

RECENT UPDATES TO TEXAS PHARMACY LAWS AND RULES

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Topic Overview

Healthcare as a profession, including pharmacy practice, is highly regulated. Texas laws and rules governing pharmacy practice are continually reviewed and updated. This review provides recent pharmacy practice updates regarding fingerprinting, re-dispensing unused prescriptions in specific situations, continuing education, intern hours, and emergency medical kits. It also shares amendments regarding emergency refills of insulin and supplies and discusses the Prescription Drug Monitoring Program. As pharmacy team members learn and adhere to the updates, they support the Texas State Board of Pharmacy's mission to prioritize the health and safety of the citizens of Texas.

Accreditation Statement:



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Universal Activity Number (UAN): The ACPE Universal Activity Number assigned to this activity is **0669-0000-23-022-H03-P**.

Credits: 1 hour of continuing education credit

Type of Activity: Knowledge

Media: Internet/Home study

Fee Information: \$4.99

Estimated time to complete activity: 1 hour, including Course Test and course evaluation

Release Date: April 24, 2023

Expiration Date: April 24, 2026

Target Audience: This educational activity is for pharmacists.

How to Earn Credit: From April 24, 2023, through April 24, 2026, participants must:

- 1) Read the “learning objectives” and “author and planning team disclosures;”
- 2) Study the section entitled “educational activity;” and
- 3) Complete the Course Test and Evaluation form. The Course Test will be graded automatically. Following successful completion of the Course Test with a score of 70% or higher, a statement of participation will be made available immediately. (No partial credit will be given.)
- 4) Credit for this course will be uploaded to CPE Monitor®.

Learning Objectives: Upon completion of this educational activity, participants should be able to:

1. **Describe** where to locate Texas pharmacy rules and laws
2. **Describe** recent changes to Texas pharmacy practice rules
3. **Identify** Texas pharmacy continuing education updates
4. **Explain** Texas pharmacy practice updates regarding emergency insulin refills and insulin-related supplies

Disclosures

The following individuals were involved in the development of this activity: Pamela Sardo, PharmD, BS. Pamela Sardo, Pharm.D., B.S., was an employee of Rhythm Pharmaceuticals until March 2022 and has no conflicts of interest or relationships regarding the subject matter discussed. There are no financial relationships relevant to this activity to report or disclose by any of the individuals involved in the development of this activity.

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Introduction

Pharmacy practice is highly regulated. The Texas State Board of Pharmacy has been very active this past year, implementing many amendments following the most recent Texas legislative session. Pharmacy practice laws and rules change to update educational requirements and processes and to address patient care and safety. Some updates are minor (grammar or vocabulary edits), while others modify requirements. Others are detailed and important for daily practice. This course is intended to highlight recent changes in Texas pharmacy laws and rules and their impact on daily pharmacy practice. These changes are relevant for pharmacists and pharmacy technicians. This program is organized by communicating the most recent updates first, with earlier effective dates and related topics located further in the article. The updates in this article are also separated by license type (*i.e.*, pharmacist, intern, or pharmacy technician) as described in the update of board rules or laws.

The History of Pharmacy and Regulations in Texas

The Spanish explorer Álvar Núñez Cabeza de Vaca was among the first Europeans to practice pharmacy and medicine in North America.¹ He was shipwrecked along the coast of Texas on November 6, 1528.² When his group landed in Texas in 1528, Native Americans enslaved them and forced them to treat victims of epidemic diseases that accompanied the explorers. Cabeza de Vaca combined his European knowledge with Native American medicine, herbs, concoctions, and magic.¹

Legislation that first recognized the need for regulating pharmacy practice in Texas was passed in 1889. The legislature established boards of "pharmaceutical examiners," which were three-man committees in each state senatorial district. These committees examined and certified pharmacists but there was no inconsistency between them. During this time, records were sparse, and no central authority coordinated the activities of each senatorial district's committee.³

This changed in 1907 when the Texas Legislature passed the first Texas Pharmacy Act to centralize pharmacy practice regulation and add consistency. This Act established the Texas State Board of Pharmacy (TSBP) as an independent state regulatory board. In 1908, the agency had its first representation at the annual meeting of the National Association of Boards of Pharmacy (NABP). The agency joined NABP that year.³

Pharmacy professions are among the most regulated industries.⁴ This regulation exists because healthcare deeply impacts people's lives and could cause harm if unregulated.⁴ As such, regulating pharmacy practice in Texas continues to change and grow.

Texas Board of Pharmacy Amended Rules

The TSBP comprises eleven Governor-appointed members and over 100 staff members who oversee a licensee population that consists of pharmacists, pharmacy technicians, and various types of pharmacies and pharmacy facilities.³ The TSBP website is the optimal resource for updates regarding pharmacy practice. The TSBP website contains an easy-to-use "Laws and Rules" tab, at <https://www.pharmacy.texas.gov/>.

Recently adopted rule change summaries can be located at https://www.pharmacy.texas.gov/Rules_Recent_Adopted_Changes.asp within the TSBP website.

The Texas State Legislature meets biennially and may pass laws affecting Texas pharmacy practice. It is important to understand these laws and the rules issued by the TSBP. The TSBP issues rules that fulfill its mission statement: to protect public health, uphold quality licensing standards, and facilitate regulation that promotes innovative, multidisciplinary, and collaborative practices and education.⁵ Pharmacy team members can contribute to the TSBP mission by prioritizing the health and safety of the citizens of Texas.

Fingerprint Check in the Texas Occupations Code Section 602.2101

A fingerprint background check is now required prior to pharmacist license renewal, beginning with pharmacists whose licenses must be renewed by February 28, 2023.⁶ This section requires a fingerprint background check for all current licensees and permit holders and requires those who completed a fingerprint requirement before June 1, 2015, to complete a new fingerprint background check. This is a one-time requirement.⁶ The requirement began with pharmacy technicians and now expands to pharmacists. Reminders of the requirement will be included with the renewal notice sent 60 days before license expiration. Fingerprint information for pharmacists, technicians, trainees, and interns is located on the TSBP website.⁶ To complete the fingerprint session outside of the renewal period, email fingerprints@pharmacy.texas.gov with the license number, full name, and the request.

Amendments Related to the Return of Prescription Drugs Effective December 2022 Board Rule §291.8

The amendments clarified that a pharmacist may redispense a prescription drug as authorized by exceptions in Chapters 431 and 442 of the Health and Safety Code.⁷ A licensed healthcare professional in a penal institution, or a consultant pharmacist, may return certain unused drugs, other than a controlled substance, to a pharmacy. The unused drugs must be sealed in unopened packaging. It also includes parenteral medications in sealed multiple-dose containers if doses have not been withdrawn. It outlines procedures for returning unused drugs from a health care facility or a penal institution to a dispensing pharmacy as specified in §562.1085 of the Occupations Code. Participation in this limited redispensing is optional.⁷

Board Rule §291.33

These amendments clarified additional aspects of the limited redispensing.⁸ A pharmacist may redispense a prescription drug only as authorized by exceptions in Chapters 431 and 442 of the Health and Safety Code. Effective December 2022, §291.33 applies to certain medications packaged in unit-of-use containers that are administered to the patient during the hospitalization and may be provided to the patient upon discharge provided the pharmacy receives a discharge order and the product bears a label containing the name of the patient; name and strength of the medication; name of the prescribing or attending practitioner; directions for use; duration of therapy; and name and telephone number of the pharmacy.⁸

Amendments Related to Continuing Education (CE) Requirements Effective December 2022 Board Rule §295.8

Thirty total hours are required for each pharmacist license renewal period.⁹ Twenty hours are required for each pharmacy technician renewal period. This rule clarifies that the requirement to complete a human trafficking prevention course for renewal of a pharmacist license does not expire on September 1, 2022.⁹ The human trafficking prevention course for pharmacists and pharmacy technicians is required in §116.002 of the Texas Occupations Code. The purpose of these requirements is to enhance the professional competency of licensed pharmacists and protect the health and welfare of the citizens of Texas.⁹

Board Rule §297.8

The update to the rule clarified that the requirement to complete a human trafficking prevention course for renewal of a registration as a pharmacy technician does not expire on September 1, 2022.¹⁰

Amendments Concerning Internship Requirements
Effective September 2022
Board Rule §283.4

The amendments to this rule removed language to establish that a person graduating from a college or school of pharmacy shall only be credited the number of hours obtained and reported by the program.¹¹ Hours can be obtained in a board-approved internship, extended internship, hours credited upon graduation from a school of pharmacy, or when certified by a board of pharmacy in another state.¹¹

Amendments Concerning Operational Standards
Effective September 2022
Board Rule §291.33

This amendment updated the patient counseling rule. It removed the requirement that verbal patient counseling on a new prescription must be done in person.⁸ The Office of the Governor initially suspended this requirement due to COVID-19.¹²

Amendments Related to Non-Resident (Class E) Pharmacies
Effective September 2022
Board Rule §291.104

The update to the rule clarified that a Class E pharmacy engaged in outsourcing prescription drug order dispensing to a central fill pharmacy shall comply with §291.125 regarding centralized prescription dispensing. A Class E Pharmacy may outsource prescription drug order dispensing to a central fill pharmacy.¹²

Board Rule §291.125

The amendments clarified that a Class E pharmacy may outsource prescription drug order dispensing to a central fill pharmacy and shall comply

with specified requirements unless compliance would violate the laws or rules in the state where the pharmacy is located.¹²

**Amendments Concerning Compounding Non-Sterile Preparations
Effective September 2022
Board Rule §291.131**

This rule adds definitions of cleaning and sanitizing and clarifies the training requirements for all personnel involved in non-sterile compounding.¹³ It updates environmental, equipment, and compounding process requirements for non-sterile compounding. Training shall include instruction and demonstration of hand hygiene, garbing, cleaning, and sanitizing, handling and transporting components and compounded non-sterile preparations, measuring and mixing, proper use of equipment and devices selected to compound non-sterile preparations, and documentation of the compounding process (*e.g.*, Master Formulation Records and Compounding Records).¹³

**Amendments Concerning Remote Emergency Medication Kits
Effective June 2022
Board Rule §291.121**

The updates to this rule removed a prohibition against duplicating drugs stored in emergency medication kits in a remote pharmacy location.¹⁴ This rule explains if more than one provider pharmacy provides an emergency kit to a remote site, the provider pharmacies must enter into a written agreement as to the emergency medications supplied by each pharmacy. The written agreement shall include reasons why an additional pharmacy is required to meet the emergency medication needs of the residents of the institution.¹⁵

**Amendments Concerning Emergency Refill of Insulin and Supplies
Effective December 2021
Board Rule §291.34**

The amendments clarified that a pharmacist may provide an emergency refill of insulin or insulin-related equipment or supplies under certain conditions.¹⁶ The rule advises that pharmacists use professional judgment regarding requests for emergency insulin or insulin-related supplies to determine appropriateness. There should be a “reasonable effort” to reach a prescriber. There must be documentation that the patient was previously prescribed insulin or related supplies.¹⁶ Pharmacy technicians should be familiar with this new rule. Refer patients to pharmacists when needed to assist implementation of this rule.

Pharmacist-Intern and Pharmacy Technician Rules

**Table 1
Pharmacist-Intern and Pharmacy Technician Ratios and Duties
Effective December 2020**

Pharmacy Class/ Regulation	Rule	License Affected	Ratio	DUTIES ADDED*		
				Receive Oral Rx	Transfer Rx	Contact Prescriber for Info†
Community (Class A)	283.5	I	Removes Ratio‡			
Community (Class A)	291.31	T		Modifies to allow		
Community (Class A)	291.32	T	1:6, max 3 trainees	Yes	Yes	Yes
Community (Class A)	291.33	T		Yes	Yes	Yes
Community (Class A)	291.34	T		Yes	Yes	Yes
Nuclear (Class B)	291.52	T		Modifies to allow		

Nuclear (Class B)	291.53	T	1:6, max 3 trainees	Yes		
Nuclear (Class B)	291.55	T		Yes	Yes	
Remote	291.121	T		Yes		
Satellite	291.129	T	Removes ratio	Yes	Yes	
Class G	291.153	T	Removes ratio	Yes	Yes	
Substitution	309.2	T		Modifies to allow		
Substitution	309.3	T		Modifies to allow		

I =Pharmacist Intern; T =Pharmacy Technician

* Expanded technician duties do not apply to controlled substances

†Expanded duties do not include technician trainees

‡Removes ratio when interns are performing technician duties under certain conditions

Table 1 was adapted from Texas State Board of Pharmacy, Texas Pharmacy Rules¹⁷

Pharmacist CE

CE Requirements Added Effective December 2019 Board Rule §295.8

Pain management

One hour of continuing education annually must be related to pain management as specified in House Bill 3285.¹⁸ Two hours per license renewal period are required for all renewals received after August 31, 2021, and before September 1, 2023. These must be taken in different years.⁹

Prescribing and monitoring controlled substances

Two hours of continuing education must be related to prescribing and monitoring controlled substances as specified in House Bill 2174.¹⁹ This requirement must be met for all renewals received beginning September 1, 2021.⁹

Human Trafficking Prevention

Pharmacists must complete a human trafficking prevention course as specified in House Bill 2059.²⁰ The Health and Human Services Commission is the approving body for the program. This requirement must be met for all renewals received after August 31, 2020, and must be completed each renewal period.⁹

Board Rule §295.8

Effective June 18, 2020

Mental Health Awareness

One hour per license renewal period must be related to mental health awareness. Any program relating to mental health awareness in terms of disease states, treatment modalities, *etc.*, should be able to be counted. This requirement must be met for all renewals received after August 31, 2021 and before September 1, 2023.⁹

Table 2 summarizes pharmacist continuing education requirements. Visit the TSBP website at www.pharmacy.texas.gov/ce to learn more about the new CE requirements and general CE frequently asked questions (FAQs).

**Table 2
Pharmacist and Newly Licensed Pharmacist CE Requirements
Board Rule §295.8**

Pharmacist CE- all below are required*				
Below 2 topics are required for a newly licensed pharmacist		3 CE topics below are exempt for initial license pharmacist renewal		
2 Hours (1 hr annually)	2 Hours	1 Hour	1 Hour	24 Hours
Pain management	Prescribing and monitoring controlled substances	Mental health awareness	Texas-specific pharmacy laws and/or rules	Any subject or special certification CE

*A Human Trafficking Prevention course is also mandatory for all
Table 2 is adapted from Board Rule §295.8⁹

Pharmacy Technician CE

Board Rule §297.8 Effective December 2019

Table 3 summarizes pharmacy technician continuing education requirements. This board rule added an amendment for a human trafficking prevention course for pharmacy technicians as specified in House Bill 2059.²⁰ This requirement must be completed each renewal period. Pharmacy technicians are subject to a random audit of CE by the TSBP. Pharmacy technicians may count CE obtained for national certification toward the state CE requirements if it meets state CE requirements and falls within the current renewal period.¹⁰

**Table 3
Pharmacy Technician CE Requirements
Board Rule §297.8**

Pharmacy Technician CE- all below are required*	
Topics below are exempt for initial pharmacy technician renewal	
1 Hour	19 Hours
Texas-specific pharmacy laws and/or rules	Can be any subject Can be special certification CE requirements such as sterile compounding

*A Human Trafficking Prevention course is also mandatory for all
Table 3 is adapted from Board Rule §297.8¹⁰

Texas Prescription Monitoring Program (PMP)

The Texas Prescription Monitoring Program (Texas PMP), also referred to as AWARxE, is managed by the Texas State Board of Pharmacy. It collects and monitors outpatient prescription data for all Schedule II, III, IV, and V controlled substances dispensed by a pharmacy in Texas. It also collects and monitors controlled substances for a Texas resident from a pharmacy located in another state.²¹

The Texas PMP is a patient care tool that can be used to inform prescribing practices, as well as address prescription drug misuse and diversion. The number of states utilizing the program is increasing. Texas PMP shares prescription data with 36 other states and entities, allowing prescribers and pharmacists to track prescriptions dispensed outside the state of Texas.²¹ Pharmacists and prescribers (other than a veterinarian) are required to check the patient’s PMP history before dispensing or prescribing opioids, benzodiazepines, barbiturates, or carisoprodol.²¹

The Texas PMP allows prescribers and pharmacists to designate an unlimited number of delegates to access patient prescription data and generate reports on their behalf. Every individual is required to register as a separate user; however, all delegate queries are attributed to the prescriber or pharmacist for whom they generate the report.²²

The Texas PMP can be accessed in several ways:

- www.pharmacy.texas.gov
- www.pharmacy.texas.gov/pmp
- txpmp.org

What's Next?

The 88th Texas Legislature convened in January 2023 and will adjourn in May 2023. Pharmacy-associated bills and a resolution have been submitted. House Resolution (H.R.) 222 resolves that because pharmacists often serve as the primary point of contact with the health care system for tens of millions of Americans and have an important role in counseling on the safe and effective use of medications, the House of Representatives designates February 28, 2023, as Texas Pharmacy Day.²³

An additional proposed bill is under consideration involving new details regarding emergency refills of insulin.²⁴ Another bill has been introduced that addresses pharmacy benefits managers.²⁵ A bill possibly impacting the insurance code, HIPAA, and pharmacy involving the disclosure of certain prescription drug information by a health benefit plan has also been introduced.²⁶ The TSBP also has a Rule Review plan through the fiscal year 2025.²⁷

Summary

The practice of pharmacy continues to evolve and the official pharmacy statutes and rules should always be consulted for comprehensive information relating to a particular statute or rule. The TSBP has implemented changes in Texas law that promote public health for Texas citizens, and that encourage innovative, multidisciplinary, and collaborative practices and education in the pharmacy and healthcare settings. Pharmacy team members contribute to this mission of prioritizing the health and safety of the citizens of Texas through learning and following the pharmacy statutes and rules in Texas.

Course Test

1. Where are the Texas pharmacy rules and laws located?

- a. <https://pharmacy.utexas.edu/>
- b. <https://www.dshs.texas.gov/pharmacy-unit>
- c. <https://www.tdi.texas.gov/wc/pharmacy/index.html>
- d. <https://www.pharmacy.texas.gov/>

2. Which statement is true regarding pharmacy professionals and fingerprints?

- a. Fingerprints are only required for professionals disciplined by the TSBP
- b. Fingerprints are no longer required for licenses after June 1, 2015
- c. A fingerprint background check is required prior to pharmacist license renewal
- d. Email fingerprints@pharmacy.texas.gov to request fingerprint exemptions

3. Which statement best describes pharmacy professional continuing education requirements?

- a. Pharmacists must complete 40 hours and pharmacy technicians must complete 30 hours in each renewal period
- b. The human trafficking CE requirement for pharmacists and pharmacy technicians expired on September 1, 2021
- c. Pharmacists' and pharmacy technicians' initial renewal period must include sterile compounding and mental health awareness CE
- d. Newly licensed pharmacists must complete 2 hours of pain management CE and initial pharmacy technician renewal must include 1 hour of pharmacy law

4. On Saturday afternoon, a patient notifies the pharmacy that they have not had their dose of insulin because they dropped their last bottle of insulin on the floor and it broke. How should pharmacy personnel proceed regarding the emergency refill request?

- a. Pharmacy technicians will refer the patient to the pharmacist to assist implementation of this rule
- b. There will be a "reasonable effort" to reach a prescriber to assist the patient with this refill request
- c. There must be documentation that the patient was previously prescribed insulin or related supplies
- d. All of the above are correct regarding emergency insulin refill requests

5. What is the pharmacist-to-technician ratio in a Class A (Community) pharmacy setting?

- a. The ratio has been removed
- b. The ratio is 1:6
- c. The ratio is 1:3
- d. The ratio is 1:7

6. Excluding pharmacy technician trainees, what duties below are allowed to be performed by a pharmacy technician?

- a. A technician can contact the prescriber for information in a Class B (Nuclear) pharmacy
- b. A technician can contact a prescriber for information in a remote pharmacy
- c. A technician can contact a prescriber for information in a satellite pharmacy
- d. A technician can contact a prescriber for information in a Class A (Community) pharmacy

7. Name 2 recent changes to Texas pharmacy practice rules.

- a. A pharmacist may redispense a penal institution prescription drug as authorized by exception in Board Rule §291.8
- b. A pharmacist may redispense an open container of metoprolol as authorized by Board Rule §295.8
- c. A pharmacist may redispense a unit of use container as described in Board Rule §291.33
- d. a and c are correct

8. Pharmacists and pharmacy technicians must be aware of pharmacy laws and rules. Which statement below is important to remember?

- a. Patient counseling is not as important as other rules, so Board Rule §291.33 concerning operational standards exempts counseling on new prescriptions
- b. Concerning operational standards, due to COVID, Board Rule §291.33 exempts oral counseling on new prescriptions from being provided in person
- c. In pharmacies that compound, Board Rule §291.131 informs that only the pharmacist-in-charge needs training on hand hygiene
- d. In pharmacies that compound, Board Rule §291.131 informs that only technicians need training on cleaning and sanitizing

9. A director of a federally operated institution and pharmacy asks the pharmacy personnel for help obtaining a remote emergency medication kit for their remote site of residents 12 miles away because their usual provider pharmacy is always out of stock. What factors should be considered?

- a. The provider pharmacies must enter into a written agreement regarding the emergency medications supplied by each pharmacy
- b. Board Rule §291.121 removes a prohibition against duplicating drugs stored in emergency medication kits in a remote pharmacy location
- c. A written agreement shall include reasons why an additional pharmacy is required to meet the emergency medication needs of the residents of the institution
- d. All of the above are correct

10. Which Class of pharmacy permit pharmacy technicians to transfer a non-controlled prescription?

- a. Class B (Nuclear) and remote pharmacies
- b. Class A (Community) and remote pharmacies
- c. Class A (Community) and Class G pharmacies
- d. Satellite and remote pharmacies

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