### 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- (2) Repealed by Acts 2015, 84th Leg., R.S., Ch. 1, Sec.
  3.1639(95), eff. April 2, 2015.
- (3) "Department" means the Department of State Health Services.
- "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.
- (4-a) "Executive commissioner" means the executive commissioner of the Health and Human Services Commission.
- (5) "Sale" includes a conveyance, exchange, barter, or trade.
- (6) "Real-time electronic logging system" means a system intended to be used by law enforcement agencies and pharmacies or other business establishments that:
- (A) is installed, operated, and maintained free of any one-time or recurring charge to the business establishment or to the state;
- (B) is able to communicate in real time with similar systems operated in other states and similar systems containing information submitted by more than one state;
- (C) complies with the security policy of the Criminal Justice Information Services division of the Federal Bureau of Investigation;

- (D) complies with information exchange standards adopted by the National Information Exchange Model;
- (E) uses a mechanism to prevent the completion of a sale of a product containing ephedrine, pseudoephedrine, or norpseudoephedrine that would violate state or federal law regarding the purchase of a product containing those substances; and
- (F) is equipped with an override of the mechanism described in Paragraph (E) that:
- (i) may be activated by an employee of a business establishment; and
- (ii) creates a record of each activation of the override.
- (b) A term that is used in this chapter but is not defined by Subsection (a) has the meaning assigned by Section 481.002.

  Added by Acts 2005, 79th Leg., Ch. 282 (H.B. 164), Sec. 9, eff. August 1, 2005.

### Amended by:

Acts 2011, 82nd Leg., R.S., Ch. 742 (H.B. 1137), Sec. 1, eff. September 1, 2011.

Acts 2015, 84th Leg., R.S., Ch. 1 (S.B. 219), Sec. 3.1250, eff. April 2, 2015.

Acts 2015, 84th Leg., R.S., Ch. 1 (S.B. 219), Sec. 3.1639(95), eff. April 2, 2015.

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 (H.B. 164), Sec. 9, eff. August 1, 2005.

Sec. 486.003. RULES. The executive commissioner shall adopt rules necessary to implement and enforce this chapter.

Added by Acts 2005, 79th Leg., Ch. 282 (H.B. 164), Sec. 9, eff. August 1, 2005.

### Amended by:

Acts 2015, 84th Leg., R.S., Ch. 1 (S.B. 219), Sec. 3.1251, eff. April 2, 2015.

Sec. 486.004. FEES.

- (a) The department shall collect fees for an inspection performed in enforcing this chapter and rules adopted under this chapter.
- (b) The executive 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 implementing and 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 (H.B. 164), Sec. 9, eff. August 1, 2005.

### Amended by:

Acts 2015, 84th Leg., R.S., Ch. 1 (S.B. 219), Sec. 3.1252, eff. April 2, 2015.

Acts 2017, 85th Leg., R.S., Ch. 967 (S.B. 2065), Sec. 4.001, eff. September 1, 2017.

- Sec. 486.005. STATEWIDE APPLICATION AND UNIFORMITY. (a) To ensure uniform and equitable implementation 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 (H.B. 164), Sec. 9, eff.

# 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 (H.B. 164), 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 licensed by 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 (H.B. 164), Sec. 9, eff. August 1, 2005.
- Sec. 486.014. PREREQUISITES TO AND RESTRICTIONS ON SALE.

  (a) 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

government-issued 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 and date of birth of the person making the purchase, the address of the purchaser, the date and time of the purchase, the type of identification displayed by the person and the identification number, and the item and number of grams purchased; and
- (3) transmit the record of sale as required by Section 486.0141.
- (b) A business establishment may not sell to a person who makes over-the-counter purchases of one or more products containing ephedrine, pseudoephedrine, or norpseudoephedrine:
- (1) within any calendar day, more than 3.6 grams of ephedrine, pseudoephedrine, norpseudoephedrine, or a combination of those substances; and
- (2) within any 30-day period, more than nine grams of ephedrine, pseudoephedrine, norpseudoephedrine, or a combination of those substances.

Added by Acts 2005, 79th Leg., Ch. 282 (H.B. 164), Sec. 9, eff. August 1, 2005.

# Amended by:

Acts 2011, 82nd Leg., R.S., Ch. 742 (H.B. 1137), Sec. 2, eff. September 1, 2011.

- Sec. 486.0141. TRANSMISSION OF SALES INFORMATION TO REAL-TIME ELECTRONIC LOGGING SYSTEM. (a) Before completing an over-the-counter sale of a product containing ephedrine, pseudoephedrine, or norpseudoephedrine, a business establishment that engages in those sales shall transmit the information in the record made under Section 486.014(a)(2) to a real-time electronic logging system.
- (b) Except as provided by Subsection (c), a business establishment may not complete an over-the-counter sale of a product containing ephedrine, pseudoephedrine, or norpseudoephedrine if the real-time electronic logging system

returns a report that the completion of the sale would result in the person obtaining an amount of ephedrine, pseudoephedrine, norpseudoephedrine, or a combination of those substances greater than the amount described by Section 486.014(b), regardless of whether all or some of the products previously obtained by the buyer were sold at the establishment or another business establishment.

- (c) An employee of a business establishment may complete a sale prohibited by Subsection (b) by using the override mechanism described by Section 486.001(a)(6)(F) only if the employee has a reasonable fear of imminent bodily injury or death from the person attempting to obtain ephedrine, pseudoephedrine, or norpseudoephedrine.
- (d) On request of the Department of Public Safety, the administrators of a real-time electronic logging system shall make available to the department a copy of each record of an over-the-counter sale of a product containing ephedrine, pseudoephedrine, or norpseudoephedrine that is submitted by a business establishment located in this state.

Added by Acts 2011, 82nd Leg., R.S., Ch. 742 (H.B. 1137), Sec. 3, eff. September 1, 2011.

Sec. 486.0142. TEMPORARY EXEMPTION. (a) On application by a business establishment that operates a pharmacy and engages in over-the-counter sales of products containing ephedrine, pseudoephedrine, or norpseudoephedrine as authorized by Section 486.011, the Texas State Board of Pharmacy may grant that business establishment a temporary exemption, not to exceed 180 days, from the requirement of using a real-time electronic logging system under this chapter.

- (b) On application by a business establishment that engages in over-the-counter sales of products containing ephedrine, pseudoephedrine, or norpseudoephedrine, the department may grant that business establishment a temporary exemption, not to exceed 180 days, from the requirement of using a real-time electronic logging system under this chapter.
- (c) A business establishment granted a temporary exemption under this section must keep records of sales in the same manner

required under Section 486.0143 for a business establishment that experiences a mechanical or electronic failure of the real-time electronic logging system.

(d) An exemption granted under this section does not relieve a business establishment of any duty under this chapter other than the duty to use a real-time electronic logging system.

Added by Acts 2011, 82nd Leg., R.S., Ch. 742 (H.B. 1137), Sec. 3, eff. September 1, 2011.

### Amended by:

Acts 2015, 84th Leg., R.S., Ch. 1 (S.B. 219), Sec. 3.1254, eff. April 2, 2015.

Acts 2017, 85th Leg., R.S., Ch. 967 (S.B. 2065), Sec. 4.002, eff. September 1, 2017.

Sec. 486.0143. WRITTEN LOG OR OTHER ELECTRONIC RECORDKEEPING. If a business establishment that engages in over-the-counter sales of a product containing ephedrine, pseudoephedrine, or norpseudoephedrine experiences a mechanical or electronic failure of the real-time electronic logging system, the business shall:

- (1) maintain a written record or an electronic record made by any means that satisfies the requirements of Section 486.014(a)(2); and
- (2) enter the information in the real-time electronic logging system as soon as practicable after the system becomes operational.

Added by Acts 2011, 82nd Leg., R.S., Ch. 742 (H.B. 1137), Sec. 3, eff. September 1, 2011.

Sec. 486.0144. ONLINE PORTAL. The administrators of a real-time electronic logging system shall provide real-time access to the information in the system to the Department of Public Safety if the department executes a memorandum of understanding with the administrators.

Added by Acts 2011, 82nd Leg., R.S., Ch. 742 (H.B. 1137), Sec. 3, eff. September 1, 2011.

Sec. 486.0145. LIMITATION ON CIVIL LIABILITY. A person is not liable for an act done or omission made in compliance with the requirements of Section 486.014 or 486.0141.

Added by Acts 2011, 82nd Leg., R.S., Ch. 742 (H.B. 1137), Sec. 3, eff. September 1, 2011.

- Sec. 486.0146. PRIVACY PROTECTIONS. (a) The privacy protections provided an individual under 21 C.F.R. Section 1314.45 apply to information entered or stored in a real-time electronic logging system.
- business establishment (b) Α that engages in of over-the-counter sales a product containing ephedrine, pseudoephedrine, or norpseudoephedrine may disclose information entered or stored in a real-time electronic logging system only to the United States Drug Enforcement Administration and other federal, state, and local law enforcement agencies.
- (c) A business establishment that engages in over-the-counter sales of a product containing ephedrine, pseudoephedrine, or norpseudoephedrine may not use information entered or stored in a real-time electronic logging system for any purpose other than for a disclosure authorized by Subsection (b) or to comply with the requirements of this chapter.
- (d) Notwithstanding Subsection (c), a business establishment that engages in over-the-counter sales of a product containing ephedrine, pseudoephedrine, or norpseudoephedrine or an employee or agent of the business establishment is not civilly liable for the release of information entered or stored in a real-time electronic logging system unless the release constitutes negligence, recklessness, or wilful misconduct.

Added by Acts 2011, 82nd Leg., R.S., Ch. 742 (H.B. 1137), Sec. 3, eff. September 1, 2011.

Sec. 486.015. MAINTENANCE OF RECORDS. (a) Except as provided by Subsection (b), a business establishment shall maintain each record made under Section 486.014(a)(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 any local,

state, or federal law enforcement agency, including the United States Drug Enforcement Administration.

- (b) Subsection (a) does not apply to a business establishment that has used a real-time electronic logging system for longer than two years.
- (c) A business establishment that has used a real-time electronic logging system for longer than two years shall destroy all paper records maintained under this section unless the destruction is otherwise prohibited by law.

Added by Acts 2005, 79th Leg., Ch. 282 (H.B. 164), Sec. 9, eff. August 1, 2005.

# Amended by:

Acts 2011, 82nd Leg., R.S., Ch. 742 (H.B. 1137), Sec. 4, eff. September 1, 2011.

#### 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 (H.B. 164), 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 (H.B. 164), 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 (H.B. 164), 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;
- (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 department by order shall impose the penalty.

Added by Acts 2005, 79th Leg., Ch. 282 (H.B. 164), Sec. 9, eff. August 1, 2005.

# Amended by:

Acts 2015, 84th Leg., R.S., Ch. 1 (S.B. 219), Sec. 3.1255, eff. April 2, 2015.

Sec. 486.025. HEARING. (a) If the person requests a hearing, the department shall refer the matter to the State Office

of Administrative Hearings, which shall promptly set a hearing date, and the department shall 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 department a written 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 (H.B. 164), Sec. 9, eff. August 1, 2005.

# Amended by:

Acts 2015, 84th Leg., R.S., Ch. 1 (S.B. 219), Sec. 3.1256, eff. April 2, 2015.

Sec. 486.026. DECISION. (a) Based on the findings of fact, conclusions of law, and proposal for a decision, the department 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 department'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 (H.B. 164), Sec. 9, eff. August 1, 2005.

# Amended by:

Acts 2015, 84th Leg., R.S., Ch. 1 (S.B. 219), Sec. 3.1257, eff. April 2, 2015.

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 (H.B. 164), 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 department by certified mail.
- (b) Following receipt of a copy of an affidavit under Subsection (a)(2), the department 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 (H.B. 164), Sec. 9, eff. August 1, 2005.

### Amended by:

Acts 2015, 84th Leg., R.S., Ch. 1 (S.B. 219), Sec. 3.1258, eff. April 2, 2015.

- 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 (H.B. 164), 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 (H.B. 164), 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 (H.B. 164), 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.

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 (H.B. 164), Sec. 9, eff. August 1, 2005.

(b) If the person gave a supersedeas bond and the amount of

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 (H.B. 164), Sec. 9, eff. August 1, 2005.