

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

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## Texas Pharmacy Law Update

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Director of Professional Services  
May 19, 2016




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### 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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### 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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### 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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### Rules Adopted by the Board at the May 3, 2016 Meeting

- Will become effective in late May or early June 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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### Pharmacist's Continuing Education

- Effective Date: March 17, 2013.
- Pharmacists can receive credit for programs approved by AMA as Category 1 CME.
- Pharmacists must report 1-hour of CE related to Texas Pharmacy Laws or Regulations on renewals received after 1/1/15.




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### Pharmacy Technician's Continuing Education

- Effective Date: June 12, 2013.
- Pharmacy Technicians must report 1-hour of CE related to Texas Pharmacy Laws or Regulations on renewals received after 1/1/15.




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### Pharmacy Technician's Continuing Education (cont.)

- 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%

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### 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%

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### 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.

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

Condition	Number of WN Issued	Total
<b>Records</b>		<b>731</b>
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	

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

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

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

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

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

Condition	Number of WN Issued	Total
<b>Drug Stock/Environment</b>		<b>421</b>
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	

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

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

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

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

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**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 CII's 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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## Current Issues




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## 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 Review Time Line

- August 2015.
  - TSBP prepares a Self-Evaluation Report.
- October 2015 – March 2016.
  - Sunset staff reviews the agency.
- Late March 2016.
  - Sunset's confidential report issued followed by a joint meeting with TSBP to discuss recommendations, followed by Sunset's formal request for agency written response.




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