

RULE REVIEW ANALYSIS

Introduction: **THIS RULE REVIEW IS SUBMITTED TO THE BOARD FOR CONSIDERATION AS A PROPOSED REVIEW**

Short Title: Administrative Practice and Procedures

Rule Number: Chapter 281

Statutory Authority: Government Code, §2001.039, added by Acts 1999, 76th Legislature, Chapter 1499, Article 1, Section 1.11.

Background: Review of these sections follow the Board's rule review plan.

**PART 15 TEXAS STATE BOARD OF PHARMACY
CHAPTER 281 ADMINISTRATIVE PRACTICE AND PROCEDURES
SUBCHAPTER A GENERAL PROVISIONS**

§281.1 Objective and Scope

The objective of this chapter is to obtain a just, fair, and equitable determination of any matter within the jurisdiction of the board. To the end that this objective may be attained with as great expedition and at the least expense as possible to the parties and the state, the provisions of this chapter shall be given a liberal construction. The provisions of this chapter govern the procedure for the institution, conduct, and determination of all proceedings before the board. All actions taken by the board shall be in accordance with the Act, the Government Code, the Occupations Code, the board's rules and any other applicable laws or rules.

§281.2 Definitions

The following words and terms, when used in this chapter, have the following meanings, unless the context clearly indicates otherwise:

- (1) Act--The Texas Pharmacy Act, Chapters 551 - 566, Texas Occupations Code, as amended.
- (2) Administrative law judge--A judge employed by the State Office of Administrative Hearings.
- (3) Agency--The Texas State Board of Pharmacy, and its divisions, departments, and employees.
- (4) Administrative Procedure Act (APA)--Government Code, Chapter 2001, as amended.
- (5) Board--The Texas State Board of Pharmacy.
- (6) Confidential address of record--The home address required to be provided by each individual, who is a licensee, registrant, or pharmacy owner and where service of legal notice will be sent. The address is confidential, as set forth in §555.001(d) of the Act, and not subject to disclosure under the Public Information Act.
- (7) Contested case--A proceeding, including but not restricted to licensing, in which the legal rights, duties, or privileges of a party are to be determined by the board after an opportunity for adjudicative hearing.
- (8) Diversion of controlled substances--An act or acts which result in the distribution of controlled substances from legitimate pharmaceutical or medical channels in violation of the Controlled Substances Act or rules promulgated pursuant to the Controlled Substances Act or rules relating to controlled substances promulgated pursuant to this Act.
- (9) Diversion of dangerous drugs--An act or acts which result in the distribution of dangerous drugs from legitimate pharmaceutical or medical channels in violation of the Dangerous Drug Act or rules promulgated pursuant to the Dangerous Drug Act or rules relating to dangerous drugs promulgated pursuant to this Act.

(10) Executive director/secretary--The secretary of the board and executive director of the agency.

(11) License--The whole or part of any agency permit, certificate, approval, registration, or similar form of permission required by law.

(12) Licensee--Any individual or person to whom the agency has issued any permit, certificate, approved registration, or similar form of permission authorized by law.

(13) Licensing--The agency process relating to the granting, denial, renewal, revocation, suspension, annulment, withdrawal, or amendment of a license.

(14) Official act--Any act performed by the board pursuant to a duty, right, or responsibility imposed or granted by law, rule, or regulation.

(15) Person--An individual, corporation, government or governmental subdivision or agency, business trust, estate, trust, partnership, association, or any other legal entity.

(16) President--The president of the Texas State Board of Pharmacy.

(17) Presiding Officer--The president of the Texas State Board of Pharmacy or, in the president's absence, the highest ranking officer present at a board meeting.

(18) Publicly available address of record--The alternate address required to be provided by each licensee, registrant, or pharmacy owner, which will be released to the public, as set forth in §555.001(d) of the Act, and is subject to disclosure under the Public Information Act.

(A) The alternate address must be a business address or other alternate address, such as the home address of the individual's relative, where mail can be received on a regular basis.

(B) A pharmacy must provide the physical address of the pharmacy to be used for this purpose.

(19) Quorum--A majority of the members of the board appointed and serving on the board.

(20) State Office of Administrative Hearings (SOAH)--The agency to which contested cases are referred by the Texas State Board of Pharmacy.

(21) Sample--A prescription drug which is not intended to be sold and is intended to promote the sale of the drug.

(22) Texas Public Information Act--Government Code, Chapter 552.

§281.3 Construction of This Chapter

(a) In the construction of this chapter, a provision of a section referring to the board, or a provision referring to the presiding officer, is construed to apply to the board or the president if the matter is within the jurisdiction of the board.

(b) Unless otherwise provided by law, any duty imposed on the board or the president may be delegated to a duly authorized representative. In such case, the provisions of any section referring to the board or the president shall be construed to also apply to the duly authorized representative(s) of the board or the president.

§281.4 Official Acts in Writing and Open to the Public

(a) All official acts of the board shall be evidenced by a written record. Such writings shall be open to the public in accordance with the Act and the Texas Public Information Act, Government Code Chapter 552. Any hearing and any Board meeting shall be open to the public in accordance with the Texas Open Meetings Act, Government Code, Chapter 551, provided, however, that pursuant to §552.011, Texas Pharmacy Act, the board may, in its discretion, conduct deliberations relative to licensee disciplinary actions in a closed meeting. The board in a closed meeting may conduct disciplinary hearings relating to a pharmacist or pharmacy student who is impaired because of chemical abuse or mental or physical illness. At the conclusion of its deliberations relative to licensee disciplinary action, the board shall vote and announce its decision relative to the licensee in open session. All disciplinary hearings before the State Office of Administrative Hearings shall be open to the public, including those relating to a pharmacist or pharmacy student who is impaired because of chemical abuse or mental or physical illness. Official action of the board shall not be bound or prejudiced by any informal statement or opinion made by any member of the board or the employees of the agency.

(b) The president shall be the chairman and preside over all meetings of the board at which the president is present unless otherwise provided for under this chapter. In the absence of the president, the vice president shall preside. In the vice president's absence, one of the other Board members shall preside as acting chairman. The acting chairman shall be selected by mutual agreement of the board members present or, lacking mutual agreement, shall be the member senior in length of service on the board.

§281.5 Initiating Proceedings Before the Board

(a) Rules. Any interested person may petition the board requesting the adoption of a rule. Petitions shall be sent to the executive director/secretary. Within 60 days after the submission of a petition, the board shall either deny the petition in writing, stating the reasons for the denial, or shall initiate rulemaking proceedings. Petitions shall be deemed sufficient if they contain:

- (1) the exact wording of the new, changed, or amended proposed rule;
- (2) specific reference to the existing rule which is proposed to be changed or amended in the case of a changed or amended rule; and
- (3) a justification for the proposed action set out in narrative form with sufficient particularity to inform the board and any other interested party of the reasons and arguments on which the petitioner is relying.

(b) Other. In any other matter, any person desiring that the board perform some official act permitted or required by law shall request such performance in writing. Such requests shall be directed to the executive director/secretary of the board. Any written request shall be deemed sufficient to initiate the proceedings and present the subject matter to the board for its official

determination if the request reasonably gives notice to the board of the act desired. The board may also initiate proceedings on its own motion.

§281.6 Mental or Physical Examination

For the purposes of the Act, §§565.001(a)(4), 565.052, 568.003(a)(5), and 568.0036, shall be applied as follows.

(1) The board may discipline an applicant, licensee, or registrant if the board finds that the applicant, licensee, or registrant has developed an incapacity that in the estimation of the board would prevent a pharmacist from engaging in the practice of pharmacy or a pharmacy technician or pharmacy technician trainee from practicing with a level of skill and competence that ensures the public health, safety, and welfare.

(2) Upon a finding of probable cause, as determined by the board or an authorized agent of the board, that the applicant, licensee, or registrant has developed an incapacity that in the estimation of the board would prevent a pharmacist from engaging in the practice of pharmacy or a pharmacy technician or pharmacy technician trainee from practicing with a level of skill and competence that ensures the public health, safety, and welfare, the following is applicable.

(A) The executive director/secretary, legal counsel of the agency, or other representative of the agency as designated by the executive director/secretary, shall request the applicant, licensee, or registrant to submit to a mental or physical examination by a physician or other healthcare professional designated by the board. The individual providing the examination shall be approved by the board. Such examination shall be coordinated through the entity that contracts with the board to aid impaired pharmacists and pharmacy students. The applicant, licensee, or registrant shall:

(i) provide the entity with written notice of the appointment at least three days prior to the appointment;

(ii) execute and return to the entity an authorization for release of relevant information on the form required by the entity, within ten days of receipt of request for the release from the entity; and

(iii) follow all other procedures of the entity for each examination.

(B) The applicant, licensee, or registrant shall be notified in writing, by either personal service or certified mail with return receipt requested, of the request to submit to the examination.

(C) The applicant, licensee, or registrant shall submit to the examination within 30 days of the date of the receipt of the request.

(D) The applicant, licensee, or registrant shall authorize the release of the results of the examination and the results shall be submitted to the board within 15 days of the date of the examination.

(3) If the applicant, licensee, or registrant does not comply with the provisions of paragraph (2) of this section, the following is applicable.

(A) The executive director/secretary shall cause to be issued an order requiring the applicant, licensee, or registrant to show cause why he/she will not submit to the examination.

(B) The executive director/secretary shall schedule a hearing on the order before a panel of three members of the board appointed by the president of the board, within 30 days after notice is served on the applicant, licensee, or registrant.

(C) The applicant, licensee, or registrant shall be notified of the hearing by either personal service or certified mail with return receipt requested.

(D) At the hearing, the applicant, licensee, or registrant has the burden of proof once probable cause has been established by the board, as required by §565.062 of the Act to rebut the probable cause. The applicant, licensee, or registrant, and if applicable, the applicant's, licensee's, or registrants' attorney, are entitled to present testimony and other evidence to show why probable cause has not been established requiring the applicant, licensee, or registrant to submit to the examination. An evaluation that has not been approved by the board and coordinated by the entity that contracts with the board to aid impaired pharmacist and pharmacy students according to its procedure cannot be admitted at the hearing in lieu of one that has been properly approved and coordinated.

(E) After the hearing, the panel shall issue an order either requiring the applicant, licensee, or registrant to submit to the examination not later than the 60th day after the date of the order or withdraw the request for examination, as applicable.

§281.7 Grounds for Discipline for a Pharmacist License

(a) For the purposes of the Act, §565.001(a)(2), "unprofessional conduct" is defined as engaging in behavior or committing an act that fails to conform with the standards of the pharmacy profession, including, but not limited to, criminal activity or activity involving moral turpitude, dishonesty, or corruption. This conduct shall include, but not be limited to:

(1) dispensing a prescription drug pursuant to a forged, altered, or fraudulent prescription;

(2) dispensing a prescription drug order pursuant to a prescription from a practitioner as follows:

(A) the dispensing of a prescription drug order not issued for a legitimate medical purpose or in the usual course of professional practice shall include the following:

(i) 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; or

(ii) dispensing controlled substances or dangerous drugs when the pharmacist knows or reasonably should have known that the controlled substances or dangerous drugs are not necessary or required for the patient's valid medical needs or for a valid therapeutic purpose;

(B) the provisions of subparagraph (A)(i) and (ii) of this paragraph are not applicable for prescriptions dispensed to persons with intractable pain in accordance with the requirements of

the Intractable Pain Treatment Act, or to a narcotic drug dependent person in accordance with the requirements of Title 21, Code of Federal Regulations, §1306.07, and the Regulation of Narcotic Drug Treatment Programs Act;

(3) delivering or offering to deliver a prescription drug or device in violation of this Act, the Controlled Substances Act, the Dangerous Drug Act, or rules promulgated pursuant to these Acts;

(4) acquiring or possessing or attempting to acquire or possess prescription drugs in violation of this Act, the Controlled Substances Act, or Dangerous Drug Act or rules adopted pursuant to these Acts;

(5) distributing prescription drugs or devices to a practitioner or a pharmacy not in the course of professional practice or in violation of this Act, the Controlled Substances Act, Dangerous Drug Act, or rules adopted pursuant to these Acts;

(6) refusing or failing to keep, maintain or furnish any record, notification or information required by this Act, the Controlled Substances Act, Dangerous Drug Act, or any rule adopted pursuant to these Acts;

(7) refusing an entry into any pharmacy for any inspection authorized by the Act;

(8) making false or fraudulent claims to third parties for reimbursement for pharmacy services;

(9) operating a pharmacy in an unsanitary manner;

(10) making false or fraudulent claims concerning any drug;

(11) persistently and flagrantly overcharging for the dispensing of controlled substances;

(12) dispensing controlled substances or dangerous drugs in a manner not consistent with the public health or welfare;

(13) failing to practice pharmacy in an acceptable manner consistent with the public health and welfare;

(14) refilling a prescription upon which there is authorized "prn" refills or words of similar meaning, for a period of time in excess of one year from the date of issuance of such prescription;

(15) engaging in any act, acting in concert with another, or engaging in any conspiracy resulting in a restraint of trade, coercion, or a monopoly in the practice of pharmacy;

(16) sharing or offering to share with a practitioner compensation received from an individual provided pharmacy services by a pharmacist;

(17) obstructing a board employee in the lawful performance of his duties of enforcing the Act;

(18) engaging in conduct that subverts or attempts to subvert any examination or examination process required for a license to practice pharmacy. Conduct that subverts or attempts to subvert the pharmacist licensing examination process includes, but is not limited to:

(A) copying, retaining, repeating, or transmitting in any manner the questions contained in any examination administered by the board or questions contained in a question pool of any examination administered by the board;

(B) copying or attempting to copy another candidate's answers to any questions on any examination required for a license to practice pharmacy;

(C) obtaining or attempting to obtain confidential examination materials compiled by testing services or the Board;

(D) impersonating or acting as a proxy for another in any examination required for a license to practice pharmacy;

(E) requesting or allowing another to impersonate or act as a proxy in any examination required for a license to practice pharmacy; or

(F) violating or attempting to violate the security of examination materials or the examination process in any manner;

(19) violating the provisions of an agreed board order or board order;

(20) dispensing a prescription drug while not acting in the usual course of professional pharmacy practice;

(21) failing 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;

(22) physically abusing a board employee during the performance of such employees lawful duties;

(23) failing to establish or maintain effective controls against the diversion or loss of controlled substances or dangerous drugs, loss of controlled substance or dangerous drug records, or failing to ensure that controlled substances or dangerous drugs are dispensed in compliance with state and federal laws or rules, by a pharmacist who is:

(A) a pharmacist-in-charge of a pharmacy;

(B) a sole proprietor or individual owner of a pharmacy;

(C) a partner in the ownership of a pharmacy; or

(D) a managing officer of a corporation, association, or joint-stock company owning a pharmacy. A pharmacist, as set out in subparagraphs (B) - (D) of this paragraph, is equally responsible with an individual designated as pharmacist-in-charge of such pharmacy to ensure that employee pharmacists and the pharmacy are in compliance with all state and federal laws or rules relating to controlled substances or dangerous drugs;

(24) failing to respond within the time specified on a warning notice to such warning notice issued as a result of a compliance inspection;

(25) responding to a warning notice as a result of a compliance inspection in a manner that is false or misleading;

(26) being the subject of civil fines imposed by a federal or state court as a result of violating the Controlled Substances Act or Dangerous Drug Act;

(27) selling, purchasing, or trading or offering to sell, purchase, or trade prescription drug samples; provided however, this paragraph does not apply to:

(A) prescription drugs provided by a manufacturer as starter prescriptions or as replacement for such manufacturer's out-dated drugs;

(B) prescription drugs provided by a manufacturer in replacement for such manufacturer's drugs that were dispensed pursuant to written starter prescriptions; or

(C) prescription drug samples possessed by a pharmacy of a health care entity which provides health care primarily to indigent or low income patients at no or reduced cost and if:

(i) the samples are possessed in compliance with the Prescription Drug Marketing Act of 1987;

(ii) the pharmacy is owned by a charitable organization described in the Internal Revenue Code of 1986, §501(c)(3), or by a city, state or county government; and

(iii) the samples are for dispensing or provision at no charge to patients of such health care entity.

(28) selling, purchasing, or trading or offering to sell, purchase, or trade prescription drugs:

(A) sold for export use only;

(B) purchased by a public or private hospital or other health care entity; or

(C) donated or supplied at a reduced price to a charitable organization described in the Internal Revenue Code of 1986, §501(c)(3);

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

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

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

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

(iv) the sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug for emergency medical reasons including the transfer of a drug between pharmacies to alleviate temporary shortages of the drug arising from delays in or interruptions of regular distribution schedules;

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

(29) selling, purchasing, or trading, or offering to sell, purchase, or trade of:

(A) misbranded prescription drugs; or

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

(30) failing to repay a guaranteed student loan, as provided in the Texas Education Code, §57.491;

(31) failing to respond and to provide all requested records within the time specified in an audit of continuing education records under §295.8 of this title (relating to Continuing Education Requirements); or

(32) allowing an individual whose license to practice pharmacy, either as a pharmacist or a pharmacist-intern, or a pharmacy technician/trainee whose registration has been disciplined by the board, resulting in the license or registration being revoked, canceled, retired, surrendered, denied or suspended, to have access to prescription drugs in a pharmacy.

(b) For the purposes of the Act, §565.001(a)(3), the term "gross immorality" shall include, but not be limited to:

(1) conduct which is willful, flagrant, and shameless, and which shows a moral indifference to standards of the community;

(2) engaging in an act which is a felony;

(3) engaging in an act that constitutes sexually deviant behavior; or

(4) being required to register with the Department of Public Safety as a sex offender under Chapter 62, Code of Criminal Procedure.

(c) For the purposes of the Act, §565.001(a)(5), the terms "fraud," "deceit," or "misrepresentation" in the practice of pharmacy or in seeking a license to act as a pharmacist shall be defined as follows.

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

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

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

§281.8 Grounds for Discipline for a Pharmacy License

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

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

(2) there is inadequate security or procedures to prevent the diversion of prescription drugs.

(b) For the purposes of §565.002(a)(3) of the Act, it is grounds for discipline for a pharmacy license when:

(1) during the time an individual's license to practice pharmacy, either as a pharmacist or a pharmacist-intern, or a pharmacy technician's registration has been disciplined by the Board, resulting in the license or registration being revoked, canceled, retired, surrendered, denied or suspended, the pharmacy employs or allows such individual access to prescription drugs;

(2) the pharmacy possesses or engages in the sale, purchase, or trade or the offer to sell, purchase, or trade prescription drug samples; provided however, this paragraph does not apply to:

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

(B) prescription drugs provided by a manufacturer in replacement for such manufacturer's drugs that were dispensed pursuant to written starter prescriptions; or

(C) prescription drug samples possessed by a pharmacy of a health care entity which provides health care primarily to indigent or low income patients at no or reduced cost and if:

(i) the samples are possessed in compliance with the Prescription Drug Marketing Act of 1987;

(ii) the pharmacy is owned by a charitable organization described in the Internal Revenue Code of 1986, §501(c)(3), or by a city, state or county government; and

(iii) the samples are for dispensing or provision at no charge to patients of such health care entity;

(3) the pharmacy possesses or engages in the sale, purchase, or trade or the offer to sell, purchase, or trade of prescription drugs:

(A) sold for export use only;

(B) purchased by a public or private hospital or other health care entity; or

(C) donated or supplied at a reduced price to a charitable organization described in the Internal Revenue Code of 1986, §501(c)(3), and possessed by a pharmacy other than one owned by the charitable organization;

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

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

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

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

(iv) the sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug for emergency medical reasons including the transfer of a drug between pharmacies to alleviate temporary shortages of the drug arising from delays in or interruptions of regular distribution schedules;

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

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

(A) misbranded prescription drugs; or

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

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

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

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

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

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

§281.9 Grounds for Discipline for a Pharmacy Technician or a Pharmacy Technician Trainee

(a) Pharmacy technicians and pharmacy technician trainees shall be subject to all disciplinary grounds set forth in §568.003 of the Act.

(b) For the purposes of the Act, §568.003(a)(10), "negligent, unreasonable, or inappropriate conduct" shall include, but not be limited to:

(1) delivering or offering to deliver a prescription drug or device in violation of this Act, the Controlled Substances Act, the Dangerous Drug Act, or rules promulgated pursuant to these Acts;

(2) acquiring or possessing or attempting to acquire or possess prescription drugs in violation of this Act, the Controlled Substances Act, or Dangerous Drug Act or rules adopted pursuant to these Acts;

(3) failing to perform the duties of a pharmacy technician or pharmacy technician trainee in an acceptable manner consistent with the public health and welfare, which contributes to a prescription not being dispensed or delivered accurately;

(4) obstructing a board employee in the lawful performance of his duties of enforcing the Act;

(5) violating the provisions of an agreed board order or board order, including accessing prescription drugs with a revoked or suspended pharmacy technician or pharmacy technician trainee registration;

(6) physically abusing a board employee during the performance of such employees lawful duties; or

(7) failing to repay a guaranteed student loan, as provided in the Texas Education Code, §57.491.

(c) For the purposes of the Act, §568.003(a)(2), the term "gross immorality" shall include, but not be limited to:

(1) conduct which is willful, flagrant, and shameless, and which shows a moral indifference to standards of the community;

(2) engaging in an act which is a felony;

(3) engaging in an act that constitutes sexually deviant behavior; or

(4) being required to register with the Department of Public Safety as a sex offender under Chapter 62, Code of Criminal Procedure.

(d) For the purposes of the Act, §568.003(a)(3), the terms "fraud," "deceit," or "misrepresentation" shall apply to an individual seeking a registration as a pharmacy technician, as well as making an application to any entity that certifies or registers pharmacy technicians, and shall be defined as follows:

(1) "Fraud" means an intentional perversion of truth for the purpose of inducing the board in reliance upon it to issue a registration; a false representation of a matter of fact, whether by words or by conduct, by false or misleading allegations, or by concealment of that which should have been disclosed, which deceives or is intended to deceive the board.

(2) "Deceit" means the assertion, as a fact, of that which is not true by any means whatsoever to deceive or defraud the board.

(3) "Misrepresentation" means a manifestation by words or other conduct which is a false

§281.10 Denial of a License

If an applicant's original application or request for renewal of a license is denied, he shall have 30 days from the date of denial to make a written request for a hearing. If so requested, the hearing will be granted and the provisions of APA and this chapter with regard to a contested case shall apply.

§281.11 Criminal History Evaluation Letter

(a) A person, who is enrolled or planning to enroll in an educational program that prepares the person for a license as a pharmacist or a registration as a pharmacy technician or trainee, or planning to take an examination required for such a license or registration, and who has reason to believe that he or she may be ineligible due to a conviction or deferred adjudication for a felony or misdemeanor offense, may request a criminal history evaluation letter regarding his or her eligibility for a license or registration.

(b) The person must submit an application for the criminal history evaluation letter on a form provided by the board which includes:

(1) a statement indicating the reasons and basis for potential ineligibility, including each criminal offense for which the person was arrested, charged, convicted, or received deferred adjudication;

(2) all legal documents related to the reasons and basis for potential ineligibility including, but not limited to, police reports, indictments, orders of deferred adjudication, judgments, probation records and evidence of completion of probation, if applicable;

(3) all requirements necessary in order for the Board to access the criminal history record information, including submitting fingerprint information and paying the required fees; and

(4) a non-refundable fee of \$150 for processing the application.

(c) The application is considered complete when all documents and other information supporting the potential reasons and basis for potential ineligibility has been received by the board. If such documentation is not received within 120 days of the initial receipt of the application, the application is considered to be expired and must be refilled along with the appropriate fees.

(d) The board shall conduct an investigation of the application and the person's eligibility for a license or registration.

(e) The person or the Board may amend the application to include additional grounds for potential ineligibility at any time before a final determination is made.

(f) A determination of eligibility will be made by the Board or its designees. Notification of the determination will be provided to the person in writing.

(1) If no grounds for ineligibility are identified, the notification shall address the determination regarding each ground of potential ineligibility.

(2) If grounds for ineligibility exist, the notification shall set out each basis for potential ineligibility and the corresponding determination.

(g) The board shall mail the determination of eligibility no later than the 90th day after the complete application, as required by subsections (b) and (c) of this section, has been received by the board.

(h) The determination of eligibility shall be made based on the law in effect on the date of receipt of a complete application.

(i) Any information the person fails to disclose on the application or any information determined to be inaccurate or incomplete shall invalidate the determination of eligibility on the basis of the information, in the discretion of the board.

(j) The administrative rules regarding disciplinary guidelines and regarding considerations and sanctions for criminal conduct apply in making the determination regarding eligibility.

(k) If a person submits an application for license or registration at the same time or within 90 days after the receipt of a complete application for criminal history evaluation letter, board will process only the application for license or registration and will not issue a separate determination of eligibility.

§281.12 Rules Governing Cooperating Practitioners

For the purposes of the Act, §565.063, a person acting under the supervision of a Board employee engaged in the lawful enforcement of the Act shall include, but not be limited to, a practitioner who provides prescriptions for use in investigations of licensees when such prescriptions are issued by a practitioner at the request of and under the supervision of a Board investigator.

§281.13 Official Action by Majority

Any official act or decision of the board shall be concurred in by a majority of its members present at a meeting. Such act or decision shall be based upon information presented to members present at official meetings of the board. There shall be at least a quorum of the board members present at any official meeting of the board. Private solicitation of individual members

in an effort to in any way influence their official actions through information or arguments not simultaneously presented to other members of the board is improper.

§281.15 Vehicle Inscription Information

(a) Exemption. As specified in the Act §554.009, vehicles assigned to or used by the compliance or investigation divisions for enforcement of pharmacy laws and rules are exempt from bearing the inscription required in Article 6701m-1 of Texas Civil Statutes. These vehicles are to be used primarily in the inspection of pharmacies and the investigation of violations of state and federal laws and rules relating to the practice of pharmacy. In addition, as specified in §554.009, of the Texas Pharmacy Act, the vehicles may be registered with the Texas Department of Transportation in an alias name for investigative personnel.

(b) Purpose. The purpose of exempting these vehicles from the inscription requirements of Article 6701m-1 is to increase the effectiveness of agency compliance officers and investigators in detecting and investigating violations of state and federal laws relating to the practice of pharmacy, thereby allowing compliance and investigative personnel to accomplish their tasks undetected, and to provide a greater degree of safety for these staff and the state property being used in the enforcement and a greater degree of case integrity.

§281.17 Historically Underutilized Businesses

The Texas State Board of Pharmacy adopts by reference the rules promulgated by the Texas Building and Procurement Commission, which are set forth in Subchapter B of 1 TAC §111.11, et al. regarding Historically Underutilized Business Certification Program.

§281.18 Reporting Professional Liability Claims

(a) Reporting responsibilities.

(1) Every insurer or other entity providing pharmacist's professional liability insurance, pharmacy technician professional and supplemental liability insurance, or druggist's professional liability insurance covering a pharmacist, pharmacy technician, or pharmacy license holder in this state shall submit to the board the information described in subsection (b) of this section at the time prescribed.

(2) The information shall be provided with respect to a notice of claim letter or complaint filed against an insured in a court, if the notice or complaint seeks damages relating to the insured's conduct in providing or failing to provide appropriate service within the scope of pharmaceutical care or services, and with respect to settlement of a claim or lawsuit made on behalf of the insured.

(3) If a pharmacist, pharmacy technician, or a pharmacy licensed in this state does not carry or is not covered by pharmacist's professional liability insurance, pharmacy technician professional and supplemental liability insurance, or druggist's professional liability insurance, or if a pharmacist, pharmacy technician, or a pharmacy licensed in this state is insured by a non-admitted carrier or other entity providing pharmacy professional liability insurance that does not

report under this Act, the duty to report information under subsection (b) of this section is the responsibility of the particular pharmacist, pharmacy technician, or pharmacy license holder.

(4) For the purposes of this section a professional liability claim or complaint shall be defined as a cause of action against a pharmacist, pharmacy, or pharmacy technician for conduct in providing or failing to provide appropriate service within the scope of pharmaceutical care or services, which proximately results in injury to or death of the patient, whether the patient's claim or cause of action sounds in tort or contract, to include pharmacist's interns, pharmacy residents, supervising pharmacists, on-call pharmacists, consulting pharmacists.

(b) Information to be reported and due dates. The following reports are required for claims initiated or resolved on or after September 1, 1999.

(1) Initial report. Not later than the 30th day after receipt of the notice of claim letter or complaint by the insurer if the insurer has the duty to report, or by the pharmacist, pharmacy technician, or a pharmacy if the license holder has the duty to report, the following information must be furnished to the board on a form provided by the board:

(A) the name and address of the insurer;

(B) the name and address of the insured and type of license or registration held (pharmacist, pharmacy or pharmacy technician):

(C) the insured's Texas pharmacist or pharmacy license number or pharmacy technician registration number;

(D) certification, if applicable;

(E) the policy number;

(F) name(s) of plaintiff(s);

(G) date of injury;

(H) county of injury;

(I) cause of injury, e.g., dispensing error;

(J) nature of injury;

(K) type of action, e.g., claim only or lawsuit;

(L) name and phone number of the person filing the report; and

(M) a copy of the notice of claim letter or the lawsuit filed in court.

(2) Follow-up report. Within 105 days after disposition of the claim, the following information must be provided to the board on a form provided by the board:

(A) the name and address of the insured and type of license or registration held (pharmacist, pharmacy or pharmacy technician):

(B) the insured's Texas pharmacist or pharmacy license number or pharmacy technician registration number;

(C) name(s) of plaintiff(s);

(D) date of disposition;

(E) type of disposition, e.g., settlement, judgment;

(F) amount of disposition;

(G) whether an appeal has been taken and by which party; and

(H) name and phone number of the person filing the report.

(3) Definition. For the purpose of this section, disposition of a claim shall include circumstances where a court order has been entered, a settlement agreement has been reached, or the complaint has been dropped or dismissed.

(c) Report format

(1) Separate reports are required for each defendant licensee or registrant.

(2) The information shall be reported on a form provided by the board.

(3) A court order or settlement agreement may be submitted as an attachment to the follow-up report.

(d) Claims not required to be reported. Examples of claims that are not required to be reported under this section are the following:

(1) product liability claims (i.e., where a licensee invented a medical device which may have injured a patient but the licensee has no personal pharmacist-patient relationship with the specific patient claiming injury by the device);

(2) antitrust allegations;

(3) allegations involving improper peer review activities;

(4) civil rights violations; or

(5) allegations of liability for injuries occurring on a licensee's property, but not involving a breach of duty (i.e., slip and fall accidents).

(e) Liability. An insurer reporting under this section, its agents or employees, or the board or its employees or representatives are not liable for damages in a suit brought by any person or entity for reporting as required by this section or for any other action taken under this section.

(f) Limit on use of information reported.

(1) Information submitted to the board under this section and the fact that the information has been submitted to the board may not be:

(A) offered in evidence or used in any manner in the trial of a suit described in this section; or

(B) used in any manner to determine the eligibility or credentialing of a pharmacy to participate in a health insurance plan defined by the Insurance Code.

(2) A report received by the board under this section is not a complaint for which a board investigation is required except that the board shall review the information relating to a pharmacist, pharmacy technician, or pharmacy license holder against whom at least three professional liability claims have been reported within a five-year period in the same manner as if a complaint against the pharmacist, pharmacy technician, or pharmacy license holder had been made under Chapter 555 of the Act. The board may initiate an investigation of pharmacist, pharmacy technician, or pharmacy license holder based on the information received under this section.

(3) The information received under this section may be used in any board proceedings as the board deems necessary.

(g) Confidentiality. Information submitted under this section is confidential, except as provided in subsection (f)(3) of this section, and is not subject to disclosure under Chapter 552, Government Code.

(h) Penalty. The Texas Department of Insurance may impose on any insurer subject to this Act sanctions authorized by §§82.051-82.055 (formerly §7, Article 1.10) of the Texas Insurance Code, if the insurer fails to report information as required by this section.

§281.19 Restrictions on Assignment of Vehicles

(a) Each agency vehicle, with the exception of the agency pool car, will be assigned to an individual field employee.

(b) The agency may assign a vehicle to a board member or an individual administrative or executive employee:

(1) on a temporary basis if field personnel are not available to assume responsibility for the car; or

(2) on a regular basis only if the agency makes a written documented finding that the assignment is critical to the needs and mission of the agency.

(c) The agency pool car is assigned to the agency motor pool and is available for checkout.

SUBCHAPTER B GENERAL PROCEDURES IN A CONTESTED CASE

§281.20 Application of Other Laws

All disciplinary action shall be taken by the board in accordance with Chapters 2001 and 2003, Government Code, the State Office of Administrative Hearings Rules of Procedure, the board's rules, and any other applicable law or rule.

§281.21 Complaints

Complaints may be filed with the agency in writing or by submitting a completed complaint form to the agency by mail or other method of delivery or through the Internet. A complaint form shall be maintained on the agency's Internet site and at the agency's office for use by a complainant. The complaint form shall request information necessary for the proper processing of the complaint by the agency, including, but not limited to:

- (1) complainant's name, address, and phone number;
- (2) name, address and phone number of subject of complaint, if known;
- (3) date of incident;
- (4) description of drug(s) involved, if any; and
- (5) description of incident giving rise to complaint.

§281.22 Informal Disposition of a Contested Case

(a) Unless precluded by law, informal disposition may be made of any contested case by stipulation, agreed settlement, consent order, default, or dismissal.

(b) Prior to the imposition of disciplinary sanction(s) against a respondent, the board shall provide the respondent with written notice of the matters asserted, including:

(1) a statement of the legal authority, jurisdiction, and alleged conduct under which the enforcement action is based, with a reference to the particular section(s) of the statutes and rules involved;

(2) information the board staff intends to use at an informal conference;

(3) an offer for the respondent to attend an informal conference at a specified time and place and show compliance with all requirements of law, in accordance with §2001.054(c) of the Administrative Procedure Act;

(4) a statement that the respondent has an opportunity for a hearing before the State Office of Administrative Hearings on the allegations; and

(5) the following statement in capital letters in 12 point boldface type: FAILURE TO RESPOND TO THE ALLEGATIONS, BY EITHER PERSONAL APPEARANCE AT THE INFORMAL CONFERENCE OR IN WRITING, WILL RESULT IN THE ALLEGATIONS BEING ADMITTED AS TRUE AND THE RECOMMENDED SANCTION MADE AT THE INFORMAL CONFERENCE BEING GRANTED BY DEFAULT. The notice shall be served by delivering a copy to the respondent in person, by courier receipted delivery, by first class mail, or by certified or

registered mail, return receipt requested to the respondent's last known address of record as shown by agency records.

(c) The respondent will be provided the opportunity to appear at an informal conference prior to a hearing at the State Office of Administrative Hearings. The notice of the time and place of the informal conference, along with the written notice required in subsection (b) of this section, will be given to the respondent at least 45 days before the date of the informal conference. If such notice is not timely provided, the respondent may reschedule the informal conference.

(d) The respondent shall respond either by personal appearance at the informal conference, or by providing a rebuttal in writing no later than 15 days before the date of the informal conference. If the respondent chooses to respond in writing, the response shall admit or deny each of the allegations. If the respondent intends to deny only a part of an allegation, the respondent shall specify so much of it is true and shall deny only the remainder. The response shall also include any other matter, whether of law or fact, upon which the respondent intends to rely upon as a defense. If the respondent fails to respond to the notice specified in subsection (b) of this section, the matter will be considered as a default case and the respondent will be deemed to have:

- (1) admitted all the factual allegations in the notice specified in subsection (b) of this section;
- (2) waived the opportunity to show compliance with the law;
- (3) waived notice of a hearing;
- (4) waived the opportunity for a hearing on the allegations; and
- (5) waived objection to the recommended sanctions made at the informal conference.

(e) Default orders.

(1) The informal conference panel may recommend that the board enter a default order, based upon the allegations set out in the notice specified in subsection (b) of this section, adopting the recommended sanctions made at the informal conference. Upon consideration of the case, the board may enter a default order under §2001.056 of the Administrative Procedure Act or direct that the case be set for a hearing at the State Office of Administrative Hearings.

(2) For a contested case before the State Office of Administrative Hearings, the judge may announce a default upon receiving the required showing of proof to support a default, and then recess the hearing, issue an order dismissing the case from the docket of the State Office of Administrative Hearings, and return the file to the board for informal disposition on a default basis in accordance with §2001.056 of the Administrative Procedure Act. The board may then enter a default order or direct the case back to the State Office of Administrative Hearings.

(f) Any default judgment granted under this section will be entered on the basis of the factual allegations in the notice specified in subsection (b) of this section, and upon proof of proper notice to the respondent's address of record. For purposes of this section, proper notice means notice sufficient to meet the provisions of §2001.054 of the Administrative Procedure Act and §281.30 of this title (relating to Pleadings and Notice in a Contested Case).

(g) A motion for rehearing which requests that the board vacate its default order under this section shall be granted if the motion presents convincing evidence that the failure to respond to the notice specified in subsection (b) of this section was not intentional or the result of conscious indifference, but due to accident or mistake, provided that the respondent has a meritorious defense to the factual allegations contained in the notice specified in subsection (b) of this section and the granting thereof will not result in delay or injury to the public or the board.

(h) Informal conferences shall be attended by the executive director/secretary or designated representative, legal counsel of the agency or an attorney employed by the office of the attorney general, and other representative(s) of the agency as the executive director/secretary and legal counsel may deem necessary for proper conduct of the conference. The respondent and/or the respondent's authorized representative(s) may attend the informal conference and shall be provided an opportunity to be heard. All communications from the respondent shall be directed to the legal counsel of the agency.

(i) In any case where charges are based upon information provided by a person (complainant) who filed a complaint with the board, the complainant may attend the informal conference, unless the proceedings are confidential under §564.002 and §564.003 of the Texas Pharmacy Act or other applicable law. A complainant who chooses to attend an informal conference shall be provided an opportunity to be heard with regard to charges based upon the information provided by the complainant. Nothing herein requires a complainant to attend an informal conference.

(j) Informal conferences shall not be deemed meetings of the board, and no formal record of the proceedings at such conferences shall be made or maintained unless the respondent requests such a recording in writing at least 15 days before the informal conference. Board staff will arrange for the presence of a court reporter to make the recording. The respondent shall be responsible for the cost of the recording. The recording will be part of the board's investigative file and will not be released to a third party unless authorized under §565.055 of the Act. The board will provide a copy of the recording to the respondent upon request.

(k) Any proposed consent order shall be presented to the board in open meeting for its review. At the conclusion of its review, the board shall approve or disapprove the proposed consent order. Should the board approve the proposed consent order, the appropriate notation shall be made in minutes of the board and the proposed consent order shall be entered as an official action of the board. Should the board disapprove the proposed consent order, the matter shall be scheduled for public hearing.

§281.23 Subpoenas

(a) A subpoena issued by the executive director/secretary under the authority of §565.058 of the Act is considered by the board to be a ministerial act. Such subpoena shall be used to obtain information and testimony at the request of board staff.

(b) If a subpoena is requested by an applicant, licensee, or registrant under §2001.089 of the APA, a showing of good cause shall be made to the executive director/secretary. Such a showing shall be by submission of a written request for the subpoena indicating the purpose of the subpoena and indicating that the subpoena is not requested in bad faith. In addition, the requesting party shall aver that the subpoena:

- (1) does not request information that is privileged;
- (2) requests information relevant to the contested case;
- (2) is not an undue burden; and
- (3) is sufficiently specific.

(c) Once the requesting party has complied with the requirements in subsection (b) of this section, the executive director/secretary may issue the subpoena.

(d) If the requesting party, the subpoenaed party, any other party to the contested case, or any person or entity affected by the subpoena objects, a challenge to the subpoena shall be filed with the Administrative Law Judge at the State Office of Administrative Hearings.

§281.30 Pleadings and Notice in a Contested Case

(a) The board initiates a contested case hearing at the State Office of Administrative Hearings by filing a complaint with notice of not less than 10 days as specified in subsection (b) of this section to the applicant, licensee, or registrant.

(1) The complaint shall contain the matters asserted by the board, including the alleged conduct under which the enforcement action is based, and a statement of legal authority to the statutes or rules allegedly violated and those establishing jurisdiction.

(2) The following statement in capital letters in 12 point boldface type shall be contained in the complaint: FAILURE TO RESPOND TO THE ALLEGATIONS IN WRITING WILL RESULT IN THE ALLEGATIONS BEING ADMITTED AS TRUE AND AN ORDER BEING ENTERED BY THE BOARD BY DEFAULT.

(b) The board may serve notice of the complaint initiating a contested case hearing at the State Office of Administrative Hearings by sending it to the party's current publicly available address of record and the party's current confidential address of record if the confidential address of record is different from the party's publicly available address of record as shown by the board's records. The notice shall be served by delivering a copy to the party either in person or by certified or registered mail, return receipt requested.

(c) The applicant, licensee, or registrant shall file a written answer with the State Office of Administrative Hearings in response to the complaint with service to the board within 23 days after the date of service of the complaint. The answer shall admit or deny each of the allegations. If the party intends to deny only a part of an allegation, the party shall specify so much of it is true and shall deny only the remainder. The response shall also include any other matter, whether of law or fact, upon which the licensee or registrant intends to rely for his or her defense. If the party fails to respond by filing a timely answer, the board's attorney files a motion to remand the case to the board for entry of a default order, and the matter will be considered as a default case and the party will be deemed to have:

- (1) admitted all the factual allegations in the notice specified in subsection (b) of this section;
- (2) waived notice of a hearing;

(3) waived the opportunity for a hearing on the allegations; and

(4) waived objection to the recommended sanctions made at the informal conference.

(d) If the contested case is remanded to the board by the State Office of Administrative Hearings as specified in subsection (c) of this section, the board may enter a default order under §2001.056 of the Administrative Procedure Act.

(e) Any default judgment granted under this section will be entered on the basis of the factual allegations in the notice specified in subsection (b) of this section, and upon proof of proper notice to the party's address of record.

(f) The party may file a motion for rehearing to set aside the default order. The motion, which requests that the Board vacate its default order under this section, shall be granted if the motion presents convincing evidence that the failure to respond to the notice specified in subsection (b) of this section was not intentional or the result of conscious indifference, but due to accident or mistake, provided that the party has a meritorious defense to the factual allegations contained in the notice specified in subsection (b) of this section and the granting thereof will not result in delay or injury to the public or the Board.

§281.31 Burden of Proof

(a) In a contested case hearing at the State Office of Administrative Hearings involving grounds for disciplinary action, the board has the burden to prove that grounds to discipline respondent exist. However, the party that claims any exemption or exception, including mitigating factors as specified in §281.62 of this chapter, has the burden to prove that the exemption or exception should be applied.

(b) In a contested case hearing at the State Office of Administrative Hearings involving a petition for reinstatement or removal of restriction, the petitioner has the burden to prove that the license should be reinstated or that a restriction on the license should be removed in accordance with §281.66 of the chapter.

(c) In a show cause hearing at the State Office of Administrative Hearings involving an applicant, licensee, or registrant who has been previously ordered by the board to submit to a mental or physical examination under §565.052 or §568.0036 of the Act, the applicant, licensee, or registrant has the burden to prove that the applicant, licensee, or registrant should not be required to submit to the examination.

§281.32 Failure to Attend Hearing and Default

(a) If a party who does not have the burden of proof fails to appear at a contested case hearing at the State Office of Administrative Hearings, the administrative law judge may announce a default upon receiving the required showing of proof to support a default, and then recess the hearing, issue an order dismissing the case from the docket of the State Office of Administrative Hearings, and return the file to the board for informal disposition on a default basis in accordance with §2001.056 of the Administrative Procedure Act. In the alternative, the judge

may issue a default proposal for decision, rather than continuing or dismissing the case and requiring the board to dispose of the case on a default basis as an informal disposition.

(b) If a party who does have the burden of proof fails to appear at a contested case hearing at the State Office of Administrative Hearings, the administrative law judge shall dismiss the case for want of prosecution, any relevant application will be withdrawn, and the board may not consider a subsequent petition from the party until the first anniversary of the date of dismissal of the case.

§281.33 Proposal for Decision

(a) The administrative law judge shall submit a proposal for decision to the agency, and the board shall render the final decision in the contested case. The board may request that the proposal for decision be presented to the board by the administrative law judge at the next board meeting.

(b) If a party submitted proposed findings of fact, the proposal for decision shall include a ruling on each proposed finding by the administrative law judge.

(c) The parties may submit to the board for consideration, prior to the final decision, an alternative proposed board order with changes to the proposal for decision in compliance with the APA.

§281.34 Record of Hearing

(a) The board shall arrange for a stenographic recording of all contested case hearings before the State Office of Administrative Hearings on a regular basis. The administrative law judge may waive the requirement as authorized by the State Office of Administrative Hearings Rules of Procedure. Any party may request a written transcript of all or part of the hearing. The cost of a transcript shall be paid by the requesting party.

(b) A party who appeals a final decision in a hearing shall pay the cost of preparation of the original or a certified copy of the record of the board proceeding that is required to be sent to the reviewing court. A charge imposed under this section is a court cost and may be assessed by the court in accordance with the Texas Rules of Civil Procedure.

§281.60 General Guidance

(a) This subchapter is promulgated to:

(1) promote consistency and guidance in the exercise of sound discretion by the agency in licensure and disciplinary matters;

(2) provide notice as to the types of conduct that constitute violations of the Act and as to the disciplinary action that may be imposed; and

(3) provide a framework of analysis for administrative law judges in making recommendations in licensure and disciplinary matters.

(b) Board's role. The board shall render the final decision in a contested case and has the responsibility to assess sanctions against licensees who are found to have violated the Act. The board welcomes recommendations of administrative law judges as to the sanctions to be imposed, but the board is not bound by such recommendations. A sanction should be consistent with sanctions imposed in other similar cases and should reflect the board's determination of the seriousness of the violation and the sanction required to deter future violations. A determination of the appropriate sanction is reserved to the board. The appropriate sanction is not a proper finding of fact or conclusion of law. This subchapter shall be construed and applied so as to preserve board member discretion in the imposition of sanctions and remedial measures pursuant to the APA and the Act's provisions related to types of discipline and administrative penalties. This subchapter shall be further construed and applied so as to be consistent with the Act, and shall be limited to the extent as otherwise proscribed by statute and board rule.

(c) Purpose of guidelines. These guidelines are designed to provide guidance in assessing sanctions for violations of the Act. The ultimate purpose of disciplinary sanctions is to protect and inform the public, deter future violations, offer opportunities for rehabilitation, if appropriate, punish violators, and deter others from violations. These guidelines are intended to promote consistent sanctions for similar violations, facilitate timely resolution of cases, and encourage settlements.

(1) The standard sanctions outlined in the subchapter apply to cases involving a single violation of the Act, and in which there are no aggravating factors that apply. The board may impose more restrictive sanctions when there are multiple violations of the Act. In cases which do not have standard sanctions outlined in the subchapter, the board may consider any aggravating and/or mitigating factors listed in §281.62 of this title (relating to Aggravating and Mitigating Factors) that are found to apply in a particular case.

(2) The standard and minimum sanctions outlined in the subchapter are applicable to first time violators. The board shall consider revoking the person's license if the person is a repeat offender.

(3) The maximum sanction in all cases is revocation of the licensee's license, which may be accompanied by an administrative penalty of up to \$5,000 per violation. Each day the violation continues is a separate violation.

(4) Each statutory violation constitutes a separate offense, even if arising out of a single act.

§281.61 Definitions of Discipline Authorized

For the purpose of the Act, §565.051 and §568.0035:

(1) "Probation" means the suspension of a sanction imposed against a license or registration during good behavior, for a term and under conditions as determined by the board.

(2) "Reprimand" means a public and formal censure against a license or registration.

(3) "Restrict" means to limit, confine, abridge, narrow, or restrain a license or registration for a term and under conditions determined by the board.

(4) "Revoke" means a license or registration is void and may not be reissued; provided, however, upon the expiration of 12 months from and after the effective date of the order revoking a license or registration, application may be made to the board by the former licensee or registrant for the issuance of a license or registration upon the successful completion of any requirements determined by the board.

(5) "Suspend" means a license or registration is of no further force and effect for a period of time as determined by the board.

(6) "Retire" means a license or registration has been withdrawn and is of no further force and effect.

§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 more severe or more restrictive action by the board:

(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;

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

(H) prior conduct of a similar or related nature;

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

(J) 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) violation of a board order;

(L) 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) lack of rehabilitative potential or likelihood for future conduct of a similar nature;

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

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

(2) 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:

(A) absence of potential harm to the public;

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

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

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

(E) absence of prior conduct of a similar or related nature;

(F) absence of disciplinary actions taken by any regulatory agency of the federal government or any state;

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

(H) rehabilitative potential;

(I) prior community service and present value to the community;

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

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

(L) treatment and/or monitoring of an impairment.

§281.63 Considerations for Criminal Offenses

(a) The purpose of this section is to establish guidelines and criteria on the eligibility of persons with criminal backgrounds to obtain a license or registration from the board and on the disciplinary actions taken by the board. The section applies to all criminal convictions and to all deferred adjudication community supervisions or deferred dispositions, as authorized by the Act, for all types of licenses and registrations.

(b) The board may suspend, revoke, or impose other authorized disciplinary action on a current license or registration, disqualify a person from receiving a license or registration, or deny to a person the opportunity to be examined for a license or registration because of a person's conviction or deferred adjudication of a crime that serves as a ground for discipline under the Act, and that the board determines directly relates to the duties and responsibilities of a licensee, a registrant, or of an owner of a pharmacy. This subsection applies to persons who are not imprisoned at the time the board considers the conviction or deferred adjudication.

(c) The board shall revoke a license or registration upon the imprisonment of the licensee, the registrant, or the owner of a pharmacy following a felony conviction or deferred adjudication, or revocation of felony community supervision, parole, or mandatory supervision.

(d) A person in prison is not eligible for a license or registration.

(e) An applicant for a license or registration from the board shall disclose in writing to the board any conviction or deferred adjudication against him or her at the time of application. A current licensee or registrant shall disclose in writing to the board any conviction or deferred adjudication against him or her at the time of renewal.

(f) The board shall by rule determine and list in this section which criminal offenses directly relate to the occupation of a licensee or registrant, or the operation of a pharmacy. For all other offenses not listed in this section, in considering whether a criminal conviction or deferred adjudication directly relates to the occupation of a licensee or a registrant, or the operation of a pharmacy, the board shall consider:

(1) the nature and seriousness of the crime;

(2) the relationship of the crime to the purposes for requiring a license or registration to engage in the occupation of the licensee or registrant, or the operation of a pharmacy;

(3) the extent to which a license or registration might afford the licensee or registrant an opportunity to repeat the criminal activity in which the person had been involved; and

(4) the relationship of the crime to the ability, capacity, or fitness required to perform the duties and discharge the responsibilities of the licensee or registrant.

(g) The board has the authority to impose disciplinary action as authorized by the Act, for those criminal offenses that provide grounds for discipline under the Act. In reaching a decision regarding the severity of the disciplinary sanction to impose on a license or registration, the board shall, in its discretion and unless otherwise specified in §281.64 of this title (relating to Sanctions for Criminal Offenses), also determine the person's fitness to perform the duties and discharge the responsibilities of a licensee or registrant by evaluating and balancing these factors in the following priority with the first being the highest priority:

(1) the extent and nature of the person's past criminal activity;

(2) the amount of time that has elapsed since the person's last criminal activity;

(3) the person's rehabilitation or rehabilitative effort while incarcerated or following release as corroborated by extrinsic evidence;

(4) the age of the person at the time of the commission of the crime, if younger than 21 years of age at the time of the crime;

(5) the conduct and work activity of the person prior to and following the criminal activity; and

(6) other evidence of the person's present fitness, including letters of recommendation from:

(A) prosecution, law enforcement, and correctional officers who prosecuted, arrested, or had custodial responsibility for the person;

(B) the sheriff and chief of police in the community where the person resides; and

(C) any other persons in contact with the person.

(h) In order to establish the factors in subsection (g) of this section, a person with a conviction or deferred adjudication shall:

(1) to the extent possible, secure and provide to the board the recommendations of the prosecution, law enforcement, and correctional authorities specified in subsection (g)(6) of this section;

(2) cooperate with the board by providing the information required by this section, including proof that he or she has:

(A) maintained a record of steady employment, as evidenced by salary stubs, income tax records or other employment records for the time since the conviction or deferred adjudication and/or release from imprisonment;

(B) supported his or her dependents, as evidenced by salary stubs, income tax records or other employment records for the time since the conviction or deferred adjudication and/or release from imprisonment, and a recommendation from the spouse or either parent;

(C) maintained a record of good conduct as evidenced by recommendations, absence of other criminal activity or documentation of community service since conviction or deferred adjudication;

(D) paid all outstanding court costs, supervision fees, fines, and restitution as may have been ordered in all criminal cases in which he or she has been convicted, as evidenced by certified copies of a court release or other documentation from the court system that all monies have been paid; and

(E) obtained appropriate treatment and/or counseling, if applicable.

(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 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) The sanctions imposed by the guidelines can be used in conjunction with other types of disciplinary actions, including administrative penalties, as outlined in this section.

(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 in paragraphs (1) - (3) of this subsection. In regard to the crimes enumerated in this rule, the board has weighed the factors, which are required to be considered from §281.63(g), in a light most favorable to the individual, and even if these factors were present, the board has concluded that the following sanctions apply to individuals with the criminal offenses as described in paragraphs (1) - (3) of this subsection:

(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 or revocation;

(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, possession with intent to deliver, or illegal dispensing:

- (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--3 years probation;

(ii) Offenses involving possession of drugs, fraudulent prescriptions, theft of drugs, or alcohol:

(I) If the offense involved only the personal use of the drugs or alcohol and/or chemical impairment:

(-a-) Currently on probation--90-day to one-year suspension followed by 5 years probation;

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

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

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

(II) Otherwise:

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

(-b-) 0-5 years since date of disposition--denial or one-year suspension followed by 5 years probation;

(-c-) 6-10 years since date of disposition--180-day suspension followed by 5 years probation;

(-d-) 11-20 years since date of disposition--3 years probation;

(-e-) 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 30- to 180-day suspension followed by 5 years probation;

(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:

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

(II) 0-10 years since date of disposition--30- to 180-day suspension followed by 5 years probation;

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

(ii) Offenses involving possession of drugs, fraudulent prescriptions, or theft of drugs:

(I) Pharmacists:

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

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

(II) Pharmacy Technicians and Pharmacy Technician Trainees:

(-a-) 0-5 years since date of disposition and offense determined to be in violation of §568.003(a)(5) or (9) of the Act--5 years probation;

(-b-) 0-5 years since date of disposition and determined not to have a drug or alcohol dependency--1 year probation;

(-c-) 6-10 years since date of disposition and offense determined to be in violation of §568.003(a)(5) or (9) of the Act--3 years probation;

(III) If 0-5 years since date of disposition, and the offense did not involve only personal use of the drugs and/or chemical impairment, an additional 30- to 90-day suspension will be imposed preceding the probation for the offenses in this clause;

(B) Intoxication and alcoholic beverage offenses as defined in the Texas Penal Code, if two such offenses involving intoxication due to ingestion of alcohol occurred in the previous ten

years or if one such offense involving intoxication due to ingestion of controlled substances or dangerous drugs occurred in the previous ten years:

(i) Pharmacists:

(I) 0-5 years since date of disposition and offense determined to be in violation of §565.001(a)(4) or (7) of the Act--5 years probation;

(II) 6-10 years since date of disposition and offense determined to be in violation of §565.001(a)(4) or (7) of the Act--3 years probation;

(ii) Pharmacy Technicians and Pharmacy Technician Trainees: 0-5 years since date of disposition and offense determined to be in violation of §568.003(a)(5) or (9) of the Act--5 years probation;

(C) Other misdemeanor offenses involving moral turpitude: 0-5 years since date of disposition--reprimand.

(d) When an individual has multiple criminal offenses or other violations, the board shall consider imposing additional more severe types of disciplinary sanctions, as deemed necessary.

(e) An individual who suffers from an impairment as described by §565.001(a)(4) or (7) or §568.003(a)(5), may provide mitigating information including treatment, counseling, and monitoring in order to mitigate the sanctions imposed.

§281.65 Schedule of 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) The following violations by a pharmacist may be appropriate for disposition with an administrative penalty with or without additional sanctions or restrictions:

(A) failure to provide patient counseling: \$1,000;

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

(C) failure to clarify a prescription with the prescriber: \$1,000;

(D) failure to properly supervise or improperly delegating a duty to a pharmacy technician: \$1,000;

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

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

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

(H) 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;

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

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

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

(L) 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;

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

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

(O) 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;

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

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

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

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

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

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

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

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

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

(Y) sale, purchase, or trade or offer to sell, purchase, or trade of prescription drug samples as provided by §281.7(a)(27) of this title (relating to Grounds for Discipline for a Pharmacist License): up to \$1,000;

(Z) failure to keep, maintain or furnish an annual inventory as required by §291.17: \$1,000;

(AA) failure to obtain training on the preparation of sterile pharmaceutical compounding: \$1,000;

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

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

(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 a disciplinary 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: \$500 - \$3,000;

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

(A) failure to respond or failure to provide all requested records within the time specified in a board audit of continuing education records: \$30 per hour of continuing education credit not provided;

(B) 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: \$500;

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

(D) violating a disciplinary Order of the Board: \$250 - \$500;

(E) failure to report or to assure the report of a malpractice claim: up to \$500;

(F) performing the duties of a pharmacy technician without a valid registration: \$250 - \$1,000;

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

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

(I) failure to obtain training on the preparation of sterile pharmaceutical compounding: \$1,000;

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

(K) failure to inform the board of any notification or information required to be reported by the Act or rules: \$100 - \$250.

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

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

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

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

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

(C) the history of previous violations;

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

(E) efforts to correct the violation; and

(F) and other matter that justice may require.

§281.66 Application for Reissuance or Removal of Restrictions of a License or Registration

(a) A person whose pharmacy license, pharmacy technician registration, or license or registration to practice pharmacy has been canceled, revoked, or restricted, whether voluntary or by action of the board, may, after 12 months from the effective date of such cancellation, revocation, or restriction, apply to the board for reinstatement or removal of the restriction of the license or registration.

(1) The application shall be given under oath and on the form prescribed by the board.

(2) A person applying for reinstatement or removal of restrictions may be required to meet all requirements necessary in order for the board to access the criminal history record information, including submitting fingerprint information and being responsible for all associated costs.

(3) A person applying for reinstatement or removal of restrictions has the burden of proof.

(4) On investigation and hearing, the board may in its discretion grant or deny the application or it may modify its original finding to reflect any circumstances that have changed sufficiently to warrant the modification.

(5) If such application is denied by the board, a subsequent application may not be considered by the board until 12 months from the date of denial of the previous application.

(6) The board in its discretion may require a person to pass an examination or examinations to reenter the practice of pharmacy.

(7) The fee for reinstatement of a license or registration shall be \$100 which is to be paid to the Texas State Board of Pharmacy and includes the processing of the reinstatement application.

(b) In reinstatement cases not involving criminal offenses, the board may consider the following items in determining the reinstatement of an applicant's previously revoked or canceled license or registration:

(1) moral character in the community;

(2) employment history;

(3) financial support to his/her family;

(4) participation in continuing education programs or other methods of maintaining currency with the practice of pharmacy;

(5) criminal history record, including arrests, indictments, and convictions relating to felonies or misdemeanors involving moral turpitude;

(6) offers of employment in pharmacy;

(7) involvement in public service activities in the community;

(8) failure to comply with the provisions of the board order revoking or canceling the applicant's license or registration;

(9) action by other state or federal regulatory agencies;

(10) any physical, chemical, emotional, or mental impairment;

(11) the gravity of the offense for which the applicant's license or registration was canceled, revoked, or restricted and the impact the offense had upon the public health, safety and welfare;

(12) the length of time since the applicant's license or registration was canceled, revoked or restricted, as a factor in determining whether the time period has been sufficient for the applicant to have rehabilitated himself/herself to be able to practice pharmacy in a manner consistent with the public health, safety and welfare;

(13) competency to engage in the practice of pharmacy; or

(14) other rehabilitation actions taken by the applicant.

(c) If reinstatement cases involves criminal offenses, the sanctions specified in §281.64 of this chapter (relating to Sanctions for Criminal Offenses) apply.

§281.67 Sanctions for Out-of-State Disciplinary Actions

(a) When determining the appropriate sanction for a disciplinary action taken by a regulatory board of another state under §565.001(a)(16), §565.002(a)(13), or §568.003(a)(13), the board has determined that the following shall be applicable for all types of licensees and registrants for such licenses and registrations issued by the board.

(1) If the other state's disciplinary action resulted in the license or registration being restricted, suspended, revoked, or surrendered, the appropriate sanction shall be the same as the sanction imposed by the other state, such that the licensee or registrant has the same restriction against practice in Texas.

(2) If the license or registration is subject to any other type of disciplinary sanctions, the appropriate sanction shall be equivalent to or less than that imposed by the other state unless contrary to board policy.

(b) The sanctions imposed by this chapter can be used in conjunction with other types of disciplinary actions, including administrative penalties, as outlined in this chapter.

(c) When a licensee or registrant has additional violations of the Texas Pharmacy Act, the board shall consider imposing additional more severe types of disciplinary sanctions, as deemed necessary.

§281.68 Remedial Plan

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

- (1) a death;
- (2) a hospitalization;
- (3) the commission of a felony;
- (4) the unlicensed practice of a licensee or registrant;
- (5) audit shortages;
- (6) diversion of controlled substances;
- (7) impairment by chemical abuse or mental or physical illness of a licensee or registrant;
- (8) unauthorized dispensing of a prescription drug;
- (9) gross immorality as defined by the board;
- (10) engaging in fraud, deceit, or misrepresentation as defined by board rule;
- (11) disciplinary action by another regulatory board of this state or another state; or
- (12) any other matter determined by the board.

(b) The board shall not impose a remedial plan if the appropriate resolution of the complaint involves 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 of \$1,000 to recover the costs of administering the plan.