

**TEXAS****PRODUCTS:**

- All products containing ephedrine (EPH), pseudoephedrine (PSE), and norpseudoephedrine (NPSE). (TX Health & Safety Code § 486.001; 25 TAC § 230.11)

**PRODUCT EXEMPTIONS:**

- EPH, PSE and NPSE products in liquid, liquid capsule or liquid gel capsule form are exempt from sales limits and restrictions, ID, record keeping and placement requirements – business establishments need not hold certificate of authority or be a licensed pharmacy to sell such products (TX Health & Safety Code § 486.001; 25 TAC § 230.11);
- All EPH, PSE and NPSE dispensed upon valid prescription products are exempt from sales limits and restrictions, ID and record keeping requirements. (TX Health & Safety Code § 486.002)

**SALES LIMITS:**

- Business establishment may not sell to a person who makes OTC purchases of one or more products containing EPH, PSE, or NPSE within a calendar day more than 3.6grams and within any 30-day period more than 9grams of EPH base, PSE base or NPSE base per transaction (TX Health & Safety Code § 486.0141; 25 TAC § 230.15).

**SALES RESTRICTIONS:**

- Only pharmacies licensed by the Texas State Board of Pharmacy (TX BoP) and business establishments that hold a certificate of authority issued by the Department of State Health Services (DSHS) may engage in OTC sales of non-liquid EPH, PSE or NPSE products (TX Health & Safety Code § 486.014);
- Sales to persons under 16 years old prohibited. (TX Health & Safety Code § 486.014)

**ID REQUIREMENTS:**

- Purchaser must display driver's license or other form of government issued ID indicating that purchaser is over 16 years old (TX Health & Safety Code § 486.014; 25 TAC § 230.15).

**RECORDKEEPING REQUIREMENTS:**

- Purchaser must sign for the purchase, and seller to make record of sale that includes purchaser name, date of birth, address, purchase date, time of purchase, type of identification displayed by the person and the identification number, product name for the item and the number of grams purchased, and

- transmit the record of sale (TX Health & Safety Code § 486.014; 25 TAC § 230.15);
- Sales records must be maintained by retailer for 2 years from the date of sale, and must be available upon request by DSHS or Department of Public Safety (DPS). (TX Health & Safety Code § 486.015; 25 TAC § 230.15)
  - Maintenance of records requirement does not apply to business establishments that has used a real-time electronic logging system for longer than 2 years. (TX Health & Safety Code § 486.015 (b) )
  - Business establishment that has used real-time electronic logging system for more than 2 years shall destroy all paper records unless the destruction is otherwise prohibited by law. (TX Health & Safety Code § 486.015 (c))

**PRODUCT PLACEMENT:**

- Pharmacies must maintain all products (except exempted liquid, liquid capsule or gel capsule products) behind pharmacy counter or in a locked case within 30 feet and in direct line of sight from a pharmacy counter staffed by an employee of the establishment (TX Health & Safety Code § 486.013);
- Business establishments holding certificate of authority must maintain all products (except exempted liquid, liquid capsule or gel capsule products) behind a sales counter or in a locked case within 30 feet and in direct line of sight from sales counter staffed by an employee of the establishment (TX Health & Safety Code § 486.013).

**REAL-TIME ELECTRONIC LOGGING SYSTEM:**

- System intended to be used by law enforcement agencies and pharmacies or business establishment that: is installed, operated, maintained, and free of any one-time or recurring charge to the business establishment or the state; (25 TAC § 230.15)
- Able to communicate in real time with similar systems operated in other states and similar systems containing information submitted by any other state;
- Complies with the security policy of the Criminal Justice Information Exchange Model; (25 TAC § 230.15)
- Use a mechanism to prevent the completion of a sale containing EPH, PSE, or NPSE, that would violate federal law regarding the purchase of a product containing those substances; (25 TAC § 230.15)
- Equipped with an override of the mechanism: may be activated by an employee of a business establishment; and creates a record of each activation of the override. (TX Health & Safety Code § 486.001 (a) (6)).

## **TRANSMISSION OF SALES INFORMATION TO REAL-TIME ELECTRONIC LOGGING SYSTEM:**

- Before completing an OTC sale of a product containing EPH, PSE, or NPSE, a business establishment that engages in those sales of shall transmit the information in the record made to a real-time electronic logging system. (25 TAC § 230.17)
- Business may not complete an OTC sale of a product containing EPH, PSE, or NPSE if the real-time electronic logging system returns a report that the completion of the sale would result in the person obtaining and of EPH, PSE, or NPSE greater than the amount limit, regardless of whether all or some the products previously obtained by the buyer were sold at the establishment or another business. (25 TAC § 230.17)
- Employee of business establishment may complete a sale prohibited by using the override mechanism only if employee has a reasonable fear of imminent bodily injury or death from the person attempting to obtain EPH, PSE, or NPSE. (25 TAC § 230.17)
- On the request of Dept. of Public Safety, administrators of real-time electronic logging system shall make available to the dept. a copy of each record of an OTC sale of a product containing EPH, PSE, or NPSE that is submitted by a business establishment located in TX. (25 TAC § 230.17)
- On application by business that operates a pharmacy and engages in OTC sales of products containing EPH, PSE, or NPSE, 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. (25 TAC § 230.17)
- Business establishment granted a temporary exemption must keep records of sales in the same manner for a business establishment that experiences mechanical or electronic failure of the real-time electronic logging system. (25 TAC § 230.17)
- An exemption granted does not relieve a business of any duty other than the duty to use a real-time electronic logging system. (25 TAC § 230.17)
- If a business establishment that engages in OTC sales of a product containing EPH, PSE, or NPSE experiences a mechanical or electronic failure of the real-time electronic logging system the business shall: maintain written record or electronic record made by any means that satisfies the requirement, enter information in the real-time electronic logging system as soon as practicable after the system becomes operational. (25 TAC § 230.17; TX Health & Safety Code § 486.0143)
- Administrators of real-time electronic system shall provide real-time access to the information to the Dept. of Public Safety if the dept. executes a memorandum of understanding with the administrators. (25 TAC § 230.17; TX Health & Safety Code § 486.0144)

**PRIVACY PROTECTIONS:**

- The privacy protections provided an individual under CFR sections 1314.45 apply to information entered or stored in real-time electronic logging system. (25 TAC § 230.18)
- Business establishment that engages in OTC sales of a product containing EPH, PSE, or NPSE may disclose information entered or stored in a real-time electronic logging system only to the DEA and other federal, state, and local law enforcement agencies. (25 TAC § 230.18)
- Business establishment that engages in OTC sales of a product containing EPH, PSE, or NPSE may not use information entered or stored in the electronic logging system for any other purpose other than for disclosure or with the requirements of this rule. (25 TAC § 230.18)

**PENALTIES:**

- All violations may be subject to an administrative penalty that may not exceed \$1,000 for each violation per day it occurs, the total amount of which may not exceed \$20,000. The penalty amount will be based on the seriousness of violation, threat to the public health or safety, any history of previous violations, the amount necessary to deter future violations, whether the violator demonstrated good faith / whether violator made good faith efforts to correct violations, and any other matter that justice may require. (TX Health & Safety Code § 486.021; TX Code § 486.022; 25 TAC § 230.16)
- DSHS may revoke a certificate of authority for a violation of the provisions described in this summary or for a conviction of any offense related to the manufacture or distribution of illegal drugs. (25 TAC § 203.16)
- Penalties may be disputed via a hearing a repeals process. (TX Health & Safety Code § 486.023-486.033)

**LIABILITIES:**

- Person is not liable for an act or omission arising from the person's compliance with the real-time electronic logging system. (TX Health & Safety Code § 486.0144)
- Business establishment that engages in OTC sales of a product containing EPH, PSE, or NPSE or an employee or agent of the business establishment isn't civilly liable for the release of information entered or stored in a real-time electronic logging system unless the release constitutes negligence, recklessness, or willful misconduct. (TX Health & Safety Code § 486.0144)

**WHOLESALE DISTRIBUTION REQUIREMENTS:**

- Exempts all PSE and EPH products as well as NPSE products in liquid form from chemical precursor transfer record requirements; instead, establishes a separate record retention requirement for PSE, EPH and NPSE products that wholesale

distributors must comply with that include retailer address, area code, phone number, amount of product sold, and any additional information that may be required by regulation. Records must be maintained for 2 years from the date of transaction. (TX Health & Safety Code § 481.077(1); TX Health & Safety Code § 481.0771)

- A retail distributor who engages in greater than 5% of gross annual sales of non-exempt PSE products to other than end-user consumers must obtain a license as a wholesaler. (25 TAC § 230.11)

#### **REPORTING SUSPICIOUS TRANSACTIONS:**

- Wholesalers must report requests for suspicious quantities to the DPS within 10 days. Those, who with reckless disregard for the duty to report, fail to do so may be subject to disciplinary action in accordance with DPS rule. (TX Health & Safety Code § 481.0771)

#### **PREEMPTION:**

- All local ordinances adopted by state political subdivisions pertaining to OTC sales of products containing EPH, PSE and NPSE are preempted and superseded; however, this preemption does not preclude state political subdivisions from imposing administrative sanctions on the holder of a license or permit issued by the political subdivision for engaging in conduct that violates sales limits and restrictions, ID, record keeping and placement requirements. (TX Health & Safety Code § 486.005)

#### **OTHER:**

- With the exception of pharmacists, pharmacies and wholesale distributors, retail establishments that sell non-exempt PSE, EPH and PPA products must obtain certificate of authority (COA) from the State Health Services Council. Separate COAs are required for each place of business. (25 TAC § 230.11; 25 TAC § 230.12; 25 TAC § 230.13)
- DSHS has the authority to inspect or audit a business establishment that has been issued a certificate of authority to ensure compliance with laws and regulations governing sale of non-liquid EPH, PSE and NPSE products. (TX Health & Safety Code § 486.012)