

RULE ANALYSIS

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

Short Title: Aggravating and Mitigating Factors

Rule Numbers: §281.62

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, update the factors which may merit an increase or decrease in the severity of disciplinary action imposed by the Board.

The Board reviewed and voted to propose the amendments during the August 7, 2018, meeting. The proposed amendments were published in the October 5, 2018, issue of the *Texas Register* at 43 TexReg 6589.

PART 15 TEXAS STATE BOARD OF PHARMACY

CHAPTER 281 ADMINISTRATIVE PRACTICE AND PROCEDURES

SUBCHAPTER C DISCIPLINARY GUIDELINES

22 TAC §281.62

The Texas State Board of Pharmacy proposes amendments to §281.62, concerning Aggravating and Mitigating Factors. The amendments, if adopted, update the factors which may merit an increase or decrease in the severity of disciplinary action imposed by the Board.

Allison Vordenbaumen Benz, R.Ph., M.S., Executive Director/Secretary, has determined that, for the first five-year period the proposed amendments are in effect, there will be no fiscal implications for state or local government as a result of enforcing or administering the rule. Ms. Benz has determined that, for each year of the first five-year period the proposed amendments will be in effect, the public benefit anticipated as a result of enforcing the amendments will be to provide clear guidance regarding the factors the Board may consider in determining whether to increase or decrease the severity of disciplinary action to be imposed. There is no anticipated impact on large, small or micro-businesses (pharmacies), rural communities, or local or state employment. Therefore, an economic impact statement and regulatory flexibility analysis are not required.

For each year of the first five years the proposed amendments will be in effect, Ms. Benz has determined the following:

- (1) The proposed rule does not create or eliminate a government program;
- (2) Implementation of the proposed rule does not require the creation of new employee positions or the elimination of existing employee positions;
- (3) Implementation of the proposed rule does not require an increase or decrease in the future legislative appropriations to the agency;
- (4) The proposed rule does not require an increase or decrease in fees paid to the agency;
- (5) The proposed rule does not create a new regulation;
- (6) The proposed rule limits and expands an existing regulation;
- (7) The proposed rule does not increase or decrease the number of individuals subject to the rule's applicability; and
- (8) The proposed rule does not positively or adversely affect this state's economy.

Written comments on the amendments may be submitted to Megan G. Holloway, Assistant General Counsel, Texas State Board of Pharmacy, 333 Guadalupe Street, Suite 3-500, Austin, Texas, 78701, FAX (512) 305-8061. Comments must be received by 5:00 p.m., November 3, 2018.

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

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

§281.62. Aggravating and Mitigating Factors.

The following factors may be considered in determining the disciplinary sanctions imposed by the board if the factors are applicable to the factual situation alleged. The factors are not applicable in situations involving criminal actions (in which case §281.63 of this title (relating to Considerations for Criminal Offenses) applies).

(1) Aggravation. The following may be considered as aggravating factors so as to merit **an increase in the severity of disciplinary sanction(s) to be imposed:** ~~[more severe or more restrictive action by the board:]~~

(A) extent and gravity of personal, economic, or public damage or harm;

(B) vulnerability of the patient(s);

(C) willful or reckless conduct, or as a result of a knowingly made professional omission, as opposed to negligent conduct;

(D) pattern of misconduct that serves as a basis of discipline;

(E) prior disciplinary action(s);

(F) attempted concealment of the conduct which serves as a basis for disciplinary action under the Act; and

(G) violation of a board order.

~~[(A) patient harm and the severity of patient harm;]~~

~~[(B) economic harm to any individual, entity, or the environment, and the severity of such harm;]~~

~~[(C) increased potential for harm to the public;]~~

~~[(D) attempted concealment of the conduct which serves as a basis for disciplinary action under the Act;]~~

~~[(E) premeditated conduct which serves as a basis for disciplinary action under the Act;]~~

~~[(F) intentional conduct which serves as a basis for disciplinary action under the Act;]~~

66 ~~[(G) motive for conduct which serves as a basis for disciplinary action under the Act;]~~
67 ~~[(H) prior conduct of a similar or related nature;]~~
68 ~~[(I) disciplinary actions taken by any regulatory agency of the federal government or any state;]~~
69 ~~[(J) prior written warnings or written admonishments from any government agency or official~~
70 ~~regarding statutes or regulations pertaining to the conduct which serves as a basis for~~
71 ~~disciplinary action under the Act;]~~
72 ~~[(K) violation of a board order;]~~
73 ~~[(L) failure to implement remedial measures to correct or mitigate harm from the conduct which~~
74 ~~serves as a basis for disciplinary action under the Act;]~~
75 ~~[(M) lack of rehabilitative potential or likelihood for future conduct of a similar nature;]~~
76 ~~[(N) relevant circumstances increasing the seriousness of the conduct which serves as a basis~~
77 ~~for disciplinary action under the Act; and]~~
78 ~~[(O) circumstances indicating intoxication due to ingestion of alcohol and/or drugs.]~~

79 (2) Extenuation and Mitigation. The following may be considered as extenuating and mitigating
80 factors so as to **merit a reduction in the severity of disciplinary sanction(s) to be**
81 **imposed:** [less severe or less restrictive action by the board:]

82 **(A) isolated incident that serves as a basis for disciplinary action;**

83 **(B) remorse for conduct;**

84 **(C) interim implementation of remedial measures to correct or mitigate harm from the**
85 **conduct which serves as a basis for disciplinary action under the Act;**

86 **(D) remoteness of misconduct, when not based on delay attributable to actions by the**
87 **respondent;**

88 **(E) extent to which respondent cooperated with board investigation;**

89 **(F) treatment and/or monitoring of an impairment;**

90 **(G) self-reported and voluntary admissions of the conduct which serves as a basis for**
91 **disciplinary action under section 565.001(a)(4) and (7) of the Act; and**

92 **(H) if acting as pharmacist-in-charge, respondent did not personally engage, either**
93 **directly or indirectly, in the conduct that serves as the basis for disciplinary action; did**
94 **not permit or encourage, either by professional oversight or extreme negligence, the**
95 **conduct that serves as the basis for disciplinary action; promptly reported the conduct to**
96 **the board or other state or federal regulatory authorities or law enforcement upon**
97 **identifying the conduct that serves as the basis for disciplinary action; and took all**

- 98 **reasonable steps to mitigate or remediate the conduct that serves as the basis for**
99 **disciplinary action.**
- 100 ~~[(A) absence of potential harm to the public;]~~
- 101 ~~[(B) self-reported and voluntary admissions of the conduct which serves as a basis for~~
102 ~~disciplinary action under the Act;]~~
- 103 ~~[(C) absence of premeditation to commit the conduct which serves as a basis for disciplinary~~
104 ~~action under the Act;]~~
- 105 ~~[(D) absence of intent to commit the conduct which serves as a basis for disciplinary action~~
106 ~~under the Act;]~~
- 107 ~~[(E) absence of prior conduct of a similar or related nature;]~~
- 108 ~~[(F) absence of disciplinary actions taken by any regulatory agency of the federal government or~~
109 ~~any state;]~~
- 110 ~~[(G) implementation of remedial measures to correct or mitigate harm from the conduct which~~
111 ~~serves as a basis for disciplinary action under the Act;]~~
- 112 ~~[(H) rehabilitative potential;]~~
- 113 ~~[(I) prior community service and present value to the community;]~~
- 114 ~~[(J) relevant circumstances reducing the seriousness of the conduct which serves as a basis for~~
115 ~~disciplinary action under the Act;]~~
- 116 ~~[(K) relevant circumstances lessening responsibility for the conduct which serves as a basis for~~
117 ~~disciplinary action under the Act; and]~~
- 118 ~~[(L) treatment and/or monitoring of an impairment.]~~