

**Texas State Board of Pharmacy
Laws and Rules Update
Webinar FAQs and Troubleshooting Tips**

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 - Complete these items to generate your certificate, which can be accessed at any time through your Lifelong Learning Account
 - **Please note:** This course is accepted by the Texas State Board of Pharmacy for both general credit and as fulfilling the law requirement. **However, it is NOT ACPE certified and will not appear in your CPE Monitor account.**



Texas Pharmacy Law Update

Allison Vordenbaumen Benz, R.Ph., M.S.
Executive Director

Michelle McDiffett, MT (ASCP), R.Ph.
Compliance Program Officer



January 24, 2018

TEXAS STATE BOARD OF PHARMACY

Goals

- Review recent changes to pharmacy rules;
- Review Legislation passed by the 2017 Texas Legislature that affects the practice of pharmacy or the Board of Pharmacy; and
- Review the Texas Prescription Monitoring Program.



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TEXAS STATE BOARD OF PHARMACY



Recently Adopted Rules



TEXAS STATE BOARD OF PHARMACY

Pharmacy Technician Registration Requirements

- At the February 2, 2017, meeting, the Board approved the ExCPT examination for pharmacy technician registration beginning September 1, 2017.



Pharmacy Technician Registration Requirements

- Effective Date: March 19, 2017.
- Amends the exam requirements for initial registration to specify that the applicant must have taken and passed a pharmacy technician certification examination approved by the board and have a current certification certificate.
- (Note: Reference to PTCB has been removed.)



Board Rule 295.14

- Effective Date: December 19, 2016
- Dispensing of Opioid Antagonist by Pharmacist
 - Allows a pharmacist to dispense an opioid antagonist under a valid prescription, including:



Board Rule 295.14

- prescription issued by a standing order, to:
 - a person at risk of experiencing an opioid-related drug overdose; or
 - a family member, friend, or other person in a position to assist a person at risk of experiencing an opioid-related drug overdose.



Board Rule 295.14

- A prescription dispensed under this section is considered as dispensed for a legitimate medical purpose in the usual course of professional practice.
- A pharmacist who, acting in good faith and with reasonable care, dispenses or does not dispense an opioid antagonist under a valid prescription is not subject to any criminal or civil liability or any professional disciplinary action for:



Board Rule 295.14

- dispensing or failing to dispense the opioid antagonist; or
- if the pharmacist chooses to dispense an opioid antagonist, any outcome resulting from the eventual administration of the opioid antagonist.



Class A Pharmacy Library Requirements

- Effective Date: September 6, 2017
- Library requirements were amended to
 - Add a new reference if the pharmacy dispenses veterinary prescriptions, the pharmacy must have a general reference text on veterinary drugs.



TEXAS STATE BOARD OF PHARMACY

Pharmacy Related Legislation Passed by the 2017 Texas Legislature



TEXAS STATE BOARD OF PHARMACY

The “Sunset” Bill (HB 2561) Effective Date: 9/1/2017



TEXAS STATE BOARD OF PHARMACY

HB 2561 by Rep. Senfronia Thompson/Sen. Van Taylor

Effective Date: 9/1/2017

Amends the Pharmacy Act to:

- **Continue TSBP until 8/31/2029;**
- Amend the duties of the Executive Director (ED) to specify that the ED may perform the duties required by the Act or designated by the Board;
- Remove the requirement that a person be of **good moral character** to obtain a license or registration;



TEXAS STATE BOARD OF PHARMACY

HB 2561 by Rep. Senfronia Thompson/Sen. Van Taylor (cont.)

Amends the Pharmacy Act to:

- Allow the Board to **refuse to renew** a license to practice pharmacy **for a license holder who is in violation of a Board order;**
- Specifies that TSBP must adopt rules relating to the CE required for pharmacy technicians.



TEXAS STATE BOARD OF PHARMACY

HB 2561 by Rep. Senfronia Thompson/Sen. Van Taylor (cont.)

Amends the Pharmacy Act to specify that pharmacy technician CE requirements must include the:

- Number of hours of CE;
- Methods for meeting the CE requirements;
- Approval of CE programs;
- Reporting completion of CE;
- Records of completion of CE; and
- Board audits to ensure compliance.



TEXAS STATE BOARD OF PHARMACY

**HB 2561 by Rep. Senfronia
Thompson/Sen. Van Taylor (cont.)**

- **Amends** the Pharmacy Act to specify that to renew a pharmacy technician registration, the registrant must, before the expiration date of the registration:
 - Pay the renewal fee; and
 - Comply with the continuing education requirements.



TEXAS STATE BOARD OF PHARMACY

**HB 2561 by Rep. Senfronia
Thompson/Sen. Van Taylor (cont.)**

- **Amends** the Pharmacy Act to specify that to renew a pharmacy technician registration **after a registration has been expired for:**
 - 90 days or <, the technician must pay a renewal fee that is equal to **1½ times** the renewal fee;
 - > than 90 days, but < 1 year, the technician must pay a renewal fee that is **2 times** the renewal fee;
 - 1 year or >, the technician **may not renew.**



TEXAS STATE BOARD OF PHARMACY

**HB 2561 by Rep. Senfronia
Thompson/Sen. Van Taylor (cont.)**

- Adds a new section 551.006 to the Pharmacy Act titled **“Exclusive Authority”** that specifies that **a pharmacist has the exclusive authority to determine whether or not to dispense a drug.**



TEXAS STATE BOARD OF PHARMACY

**HB 2561 by Rep. Senfronia
Thompson/Sen. Van Taylor (cont.)**

- Adds a new section 551.008 to the Pharmacy Act titled: **“Prohibition on Rule Violating Sincerely Held Religious Belief”** that specifies:
 - All rules or policies adopted by TSBP may not violate the Religious Freedom provisions of the Texas Civil Practice and Remedies Code; and



TEXAS STATE BOARD OF PHARMACY

**HB 2561 by Rep. Senfronia
Thompson/Sen. Van Taylor (cont.)**

- A person may assert a violation of the religious freedom provisions as an affirmative defense in an administrative hearing or as a claim or defense in a judicial proceeding.



TEXAS STATE BOARD OF PHARMACY

**HB 2561 by Rep. Senfronia
Thompson/Sen. Van Taylor (cont.)**

- **Amends** the Pharmacy Act to add the following definitions:
 - “*Provider pharmacy*” – a Class A phcy that provides phcy services through a telepharmacy system at a remote dispensing site.
 - “*Remote dispensing site*” – a location licensed as a telepharmacy that is authorized by a provider phcy through a telepharmacy system to store and dispense Rx drugs/devices including dangerous drugs and controlled substances.



TEXAS STATE BOARD OF PHARMACY

**HB 2561 by Rep. Senfronia
Thompson/Sen. Van Taylor (cont.)**

- **Adds** the following definitions to the Pharmacy Act:
 - “Direct supervision” – supervision by a pharmacist who directs the activities of a pharmacist-intern, pharmacy technician, or pharmacy technician trainee **to a sufficient degree** to ensure the activities are performed accurately, safely, and without risk of harm to patients, as specified by Board rule.



TEXAS STATE BOARD OF PHARMACY

**HB 2561 by Rep. Senfronia
Thompson/Sen. Van Taylor (cont.)**

- **Amends** the Pharmacy Act to allow a Class A or Class C pharmacy to provide pharmacy services, including the dispensing of drugs, through a telepharmacy system **at locations separate from** the Class A or Class C pharmacy.



TEXAS STATE BOARD OF PHARMACY

**HB 2561 by Rep. Senfronia
Thompson/Sen. Van Taylor (cont.)**

- **Specifies** that Board must adopt rules regarding the use of a telepharmacy system **including the locations eligible to be licensed as remote dispensing sites**, which must include:
 - Locations in medically underserved areas;
 - Areas with a medically underserved population; and
 - Health professional shortage areas.



TEXAS STATE BOARD OF PHARMACY

**HB 2561 by Rep. Senfronia
Thompson/Sen. Van Taylor (cont.)**

- **The Board must adopt rules** specifying licensing and operating requirements, including a requirement that a:
 - Remote dispensing site license identify the provider pharmacy that will provide pharmacy services at the remote dispensing site;
 - Provider pharmacy be allowed to provide phcy services at **no more than 2 remote sites;**



TEXAS STATE BOARD OF PHARMACY

**HB 2561 by Rep. Senfronia
Thompson/Sen. Van Taylor (cont.)**

- **The Board must adopt rules** that require:
 - A RPh employed by a provider phcy **make at least monthly on-site visits to a remote dispensing site** or more frequent visits if specified by Board rule;
 - The perpetual inventory of controlled substances at the remote site be **reconciled monthly** by a RPh employed by the provider pharmacy;



TEXAS STATE BOARD OF PHARMACY

**HB 2561 by Rep. Senfronia
Thompson/Sen. Van Taylor (cont.)**

- **The Board must adopt rules** that require:
 - A RPh employed by a provider pharmacy be physically present when providing services requiring the physical presence of the pharmacist, including immunizations;
 - A remote site be staffed by **an on-site pharmacy tech under the continuous supervision of a RPh;**



TEXAS STATE BOARD OF PHARMACY

**HB 2561 by Rep. Senfronia
Thompson/Sen. Van Taylor (cont.)**

- **The Board must adopt rules** that require:
 - **All pharmacy technicians at a remote site be counted** when establishing **the pharmacist/pharmacy technician ratio** of the provider phcy, which, **may not exceed 3 pharmacy technicians for each pharmacist;**



TEXAS STATE BOARD OF PHARMACY

**HB 2561 by Rep. Senfronia
Thompson/Sen. Van Taylor (cont.)**

- **The Board must adopt rules** that require:
 - **Before working at a remote site**, a pharmacy technician must have:
 - **Worked at least 1-year at a retail phcy** during the 3-years preceding the date the pharmacy tech begins working at the remote site; and
 - **Have completed a Board-approved training program** on the proper use of a telepharmacy system;



TEXAS STATE BOARD OF PHARMACY

**HB 2561 by Rep. Senfronia
Thompson/Sen. Van Taylor (cont.)**

- **The Board must adopt rules** that specify that:
 - A pharmacy tech **may not perform extemporaneous sterile or nonsterile compounding** but may prepare commercially available meds for dispensing, including the reconstitution of powder antibiotics; and
 - **Any additional training or practice experience for pharmacy techs at a remote site.**



TEXAS STATE BOARD OF PHARMACY

**HB 2561 by Rep. Senfronia
Thompson/Sen. Van Taylor (cont.)**

- **The bill specifies** that a telepharmacy system at a remote dispensing site **may not:**
 - **Dispense CII** controlled substances; and
 - **that** a telepharmacy system **may not be located within 22 miles** by road **of a Class A pharmacy.**
 - If a Class A pharmacy is established within 22 miles of a currently operating site, the remote site may continue to operate at that location.



TEXAS STATE BOARD OF PHARMACY

**HB 2561 by Rep. Senfronia
Thompson/Sen. Van Taylor (cont.)**

- The Act specified that **the Board by rule shall require and develop a process for a remote site to apply for a Class A phcy license IF the average number of Rxs dispensed each day** the remote dispensing site is open for business **is more than 125**, as calculated each calendar year.



TEXAS STATE BOARD OF PHARMACY

**HB 2561 by Rep. Senfronia
Thompson/Sen. Van Taylor (cont.)**

- **The bill adds** a new Sec. 481.0766 to the Texas Controlled Substances Act (TCSA) titled *“Reports of Wholesale Distributors”* to **require wholesalers to report to TSBP the sale of a controlled substance** made by the distributor to a person in this state.



TEXAS STATE BOARD OF PHARMACY

**HB 2561 by Rep. Senfronia
Thompson/Sen. Van Taylor**

- **The bill amends** the TCSA to require pharmacies to **send all required information for Schedule II – V prescriptions to the PMP not later than the next business day** after the date the prescription is completely filled.



TEXAS STATE BOARD OF PHARMACY

**HB 2561 by Rep. Senfronia
Thompson/Sen. Van Taylor (cont.)**

- **The bill amends the TCSA** to require **each regulatory agency** that issues a license, to a prescriber to promulgate **specific guidelines for prescribers** regulated by that agency for the **responsible prescribing of opioids, benzodiazepines, barbiturates, or carisoprodol.**



TEXAS STATE BOARD OF PHARMACY

**HB 2561 by Rep. Senfronia
Thompson/Sen. Van Taylor (cont.)**

- **The bill amends the TCSA** to specify that **after 9/1/2019**, a pharmacist or prescriber authorized to access the PMP, other than a veterinarian, **shall access** the PMP for the patient **before prescribing or dispensing:**
 - Opioids;
 - Benzodiazepines;
 - Barbiturates; or
 - Carisoprodol.



TEXAS STATE BOARD OF PHARMACY

Data from the PMP- FY2017

Controlled Substance Dispensed	# Rxs Dispensed	% of the 4 Controlled Substances Dispensed	% of ALL Controlled Substances Dispensed
Barbiturates	192,974	<1%	<1%
Benzodiazepines	8,308,209	31%	21%
Carisoprodol	528,543	2%	1%
Opioids	17,984,222	66%	45%
Total of Above Controlled Substances Dispensed	27,013,858		68%
Total of Other Controlled Substance Dispensed	12,405,658		32%
Grand Total of All Controlled Substance Dispensed	39,419,516		
BARBITURATES, BENZODIAZEPINES, CARISOPRODOL AND OPIOIDS REPRESENT <u>68% OF ALL CONTROLLED SUBSTANCES DISPENSED DURING THIS PERIOD</u>			

HB 2561 by Rep. Senfronia Thompson/Sen. Van Taylor (cont.)

- **The bill amends the TCSA** to specify that a:
 - A dispenser or prescriber **may access information of a patient** before dispensing or prescribing any controlled substance; and
 - A **veterinarian** may access the info for Rxs dispensed **only for the animals of an owner** and may not consider the personal Rx history of the owner.



TEXAS STATE BOARD OF PHARMACY

HB 2561 by Rep. Senfronia Thompson/Sen. Van Taylor (cont.)

- **The bill amends the TCSA** to specify that if a **prescriber or dispenser** violates the law related to the access of the PMP, **this action is grounds for disciplinary action** by the regulatory agency that issued a license to the person who committed the violation.



TEXAS STATE BOARD OF PHARMACY

**HB 2561 by Rep. Senfronia
Thompson/Sen. Van Taylor (cont.)**

- **The bill amends the TCSA** to specify that a **prescriber is not subject to the grounds for discipline** requirements **if the:**

- Patient has been diagnosed with cancer or the patient is receiving hospice care; and
- Prescriber clearly notes on the Rx that the patient was diagnosed with cancer or is receiving hospice care, as applicable.



TEXAS STATE BOARD OF PHARMACY

**HB 2561 by Rep. Senfronia
Thompson/Sen. Van Taylor (cont.)**

- **The bill amends the TCSA** to specify that a **dispenser** is not subject to the grounds for discipline requirements **if:**
- **It is clearly noted in the prescription** record that the patient has been diagnosed with cancer or is receiving hospice care.



TEXAS STATE BOARD OF PHARMACY

**HB 2561 by Rep. Senfronia
Thompson/Sen. Van Taylor (cont.)**

- **The bill amends the TCSA to specify** that a prescriber or dispenser is **not subject to the requirements mandatory lookup IF** the prescriber or dispenser **makes a good faith attempt to comply** but is unable to access PMP because of circumstances outside the control of the prescriber or dispenser.



TEXAS STATE BOARD OF PHARMACY

HB 2561 by Rep. Senfronia Thompson/Sen. Van Taylor (cont.)

- **The bill amends the Health and Safety Code** to add a new Chapter 442 titled "Donation Of Prescription Drugs."
- The new chapter specifies requirements for an individual to donate unused Rx drugs (dangerous drugs only) to a participating provider (health-care facility or pharmacy).



TEXAS STATE BOARD OF PHARMACY

HB 2561 by Rep. Senfronia Thompson/Sen. Van Taylor (cont.)



- The bill amends the education code to specify that:

The college **shall be known as** the Texas A&M University System Health Science Center Irma Lerma Rangel College of Pharmacy, and the primary building in which the school is operated **shall be located** in Kleberg County **and** must include "Irma Rangel" in its official name.



TEXAS STATE BOARD OF PHARMACY

Other Pharmacy Related Bills Passed by the Texas Legislature



TEXAS STATE BOARD OF PHARMACY

HB 1178
by Rep. Kuempel/Sen. Hinojosa

- **Effective Date: 9/1/2017.**
- **Increases** the penalty for stealing a controlled substance to a **felony** if the:
 - **Building in which a controlled substance is stored is a pharmacy**, clinic, hospital, or nursing facility; and
 - **Person entered or remained concealed in that building with intent to commit a theft of a controlled substance.**



TEXAS STATE BOARD OF PHARMACY

HB 1178
by Rep. Kuempel/Sen. Hinojosa (cont.)

- **Amends** the penal code to specify that an offense is a **state jail felony** if a controlled substance is taken, **regardless of the value of the controlled substance stolen.**



TEXAS STATE BOARD OF PHARMACY

**Texas Prescription
Monitoring Program**



TEXAS STATE BOARD OF PHARMACY

PMP AWA_xE

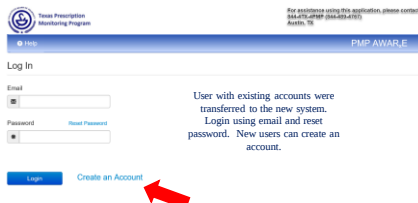
Go to the PMP Website:

texas.pmpaware.net

OR

Go to the TSBP Website:

www.pharmacy.texas.gov



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Novartis®

 Support: 888-874-4FMP (344-696-4767)

Patient Request

 [Patient Rx Request Tutorial](#)
 Click view the Novartis Patient Request Tutorial
** Indicates Required Field*

Patient Info

First Name*	Last Name*
☐ Partial Spelling	☐ Partial Spelling
Date of Birth*	
☐ MM/DD/YYYY	
Phone Number	

Prescription Fill Dates

No earlier than 3 years from today

From*	To*
12/18/2016	12/18/2017

Patient Location

Select pharmacy can be improved by including the address

Street Address

City State Province Zip Code

Select State

PMP Interconnect Search

[illegible]

Street Address

City State/Province Zip Code

PMP Interconnect Search
To search in other states as well as your home state for patient information, select the states you wish to include in your search.

A ☐ Alabama ☐ Arizona ☐ Arkansas
C ☐ Connecticut
I ☐ Idaho
K ☐ Kansas
L ☐ Louisiana
M ☐ Massachusetts ☐ Minnesota ☐ Mississippi ☐ Montana
N ☐ New Mexico ☐ New York ☐ North Dakota
O ☐ Oklahoma
P ☐ Pennsylvania
S ☐ South Carolina
T ☐ Tennessee

☒ I agree to the terms of the acknowledgment.

[Submit](#)

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Menu **Texas Doctor**

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Patient Report [Reflex Search](#)

Report Prepared: 12/18/2017
Date Range: 12/18/2016 – 12/18/2017

Test Patient

Summary

Prescriptions: 3
Prescribers: 4
Pharmacies: 3
Pharm. Fee: 0
Active Daily MRE: 18.487

Prescriptions

Id	Qty	Days	Prescriber	Pharmacy	MRE	Print Type	PMP					
07020017 1	07/10/2017	MOXAPRIL 200	MD TABLET	188.0	233	Al Tex	Unapp	Swatt	(1116)	0	Medicaid	TX
07040017 2	07/16/2017	LOXAZEPAM 2	MGML VIAL	811.0	923	Al Tex	vHapMedGAL20Hfmg	Swatt	(1116)	0	Medicaid	TX
07040017 2	07/13/2017	OLXZETINE HCL	DR 60 MG CAP	435.0	434	Ja Tex	ST71NUE3	Prodea	(4561)	0	Other	TX
07020017 3	07/10/2017	ACEZINAPAM 2	7.5-325	565.0	358	Ja Tex	vHapMedGAL20Hfmg	Swatt	(1116)	0	Medicaid	TX
07020017 2	07/14/2017	LOXAZEPAM 2	MGML VIAL	877.0	810	Ja Tex	vHapMedGAL20Hfmg	Prodea	(4561)	0	Medicaid	TX

*Pharmacy is created using a combination of pharmacy name and the last four digits of the pharmacy license number.

The CDC guidance, the conversion factors and associated daily morphine milligram equivalents for drugs prescribed as part of medication-assisted treatment for opioid use disorder should not be used to benchmark against dosage thresholds meant for opioids prescribed for pain.

Prescribers

Prescriptions

Id	Qty	Days	Prescriber	Pharmacy	MRE	Print Type	PMP					
07020017 2	07/14/2017	LOXAZEPAM 2	MGML VIAL	877.0	810	Ja Tex	vHapMedGAL20Hfmg	Prodea	(4561)	0	Medicaid	TX

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The CDC guidance, the conversion factors and associated daily morphine milligram equivalents for drugs prescribed as part of medication-assisted treatment for opioid use disorder should not be used to benchmark against dosage thresholds meant for opioids prescribed for pain.

Prescribers

Name	Address	City	State	Zip	Phone
TestPh, Alexander R			TX		(214)410555
TestPh, Alice C			TX		7485440020
TestPh, Jerry M			TX		8713017708
TestPh, Michael, Kelly P			TX		

Dispensaries

Pharmacy	Address	City	State	Zip	Phone
Prodea (Medicaid)	550 TANGLEWOOD DR	CARTERSVILLE	GA	30129	(201)552244
Prodea and State Test Pharmacy (1116)	8775 SOUTHAMPTON ROAD	RICHARDSON	TX	75080	
Swatt, Corner and Swatt Test Pharmacy (1116)	88 ANDOVER RD	FORNEY	TX	75126	

Pharmacy ID: 000 (Medicaid)

I understand that I must treat the information in the PMP system as confidential healthcare information in accordance with federal and state law. I understand that inappropriate access or disclosure of PMP information is a violation of federal and state law, and may result in disciplinary action, revocation of PMP database access, civil penalties, and/or criminal action. I understand the PMP administrator will conduct auditing activities to monitor for unusual or potentially unauthorized use of the system. The information in the PMP database and reports generated from the information may contain errors resulting from the information submitted by dispensers. The Texas State Board of Pharmacy recommends independent verification of the patient prescription information with pharmacies and prescribers where practical or necessary. The data available from other state Prescription Monitoring Programs is based on the data submitted by the dispensers in the specific state in accordance with their state's reporting requirements.

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PRESCRIPTION MONITORING PROGRAM FY2017 Quarterly Reports					
	1 st Quarter	2 nd Quarter	3 rd Quarter	4 th Quarter	Year-to-Date
Registered Users	43,227	5,494	4,773	5,148	58,642
Searches	800,041	982,602	1,113,526	1,279,436	4,175,605
Prescriptions Dispensed	10,123,585	10,092,111	9,856,895	9,346,925	39,419,516

[illegible]

Still valid prescription forms!

FIRST M LAST MD
123 SAMPLE ST
AUSTIN TX 78701
Phone # (512) 555-5555

CLEAR ID-MD-K00001S

[Barcode]

CTBL# R9024Z0001199

[Barcode]

Name _____
Address _____
Age or DOB _____ Date _____

R [Seal of The State of Texas]

"Practitioner Signature - Indicate if "Grav Medically Necessary"

Patient's Signature

No Name_____Date Filled_____
SECURITY FEATURES ON BACK

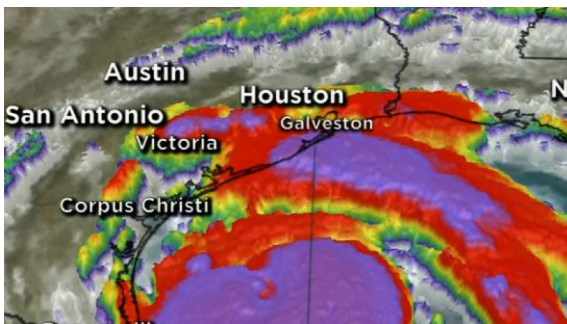
Texas Prescription Monitoring Program Facebook Page



www.facebook.com/TexasPMP/

The Texas PMP Facebook page will offer news and updates specific to the program.

Hurricane Harvey



Hurricane Harvey Statistics

	# Issued
Emergency Temporary Pharmacist Licenses	451
Emergency Remote Pharmacy Licenses	18
Emergency Temporary Pharmacy Technician Registrations	80



Final Reminders

- **Receiving Credit**
 - Look for the quiz and evaluation to be posted in your Lifelong Learning Account 5-7 days from now
 - An email notification will be sent to you when these are available
 - **You will have 30 days from the date they are posted to complete them.**
 - Complete these items to generate your certificate, which can be accessed at any time through your Lifelong Learning Account.

Trouble accessing your Lifelong Learning Account?

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1-800-215-0641

Select Option 1

Please note: This course is accepted by the Texas State Board of Pharmacy for both general credit and as fulfilling the law requirement. **However, it is NOT ACPE certified and will not appear in your CPE Monitor account.**



Thank You!

Thank you for your attendance!

If you have additional compliance-related questions, please call the TSBP Compliance Line at 512-305-8070.

For questions about today's presentation, please email us at:

educationcoordinator@pharmacy.texas.gov

