



TO: Health and Human Services Commission
Executive Council

DATE: February 22, 2018

FROM: Jonathan R. Huss, Consumer Protection
Division

AGENDA ITEM: 2.a

SUBJECT: Certificate of Authority for Retailers of Pseudoephedrine, Ephedrine and Norpseudoephedrine Products

BACKGROUND: Federal Legislative Other: Program Initiative

The proposed rules are necessary to comply with Senate Bill 2065, 85th Legislature, Regular Session, 2017, that amended Health and Safety Code, Chapter 486, by eliminating §486.004(a) and §486.004(b)(1-4), relating to the requirement for a non-pharmacy retailer to obtain a certificate of authority in order to sell products containing pseudoephedrine, ephedrine and norpseudoephedrine products. It has been determined that no non-pharmacy retailers have applied for a certificate of authority in recent years, and all sales of these products are conducted through pharmacies.

The 79th Legislature passed House Bill 164, creating Health and Safety Code, Chapter 486, Over-the-Counter Sales of Ephedrine, Pseudoephedrine, and Norpseudoephedrine, which required all non-pharmacy retailers of ephedrine, pseudoephedrine and norpseudoephedrine to obtain a certificate of authority to sell the products and to meet certain requirements prior to sale. The Department of State Health Services (DSHS) manages the Certificate of Authority Program.

The rules changes to Texas Administrative Code, Title 25, Part 1, are amendments to §230.11 and §230.16, repeal of §§230.12 - 230.14, and new §230.19. The purpose of the amendments and repeals is to eliminate the requirement for businesses to obtain a certificate of authority. The purpose of the new section is to establish a fee, as required by Health and Safety Code, §486.004, for investigation of complaints.

ISSUES AND ALTERNATIVES:

There are no anticipated concerns or issues related to the proposal because businesses are no longer applying for the certificate of authority.

STAKEHOLDER INVOLVEMENT:

The draft proposed rules were posted on the DSHS website for review by stakeholders on November 6, 2017. The Consumer Healthcare Product Association, as the primary stakeholder, was notified on August 10, 2017, of the changes to the law. Stakeholders have an opportunity to provide comments during the 30-day comment period after the rules are published in the *Texas Register*.

FISCAL IMPACT:

None

SERVICES IMPACT STATEMENT:

The proposed rules will have no impact on the health and human services client population.

RULE DEVELOPMENT SCHEDULE:

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|-------------------|---|
| February 22, 2018 | Presentation at the HHSC Executive Council |
| March 2018 | Publish proposed rules in <i>Texas Register</i> |
| July 2018 | Publish adopted rules in <i>Texas Register</i> |
| July 2018 | Effective date |

PROPOSED PREAMBLE

The Executive Commissioner of the Health and Human Services Commission (HHSC), on behalf of the Department of State Health Services (DSHS), proposes an amendment to §230.11, concerning General Provisions; the repeal of §230.12, concerning Exemptions; the repeal of §230.13, concerning Certificate of Authority; the repeal of §230.14, concerning Minimum Standards for Certificate of Authority; an amendment to §230.16, concerning Real-time Electronic Logging System; and new §230.19, concerning Inspection.

BACKGROUND AND PURPOSE

The purpose of the amendments, repeal of rules and new section will implement Senate Bill (SB) 2065, 85th Legislature, Regular Session, 2017, which amended Texas Health and Safety Code, Chapter 486, regarding the retail sale of drug products containing ephedrine, pseudoephedrine and norpseudoephedrine. SB 2065 eliminates the certificate of authority program for non-pharmacy retailers that were selling drug products containing ephedrine, pseudoephedrine and norpseudoephedrine. The certificate of authority program is no longer needed because there are no known non-pharmacy business retailers of these drugs, and these drugs are sold exclusively by pharmacies. Also, there are amendments that were included to provide clarity and readability.

SECTION-BY-SECTION SUMMARY

The proposed amendment to §230.11(b)(3) eliminates the definition of "certificate of authority" as the definition is no longer needed. The proposed amendment to §230.11(b)(4) eliminates the definition of "certificate of authority holder" as the definition is no longer needed. The proposed amendment to §230.11(b)(7) eliminates the last two sentences of the definition of "regulated products." Liquid products are not exempt under federal law and maintaining a list of regulated products on the website is no longer necessary. The paragraph is also renumbered as §230.11(b)(5).

The proposed amendment to §230.11(b)(9)(B) replaces the term "real" with "real-time" to make the language consistent with the statute. The paragraph is renumbered as §230.11(b)(7).

Proposed amendments to §230.11(b)(3) - (9) are renumbered as (b)(3) – (7) to reflect the removal of paragraphs (3) and (4).

The proposed repeal of §§230.12 - 230.14 deletes the rules as mandated by legislation.

The proposed amendment to §230.16(c) changes the rule reference from §230.11(b)(9)(F) to §230.11(b)(7)(F) to reflect changes in numbering. The proposed amendment to §230.16(e) removes this subsection containing the reference to the granting of 180 day exemptions by the Texas State Board of Pharmacy for those pharmacies without a real-time electronic logging system. This is no longer necessary as all pharmacies now have a real-time electronic logging system.

The proposed amendment to §230.16(f) removes the phrase “a certificate of authority issued under §230.12 of this title” and adds the word “subchapter” because a certificate of authority no longer exists. Subsection (f) is re-lettered as §230.16(e).

The proposed amendment to §230.16(g) changes a reference from subsection (i) to subsection (h) to reflect the re-lettering. Subsection (g) is re-lettered as §230.16(f).

The proposed amendments to §230.16(e) - (i) are re-lettered to reflect the removal of subsection (e).

New §230.19 authorizes DSHS to conduct inspections of pharmacies and non-pharmacy business establishments in order to enforce the subchapter; and to collect a non-refundable \$400.00 fee to recover the cost of an inspection. The fee is required by Texas Health and Safety Code, §486.004.

FISCAL NOTE

Donna Sheppard, Chief Financial Officer, has determined that for each year of the first five years that the sections will be in effect, there will be minimal or no fiscal implications to state or local governments as a result of enforcing and administering the sections as proposed because retailers no longer sell the regulated products outside of a pharmacy, and have no need for the program. DSHS no longer has a need to conduct routine inspections. DSHS has not received complaints to inspect pharmacies or non-pharmacies for the preceding six years. A \$400 nonrefundable fee will only be charged to a business to recover costs associated with a complaint investigation.

GOVERNMENT GROWTH IMPACT STATEMENT

DSHS has determined that during the first five years that the sections will be in effect:

- (1) the proposed rules will not eliminate a government program;
- (2) implementation of the proposed rules will not affect the number of employee positions;
- (3) implementation of the proposed rules will not require an increase in future legislative appropriations;
- (4) the proposed rules will have minimal or no fees paid to the agency based on the historical need for inspections;
- (5) the proposed rules will repeal three rules, create a new rule and amend two rules;
- (6) the proposed rules will not expand an existing rule;
- (7) the proposed rules will not change the number of individuals subject to the rule; and
- (8) the proposed rules will not affect the state's economy.

SMALL AND MICRO-BUSINESS IMPACT ANALYSIS AND RURAL COMMUNITY IMPACT ANALYSIS AND ECONOMIC COSTS TO PERSONS

Mr. Jon Huss, Associate Commissioner, Consumer Protection Division, has determined that there will be no adverse impact on small businesses or micro-businesses, rural communities and persons required to comply with the sections as proposed. It was determined that there are no retail businesses, other than pharmacies, engaged in sales of ephedrine, pseudoephedrine and norpseudoephedrine.

IMPACT ON LOCAL EMPLOYMENT

There is no anticipated negative impact on local employment.

COSTS TO REGULATED PERSONS

Texas Government Code, §2001.0045 does not apply to these rules because the rules are necessary to protect the health, safety, and welfare of the residents of Texas.

PUBLIC BENEFIT

Mr. Huss has determined that for each year of the first five years the sections are in effect, the benefit to the public is to remove rules that are no longer necessary due to SB 2065. In addition, Mr. Huss has also determined the public will benefit from the remaining, intact sections. The continued enforcement of these sections will prevent access to quantities of ephedrine, pseudoephedrine and norpseudoephedrine that exceed amounts mandated by law.

TAKINGS IMPACT ASSESSMENT

DSHS has determined that the proposal does not restrict or limit an owner's right to his or her property that would otherwise exist in the absence of government action and, therefore, does not constitute a taking under Texas Government Code, §2007.043.

PUBLIC COMMENT

Written comments on the proposal may be submitted to Karen Tannert, Consumer Protection Division, Mail Code 1987, P.O. Box 149347, Austin, Texas 78714-9347; by fax to (512) 834-6759; or by email to HHSRulesCoordinationOffice@hhsc.state.tx.us within 30 days of publication of this proposal in the *Texas Register*. When faxing or emailing comments, please indicate "Comments on Proposed Rule 18R001" in the subject line. To be considered, comments must be submitted no later than 30 days following publication of the proposal in the *Texas Register*. The last day to submit comments falls on a Sunday; however, comments postmarked, shipped, faxed or emailed before midnight on the following Monday will be accepted.

STATUTORY AUTHORITY

The amendments, repeal of rules, and new section are authorized by Texas Health and Safety Code, §486.003, which provides DSHS with the authority to adopt rules to enforce the Over-the-Counter Sales of Ephedrine, Pseudoephedrine and Norpseudoephedrine Act. The rules are also authorized by Texas Government Code, §531.0055, and Texas Health and Safety Code, §1001.075, which authorize the Executive Commissioner of HHSC to adopt rules and policies necessary for the operation and provision of health and human services by DSHS and for the administration of Texas Health and Safety Code, Chapter 1001.

The amendments, repeal of rules and new section are authorized by Texas Health and Safety Code, Chapters 486 and 1001; and Texas Government Code, Chapter 531.

The agency certifies that legal counsel has reviewed the proposal and found it to be within the state agency's legal authority to adopt.

For further information, please call: 512-834-6755.

TITLE 25 HEALTH SERVICES
PART 1 DEPARTMENT OF STATE HEALTH SERVICES
CHAPTER 230 SPECIFIC ADDITIONAL REQUIREMENTS FOR DRUGS
SUBCHAPTER B LIMITATIONS ON SALES OF PRODUCTS CONTAINING
EPHEDRINE, PSEUDOEPHEDRINE, AND
NORPSEUDOEPHEDRINE

§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.]~~

(3)~~[(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.

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

(5)~~[(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.~~]

(6)~~[(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.

(7)~~[(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 [~~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.

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~~§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, Subchapter I or N, or who is specifically exempted from licensure under HSC, Chapter 431, Subchapter 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 these 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.]~~

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§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)(7)(F) [~~§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.]

(e)[(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 subchapter [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.

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

(g)[(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.

(h) [(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.

(i)[(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.

§230.19. Inspection.

(a) The department may inspect a business establishment under this subchapter in order to implement and enforce this chapter.

(b) The department shall collect fees for an inspection conducted to enforce Health and Safety Code, Chapter 486 and this subchapter.

(c) A nonrefundable fee of \$400.00 for inspections of pharmacies and non-pharmacy retailers conducted by the department will be required.