the investigative file and may not be released to a third party unless authorized under this subtitle. The board may charge the license holder a fee to cover the cost of recording the meeting. The board shall provide a copy of the recording to the

license holder on the license holder's request.

SECTION 4. Subchapter B, Chapter 565, Occupations Code, is amended by adding Section 565.060 to read as follows:

Sec. 565.060. REMEDIAL PLAN. (a) The board may issue and establish the terms of a remedial plan to resolve the investigation of a complaint relating to this subtitle.

(b) A remedial plan may not be imposed to resolve a complaint:

(1) concerning:

(A) a death;

(B) a hospitalization;

(C) the commission of a felony; or

(D) any other matter designated by board rule; or

(2) in which the appropriate resolution may involve a restriction on the manner in which a license holder practices pharmacy.

(c) The board may not issue a remedial plan to resolve a complaint against a license holder if the license holder has entered into a remedial plan with the board in the preceding 24 months for the resolution of a different complaint relating to this subtitle.

(d) If a license holder complies with and successfully completes the terms of a remedial plan, the board shall remove all records of the remedial plan from the board's records on the fifth

anniversary of the date the board issued the terms of the remedial plan.

(e) The board may assess a fee against a license holder participating in a remedial plan in an amount necessary to recover the costs of administering the plan.

(f) The board shall adopt rules necessary to implement this section.

SECTION 5. (a) Sections 555.005 and 565.056, Occupations Code, as amended by this Act, and Subsection (d), Section 555.007, Occupations Code, as added by this Act, apply only to the investigation of a complaint filed on or after the effective date of this Act. The investigation of a complaint filed before that date is governed by the law in effect on the date the complaint was filed, and that law is continued in effect for that purpose.

(b) The Texas State Board of Pharmacy shall adopt rules under Section 565.060, Occupations Code, as added by this Act, not later than January 1, 2014.

(c) Section 565.060, Occupations Code, as added by this Act, applies only to a complaint under Subtitle J, Title 3, Occupations Code, filed on or after the effective date of this Act. A complaint under Subtitle J, Title 3, Occupations Code, filed before that date is governed by the law in effect on the date the complaint was filed, and that law is continued in effect for that purpose.

SECTION 6. This Act takes effect September 1, 2013.

President of the Senate

Speaker of the House

I hereby certify that S.B. No. 404 passed the Senate on March 21, 2013, by the following vote: Yeas 31, Nays 0.

Secretary of the Senate

I hereby certify that S.B. No. 404 passed the House on May 22, 2013, by the following vote: Yeas 141, Nays 7, two present not voting.

Chief Clerk of the House

Approved:

Date

Governor