HEALTH AND SAFETY CODECHAPTER 486. OVER-THE-COUNTER SALES OF EPHEDRINE, PSEUDOEPHEDRINE, AND NORPSEUDOEPHEDRINE

## HEALTH AND SAFETY CODE

TITLE 6. FOOD, DRUGS, ALCOHOL, AND HAZARDOUS SUBSTANCES SUBTITLE C. SUBSTANCE ABUSE REGULATION AND CRIMES CHAPTER 486. OVER-THE-COUNTER SALES OF EPHEDRINE, PSEUDOEPHEDRINE, AND NORPSEUDOEPHEDRINE SUBCHAPTER A. GENERAL PROVISIONS

Sec. 486.001. DEFINITIONS. (a) In this chapter:

(1) "Commissioner" means the commissioner of state health services.

(2) "Council" means the State Health Services Council.

(3) "Department" means the Department of State HealthServices.

(4) "Ephedrine," "pseudoephedrine," and "norpseudoephedrine" mean any compound, mixture, or preparation containing any detectable amount of that substance, including its salts, optical isomers, and salts of optical isomers. The term does not include any compound, mixture, or preparation that is in liquid, liquid capsule, or liquid gel capsule form.

(5) "Sale" includes a conveyance, exchange, barter, or trade.

(b) A term that is used in this chapter but is not defined bySubsection (a) has the meaning assigned by Section 481.002.Added by Acts 2005, 79th Leg., Ch. 282, Sec. 9, eff. August 1, 2005.

Sec. 486.002. APPLICABILITY. This chapter does not apply to the sale of any product dispensed or delivered by a pharmacist according to a prescription issued by a practitioner for a valid medical purpose and in the course of professional practice. Added by Acts 2005, 79th Leg., Ch. 282, Sec. 9, eff. August 1, 2005.

Sec. 486.003. RULES. The council shall adopt rules necessary to implement and enforce this chapter. Added by Acts 2005, 79th Leg., Ch. 282, Sec. 9, eff. August 1, 2005.

Sec. 486.004. FEES. (a) The department shall collect fees for:

(1) the issuance of a certificate of authority under this chapter; and

(2) an inspection performed in enforcing this chapter and rules adopted under this chapter.

(b) The commissioner by rule shall set the fees in amounts that allow the department to recover the biennial expenditures of state funds by the department in:

(1) reviewing applications for the issuance of a certificate of authority under this chapter;

(2) issuing certificates of authority under this
chapter;

(3) inspecting and auditing a business establishment that is issued a certificate of authority under this chapter; and

(4) otherwise implementing enforcing this chapter.

(c) Fees collected under this section shall be deposited to the credit of a special account in the general revenue fund and appropriated to the department to implement and enforce this chapter.

Added by Acts 2005, 79th Leg., Ch. 282, Sec. 9, eff. August 1, 2005.

486.005. STATEWIDE APPLICATION AND UNIFORMITY. Sec. (a) To ensure uniform equitable implementation and and enforcement throughout this state, this chapter constitutes the whole field of regulation regarding over-the-counter sales of products that contain ephedrine, pseudoephedrine, or norpseudoephedrine.

(b) This chapter preempts and supersedes a local ordinance, rule, or regulation adopted by a political subdivision of this state pertaining to over-the-counter sales of products that contain ephedrine, pseudoephedrine, or norpseudoephedrine.

(c) This section does not preclude a political subdivision from imposing administrative sanctions on the holder of a business or professional license or permit issued by the political subdivision who engages in conduct that violates this chapter. Added by Acts 2005, 79th Leg., Ch. 282, Sec. 9, eff. August 1, 2005.

## SUBCHAPTER B. OVER-THE-COUNTER SALES

Sec. 486.011. SALES BY PHARMACIES. A business establishment that operates a pharmacy licensed by the Texas State Board of Pharmacy may engage in over-the-counter sales of ephedrine, pseudoephedrine, and norpseudoephedrine. Added by Acts 2005, 79th Leg., Ch. 282, Sec. 9, eff. August 1, 2005.

486.012. SALES ESTABLISHMENTS Sec. ΒY OTHER THAN business PHARMACIES; CERTIFICATE OF AUTHORITY. (a) Α establishment that does not operate a pharmacy licensed by the Texas State Board of Pharmacy may engage in over-the-counter sales of ephedrine, pseudoephedrine, or norpseudoephedrine only if the establishment holds a certificate of authority issued under this section.

(b) The department may issue a certificate of authority to engage in over-the-counter sales of ephedrine, pseudoephedrine, and norpseudoephedrine to a business establishment that does not operate a pharmacy licensed by the Texas State Board of Pharmacy if the establishment:

(1) applies to the department for the certificate in accordance with department rule; and

(2) complies with the requirements established by the department for issuance of a certificate.

(c) The department by rule shall establish requirements for the issuance of a certificate of authority under this section. The rules must include a consideration by the department of whether the establishment:

(1) complies with the requirements of the Texas StateBoard of Pharmacy for the issuance of a license to operate apharmacy;

(2) sells a wide variety of healthcare products; and

(3) employs sales techniques and other measures designed to deter the theft of products containing ephedrine, pseudoephedrine, or norpseudoephedrine and other items used in the manufacture of methamphetamine.

(d) The department may inspect or audit a business

establishment that is issued a certificate of authority under this section at any time the department determines necessary. Added by Acts 2005, 79th Leg., Ch. 282, Sec. 9, eff. August 1, 2005.

Sec. 486.013. RESTRICTION OF ACCESS TO EPHEDRINE, PSEUDOEPHEDRINE, AND NORPSEUDOEPHEDRINE. A business establishment that engages in over-the-counter sales of products containing ephedrine, pseudoephedrine, or norpseudoephedrine shall:

(1) if the establishment operates a pharmacy licensedby the Texas State Board of Pharmacy, maintain those products:

(A) behind the pharmacy counter; or

(B) in a locked case within 30 feet and in a direct line of sight from a pharmacy counter staffed by an employee of the establishment; or

(2) if the establishment does not operate a pharmacy licensed by the Texas State Board of Pharmacy, maintain those products:

(A) behind a sales counter; or

(B) in a locked case within 30 feet and in a direct line of sight from a sales counter continuously staffed by an employee of the establishment.

Added by Acts 2005, 79th Leg., Ch. 282, Sec. 9, eff. August 1, 2005.

Sec. 486.014. PREREQUISITES TO SALE. Before completing an over-the-counter sale of a product containing ephedrine, pseudoephedrine, or norpseudoephedrine, a business establishment that engages in those sales shall:

(1) require the person making the purchase to:

(A) display a driver's license or other form of identification containing the person's photograph and indicating that the person is 16 years of age or older; and

(B) sign for the purchase;

(2) make a record of the sale, including the name of the person making the purchase, the date of the purchase, and the item and number of grams purchased; and

(3) take actions necessary to prevent a person who makes over-the-counter purchases of one or more products containing

ephedrine, pseudoephedrine, or norpseudoephedrine from obtaining from the establishment in a single transaction more than:

(A) two packages of those products; or

(B) six grams of ephedrine, pseudoephedrine, norpseudoephedrine, or a combination of those substances.Added by Acts 2005, 79th Leg., Ch. 282, Sec. 9, eff. August 1, 2005.

Sec. 486.015. MAINTENANCE OF RECORDS. The business establishment shall maintain each record made under Section 486.014(2) until at least the second anniversary of the date the record is made and shall make each record available on request by the department or the Department of Public Safety.

Added by Acts 2005, 79th Leg., Ch. 282, Sec. 9, eff. August 1, 2005.

## SUBCHAPTER C. ADMINISTRATIVE PENALTY

Sec. 486.021. IMPOSITION OF PENALTY. The department may impose an administrative penalty on a person who violates this chapter.

Added by Acts 2005, 79th Leg., Ch. 282, Sec. 9, eff. August 1, 2005.

Sec. 486.022. AMOUNT OF PENALTY. (a) The amount of the penalty may not exceed \$1,000 for each violation, and each day a violation continues or occurs is a separate violation for purposes of imposing a penalty. The total amount of the penalty assessed for a violation continuing or occurring on separate days under this subsection may not exceed \$20,000.

(b) The amount shall be based on:

(1) the seriousness of the violation, including the nature, circumstances, extent, and gravity of the violation;

(2) the threat to health or safety caused by the violation;

(3) the history of previous violations;

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

(5) whether the violator demonstrated good faith, including when applicable whether the violator made good faith efforts to correct the violation; and

(6) any other matter that justice may require.

Added by Acts 2005, 79th Leg., Ch. 282, Sec. 9, eff. August 1, 2005.

Sec. 486.023. REPORT AND NOTICE OF VIOLATION AND PENALTY. (a) If the department initially determines that a violation occurred, the department shall give written notice of the report by certified mail to the person.

(b) The notice must:

(1) include a brief summary of the alleged violation;

(2) state the amount of the recommended penalty; and

(3) inform the person of the person's right to a hearing on the occurrence of the violation, the amount of the penalty, or both.

Added by Acts 2005, 79th Leg., Ch. 282, Sec. 9, eff. August 1, 2005.

Sec. 486.024. PENALTY TO BE PAID OR HEARING REQUESTED. (a) Before the 21st day after the date the person receives notice under Section 486.023, the person in writing may:

(1) accept the determination and recommended penalty;or

(2) make a request for a hearing on the occurrence of the violation, the amount of the penalty, or both.

(b) If the person accepts the determination and recommended penalty or if the person fails to respond to the notice, the commissioner by order shall approve the determination.

Added by Acts 2005, 79th Leg., Ch. 282, Sec. 9, eff. August 1, 2005.

Sec. 486.025. HEARING. (a) If the person requests a hearing, the commissioner shall refer the matter to the State Office of Administrative Hearings, which shall promptly set a hearing date and give written notice of the time and place of the hearing to the person. An administrative law judge of the State Office of Administrative Hearings shall conduct the hearing.

(b) The administrative law judge shall make findings of fact and conclusions of law and promptly issue to the commissioner a proposal for a decision about the occurrence of the violation and the amount of a proposed penalty.

Added by Acts 2005, 79th Leg., Ch. 282, Sec. 9, eff. August 1, 2005.

Sec. 486.026. DECISION. (a) Based on the findings of fact, conclusions of law, and proposal for a decision, the commissioner by order may:

(1) find that a violation occurred and impose a penalty; or

(2) find that a violation did not occur.

(b) The notice of the commissioner's order under Subsection(a) that is sent to the person in the manner provided by Chapter2001, Government Code, must include a statement of the right of the person to judicial review of the order.

Added by Acts 2005, 79th Leg., Ch. 282, Sec. 9, eff. August 1, 2005.

Sec. 486.027. OPTIONS FOLLOWING DECISION: PAY OR APPEAL. Before the 31st day after the date the order under Section 486.026 that imposes an administrative penalty becomes final, the person shall:

(1) pay the penalty; or

(2) file a petition for judicial review of the order contesting the occurrence of the violation, the amount of the penalty, or both.

Added by Acts 2005, 79th Leg., Ch. 282, Sec. 9, eff. August 1, 2005.

Sec. 486.028. STAY OF ENFORCEMENT OF PENALTY. (a) Within the period prescribed by Section 486.027, a person who files a petition for judicial review may:

(1) stay enforcement of the penalty by:

(A) paying the amount of the penalty to the court for placement in an escrow account; or

(B) giving the court a supersedeas bond approved by the court that:

(i) is for the amount of the penalty; and

(ii) is effective until all judicial review
of the order is final; or

(2) request the court to stay enforcement of the penalty by:

(A) filing with the court an affidavit of the

person stating that the person is financially unable to pay the penalty and is financially unable to give the supersedeas bond; and

(B) sending a copy of the affidavit to the commissioner by certified mail.

(b) Following receipt of a copy of an affidavit under Subsection (a)(2), the commissioner may file with the court, before the sixth day after the date of receipt, a contest to the affidavit. The court shall hold a hearing on the facts alleged in the affidavit as soon as practicable and shall stay the enforcement of the penalty on finding that the alleged facts are true. The person who files an affidavit has the burden of proving that the person is financially unable to pay the penalty or to give a supersedeas bond.

Added by Acts 2005, 79th Leg., Ch. 282, Sec. 9, eff. August 1, 2005.

Sec. 486.029. COLLECTION OF PENALTY. (a) If the person does not pay the penalty and the enforcement of the penalty is not stayed, the penalty may be collected.

(b) The attorney general may sue to collect the penalty.Added by Acts 2005, 79th Leg., Ch. 282, Sec. 9, eff. August 1, 2005.

Sec. 486.030. DECISION BY COURT. (a) If the court sustains the finding that a violation occurred, the court may uphold or reduce the amount of the penalty and order the person to pay the full or reduced amount of the penalty.

(b) If the court does not sustain the finding that a violation occurred, the court shall order that a penalty is not owed.

Added by Acts 2005, 79th Leg., Ch. 282, Sec. 9, eff. August 1, 2005.

Sec. 486.031. REMITTANCE OF PENALTY AND INTEREST. (a) If the person paid the penalty and if the amount of the penalty is reduced or the penalty is not upheld by the court, the court shall order, when the court's judgment becomes final, that the appropriate amount plus accrued interest be remitted to the person before the 31st day after the date that the judgment of the court becomes final.

(b) The interest accrues at the rate charged on loans to depository institutions by the New York Federal Reserve Bank.

(c) The interest shall be paid for the period beginning on the date the penalty is paid and ending on the date the penalty is remitted.

Added by Acts 2005, 79th Leg., Ch. 282, Sec. 9, eff. August 1, 2005.

Sec. 486.032. RELEASE OF BOND. (a) If the person gave a supersedeas bond and the penalty is not upheld by the court, the court shall order, when the court's judgment becomes final, the release of the bond.

(b) If the person gave a supersedeas bond and the amount of the penalty is reduced, the court shall order the release of the bond after the person pays the reduced amount. Added by Acts 2005, 79th Leg., Ch. 282, Sec. 9, eff. August 1, 2005.

Sec. 486.033. ADMINISTRATIVE PROCEDURE. A proceeding to impose the penalty under this subchapter is considered to be a contested case under Chapter 2001, Government Code. Added by Acts 2005, 79th Leg., Ch. 282, Sec. 9, eff. August 1, 2005.