Texas Department of State Health Services

LIMITATIONS ON SALES OF PRODUCTS CONTAINING EPHEDRINE, PSEUDOEPHEDRINE, AND NORPSEUDOEPHEDRINE
(25 Texas Administrative Code, §§230.11 – 230.18)

Section

§230.11. General Provisions.

(a) Purpose and applicability. The purpose of this subchapter is to implement the duties of the Department of State Health Services (department) under the Health and Safety Code (HSC), Chapter 486, relating to over-the-counter sales of ephedrine, pseudoephedrine, and norpseudoephedrine.

(b) Definitions. The following words and terms, when used in this subchapter, shall have the following meanings, unless the context clearly indicates otherwise.

(1) Business establishment -- A retail distributor such as a grocery store; general merchandise store; drug store; or other entity or person, other than a licensed pharmacy, that engages in direct sales to end-user consumers. A distributor who engages in greater than 5% of gross annual sales of regulated products to other than end-user consumers must obtain a license as a wholesaler under HSC, Chapter 431, Subchapter I or Subchapter N.

(2) Department -- The Department of State Health Services.

(3) Certificate of authority (COA) -- A grant of authority to engage in over-the counter sales of regulated products, issued by the department to a person under this subchapter.

(4) Certificate of authority holder (COA holder) -- A person that has been issued a certificate of authority by the department to engage in over-the-counter sales of regulated products.

(5) Pharmacy -- A person holding a current license to operate a pharmacy issued by the Texas State Board of Pharmacy (Board of Pharmacy) under Occupations Code, Chapter 560.

(6) Record of sale -- The paper or electronic documentation prepared and maintained in compliance with §230.15 of this title (relating to Records).

(7) Regulated products--Any compound, mixture, or preparation containing any detectable amount of ephedrine, pseudoephedrine, or norpseudoephedrine, 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. A list of regulated products, by name and universal product code (commonly referred to as UPC) or stock-keeping unit (commonly referred to as SKU) identifiers, may be obtained from the Department of State Health Services, P.O. Box 149347, Austin, Texas 78714-9347.

(8) Over-the-counter sale--The sale within any calendar day of no more than 3.6 grams of ephedrine, pseudoephedrine, norpseudoephedrine, or a combination of those substances; and within any 30-day period, no more than nine grams of ephedrine, pseudoephedrine, norpseudoephedrine, or a combination of those substances to an individual.

(9) "Real-time electronic logging system"--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 subparagraph (E) of this paragraph that:

(i) may be activated by an employee of a business establishment; and

(ii) creates a record of each activation of the override.

(c) Persons who sell or distribute ephedrine, pseudoephedrine, norpseudoephedrine or phenylpropanolamine may be subject to additional federal statutes and regulations adopted thereunder.

§230.12. Exemptions. The following persons are exempt from the requirement to obtain a COA from the department before engaging in the sale of regulated products:

(1) a person licensed by the department under HSC, Chapter 431, Subchapters I or N, or who is specifically exempted from licensure under HSC, Chapter 431, Subchapters I or N;

(2) a person licensed as a pharmacist under Occupations Code, Chapter 558, who dispenses or delivers regulated products according to prescription issued by a practitioner for a valid medical purpose and in the course of professional practice; and

(3) a person licensed by the Board of Pharmacy to operate a pharmacy under Occupations Code, Chapter 560. Business establishments operating a licensed pharmacy must follow the requirements of the Texas State Board of Pharmacy and the provisions of HSC, Chapter 486. Those business establishments may not be issued a COA.

§230.13. Certificate of Authority.

(a) General.

(1) Except for persons who are exempt under §230.12 of this title (relating to Exemptions), a person is prohibited from engaging in over-the-counter sales of regulated products without a COA issued by the department under these sections.

(2) The grant of authority to sell regulated products under a COA confers only the right to sell regulated products in compliance with these sections.

(3) A COA is effective on the date of issuance and terminates on the expiration date. There is no implied or ongoing right or authority to sell regulated products beyond the expiration date on a COA.

(4) A COA confers no right or interest in property.

(5) A separate COA is required for each place of business.

(6) A COA cannot be conveyed, sold or transferred.

(b) Application. A person must submit an application for each place of business on a form, or in an electronic format through Texas Online (www.Texasonline.com), as prescribed by the department. Incomplete applications or applications submitted without the required fees will not be processed by the department. At a minimum the applicant must provide the following

information:

(1) the name, home address, and business address of the applicant;

(2) the type of entity, whether sole proprietor, partnership, corporation, or other legal entity;

(3) the registered or trade name under which business is conducted;

(4) the name, residential address, and driver's license number of the person responsible for compliance with these rules at the place of business where regulated products will be sold, as well as all corporate officers, and all partners, if applicable;

(5) the normal business hours of the place of business;

(6) the name(s), address(es), and contact person(s) of the applicant's wholesale distributor(s);

(7) an indication of all health care products, by type, sold at the place of business;

(8) a list or inventory, including brand name, of all regulated products the applicant proposes to sell at the place of business;

(9) a detailed description of training provided to employees or other persons who will have access to; conduct sales of; and/or prepare records of sales of regulated products, including sales techniques and other measures designed to deter theft of regulated products; and

(10) written procedures on how regulated products will be kept; whether behind a sales counter, or in a locked display case within 30 feet and in the direct line of sight of a sales counter continuously staffed by an employee.

(c) Fees. The fee for a COA is $600 for a two-year license. All fees, including any late fee or past due fee, must be paid before a COA will be issued. All fees are non-refundable.

(d) Term and expiration. The term of a COA is two years. The department may stagger the expiration dates of COAs issued under theses sections. The department determines the expiration date. The grant of authority to sell regulated products ends on the expiration date indicated on a COA. Any sale under an expired COA is a violation of HSC, Chapter 486, and these rules.

(e) Renewal. The department may renew a COA only if the COA holder is in substantial compliance with these sections. A COA holder must submit a renewal application along with the required fee before the expiration date on the current certificate to avoid a lapse in authority to sell regulated products under these sections.

§230.14. Minimum Standards for Certificate of Authority.

(a) Criminal history of applicant. A COA may be denied to an applicant if the applicant, or a partner, or a corporate officer, or the person responsible for business operations such as a manager, has been convicted of an offense related to the manufacture or sale of illegal drugs or has been convicted of any felony reasonably related to the COA requested.

(b) Failures or omissions. A COA may be denied to an applicant who:

(1) has furnished material information in an application that is false, fraudulent, or misleading;

(2) has failed to establish or maintain effective theft prevention and deterring measures;

(3) has failed to maintain records required to be kept by §230.15 of this title (relating to Records);

(4) has refused to allow an inspection as authorized by HSC, Chapter 486, or refused or failed to produce required records for inspection; or

(5) has violated HSC, Chapter 486, or these rules.

(c) Theft prevention and deterring measures.

(1) A COA holder shall maintain regulated products behind a sales counter or in a locked case within 30 feet and in direct line of sight from a sales counter continuously staffed by an employee.

(2) A COA holder must document and implement sales techniques and other measures designed to deter the theft of regulated products and other products commonly used in the illicit manufacture of methamphetamines. Written procedures must be developed by the COA holder to include:

(A) security of regulated products, including receiving at the business; storage in the stockroom or other storage facility; and stocking of the sales counter or locked display cabinet;

(B) measures to ensure that employees and other staff who have a criminal drug history do not have access to regulated products; and

(C) measures to ensure that regulated products cannot be accessed without the assistance of an authorized employee of the business.

§230.15. Records.

(a) Before completing a sale of a regulated product, an employee with authority to access regulated products must:

(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, using a format approved or provided by the department for this purpose, that includes 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, the product name for the item purchased, and the number of grams purchased; and

(3) transmit the record of sales as required by §230.16 of this title (relating to Real-Time Electronic Logging System).

(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 9 grams of ephedrine, pseudoephedrine, norpseudoephedrine, or a combination of those substances.

(c) Except as provided by subsection (d) of this section, a business establishment shall maintain each record made under subsection (a)(2) of this section 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.

(d) Subsection (c) of this section does not apply to a business establishment that has used a real-time electronic logging system for longer than two years.

(e) 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.

§230.16. 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 §230.15(a)(2) of this title (relating to Records) to a real-time electronic logging system.

(b) Except as provided by subsection (c) of this section, 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 §230.15(b) of this title, 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) of this section by using the override mechanism described by §230.11(b)(9)(F) of this title (relating to General Provisions) 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 of Public Safety 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.

(e) 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 §230.12 of this title (relating to Exemptions), the 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 subchapter.

(f) On application by a business establishment that engages in over-the-counter sales of products containing ephedrine, pseudoephedrine, or norpseudoephedrine in accordance with a certificate of authority issued under §230.12 of this title, 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 subchapter.

(g) A business establishment granted a temporary exemption under this section must keep records of sales in the same manner required under subsection (i) of this section for a business establishment that experiences a mechanical or electronic failure of the real-time electronic logging system.

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

(i) 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 §230.15(a)(2) of this title; and

(2) enter the information in the real-time electronic logging system as soon as practicable after the system becomes operational.

(j) The administrators of a real-time electronic logging system must comply with Health and Safety Code §486.0144 (relating to Online Portal), which requires providing real-time access to the information in the system to the Department of Public Safety if the Department of Public Safety executes a memorandum of understanding with the administrators.

§230.17. Enforcement.

(a) The department may impose an administrative penalty for a violation of the Health and Safety Code (HSC), Chapter 486, or this subchapter.

(b) The amount of the administrative penalty may not exceed $1,000 per violation. 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 may not exceed $20,000.

(c) The amount of the penalty 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 good faith efforts to correct the violation; and

(6) any other matter that justice may require.

(d) If the department initially determines that a violation has occurred, the department will provide notice of the violation in writing to the person. The person may respond to the notice in writing not later than the 20th day after the date the person receives the notice, informing the department that the person:

(1) accepts the determination and recommended penalty; or

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

(e) If a person does not respond to the department's notice within 20 calendar days after receiving the notice, the department will issue an order approving the determination by default.

(f) Hearings will be held at the State Office of Administrative Hearings and will be conducted under Government Code, Chapter 2001.

§230.18. Privacy Protections.

(a) The privacy protections provided an individual under Title 21, Code of Federal Regulations, §1314.45, apply to information entered or stored in a real-time electronic logging system.

(b) A business establishment that engages in over-the-counter sales of 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) of this section or to comply with the requirements of this subchapter.