TEXAS DEPARTMENT OF STATE HEALTH SERVICES

LIMITATIONS ON SALES OF PRODUCTS CONTAINING EPHEDRINE, PSEUDOEPHEDRINE, AND NORPSEUDOEPHEDRINE
(25 Texas Administrative Code, §§230.11 – 230.16)

Section

§230.11. General Provisions.

(a) Purpose and applicability. The purpose of these sections 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. Unless otherwise specified, the terms have the meaning assigned by HSC, Chapters 481 and 486, or their common use meaning.

(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 (UPC) or stock-keeping unit (SKU) identifiers, may be obtained from the Department of State Health Services, 1100 West 49th, Austin, Texas 78756.

(8) Over-the-counter sale -- The sale of not more than two packages or six grams of regulated products, in a single transaction to an individual.

(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 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 of the person making the purchase, the date of the purchase, the product name for the item purchased, and the number of grams purchased, and;

(3) take reasonable measures to limit single sales transactions to:

(A) two packages of a regulated product; or

(B) no more than 6 grams of ephedrine, pseudoephedrine, or norpseuodoephedrine base.

(b) The COA holder must maintain these records at the business establishment for a minimum of two years from the date the record is made.

(c) The COA holder must make the records available to the agent(s) of the Department of State Health Services or the Department of Public Safety upon request.

§230.16. Enforcement.

(a) The department may impose an administrative penalty for a violation of HSC, Chapter 486, or these rules.

(b) The amount of the administrative penalty may be up to $1000 per violation per day, not to exceed $20,000 for a violation of a continuing nature.

(c) The amount of the penalty is based on:

(1) the seriousness 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) The department may revoke a COA for a violation of HSC, Chapter 486, or these rules. The department may also revoke a COA if the COA holder is convicted of any offense related to the manufacture or distribution of illegal drugs.

(e) A request for a hearing by a COA holder in response to a notice of violation will be referred to the State Office of Administrative Hearings. An informal enforcement conference with the department may be held prior to a hearing to dispose of all matters related to the notice of violation.

(f) Failure to respond within 15 days to a Notice of Violation letter issued by the department may result in the factual allegations listed in the notice being deemed admitted, and the relief sought in the notice of hearing may be granted by default. The Commissioner of the Department of State Health Services or his designee may sign the default order.

(g) Hearings at the State Office of Administrative Hearings are governed by the procedures in Government Code, Chapter 2001, and by Health and Safety Code, Chapter 486.