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

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TEXAS STATE BOARD OF PHARMACY

Texas Pharmacy Law Update

Allison Vordenbaumen Benz, R.Ph., M.S.
Director of Professional Services
February 23, 2017

TEXAS STATE BOARD OF PHARMACY

Goals

- Review recent changes to pharmacy rules;
- Review the most common Warning Notices Issued to Pharmacies;
- Review pharmacy related legislation passed by the 2015 Legislature; and
- Review some current issues facing the Board.

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Recently Adopted Rules

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Grounds for Discipline

- Effective Date: December 6, 2015.
- It is a ground for discipline of a pharmacist or pharmacy technician if the individual exhibits abusive, intimidating, or threatening behavior toward a board member or employee during the performance of a member's or employee's lawful duties.

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Grounds for Discipline

- Effective Date: March 10, 2016.
- It is a ground for discipline of a pharmacy license if the owner, managing officer(s), or other pharmacy employee(s) exhibits abusive, intimidating, or threatening behavior toward a board member or employee during the performance of a member's or employee's lawful duties.

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Grounds for Discipline

- Effective September 11, 2016
- Implement provisions of SB 460
- It is a ground for discipline of a pharmacy license if the pharmacy waives, discounts, or reduces, or offers to waive, discount, or reduce, a patient copayment or deductible for a compounded drug in the absence of:

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Grounds for Discipline

- a legitimate, documented financial hardship of the patient; or
- evidence of a good faith effort to collect the copayment or deductible from the patient.

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Pharmacist-in-Charge

- Effective Date: December 6, 2015.
- A pharmacist-in-charge (PIC) of a Class A Pharmacy may not also be the PIC of a:
  - Class B Pharmacy; or
  - Class C Pharmacy in a hospital with 101 beds or more.

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Administration of Immunizations and Vaccines

- Effective Date: December 6, 2015.
- Before preparing an immunization/vaccine **and** between each patient contact:
  - Pharmacist must:
    - cleanse their hands with an alcohol-based waterless antiseptic hand rub; or
    - wash their hands with soap and water.
  - If gloves are worn, pharmacists must change gloves between patients.

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Prescription Transfers

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

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Pharmacists and Pharmacy Technicians

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Pharmacy Technician's 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.

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Licensing Fee Changes

License	Renewal Fee Effective October 1, 2015	Change
Pharmacist	$276	$25 decrease
Pharmacies	$452	$80 decrease
Pharmacy Technicians	$77	$19 decrease
Pharmacy Technician Trainees	$52	$10 decrease

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Conditions Receiving "Warning Notices" FY2015

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Number of Inspections

Class	FY2015	% of FY2015 Inspections
Class A Pharmacies	2,275	76%
Class A-S	144	5%
Class B Pharmacies	5	<1%
Class C Pharmacies	268	9%
Class C-S	128	4%
Class D Pharmacies	95	3%
Class F Pharmacies	61	2%
Class G Pharmacies	15	<1%
Totals	2,991	100%

Warning Notices

Class	# Pharmacies Receiving WN	% Receiving WN
Class A	992	77%
Class A-S	84	6%
Class B	2	<1%
Class C	80	6%
Class C-S	87	7%
Class D	31	2%
Class F	17	1%
Class G	0	N/A
Totals	1,293	100%

Most Common Warning Notices (All Classes of Pharmacy)

Violation	Number of WN Issued*
Records	731
Sterile Preparations	647
Pharmacy Technicians	564
Drug/Stock Environment	421
Prescriptions	335
Inventory	319

* One pharmacy may receive multiple Warning Notice violations.

Most Common Warning Notices (All Classes of Pharmacy) cont.

Condition	Number of WN Issued	Total
Records		**731**
Records Not Available	314	
Absence of R.Ph. Record	66	
Rx Not Separated	17	
Rx Records Not Numerical Order	25	
Improper Transfer of RX copies	3	
Invoices Not Separated/Retrievable	122	
Records for Non-Sterile Compounds	169	
No Written Information on RX	10	

Most Common Warning Notices (All Classes of Pharmacy) cont.

Condition	Number of WN Issued	Total
Sterile Preparations		**647**
No/Incomplete QA/QC	99	
No/Incomplete P&P Manual	237	
No/Inadequate Preparation Area	165	
IV Preparation	131	
No DUR	13	
Cytoxic/Bio Procedures	2	

Most Common Warning Notices (All Classes of Pharmacy) cont.

Condition	Number of WN Issued	Total
Pharmacy Technicians		**564**
No/Incomplete Training	510	
No/Improper Supervision	19	
Improper Registration	29	
No Name Tags	6	

Most Common Warning Notices (All Classes of Pharmacy) cont.

Condition	Number of WN Issued	Total
Drug Stock/Environment		**421**
Improper Environment	137	
Out-of-Date Drug Stock	158	
Security	65	
Unsanitary	32	
Improper Drug Storage	20	
Area for Non-Sterile Compounding	7	
Violation of Limited Formulary	2	

Most Common Warning Notices (All Classes of Pharmacy) cont.

Condition	Number of WN Issued	Total
Prescriptions		**335**
Lack Proper Information	159	
Prescription Label Incorrect	136	
Official Rx Non-Compliance	40	

Most Common Warning Notices (All Classes of Pharmacy) cont.

Condition	Number of WN Issued	Total
Inventory		**319**
No Annual Inventory	84	
No Change of Ownership Inventory	5	
No Change of PIC Inventory	35	
Incomplete Inventory	194	
Improper Drug Destruction	1	

Violations NOT Resulting in Warning Notices

- Individuals performing technician duties without an active registration.
- Technicians performing technician duties with no pharmacist on site.
- Technicians performing pharmacist-only duties with no pharmacist on site (results in emergency temporary suspension hearing).
- Pharmacists who do not verbally counsel a patient on a new prescription.

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Violations NOT Resulting in Warning Notices

- Pharmacy is not able to produce 2 consecutive annual inventories.
- PIC falsifies response to a Warning Notice.
- Pharmacies dispensing/shipping prescription drugs into other states without holding a pharmacy license in that state.
- Pharmacies compounding sterile preparations without proper licensure (e.g., Class A who should have a Class A-S pharmacy license).

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Violations NOT Resulting in Warning Notices

- Egregious Conditions
  - Dispensing CIIs pursuant to prescriptions not issued on an Official Form;
  - Excessive quantity of out-of-date stock (i.e., more than 25% of the inventory);
  - Pharmacy closed and did not notify TSBP of closing;
  - Operating without a PIC for an extended period of time (i.e., 3 months or more).

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Violations NOT Resulting in Warning Notices

- Continuing threat – For example:
  - Impaired pharmacist on duty; or
  - Sterile compounding pharmacies who have extensive non-compliance with Board Rule 291.133 and will not voluntarily agree to *"cease and desist"* sterile compounding until conditions have been corrected.
- Both of these scenarios would result in an Emergency Temporary Suspension Hearing.

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Pharmacy Related Legislation Passed by the 2015 Legislature

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S.B. 195 by Sen. Schwertner

- This bill:
- Moves the Prescription Monitoring Program from the Department of Public Safety (DPS) to the Board of Pharmacy; and
- Eliminates the Texas Controlled Substance Registration program.

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Timeline for Transfer of the PMP Program

- **November 2015** – RFP for the new PMP issued by TSBP.
- **January 2016** – **Appriss selected as the vendor.**
- **February – May 2016** – System installation at TSBP.
- **May/June 2016** –Testing of program.
- **September 1, 2016** – NEW PMP goes live.

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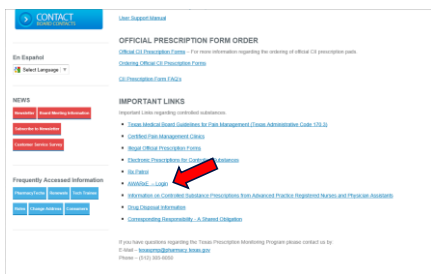
Pharmacies submit data to AWARxE through Clearinghouse.



PMP AWARxE

- Login to website:
- texas.pmpaware.net

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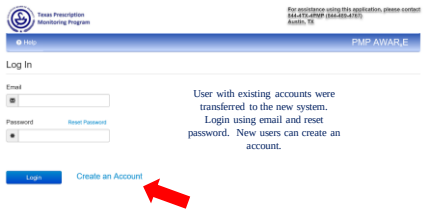


User with existing accounts were transferred to the new system. Login using email and reset password. New users can create an account.

Quick Reference Guide – Making a Request in PMP AWARxE

1. Go to the PMP AWARxE login page (https://texas.pmpaware.net/login). *If a password reset is needed, use the **"Reset Password"** link.*

2. Once you're logged in, select the **RxSearch** tab, then choose **Patient Request**.

3. Enter search criteria.

At a minimum, you must provide:

- ***First name*** (full or partial*)
- ***Last name*** (full or partial*)
- ***Date of birth*** (must be in MM/DD/YYYY format)
- ***Prescription fill dates*** (must be in MM/DD/YYYY format)

4. Click ***Search*** at the bottom of the screen to submit your request.

5. Matching patient history will now display. If ***multiple patients*** are identified, you will be presented with the option to ***refine your search*** by providing additional search information or you can select a ***single, multiple, or all returned patient groups*** to include in your patient prescription request results.

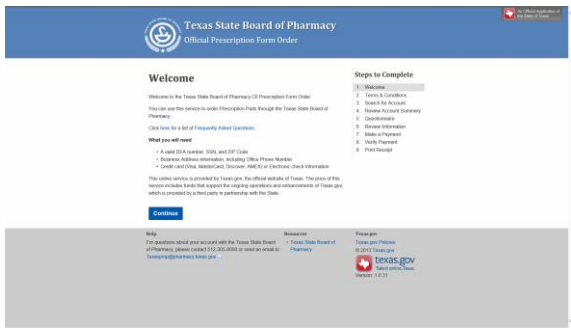
6. Click on "**Run Report**", the patient prescription results will be displayed.

7. Print form by clicking on the PDF button or convert the form to a CSV (Microsoft Excel) file. You may retrieve your searches and the search results of any delegates by clicking on the **Requests History** tab.

Search Tips:

- ***Partial Spelling**: Using Partial Spelling can be helpful for hyphenated or commonly abbreviated names (Will vs. William). At a minimum, enter the first three characters of the patient's first and/or last name.
- ***Prescription Fill Dates*** - The maximum time period for your search is 36 months.
- ***PMP Interconnect Search*** - allows you to search other participating state databases for the patient's records. Select all that apply.
  - To improve the likelihood of finding a specific patient:
    - For out-of-state searches - Limit your search criteria to only the required fields.
    - For in-state searches – In addition to the required fields, include as many details as possible (such as address, city, state and/or ZIP code).

Prescription forms, including triplicate forms, issued by DPS prior to 9/1/16 remain valid.



Texas Prescription Monitoring Program Facebook Page

www.facebook.com/TexasPMP/

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

H. B. 1550 by Zerwas/Kolkhorst

- Effective Date: 9/1/2015.
  - Rules adopted by the Board in February 2016.
    - §295.16 Administration of Epinephrine by a Pharmacist.
- This bill amends the Pharmacy Act to:
  - Allow a pharmacists to administer epinephrine, using an auto-injector, to a patient in an emergency situation.

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H. B. 1550 by Zerwas/Kolkhorst (cont.)

- This bill amends the Pharmacy Act to:
  - Specify 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.

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Bullard pharmacist saves patient's life thanks to new law

Published on Thursday, 17 March 2016 17:55 - Written by CORNANDRA DILLARD, cdillard@tylerpaper.com

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Pharmacist Elly Baker, pictured Thursday March 17, 2016, helped save a woman's life by administering an EpPen, 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 EpPen 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.

Current Issues

TEXAS STATE BOARD OF PHARMACY

Sunset Review

- Texas Pharmacy Act, Sec. 551.005. Application of Sunset Act.
  - The Texas State Board of Pharmacy is subject to Chapter 325, Government Code (Texas Sunset Act). Unless continued in existence as provided by that chapter, the board is abolished and this subtitle expires September 1, 2017.

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Sunset Recommendations

- The Texas State Board of Pharmacy has established itself as a well-run agency capable of effectively responding to new regulatory issues and legislative mandates within its limited resources.
- Absent major problems with the board's basic duties, Sunset staff focused on the prescription drug abuse epidemic facing the country, which claimed 23,000 lives nationally in 2013 and was a constant backdrop to the review.

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Sunset Recommendations (cont.)

- Staff closely evaluated the board's new role over the Prescription Monitoring Program, the state's key tool for keeping track of the more than 11 million prescriptions distributed in Texas each year for highly addictive drugs such as Vicodin, Xanax, and OxyContin.

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Sunset Recommendations (cont.)

- ***Issue 1* – Key Recommendations**
  - Beginning in 2018, require pharmacists to search the Prescription Monitoring Program database before dispensing certain controlled substances.
  - Require pharmacists to enter dispensing information in the Prescription Monitoring Program database within one business day of dispensing controlled substances.

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Sunset Recommendations (cont.)

- Authorize the board to send push notifications and to set related thresholds.
- Direct the board to create delegate accounts for pharmacy technicians, work to integrate the program with pharmacy software systems, and make trend data on dispensing publicly available.

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Sunset Recommendations (cont.)

- ***Issue 2* – Key Recommendations**
  - Require the board to create a system of graduated penalties for late renewal of pharmacy technician registration.
  - Authorize the board to deny renewal applications for licensees and registrants who are noncompliant with an existing board order.
  - Direct the board to remove burdensome requirements that pharmacy licensure renewal forms be notarized.
  - Direct the board to query a national disciplinary database before license renewal.

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Sunset Recommendations (cont.)

- ***Issue 3* – Key Recommendations**
  - Continue the Texas State Board of Pharmacy for 12 years.
  - The board should develop and implement a succession plan to prepare for impending retirements.

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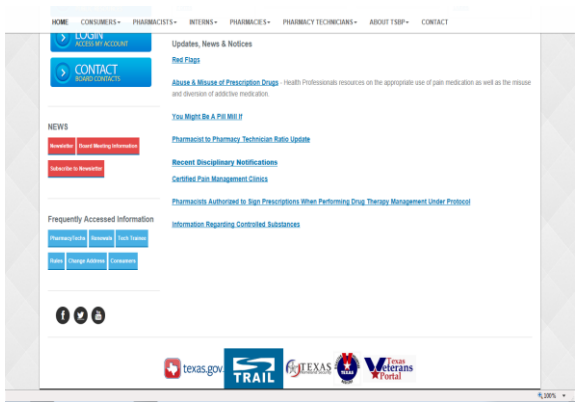
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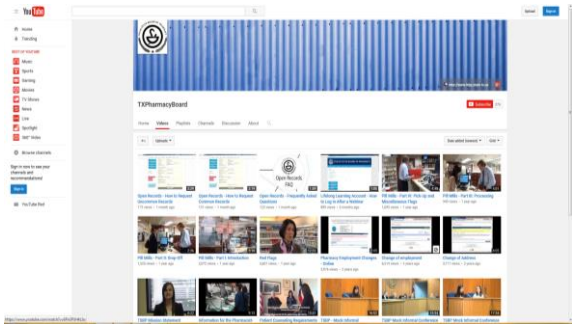

Final Reminders

- **Receiving Credit**
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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

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