

TITLE 22. EXAMINING BOARDS

PART 15. TEXAS STATE BOARD OF PHARMACY

CHAPTER 281. ADMINISTRATIVE PRACTICE AND PROCEDURES

SUBCHAPTER C. DISCIPLINARY GUIDELINES

22 TAC §§281.62 - 281.65

The Texas State Board of Pharmacy proposes amendments to §281.62, concerning Aggravating and Mitigating Factors, §281.63, concerning Considerations for Criminal Offenses, §281.64, concerning Sanctions for Criminal Offenses, and §281.65, concerning Schedule of Administrative Penalties. The proposed amendments, if adopted, clarify disciplinary guidelines to reflect that the Board has given careful consideration to the guidelines and intends the guidelines to reflect the regulatory polices and goals of the Board to protect the public health and safety.

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

Ms. Dodson has determined that, for each year of the first five-year period the rules will be in effect, the public benefit anticipated as a result of enforcing the rules will ensure that the disciplinary guidelines reflect the regulatory polices of the Board protect the public health and safety. There is no fiscal impact for individuals, small or large businesses or to other entities which are required to comply with the sections.

Comments on the proposed amendments may be submitted to Allison Benz, R.Ph., M.S., Director of Professional Services, Texas State Board of Pharmacy, 333 Guadalupe Street, Suite 3-600, Austin, Texas 78701, FAX (512) 305-8082. Comments must be received by 5:00 p.m., July 21, 2008.

The amendments are proposed under §551.002 and §554.051 of the Texas Pharmacy Act (Chapters 551 - 566 and 568 - 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 the amendments: Chapters 551 - 566 and 568 - 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) ~~[(a)]~~ Aggravation. The following may be considered as aggravating factors so as to merit more severe or more restrictive action by the board:

(A) ~~[(1)]~~ patient harm and the severity of patient harm;

(B) ~~[(2)]~~ economic harm to any individual, entity, or the environment, and the severity of such harm;

(C) ~~[(3)]~~ increased potential for harm to the public;

(D) ~~[(4)]~~ attempted concealment of the conduct which serves as a basis for disciplinary action under the Act;

(E) ~~[(5)]~~ premeditated conduct which serves as a basis for disciplinary action under the Act;

(F) ~~[(6)]~~ intentional conduct which serves as a basis for disciplinary action under the Act;

(G) ~~[(7)]~~ motive for conduct which serves as a basis for disciplinary action under the Act;

(H) ~~[(8)]~~ prior conduct of a similar or related nature;

(I) ~~[(9)]~~ disciplinary actions taken by any regulatory agency of the federal government or any state;

(J) ~~[(10)]~~ prior written warnings or written admonishments from any government agency or official regarding statutes or regulations pertaining to the conduct which serves as a basis for disciplinary action under the Act;

(K) ~~[(11)]~~ violation of a board order;

(L) ~~[(12)]~~ failure to implement remedial measures to correct or mitigate harm from the conduct which serves as a basis for disciplinary action under the Act;

(M) ~~[(13)]~~ lack of rehabilitative potential or likelihood for future conduct of a similar nature;

(N) ~~[(14)]~~ relevant circumstances increasing the seriousness of the conduct which serves as a basis for disciplinary action under the Act; and

(O) ~~[(15)]~~ circumstances indicating intoxication due to ingestion of alcohol and/or drugs.

(2) ~~[(b)]~~ Extenuation and Mitigation. The following may be considered as extenuating and mitigating factors so as to merit less severe or less restrictive action by the board:

~~[(1) absence of patient harm;]~~

~~[(2) absence of economic harm to any individual or entity;]~~

(A) ~~[(3)]~~ absence of potential harm to the public;

(B) [~~(4)~~] self-reported and voluntary admissions of the conduct which serves as a basis for disciplinary action under the Act;

(C) [~~(5)~~] absence of premeditation to commit the conduct which serves as a basis for disciplinary action under the Act;

(D) [~~(6)~~] absence of intent to commit the conduct which serves as a basis for disciplinary action under the Act;

[~~(7)~~ motive;]

(E) [~~(8)~~] absence of prior conduct of a similar or related nature;

(F) [~~(9)~~] absence of [~~a~~] disciplinary actions taken by any regulatory agency of the federal government or any state;

(G) [~~(10)~~] implementation of remedial measures to correct or mitigate harm from the conduct which serves as a basis for disciplinary action under the Act;

(H) [~~(11)~~] rehabilitative potential;

(I) [~~(12)~~] prior community service and present value to the community;

(J) [~~(13)~~] relevant circumstances reducing the seriousness of the conduct which serves as a basis for disciplinary action under the Act;

(K) [~~(14)~~] relevant circumstances lessening responsibility for the conduct which serves as a basis for disciplinary action under the Act; and

(L) [~~(15)~~] treatment and/or monitoring of an impairment.

§281.63. Considerations for Criminal Offenses.

(a) - (h) (No change.)

(i) The board has determined that the following crimes directly relate to duties and responsibilities of board licensees or registrants. The commission of each indicates an inability or a tendency for the person to be unable to perform or to be unfit for licensure or registration, because commission [~~violation~~] of such crimes indicates a lack of integrity and respect for one's fellow human being and the community at large. Even if the commission of these crimes did not occur while the licensee or registrant was on-duty or employed at a pharmacy, the board has determined that the crimes directly relate to the practice of pharmacy based on a lack of integrity and good moral character exhibited by the commission of the crimes. In addition, the direct relationship to a license or registration is presumed when any crime occurs in connection with the practice of pharmacy or the operation of a pharmacy. The crimes are as follows:

(1) practicing or operating a pharmacy without a license or registration and other violations of the Pharmacy Act;

- (2) deceptive business practices under the Texas Penal Code;
- (3) medicare or medicaid fraud;
- (4) a misdemeanor or felony offense under the Texas Penal Code involving:
 - (A) murder;
 - (B) assault;
 - (C) burglary;
 - (D) robbery;
 - (E) theft;
 - (F) sexual assault;
 - (G) injury to a child;
 - (H) injury to an elderly person;
 - (I) child abuse or neglect;
 - (J) tampering with a governmental record;
 - (K) forgery;
 - (L) perjury;
 - (M) failure to report abuse;
 - (N) bribery;
 - (O) harassment;
 - (P) insurance claim fraud;
 - (Q) driving while intoxicated;
 - (R) solicitation of professional employment under the Penal Code §38.12(d) or Occupations Code, Chapter 102;
 - (S) mail fraud; or
 - (T) any criminal offense which requires the individual to register with the Department of Public Safety as a sex offender under Chapter 62, Code of Criminal Procedure.

(5) any crime of moral turpitude;

(6) a misdemeanor or felony offense under Chapters 431 and 481 through 486, Health and Safety Code and the Comprehensive Drug Abuse Prevention and Control Act of 1970; or

(7) other misdemeanors or felonies which serve as grounds for discipline under the Act, including violations of the Penal Code, Titles 4, 5, 6, 7, 8, 9, and 10, which indicate an inability or tendency for the person to be unable to perform as a licensee or registrant, or to be unfit for licensure or registration, if action by the board will promote the intent of the Pharmacy Act, board rules including this chapter, and Occupations Code, Chapter 53.

§281.64.Sanctions for Criminal Offenses.

(a) The guidelines for disciplinary sanctions apply to criminal convictions and to deferred adjudication community supervisions or deferred dispositions, as authorized by the Act, for all types of licensees and registrants including applicants for such licenses and registrations issued by the board. The board considers criminal behavior to be highly relevant to an individual's fitness to engage in pharmacy practice and has determined that the sanctions imposed by these guidelines promote the intent of §551.002 of the Act. The "date of disposition," when referring to the number of years used to calculate the application of disciplinary sanctions, refers to the date a conviction, a deferred adjudication, or a deferred disposition is entered by the court. The use of the term "currently on probation" is construed to refer to individuals currently serving community supervision or any other type of probationary term imposed by an order of a court for a conviction, deferred adjudication, or deferred disposition.

(b) (No change.)

(c) The board has determined that the nature and seriousness of certain crimes outweigh other factors to be considered in §281.63(g) of this title (relating to Considerations for Criminal Offenses) and necessitate the disciplinary action listed below. The following sanctions apply to individuals with the criminal offenses as described below:

(1) Criminal offenses which require the individual to register with the Department of Public Safety as a sex offender under Chapter 62, Code of Criminal Procedure--denial;

(2) Felony offenses:

(A) Drug-related offenses, such as those listed in Chapter 481 or 483, Health and Safety Code:

(i) Offenses involving manufacture, delivery, or possession with intent to deliver, fraud, or theft of drugs:

(I) Currently on probation--denial or revocation;

(II) 0 - 5 years since date of disposition--denial or revocation;

(III) 6 - 10 years since date of disposition--denial or revocation;

(IV) 11 - 20 years since date of disposition--denial or revocation;

(V) Over 20 years since date of disposition--5 years probation;

(ii) Offenses involving possession of drugs:

(I) Currently on probation--denial, revocation, or suspension; [~~or revocation~~];

(II) 0 - 5 years since date of disposition--evaluation by a mental health professional indicating the individual is safe to engage in pharmacy practice and 5 years probation;

(III) 6 - 10 years since date of disposition--evaluation by a mental health professional indicating the individual is safe to engage in pharmacy practice and 3 years probation;

(IV) 11 - 20 years since date of disposition--2 years probation;

(V) Over 20 years since date of disposition--1 year probation;

(B) Offenses involving sexual contact or violent acts, or offenses considered to be felonies of the first degree under the Texas Penal Code:

(i) Currently on probation--denial or revocation;

(ii) 0-5 years since date of disposition--denial or revocation;

(iii) 6-10 years since date of disposition--denial or revocation;

(iv) 11-20 years since date of disposition--5 years probation;

(v) Over 20 years since date of disposition--1 year probation;

(C) Other felony offenses:

(i) Currently on probation--denial, revocation, or suspension; [~~or revocation~~];

(ii) 0 - 5 years since date of disposition--5 years probation;

(iii) 6 - 10 years since date of disposition--3 years probation;

(iv) 11 - 20 years since date of disposition--1 year probation;

(3) Misdemeanor offenses:

(A) Drug-related offenses, such as those listed in Chapter 481 or 483, Health and Safety Code:

(i) Offenses involving manufacture, delivery, or possession with intent to deliver, fraud, or theft of drugs:

- (I) Currently on probation--denial or revocation;
- (II) 0-10 years since date of disposition--5 years probation;
- (III) Over 10 years since date of disposition--3 years probation;
- (ii) Offenses involving possession of drugs:
 - (I) Pharmacists:
 - (-a-) 0 - 5 years since date of disposition--evaluation by a mental health professional indicating the individual is safe to engage in pharmacy practice and 5 years probation;
 - (-b-) 6 - 10 years since date of disposition--evaluation by a mental health professional indicating the individual is safe to engage in pharmacy practice and 3 years probation;
 - (II) Pharmacy Technicians and Pharmacy Technician Trainees:
 - (-a-) 0 - 5 years since date of disposition and determined to have a drug or alcohol dependency--5 years probation;
 - (-b-) 0 - 5 years since date of disposition and not determined to have a drug or alcohol dependency--1 year probation;
 - (-c-) 6 - 10 years since date of disposition and determined to have a drug or alcohol dependency--3 years probation;
- (B) Intoxication and alcoholic beverage offenses as defined in the Texas Penal Code, if two such offenses occurred in the previous ten years:
 - (i) Pharmacists:
 - (I) 0-5 years since date of disposition--evaluation by a mental health professional indicating the individual is safe to engage in pharmacy practice and 5 years probation;
 - (II) 6-10 years since date of disposition--evaluation by a mental health professional indicating the individual is safe to engage in pharmacy practice and 3 years probation;
 - (ii) Pharmacy Technicians and Pharmacy Technician Trainees: 0- 5 years since date of disposition and determined to have a drug or alcohol dependency--5 years probation;
- (C) Other misdemeanor offenses involving moral turpitude: 0 - 5 years since date of disposition--reprimand.
- (d) - (e) (No change.)

§281.65.Schedule of Administrative Penalties [~~administrative penalties~~].

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

(1) (No change.)

(2) The following violations by a pharmacy may be appropriate for disposition with an administrative penalty with or without additional sanctions or restrictions:

(A) failure to provide patient counseling: \$1,500;

(B) failure to conduct a drug regimen review or inappropriate drug regimen reviews provided by §291.33(c)(2)(A) of this title (relating to Operational Standards): \$1,500;

(C) failure to clarify a prescription with the prescriber: \$1,500;

(D) failure to properly supervise or improperly delegating a duty to a pharmacy technician: \$1,500;

(E) failure to identify the dispensing pharmacist on required pharmacy records: \$500;

(F) failure to maintain records of prescriptions: \$500;

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

(H) shortages of prescription drugs following an accountability audit: up to \$5,000;

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

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

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

(L) violating the reporting provisions of an Order of the Board: \$1,000 - \$5,000;

(M) failure to report or to assure the report of a malpractice claim: up to \$1,000;

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

(O) allowing a pharmacist to practicing pharmacy with a delinquent license: \$250 - \$1,000;

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

(Q) allowing an individual to perform the duties of a pharmacy technician without a valid registration: \$250 - \$1500; [~~\$250—\$1,000~~];

(R) failure to comply with the requirements of the Official Prescription Program: up to \$1,000;

(S) aiding and abetting the unlicensed practice of pharmacy, if an employee of the pharmacy knew or reasonably should have known that the person engaging in the practice of pharmacy was unlicensed at the time: up to \$5,000;

(T) a conviction or deferred adjudication for a misdemeanor or felony which serves as a ground for discipline under the Act: up to \$5,000;

(U) unauthorized substitutions: \$1,000;

(V) false or fraudulent claims to third parties for reimbursement of pharmacy services: up to \$5,000;

(W) possessing or engaging in the sale, purchase, or trade or the offer to sell, purchase, or trade of misbranded prescription drugs or prescription drugs beyond the manufacturer's expiration date: up to \$1,000;

(X) possessing or engaging in the sale, purchase, or trade or the offer to sell, purchase, or trade of prescription drug samples as provided by §281.8(b)(2) of this title (relating to Grounds for Discipline for a Pharmacy License): up to \$1,000;

(Y) failure to keep, maintain or furnish an annual inventory as required by §291.17 of this title (relating to Inventory Requirements): \$1,000;

(Z) failure to obtain training on the preparation of sterile pharmaceutical compounding: \$1,500;

(AA) failure to maintain the confidentiality of prescription records: \$1,000 - \$5,000;

(BB) failure to inform the board of any notification or information required to be reported by the Act or rules: \$250 - \$500.

(3) - (6) (No change.)

This agency hereby certifies that the proposal has been reviewed by legal counsel and found to be within the agency's legal authority to adopt.

Filed with the Office of the Secretary of State on June 9, 2008.

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Gay Dodson, R.Ph.

Executive Director/Secretary

Texas State Board of Pharmacy

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For further information, please call: (512) 305-8028