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

- **We will be using the *Chat* box to deliver general information.**
- **If you have questions, please use the *Q&A* box to submit.**
- **You may send all follow-up questions or handout requests to *educationcoordinator@pharmacy.texas.gov***
- **You do not need a microphone – just log in to watch and listen.**
- **We will be doing periodic sound checks before the presentation begins.**
  - Want to use your phone for audio?
    - Call 1-415-655-0003
    - Enter access code/event number for this webinar (found in the Event Info tab and will be posted in the "Chat" box pane)
  - ***Still having trouble? Call the help desk at any time during the presentation: 1-866-569-3239***
- **Receiving Credit**
  - Look for the quiz and evaluation to be posted in your Lifelong Learning Account 5-7 ***business*** days from now
    - An email notification will be sent to you when these are available
  - 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 STATE BOARD OF PHARMACY

Texas Pharmacy Law Update

Allison Vordenbaumen Benz, R.Ph., M.S.
Director of Professional Services

September 13, 2017

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.

TEXAS STATE BOARD OF PHARMACY

Board of Pharmacy Members

Jeanne D. Waggener, R.Ph.
President – Waco

Jenny Downing Yoakum, R.Ph.
Vice-President – Kilgore

Bradley A. Miller, Ph.T.R.
Treasurer – Austin

Buford T. Abeldt, Sr., R.Ph.
Lufkin

Christopher M. Dembny, R.Ph.
Richardson

L. Suzan Kedron
Dallas

Alice G. Mendoza, R.Ph.
Kingsville

Phyllis A. Stine
Abilene

Chip Thornsburg
San Antonio

Suzette Tijerina, R.Ph.
Castle Hills

Dennis F. Wiesner, R.Ph.
Austin

TEXAS STATE BOARD OF PHARMACY

Recently Adopted Rules

TEXAS STATE BOARD OF PHARMACY

Prescription Transfers

- Effective June 12, 2016.
- The transfer of prescriptions must be completed within 4 business hours of the request.

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.

TEXAS STATE BOARD OF PHARMACY

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.)

TEXAS STATE BOARD OF PHARMACY

Pharmacy Technician Continuing Education

- Effective Date: September 14, 2015. Amendments to §297.8 (Continuing Education) rules to:
  - Decrease the number of in-service hours from 10 to 5 hours;
  - Clarify the requirements for CE; and
  - Clarify the types of programs that count for continuing education.

TEXAS STATE BOARD OF PHARMACY

Board Rule 295.16

- Effective Date: January 1, 2016.
- Administration of Epinephrine by a Pharmacist
  - Allows a pharmacist to administer epinephrine, using an auto-injector, to a patient in an emergency situation.

TEXAS STATE BOARD OF PHARMACY

Board Rule 295.16 (cont.)

- A pharmacist:
  - May not receive remuneration for the administration of epinephrine but may seek reimbursement for the cost of the epinephrine auto-injector.
  - Who administers epinephrine through an auto-injector device is not liable for civil damages if the pharmacist acts in good faith and complies with Board rules.

TEXAS STATE BOARD OF PHARMACY

Home / News / Health / Bullard pharmacist saves patient's life thanks to new law

Bullard pharmacist saves patient's life thanks to new law

Published on Thursday, 17 March 2016 17:00 - Written by COSHANDRA ZILLIKS, czillks@tylerpaper.com

Like 28 Tweet Pin it Share 16

Pharmacist Elly Baker, pictured Thursday March 17, 2016, helped save a woman's life by administering an EpiPen, a device which stops life-threatening allergic reactions. (Sarah A. Miller/Tyler Morning Telegraph)

Bullard pharmacist Elly Baker saved a woman's life, thanks to a new law enacted in Texas earlier this year.

A customer walked in the Brookshire's pharmacy in Bullard with her husband on March 4, visibly in need of medical attention. She asked for allergy medicine.

"It was pretty clear that she needed more than Benadryl, because her eyes were swollen shut, and she had trouble breathing," Ms. Baker said.

The Bullard native grabbed an EpiPen and injected the medicine into the patient's thigh. Ms. Baker said the patient felt better soon after and could breath again. She monitored the woman for a while until the swelling had gone down, and she could breathe freely, as required. She then called 911, notified her physician and documented what happened.

Before, she would not have been able to legally administer the drug to a patient. In January, Texas legislators passed a law that allows a pharmacist to administer an epinephrine auto-injector to a patient in an emergency situation. It also provides liability protections for administering the drug.

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:

TEXAS STATE BOARD OF PHARMACY

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.

TEXAS STATE BOARD OF PHARMACY

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:

TEXAS STATE BOARD OF PHARMACY

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.

TEXAS STATE BOARD OF PHARMACY

Class A Pharmacy Library Requirements

- Effective Date: September 20, 2017
- Library requirements were amended to:
  - Delete specific references and the rule now reads:
    - At least one current or updated general drug information reference which is required to contain drug interaction information including information needed to determine severity or significance of the interaction and appropriate recommendations or actions to be taken; and

18

TEXAS STATE BOARD OF PHARMACY

Class A Pharmacy Library Requirements (cont.)

- A separate reference is not required if other references maintained by the pharmacy contain drug interaction information including information needed to determine severity or significance of the interaction and appropriate recommendations or actions to be taken;
- Add a new reference:
  - if the pharmacy dispenses veterinary prescriptions, 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 tech. must pay a renewal fee that is equal to **1½ times** the renewal fee;
  - > than 90 days, but < 1 year, the tech. must pay a renewal fee that is **2 times** the renewal fee;
  - 1 year or >, the tech. **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.
  - **Be located within 25 miles**, by road, **of a Class A pharmacy.**
    - Except if a Class A pharmacy is established within 25 miles of a remote dispensing site that is currently operating, the remote dispensing site may continue to operate at that location.

TEXAS STATE BOARD OF PHARMACY

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

- **The bill specifies that** a telepharmacy system located at a remote site in a county with a population of at least 13,000 but not more than 14,000 **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 specifies** that a **provider pharmacy may not provide remote services if** a Class A or C pharmacy is located in the same community. A community is defined as:
  - The census tract where the remote site is located, if the remote site is located in a Metropolitan Statistical Area as defined by the US Census Bureau in the most recent U.S. Census; or
  - Within 10 miles of the remote site, if the remote site is not located in a MSA.

TEXAS STATE BOARD OF PHARMACY

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

- **The bill adds** a new Sec. 481.0764 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 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

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 in 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

SB 1633
by Sen. Perry/ Rep. Oliverson

NOTE: These provisions are also contained in the HB 2561

- **Effective Date:** Takes effect immediately on signature of the Governor. **The Board shall adopt rules no later than 1/1/2018.**

TEXAS STATE BOARD OF PHARMACY

Texas Prescription Monitoring Program

TEXAS STATE BOARD OF PHARMACY

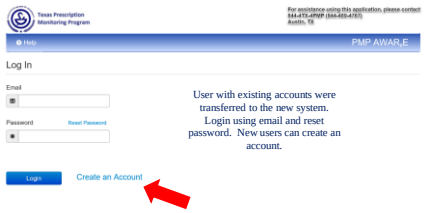
PMP AWARxE

Go to the PMP Website:
texas.pmpaware.net

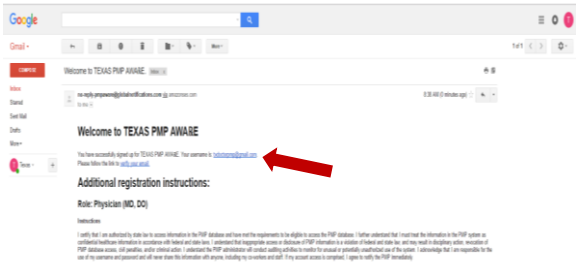
OR

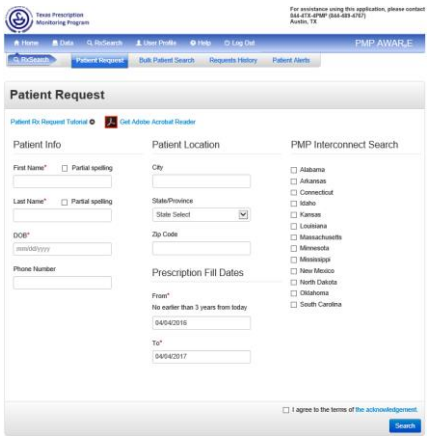
Go to the TSBP Website:
www.pharmacy.texas.gov

TEXAS STATE BOARD OF PHARMACY



User with existing accounts were transferred to the new system. Login using email and reset password. New users can create an account.



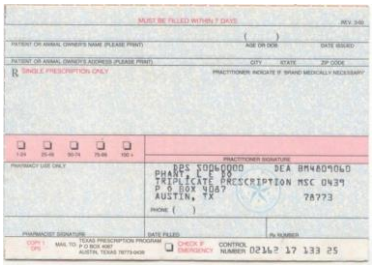


Data from the PMP from 1/2017 through 7/2017			
Controlled Substance Dispensed	# Rxs Dispensed	% of the 4 Controlled Substances Dispensed	% of ALL Controlled Substances Dispensed
Barbiturates	219,430	<1%	<1%
Benzodiazepines	9,490,800	31%	21%
Carisoprodol	603,378	2%	1%
Opioids	20,559,108	68%	45%
Total of Above Controlled Substances Dispensed	30,269,338		67%
Total of Other Controlled Substance Dispensed	14,932,684		33%
Grand Total of All Controlled Substance Dispensed	45,202,022		
BARBITURATES, BENZODIAZEPINES, CARSIPRODOL AND OPIOIDS REPRESENT *67% OF ALL CONTROLLED SUBSTANCES DISPENSED* DURING THIS PERIOD			

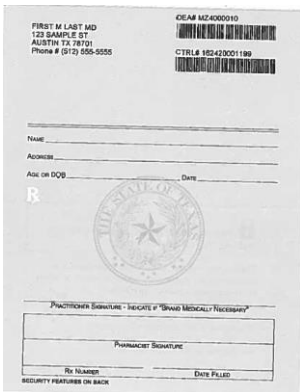
Texas Prescription Monitoring Program Facebook Page

www.facebook.com/TexasPMP/

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

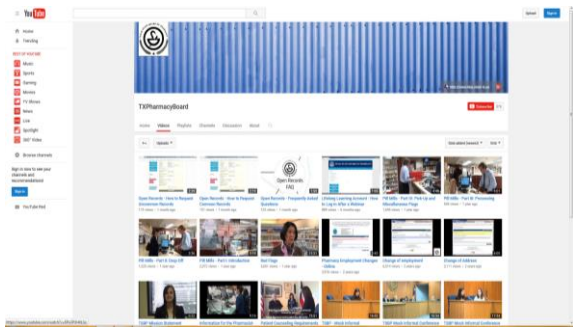


Still valid prescription forms!



facebook
Texas State Board of Pharmacy
Government Organization
FDA Requires Class-Wide Labeling Changes for Immu...
Drug Disposal Information - National Take-Back Initi...

TX Pharmacy Board


TXPharmacyBoard

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?
Questions about your attendance?
Call the help desk:
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.***

TEXAS STATE BOARD OF PHARMACY

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

TEXAS STATE BOARD OF PHARMACY