

OCCUPATIONS CODE

TITLE 3. HEALTH PROFESSIONS

SUBTITLE J. PHARMACY AND PHARMACISTS

CHAPTER 556. ADMINISTRATIVE INSPECTIONS AND WARRANTS

SUBCHAPTER A. GENERAL PROVISIONS

Sec. 556.001. DEFINITION. In this chapter, "facility" means a place:

- (1) for which an application has been made for a pharmacy license under this subtitle;
- (2) at which a pharmacy licensed under this subtitle is located;
- (3) at which a pharmacy is being operated in violation of this subtitle; or
- (4) where the practice of pharmacy occurs.

Acts 1999, 76th Leg., ch. 388, Sec. 1, eff. Sept. 1, 1999.

SUBCHAPTER B. INSPECTIONS

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

- (1) drug storage and security;
- (2) equipment;
- (3) components used in compounding, finished and unfinished products, containers, and labeling of any item;
- (4) sanitary conditions;
- (5) records, reports, or other documents required to be kept or made under this subtitle, Chapter 481 or 483, Health and Safety Code, or the Comprehensive Drug Abuse Prevention and Control Act of 1970 (21 U.S.C. Section 801 et seq.) or rules adopted under one of those laws; or
- (6) subject to Subsection (b), financial records relating to the operation of the facility.

(b) The board or a representative of the board may inspect financial records under Subsection (a) only in the course of the

investigation of a specific complaint. The board or representative may inspect only records related to the specific complaint. The inspection is subject to Section 565.055.

Acts 1999, 76th Leg., ch. 388, Sec. 1, eff. Sept. 1, 1999.

Amended by:

Acts 2005, 79th Leg., Ch. 28 (S.B. 492), Sec. 2, eff. September 1, 2005.

Acts 2015, 84th Leg., R.S., Ch. 599 (S.B. 460), Sec. 3, eff. September 1, 2015.

Sec. 556.052. REQUIREMENTS BEFORE ENTRY AND INSPECTION.

(a) Before an entry and inspection of the facility, the person authorized to represent the board must:

(1) state the purpose for the inspection; and

(2) present to the owner, pharmacist, or agent in charge of the facility:

(A) appropriate credentials; and

(B) written notice of the authority for the inspection.

(b) If an inspection is required by or is supported by an administrative inspection warrant, the warrant is the notice for purposes of Subsection (a)(2)(B).

Acts 1999, 76th Leg., ch. 388, Sec. 1, eff. Sept. 1, 1999.

Sec. 556.053. EXTENT OF INSPECTION; CONFIDENTIALITY. (a)

Except as otherwise provided in an inspection warrant, the person authorized to represent the board may:

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

(2) inspect, within reasonable limits and in a reasonable manner, a facility's storage, equipment, security, prescription drugs or devices, components used in compounding, finished and unfinished products, or records; or

(3) perform an inventory of any stock of prescription

drugs or devices, components used in compounding, or finished and unfinished products in a facility and obtain samples of those substances.

(b) Reports, records, formulas, and test results of samples of products compounded by pharmacies obtained by the board may be provided to the pharmacy that compounded the product but otherwise are confidential and do not constitute public information for purposes of Chapter 552, Government Code. The board may create, use, or disclose statistical information from the test results of samples of compounded products.

(c) The board may disclose information confidential under Subsection (b):

(1) in a disciplinary hearing before the board or in a subsequent trial or appeal of a board action or order;

(2) to a pharmacist licensing or disciplinary authority of another jurisdiction; or

(3) under a court order.

(d) The board shall require a pharmacy to recall a compounded product and may release the results of the tests of the samples of the compounded product if the board determines that:

(1) the test results indicate a patient safety problem that may involve potential harm to a patient; and

(2) the release of the test results is necessary to protect the public.

(e) The board shall release the test results described by Subsection (d) if a pharmacy is unable to or does not recall the compounded product within 48 hours after the board's request under that subsection.

Acts 1999, 76th Leg., ch. 388, Sec. 1, eff. Sept. 1, 1999.

Amended by:

Acts 2005, 79th Leg., Ch. 28 (S.B. 492), Sec. 3, eff. September 1, 2005.

Acts 2009, 81st Leg., R.S., Ch. 785 (S.B. 1127), Sec. 1, eff. June 19, 2009.

Sec. 556.054. CONFIDENTIALITY OF CERTAIN INFORMATION. The following information obtained by the board during an inspection of

a facility is confidential and not subject to disclosure under Chapter 552, Government Code:

- (1) financial data;
- (2) sales data, other than shipment data; and
- (3) pricing data.

Acts 1999, 76th Leg., ch. 388, Sec. 1, eff. Sept. 1, 1999.

Amended by:

Acts 2015, 84th Leg., R.S., Ch. 599 (S.B. 460), Sec. 4, eff. September 1, 2015.

Sec. 556.055. INSPECTIONS WITH WARNING NOTICE. Before a complaint may be filed with the board as the result of a written warning notice that is issued during an inspection authorized by this chapter and that lists a specific violation of this subtitle or a rule adopted under this subtitle, the license holder must be given a reasonable time, as determined by the board, to comply with this subtitle or rules adopted under this subtitle.

Acts 1999, 76th Leg., ch. 388, Sec. 1, eff. Sept. 1, 1999.

Sec. 556.0551. INSPECTION OF LICENSED NONRESIDENT PHARMACY.

(a) The board may inspect a nonresident pharmacy licensed by the board that compounds sterile preparations as necessary to ensure compliance with the safety standards and other requirements of this subtitle and board rules.

(b) A nonresident pharmacy shall reimburse the board for all expenses, including travel, incurred by the board in inspecting the pharmacy as provided by Subsection (a).

Added by Acts 2013, 83rd Leg., R.S., Ch. 608 (S.B. 1100), Sec. 1, eff. September 1, 2013.

Sec. 556.0555. INSPECTIONS. (a) At least annually, the board shall conduct random inspections of Canadian pharmacies designated under Section 554.016 as necessary to ensure compliance with the safety standards and other requirements of this subtitle and board rules.

(b) Notwithstanding the requirements of this chapter, the board by rule may establish the standards and procedures for

inspections under this section.

(c) The board may enter into a written agreement with another state for an agency or employee of the state to perform services for the board related to inspecting a Canadian pharmacy designated by the board under Section 554.016 to dispense prescription drugs to residents in this state. This subsection does not apply to the initial inspection of the pharmacy.

Added by Acts 2005, 79th Leg., Ch. 1345 (S.B. 410), Sec. 38, eff. September 1, 2005.

Sec. 556.056. CODE OF PROFESSIONAL RESPONSIBILITY. (a) The board shall adopt a code of professional responsibility to regulate the conduct of a representative of the board authorized to inspect and survey a pharmacy.

(b) The code must contain:

(1) a procedure to be followed by a person authorized to represent the board:

(A) on entering a pharmacy;

(B) during inspection of the pharmacy; and

(C) during an exit conference; and

(2) standards of conduct that the person must follow in dealing with the staff and management of the pharmacy and the public.

(c) The board shall establish a procedure for receiving and investigating a complaint of a code violation. The board shall investigate each complaint of a code violation. The board shall forward results of an investigation to the complainant.

(d) The board may adopt rules establishing sanctions for code violations.

Acts 1999, 76th Leg., ch. 388, Sec. 1, eff. Sept. 1, 1999.

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

Added by Acts 2015, 84th Leg., R.S., Ch. 599 (S.B. 460), Sec. 5,

eff. September 1, 2015.

SUBCHAPTER C. WARRANTS

Sec. 556.101. WARRANT NOT REQUIRED. A warrant is not required under this chapter to:

(1) inspect books or records under an administrative subpoena issued under this subtitle; or

(2) enter a facility or conduct an administrative inspection of a facility if:

(A) the owner, pharmacist, or agent in charge of the facility consents to the inspection;

(B) the situation presents imminent danger to the public health and safety;

(C) the situation involves inspection of a conveyance, if there is reasonable cause to believe that the mobility of the conveyance makes it impracticable to obtain a warrant; or

(D) any other exceptional situation or emergency exists involving an act of God or natural disaster in which time or opportunity to apply for a warrant is lacking.

Acts 1999, 76th Leg., ch. 388, Sec. 1, eff. Sept. 1, 1999.

Sec. 556.102. COMPLIANCE WITH CHAPTER. An administrative inspection warrant may be issued and executed only in accordance with this chapter.

Acts 1999, 76th Leg., ch. 388, Sec. 1, eff. Sept. 1, 1999.

Sec. 556.103. ISSUANCE OF WARRANT. (a) In this section, "probable cause" means a valid public interest exists in the effective enforcement of this subtitle or a rule adopted under this subtitle that is sufficient to justify an administrative inspection of the facility, area, building, or conveyance, or its contents in the circumstances specified in the application for the warrant.

(b) A district judge may, on proper oath or affirmation that shows probable cause, issue a warrant to:

(1) conduct an administrative inspection authorized

by this chapter or rules adopted under this subtitle; and

(2) seize property appropriate to the inspection.

(c) A warrant may be issued only on an affidavit that:

(1) is given by a board representative who has knowledge of the facts alleged;

(2) is sworn to before the judge; and

(3) establishes the grounds for issuance of the warrant.

(d) The judge shall issue a warrant if the judge is satisfied that grounds for the application exist or that there is probable cause to believe they exist.

Acts 1999, 76th Leg., ch. 388, Sec. 1, eff. Sept. 1, 1999.

Sec. 556.104. CONTENTS OF WARRANT. The warrant must:

(1) identify:

(A) the facility, area, building, or conveyance to be inspected;

(B) the purpose of the inspection;

(C) the type of property to be inspected, if appropriate; and

(D) each item or type of property to be seized, if any;

(2) state the grounds for issuance of the warrant and the name of each person whose affidavit has been taken in support of the warrant;

(3) be directed to a person authorized under this chapter to execute the warrant;

(4) command the person to whom the warrant is directed to inspect the facility, area, building, or conveyance identified for the purpose specified;

(5) direct the seizure of the property specified, if appropriate;

(6) direct that the warrant be served during normal business hours; and

(7) designate the judge to whom the warrant is to be returned.

Acts 1999, 76th Leg., ch. 388, Sec. 1, eff. Sept. 1, 1999.

Sec. 556.105. EXECUTION AND RETURN OF WARRANT. (a) A warrant issued under this chapter must be executed and returned not later than the 10th day after the date of the warrant's issuance unless the judge allows additional time in the warrant after a showing by the board of a need for additional time.

(b) A person who seizes property under a warrant shall provide a copy of the warrant and a receipt for the property taken by:

(1) giving the copy and receipt to the person from whom or from whose facility the property was taken; or

(2) leaving the copy and receipt at the facility from which the property was taken.

(c) The return of the warrant shall be made promptly and be accompanied by a written inventory of any property taken. The inventory shall be:

(1) prepared in the presence of the person executing the warrant and of:

(A) the person from whose possession or facility the property was taken, if present; or

(B) at least one credible person other than the person preparing the inventory; and

(2) verified by the person executing the warrant.

(d) The judge, on request, shall deliver a copy of the inventory to:

(1) the person from whose possession or facility the property was taken; and

(2) the applicant for the warrant.

Acts 1999, 76th Leg., ch. 388, Sec. 1, eff. Sept. 1, 1999.

Sec. 556.106. FILING WITH DISTRICT COURT. (a) A judge who issues a warrant under this chapter shall attach to the warrant:

(1) a copy of the return; and

(2) the papers filed in connection with the warrant.

(b) The judge shall file the copy of the return and the papers with the clerk of the district court with jurisdiction of the area in which the inspection was conducted.

Acts 1999, 76th Leg., ch. 388, Sec. 1, eff. Sept. 1, 1999.

Sec. 556.107. DISPOSAL OF SEIZED PROPERTY. Property seized under this chapter must be disposed of in a manner considered appropriate by the board if the board has jurisdiction over the property or the district court if the court has jurisdiction over the property.

Acts 1999, 76th Leg., ch. 388, Sec. 1, eff. Sept. 1, 1999.