

## **BILL ANALYSIS**

C.S.S.B. 107  
By: Estes  
Law Enforcement  
Committee Report (Substituted)

### **BACKGROUND AND PURPOSE**

Currently a person can purchase certain kinds of pseudoephedrine over-the-counter without a prescription. Pseudoephedrine is the single ingredient that "cooks" of methamphetamine must have to produce methamphetamine.

C.S.S.B. 107 limits over-the-counter sales of pseudoephedrine by requiring a business establishment to implement safeguards, such as requiring identification for purchases and making the substances available only with the assistance of an employee. This law will not apply to a product dispensed or delivered by a pharmacist according to a prescription issued by a physician. This bill also regulates wholesale nonprescription drug distributors.

### **RULEMAKING AUTHORITY**

It is the committee's opinion that rulemaking authority is expressly granted to the Department of Public Safety in SECTION 2.01 of this bill, the State Health Services Council, the commissioner of State Health Services and the Department of State Health Services in SECTION 2.02 of this bill, the director of the Department of Public Safety in SECTION 2.03 of this bill, the State Health Services Council in SECTION 2.04 of this bill, and to the executive commissioner of the Health and Human Services Commission in SECTIONS 3.05, 3.06, and 3.09 of this bill.

### **ANALYSIS**

C.S.S.B. 107 amends Section 481.124(b), Health and Safety Code to provide that, for purposes of this section, an intent to unlawfully manufacture the controlled substance methamphetamine is presumed if the actor possesses or transports at least three of the following items:

- (1) an item of equipment subject to regulation under Section 481.080, if the person is not registered under Section 481.063; or
- (2) glassware, a plastic or metal container, tubing, a hose, or other item specially designed, assembled, or adapted for use in the manufacture, processing, analyzing, storing, or concealing of methamphetamine.

The bill amends Section 481.136(a), Health and Safety Code, to provide that a person commits an offense if the person sells, transfers, furnishes, or receives a chemical precursor subject to Section 481.077(a) and the person:

- ‡ does not comply with Section 481.077 or 481.0771;
- ‡ knowingly makes a false statement in a report or record required by Section 481.077, 481.0771, or 481.078; or
- ‡ knowingly violates a rule adopted under Section 481.077, 481.0771, or 481.078.

The bill amends Section 99.003, Civil Practice and Remedies Code, to provide that a person who manufactures methamphetamine is strictly liable for any exposure by an individual to the manufacturing process, including exposure to the methamphetamine itself or any of the by-products or waste products incident to the manufacture, for the greater of actual damages for personal injury, death, or property damage as a result of the exposure or \$20,000 for each incident of exposure.

The bill amends Section 262.104, Family Code, by adding Subsection (b) to provide that an authorized representative of the Department of Family and Protective Services (DFPS), a law enforcement officer, or a juvenile probation officer may take possession of a child under

C.S.S.B. 107 79(R)

Subsection (a) on personal knowledge or information furnished by another, that has been corroborated by personal knowledge, that would lead a person of ordinary prudence and caution to believe that the parent or person who has possession of the child has permitted the child to remain on premises used for the manufacture of methamphetamine.

The bill amends Section 22.041, Penal Code by adding Subsection (c-1) to provide that for the purposes of Subsection (c), it is presumed that a person engaged in conduct that places a child in imminent danger of death, bodily injury, or physical or mental impairment if the person manufactured the controlled substance methamphetamine in the presence of the child.

The bill adds Section 481.0771, Health and Safety Code, as follows:

- Adds Subsection (a) to require a wholesaler who sells, transfers, or otherwise furnishes pseudoephedrine to a retailer to make available to the director of the Department of Public Safety or an employee of the department designated by the director all records of the transaction in accordance with department rule.
- Adds Subsection (b) to require a wholesaler to submit to the director of the Department of Public Safety or an employee of the department designated by the director a report of an order for pseudoephedrine not later than five business days after receipt of the order, in accordance with department rule, if the order requests delivery of a suspicious quantity of pseudoephedrine as determined by department rule.
- Adds Subsection (c) to provide that a wholesaler who, with reckless disregard for the duty to report under Subsection (b), fails to report as required by that subsection may be subject to disciplinary action in accordance with department rule.

The bill adds Chapter 486 to the Health and Safety Code, as follows:

- Adds Section 486.001 to define, for purposes of this chapter:
  - (1) "Commissioner" as the commissioner of state health services,
  - (2) "Council" as the State Health Services Council,
  - (3) "Department" as the Department of State Health Services,
  - (4) "Pseudoephedrine" as any compound, mixture, or preparation containing any detectable amount of pseudoephedrine, including its salts, optical isomers, and salts of optical isomers, but not any compounds, mixtures, or preparations that are in liquid, liquid capsule, or gel capsule form and in which pseudoephedrine is not the only active ingredient, and
  - (5) "Sale" to include a conveyance, exchange, barter, or trade.
  - ‡ Provides that a term used in this chapter that is not defined by Subsection (a) has the meaning assigned by Section 481.002.
- Adds Section 486.002 to provide that 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.
- Adds Section 486.003 to require the State Health Services Council to adopt rules necessary to implement and enforce this Chapter.
- Adds Section 486.004 as follows:
  - ‡ Adds subsection (a) to provide that the department shall collect fees for the issuance of a certificate of authority under this chapter and an inspection performed in enforcing this chapter and rules adopted under it.
  - ‡ Adds subsection (b) to require the commissioner, by rule, to set the fees in amounts that allow the department to recover the biennial expenditures of state funds by the department in reviewing applications for a certificate of authority, issuing certificates, inspecting and auditing certified businesses, and otherwise implementing and enforcing this chapter.
  - ‡ Adds subsection (c) to require that fees collected under this section 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.
- Adds Section 486.011 to provide that a business establishment that operates a pharmacy licensed by the Texas State Board of Pharmacy may engage in over-the-counter sales of pseudoephedrine.
- Adds Section 486.012 as follows:
  - ‡ Adds Subsection (a) to provide that a business that does not operate a pharmacy licensed by the Texas State Board of Pharmacy may engage in over-the-counter

sales of pseudoephedrine only if the establishment holds a certificate of authority issued under this section.

‡ Adds Subsection (b) to authorize the department to issue a certificate of authority to engage in over-the-counter sales of pseudoephedrine to a business establishment that does not operate a pharmacy licensed by the Texas State Board of Pharmacy if the establishment applies to the department for the certificate in accordance with department rule and complies with the requirements established by the department for issuance of a certificate.

‡ Adds Subsection (c) to require the department to establish, by rule, requirements for the issuance of a certificate of authority under this section. Requires the rules to include a consideration by the department of whether the establishment complies with the requirements of the Texas State Board of Pharmacy for the issuance of a license to operate a pharmacy, sells a wide variety of pharmaceutical products, and employs sales techniques and other measures designed to deter the theft of products containing pseudoephedrine and other items used in the manufacture of methamphetamine.

‡ Adds Subsection (d) to authorize the department to inspect or audit a business establishment that is issued a certificate of authority under this section at any time the department determines necessary.

- Adds Section 486.013 to require a business that engages in over-the-counter sales of pseudoephedrine to display it in a manner that makes it accessible to a patron of the business establishment only with the assistance of an employee of the establishment.
- Adds Section 486.014 to require that a business, before completing an over-the-counter sale of pseudoephedrine:
  - (1) require the person purchasing pseudoephedrine to 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 sign for the purchase;
  - (2) make a record of the sale, including the name of the person purchasing the pseudoephedrine, the date of purchase, and the 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 pseudoephedrine from obtaining from the establishment in a single transaction more than two packages of a product containing pseudoephedrine or more than six grams.
- Adds Section 486.015 to require a business that sells pseudoephedrine over-the-counter to maintain all records made under Section 486.014(2) in a secure centralized location until at least the second anniversary of the date the record is made.
- Adds Section 486.021 to authorize the department to impose an administrative penalty on a person who violates Chapter 486.
- Adds Section 486.022, as follows:
  - ‡ Adds Subsection (a) to provide that the amount of the penalty may not exceed \$1,000 for each violation; provides that each day a violation continues or occurs is a separate violation for purposes of imposing a penalty; provides that the total amount of the penalty assessed for a violation continuing or occurring on separate days under this subsection may not exceed \$10,000.
  - ‡ Adds Subsection (b) to require that the amount of the penalty be based on the following factors:
    - (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.
- Adds Section 486.023 to require the department, if it initially determines that a violation occurred, to give written notice of the report by certified mail to the person, and require that the notice include a brief summary of the alleged violation, state the amount of the recommended penalty, and inform the person of the person's right to a hearing on the occurrence of the violation, the amount of the penalty, or both.
- Adds Section 486.024 to provide that before the 21st day after the date the person receives notice under Section 486.023, the person in writing may accept the determination and

recommended penalty or make a request for a hearing on the occurrence of the violation, the amount of the penalty, or both; requires the commissioner by order to approve the determination if the person accepts the determination and recommended penalty or fails to respond to the notice.

- Adds Section 486.025 to require the commissioner to refer matters upon which a hearing has been requested to the State Office of Administrative Hearings and to provide notice and hearing procedures.
- Adds Section 486.026 to provide procedures for decision and notice of the commissioner's order and the right to judicial review after the administrative hearing.
- Adds Section 486.027 to require a person to either pay the penalty or file a petition for judicial review of the order contesting the occurrence of the violation, the amount of the penalty, or both, before the 31st day after the date the order under Section 486.026 imposing an administrative penalty becomes final.
- Adds Section 486.028 to provide for the stay of enforcement of a penalty while judicial review is pending if certain conditions are met.
- Adds Section 486.029 to provide that if the person does not pay the penalty and the enforcement is not stayed, the penalty may be collected, and the attorney general may sue to collect the penalty.
- Adds Section 486.030 to provide that if the court sustains a finding that a violation occurred, the court may uphold or reduce the amount of the penalty and order the person to pay the penalty, and that if the court does not sustain the finding that a violation occurred, the court shall order that a penalty is not owed.
- Adds Section 486.031 to require that if the penalty is not upheld or the amount is reduced by the court, the court shall order, when judgment becomes final, that the appropriate amount plus interest accrued at the Federal Reserve rate from the date the penalty is paid to the date the penalty is remitted be remitted to the person before the 31st day after the date the judgment becomes final.
- Adds Section 486.032 to provide for release of supersedeas bond if the penalty is not upheld by the court.
- Adds Section 486.033 to provide that a proceeding to impose the penalty is considered to be a contested case under Chapter 2001, Government Code.

The bill amends the heading to Subchapter I, Chapter 431, Health and Safety Code.

The bill amends Section 431.201, Health and Safety Code, as follows:

- Defines "nonprescription drug" as any drug that is not a prescription drug as defined by Section 431.401; and
- Amends the definition of "wholesale distribution" to include distribution by a repackager, broker, or warehouse.

The bill adds Section 431.2011 to the Health and Safety Code to provide that Subchapter I, Chapter 431, Health and Safety Code, applies only to the wholesale distribution of nonprescription drugs.

The bill amends Section 431.202, Health and Safety Code, as follows:

- Amends the title.
- Amends Subsection (a) to prohibit a person from engaging in the wholesale distribution of nonprescription drugs in this state unless the person holds a wholesale drug distribution license issued by the Texas Department of Health under this subchapter or Subchapter N.
- Amends Subsection (b) to require an applicant for a license under this subchapter to submit an application to the department on the form prescribed by the department or electronically on the TexasOnline Internet website.
- Adds Subsection (c) to provide that a license issued under this subchapter expires on the second anniversary of the date of issuance.

The bill amends Section 431.204, Health and Safety Code, as follows:

- Provides that the Department of Health shall collect fees for a wholesale drug distributor's license that is filed, renewed, or amended, as well as fees for an inspection performed in enforcing this subchapter and rules adopted under it.

- Provides that the executive commissioner of the Health and Human Services Commission by rule shall set the fees in amount that allow the department to recover the biennial expenditures of state funds by the department in reviewing, acting on, amending, and renewing licenses, inspecting a licensed facility, and implementing and enforcing this subchapter and rules or orders adopted or licenses issued under it.
- Provides that fees collected under this section shall be appropriated to the department to carry out the administration and enforcement of this chapter.

The bill amends Section 431.206, Health and Safety Code, as follows:

- Requires a licensee to notify the department in writing of the licensee's intent to change the location of a licensed place of business not fewer than 30 days in advance of the change.
- Requires the licensee, not more than 10 days after the completion of the change of location, to notify the department in writing to confirm completion of the change of location and provide verification of the information previously provided or correct and confirm any information that has changed since providing the notice of intent.
- Provides that the notice and confirmation required by this section are deemed adequate if the licensee sends the notices by certified mail, return receipt requested, to the central office of the department or submits them electronically through the TexasOnline internet website.

The bill amends Section 431.207, Health and Safety Code, as follows:

- Authorizes the commissioner of state health services to refuse an application for a license or suspend or revoke a license under certain circumstances.
- Provides that the commissioner of state health services may refuse an application for a license or may suspend or revoke a license if the applicant or licensee:
  - ‡ has violated Section 431.021(1)(3), relating to the counterfeiting of a drug or the sale or holding for sale of a counterfeit drug;
  - ‡ has violated Chapter 481 (Texas Controlled Substances Act) or 483 (Texas Dangerous Drugs Act);
  - ‡ has violated the rules of the director of the Department of Public Safety, including being responsible for a significant discrepancy in the records that state law requires the applicant or licensee to maintain; or
  - ‡ fails to complete a license application or submits an application that contains false, misleading, or incorrect information or contains information that cannot be verified by the department.
- Requires the executive commissioner of the Health and Human Services Commission by rule to establish minimum standards require for the issuance or renewal of a license under this subchapter.
- Provides that the refusal to license an applicant or the suspension or revocation of a license by the department and the appeal from that action are governed by the procedures for a contested case hearing under Chapter 2001, Government Code.

The bill amends Section 431.021, Health and Safety Code, to provide that the following acts and the causing of the following acts within this state are unlawful and prohibited:

- ‡ engaging in the wholesale distribution of drugs or operating as a distributor or manufacturer of devices in this state without obtaining a license issued by the department under Subchapter I, L, or N, as applicable;
- ‡ making a false statement or false representation in an application for a license or in a statement, report, or other instrument to be filed with or requested by the department under this subchapter;
- ‡ failing to comply with a requirement or request to provide information or failing to submit an application, statement, report, or other instrument required by the department; or
- ‡ performing, causing the performance of, or aiding and abetting the performance of an act described by Subdivision (x) (engaging in the wholesale distribution of drugs or operating as a distributor or manufacturer of devices without the proper license).

The bill repeals Sections 431.2021 and 431.205, Health and Safety Code.

The bill provides transitional language, including dates by which rules must be adopted, effective dates for specific articles and sections, application of specific articles, and enactment contingencies.

The bill makes conforming and non-substantive changes.

### **EFFECTIVE DATE**

June 1, 2005, or, if the Act does not receive the necessary vote, the Act takes effect September 1, 2005.

### **COMPARISON OF ORIGINAL TO SUBSTITUTE**

The original SB 107 adds an offense to the Health and Safety Code for possession or transport of anhydrous ammonia, use of or tampering with equipment. The substitute does not add this offense.

The original bill repeals Chapter 504, Health and Safety Code, ANHYDROUS AMMONIA. The substitute does not repeal this chapter.

The original bill authorizes a business to sell products containing ephedrine, pseudoephedrine, or norpseudoephedrine over-the-counter only if the establishment operates a pharmacy licensed by the Texas State Board of Pharmacy, engages only in direct retail sales to patrons for their personal use, and complies with the requirements of the section. The substitute authorizes a business that does not operate a pharmacy licensed by the Texas State Board of Pharmacy to engage in over-the-counter sales of pseudoephedrine only if the establishment holds a certificate of authority issued by the Department of State Health Services.

The original bill requires that products containing ephedrine, pseudoephedrine, or norpseudoephedrine as the only active ingredient be kept behind the pharmacy counter, and that products containing ephedrine, pseudoephedrine, or norpseudoephedrine combined with at least one other active ingredient be kept either behind the pharmacy counter or in a locked case within 30 feet and in a direct line of sight of the pharmacy counter staffed by an employee of the establishment. The substitute requires that pseudoephedrine products be displayed in a manner that makes them accessible to a patron of the business establishment only with the assistance of an employee.

The original bill requires that a business establishment, before completing an over-the-counter sale of a product containing ephedrine, pseudoephedrine, or norpseudoephedrine require the purchaser to display a driver's license or other photo identification indicating the person's birth date. The substitute requires that the person display a driver's license or other photo identification showing that the person is at least 16 years old.

The original bill requires that a business make records of these sales available on request by the Texas State Board of Pharmacy. The substitute does not so require.

The original bill amends Section 481.077 of the Health and Safety Code to provide that the section does not apply to a sale or transfer of any compound, mixture, or preparation containing norpseudoephedrine that is in liquid, liquid capsule, or liquid gel capsule form. The substitute does not amend Section 481.077. However, the substitute adds subsection 486.001(4), providing that the term "pseudoephedrine" means any compound, mixture, or preparation containing any detectable amount of pseudoephedrine, including its salts, optical isomers, and salts of optical isomers, but not any compounds, mixtures, or preparations that are in liquid, liquid capsule, or gel capsule form and in which pseudoephedrine is not the only active ingredient.

The substitute adds or amends the following sections or chapters, not added or amended by the original bill:

- § 481.124, Health and Safety Code;
- § 481.136, Health and Safety Code;

C.S.S.B. 107 79(R)

- § 99.003, Civil Practice and Remedies Code;
- § 262.104, Family Code;
- § 22.041, Penal Code;
- Chapter 486, Health and Safety Code;
- §§ 431.201, 431.2011, 431.202, 431.204, 431.206, 431.207, Health and Safety Code; and
- § 431.021, Health and Safety Code.

The substitute repeals §§ 431.2021 and 431.205, Health and Safety Code, which were not repealed by the original bill.

Transition language in the substitute, including deadlines for adoption of rules, effective dates, and enactment contingencies, has been substantially altered from the original bill.