

Texas State Board of Pharmacy

Laws and Rules Update

Webinar FAQs and Troubleshooting Tips

- **Test your sound – We will be doing periodic sound checks before the presentation begins.**
 - If you do not have sound:
 - Click the Quick Start tab
 - Click “Communicate”
 - Then click “Audio Conference”
 - Select “Use Phone” to call in by telephone

***Still having trouble? Call the helpdesk 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 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 Pharmacy Law Update

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

August 20, 2015



TEXAS STATE BOARD OF PHARMACY

Goals

- Review recent changes to pharmacy rules;
- Review the most common Warning Notices Issued to Class A and Class C Pharmacies; and
- Review pharmacy related legislation passed by the 2015 Legislature.



Board of Pharmacy Members

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

Buford T. Abeldt, Sr., R.Ph. –
Vice President - Lufkin

Christopher M. Dembny,
R.Ph. – Treasurer -
Richardson

W. Benjamin Fry, R.Ph.,
FIACP, FACA – San Benito

L. Suzan Kedron – Dallas

Alice G. Mendoza, R.Ph. –
Kingsville

Bradley A. Miller, Ph.T.R. –
Austin

Phyllis A. Stine – Abilene

Joyce Tipton, R.Ph., MBA
– Houston

Dennis F. Wiesner, R.Ph.
– Austin

Charles F. Wetherbee –
Boerne





Class A Pharmacies



TEXAS STATE BOARD OF PHARMACY

Patient Counseling Regulations

- Effective Date: December 7, 2014.
- Patient counseling must be provided to **new and existing patients** of a pharmacy **with each new prescription drug order.**
- A new prescription drug order is **one that has not been dispensed by the pharmacy to the patient in the same dosage and strength within the last year.**



Patient Counseling Regulations (cont).

- Written information may now be provided to the patient in an electronic format, such as by e-mail, if:
 - The patient or patient's agent requests the information in an electronic format; and
 - The pharmacy documents the request.



Patient Counseling Regulations (cont).

- **Eliminated** the requirement for a pharmacy to:
 - Offer counseling on a refill prescription; and
 - Post a sign that said "*Do you have questions about your prescription? Ask the pharmacist.*"



Transfer of Prescription Information

- Effective Date: December 7, 2014.
- Updated the transfer regulations to allow for the:
 - Electronic transfer of records;
 - Electronic transfer of multiple or bulk prescription records between two pharmacies; and
 - Match DEA's regulations.



Class C Pharmacy Regulations



TEXAS STATE BOARD OF PHARMACY

Number of Beds in a Hospital

- Effective Date: December 7, 2014
- Number of Beds – The total number of beds is determined by the number of:
 - Beds that the hospital is licensed for by the Texas Department of State Health Services; or
 - Inpatients admitted during the previous calendar year divided by 365 (or 366 if the previous calendar year is a leap year).



Pharmacists and Pharmacy Technicians



TEXAS STATE BOARD OF PHARMACY

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.



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.



Conditions Receiving "Warning Notices" FY2014



TEXAS STATE BOARD OF PHARMACY

Number of Inspections

Class	FY2014	% of FY2014 Inspections
Class A Pharmacies	1,181	69%
Class A-S	4	<1%
Class B Pharmacies	3	<1%
Class C Pharmacies	447	26%
Class C-S	4	<1%
Class D Pharmacies	57	3%
Class F Pharmacies	5	<1%
Class G Pharmacies	5	<1%
Totals	1,706	100%



Warning Notices

Class	# Phcys Receiving WN	% Receiving WN
Class A	537	61%
Class A-S	3	<1%
Class B	0	N/A
Class C	316	36%
Class C-S	4	<1%
Class D	18	2%
Class F	2	<1%
Class G	0	N/A
Totals	880	100%



Most Common Warning Notices (All Classes of Pharmacy)

Violation	Number of WN Issued*	% of Total WN
Sterile Product	855	29%
Pharmacy Technician	398	14%
Records	273	9%
Drug Stock/Environment	272	9%
Prescriptions	160	5%
Inventory	156	5%
OBRA	152	5%

* One pharmacy may receive multiple Warning Notice violations.



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

Condition	Number of WN Issued	Total
Sterile Product		855
No/Incomplete QA/QC	140	
No/Incomplete P&P Manual	128	
No/Inadequate Preparation Area	370	
IV Preparation	196	
No DUR	14	
Cytotoxic/Bio Procedures	7	



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

Condition	Number of WN Issued	Total
Pharmacy Technicians		398
No/Incomplete Training	367	
No/Improper Supervision	10	
Improper Registration	16	
No Name Tags	5	



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

Condition	Number of WN Issued	Total
Records		273
Records Not Available	90	
Absence of R.Ph. Record	15	
Rx Not Separated	7	
Rx Records Not Numerical Order	5	
Improper Transfer of RX copies	5	
Invoices Not Separated/Retrievable	52	
Records for Non-Sterile Compounds	77	
No Written Information on RX	22	



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

Condition	Number of WN Issued	Total
Drug Stock/Environment		272
Improper Environment	101	
Out-of-Date Drug Stock	83	
Security	36	
Unsanitary	30	
Improper Drug Storage	16	
Area for Non-Sterile Compounding	2	
Violation of Limited Formulary	4	



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

Condition	Number of WN Issued	Total
Prescriptions		160
Lack Proper Information	77	
Prescription Label Incorrect	68	
Official Rx Non-Compliance	15	



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

Condition	Number of WN Issued	Total
Inventory		156
No Annual Inventory	47	
No Change of Ownership Inventory	6	
No Change of PIC Inventory	32	
Incomplete Inventory	68	
No Perpetual inventory (Class C)	2	
Improper Drug Destruction	1	



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

Condition	Number of WN Issued	Total
OBRA		152
Written Information Not Provided	22	
No Patient Counseling	117	
PMR Absent or Incomplete	13	



Pharmacy Related Legislation Passed by the 2015 Legislature



TEXAS STATE BOARD OF PHARMACY

S.B. 195 by Sen. Schwertner

- Effective Date: 6/20/2015 for some provisions and 9/1/2016 for others.
- This bill:
 - Allows the Board, on or after 6/20/2015 to :
 - Adopt rules to implement the PMP and certain other provisions related to prescriptions in the Controlled Substances Act.
 - Sign a contract with a vendor to operate the PMP.
 - Call a meeting of the Prescription Monitoring Work Group.



S.B. 195 by Sen. Schwertner (cont.)

- Effective 9/1/2016:
 - The Board may establish a program to fund the Prescription Monitoring Program (PMP) through a surcharge on the license fees of persons authorized to access the PMP.
 - The PMP is transferred from the DPS to TSBP.
 - The Controlled Substance Registration program is abolished.



S.B. 460 by Sen. Schwertner

- Effective Date: 9/1/2015.
- This bill amends the Pharmacy Act to:
 - Allow a pharmacy to notify consumers how to file a complaint using an electronic messaging system.
 - Allow the Board to inspect financial records relating to the operation of a pharmacy only in the course of an investigation of a specific complaint.



S.B. 460 by Sen. Schwertner (cont.)

- Amends the Pharmacy Act to:
 - Eliminate the Generic Substitution Sign and modify the requirement for the Complaint Notification to allow electronic posting;
 - Require a pharmacy to file an application to change location at least 30-days prior to the move; and
 - Specify that a pharmacy license may not be renewed if it has expired for 91 days or more.



S.B. 460 by Sen. Schwertner (cont.)

- Amends the Pharmacy Act for Class E Pharmacies to:
 - Allow the Board to discipline the pharmacy if it has been disciplined in their state.
 - Prohibit a person from owning the pharmacy if their RPh license was revoked, suspended, restricted, surrendered in another state.
 - Require the pharmacy to have a Texas licensed pharmacist serve as the PIC for the Texas license.



S.B. 1462 by Sen. Royce West

- Effective Date: 9/1/2015.
- This bill adds a new Subchapter E. Opioid Antagonist to the Dangerous Drug Act that:
 - Allows Drs to prescribe/issue a standing order for an opioid antagonist, without risk of discipline, 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.



S.B. 1462 by Sen. Royce West (cont.)

- Allows a R.Ph. who dispenses or does not dispense an opioid antagonist under a valid Rx is not subject to criminal/civil liability or disciplinary action for:
 - dispensing or failing to dispense the opioid antagonist; or
 - if the R.Ph. dispenses an opioid antagonist, any outcome resulting from the eventual administration of the opioid antagonist.



H.B. 751 by Rep. Zerwas

- Effective Date: 9/1/2015.
- The bill allows the substitution of interchangeable biological products.
- Interchangeable biological products are those rated equivalent by FDA (Purple Book).



H.B. 751 by Rep. Zerwas (cont.)

- The bill specifies that not later than the 3rd business day after dispensing the R.Ph. must “communicate” to the prescribing Dr. the name of the product provided and the manufacturer or NDC number.



H.B. 751 by Rep. Zerwas (cont.)

- Notification is not required if:
 - There is no interchangeable biological product approved by FDA; or
 - A refill prescription is not changed from the product dispensed on the prior dispensing.
- The notification section of the bill expires on 9/1/2019.



H. B. 1550 by Zerwas/Kolkhorst

- Effective Date: 9/1/2015.
- This bill amends the Pharmacy Act to:
 - Allow a RPhs to administer epinephrine using an auto-injector to a patient in an emergency situation.
 - Specify a RPh may not receive remuneration for the administration of epinephrine but may seek reimbursement for the cost of the epinephrine auto-injector.



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

- This bill amends the Pharmacy Act to:
 - Specify that a R.Ph. 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.



SB 1462 by Senator West

- Effective Date: 9/1/2015.
- The bill amends the Dangerous Drug Act to allow Drs to prescribe/issue a standing order for an opioid antagonist, without risk of discipline, to a:
 - Person at risk of an opioid-related overdose; or
 - Family member, friend, or other person in a position to assist a person at risk of experiencing an opioid-related drug overdose.



SB 1462 by Senator West (cont.)

- Specifies a R.Ph. who dispenses or does not dispense an opioid antagonist under a valid Rx is not subject to criminal/civil liability or disciplinary action for:
 - Dispensing or failing to dispense the opioid antagonist; or
 - If the R.Ph. dispenses an opioid antagonist, any outcome resulting from the administration of the opioid antagonist.



SB 1243 by Sen. Burton

- Effective Date: 1/1/16.
- This bill establishes a Prescription Drug Donation Pilot Program in the DSHS.
- The Program must be established in one or more cities with a population of more than 500,000 but less than one million.



SB 1243 by Sen. Burton (cont.)

- A Dr., Phcy. Nursing Home, Mfr, etc., may donate non-controlled Rx drugs to DSHS.
- The donated drugs may be provided or administered to patients only by a:
 - Charitable medical clinic;
 - Dr's office for patients who receive assistance from an indigent health care program; or
 - Licensed health care professional in a penal institution.



SB 1243 by Sen. Burton (cont.)

- DSHS must establish and maintain an electronic database which:
 - Lists the name and quantity of each drug donated to DSHS under the program; and
 - Allows a charitable medical clinic, physician, or other licensed health care professional to search for and request drugs.



SB 1243 by Sen. Burton (cont.)

- The entity providing or administering the drug may charge a nominal handling fee in an amount prescribed by DSHS rule.
- DSHS must adopt rules for by 12/1/2015.



S.B 1697 by Sen. Huffman

- Effective Date: 9/1/2015.
- The bill makes identifying information of:
 - Any person who participates in an execution procedure; and
 - Any person or entity that manufactures, compounds, prescribes, dispenses, or provides a substance or supplies used in an execution.



New Look for the TSBP Website

www.pharmacy.texas.gov



TEXAS STATE BOARD OF PHARMACY



TEXAS STATE BOARD OF PHARMACY

- HOME
- CONSUMERS ▾
- PHARMACISTS ▾
- INTERNS ▾
- PHARMACIES ▾
- PHARMACY TECHNICIANS ▾
- ABOUT TSBP ▾
- CONTACT ▾

[Hydrocodone Combination Products Now Schedule II](#)

Categories

- Pharmacy Laws / Rules
- TSBP Educational Programs
- Training/Informational Videos
- License Renewals
- Change of Address / Employment
- Open Records Requests
- Complaint Process



Pharmacists



Pharmacists

- [Apply for License](#)
- [Renew License](#)
- [Forms](#)

Interns



Interns

- [Apply- Student Application](#)
- [Apply- Extended Application](#)

Pharmacies



Pharmacies

- [Apply for License](#)
- [Update License](#)

Technicians



Technicians

- [Apply for License](#)
- [FAQs](#)
- [Duties](#)

The [Texas State Board of Pharmacy](#) is the state agency responsible for the licensing/registration of Texas pharmacists, pharmacy technicians, and pharmacies; for establishing regulations for pharmacy practice; and for disciplining licensees and registrants. Look here for information about the Board's [mission](#), [Compact with Texans](#), [policies and guidelines](#), [members](#), [staff](#), [public information reports](#), [statutes](#), [meeting agendas](#), [calendar of events](#) and more.

Updates, News & Notices

[Board Issues PDMP Request for Information](#)

[Ebola Resources](#)

[DEA Finalizes Rule to Schedule Tramadol](#)

[VERIFICATIONS](#)
CHECK LICENSE STATUS

[CONSUMERS](#)
PUBLIC RESOURCES

[LOGIN](#)
ACCESS MY ACCOUNT

[CONTACT](#)
BOARD CONTACTS



TEXAS STATE BOARD OF PHARMACY

- HOME
- CONSUMERS ▾
- PHARMACISTS ▾
- INTERNS ▾
- PHARMACIES ▾
- PHARMACY TECHNICIANS ▾
- ABOUT TSBP ▾
- CONTACT ▾

Categories

- Pharmacy Laws / Rules
- TSBP Educational Programs
- Training/Informational Videos
- License Renewals
- Change of Address / Employment
- Open Records Requests
- Complaint Process

TSBP Continuing Education Programs

NEED YOUR TEXAS PHARMACY LAW CE CREDIT?

Continuing education (CE) programs provided by TSBP meet the Texas pharmacy law CE requirement for both pharmacists and pharmacy technicians. In addition, ACPE-approved programs covering Texas pharmacy laws or rules will also satisfy the requirement.

WHO CAN TAKE TSBP'S COURSES?

Both pharmacists and pharmacy technicians may attend CE programs hosted by TSBP. Once your Texas pharmacy law credit has been completed, you can continue to attend TSBP hosted programs for general credit.

EXAMPLE: If you are a pharmacy technician, you may still take a Pharmacist-in-Charge training and count it toward your Texas pharmacy law CE credit. If you've already completed your Texas pharmacy law CE, you may count the course as general CE credit.

Please visit the [Catalog Page](#) for upcoming CE courses.

[TSBP Educational Videos](#)





TEXAS STATE BOARD OF PHARMACY

[HOME](#) [CONSUMERS](#) [PHARMACISTS](#) [INTERNS](#) [PHARMACIES](#) [PHARMACY TECHNICIANS](#) [ABOUT TSBP](#) [CONTACT](#)

Categories

Pharmacy Laws / Rules
TSBP Educational Programs
Training/Informational Videos
License Renewals
Change of Address / Employment
Open Records Requests
Complaint Process

Catalog

[Login](#) [Need Help?](#)
Lifelong Learning Account

The Texas State Board of Pharmacy offers the following Continuing Education Activities which are listed below. Please click the links below for more information.

Webinars

- [Class C Pharmacist In Charge](#)
- [Opioid Abuse Training](#)
- [Laws and Rules Update](#)
- [Class A Pharmacist-In-Charge Training](#)



We can email you your [activity history](#) as of Sept 1st, 2014.

[> VERIFICATIONS](#)
CHECK LICENSE STATUS

[> CONSUMERS](#)
PUBLIC RESOURCES

[> LOGIN](#)
ACCESS MY ACCOUNT



Categories

[Pharmacy Laws / Rules](#)

[TSBP Educational Programs](#)

[Training/Informational Videos](#)

[License Renewals](#)

[Change of Address / Employment](#)

[Open Records Requests](#)

[Complaint Process](#)

Catalog

[Login](#)

[Need Help?](#)

Lifelong Learning Account

The Texas State Board of Pharmacy offers the following Continuing Education Activities which are listed below. Please click the links below for more information.

Webinars

- [Class C Pharmacist In Charge Training](#)
- [Opioid Abuse Training](#)
- [Laws and Rules Update](#)

The program will review recent changes to pharmacy rules, and review the most common deficiencies found during inspections of pharmacies.

- [Thu Aug 20 2015 10:00 - 11:00 Webinar On-line](#)
- [Thu Nov 12 2015 10:00 - 11:00 Webinar On-line](#)

Duration: 1.00

Cost: \$9.00

- [Class A Pharmacist-In-Charge Training](#)

We can email you your [activity history](#) as of Sept 1st, 2014.

[VERIFICATIONS](#)
CHECK LICENSE STATUS

[CONSUMERS](#)
PUBLIC RESOURCES

[LOGIN](#)
ACCESS MY ACCOUNT

-
- For more specific information on these requirements, refer to the Board Rules located on the TSBP website:

www.pharmacy.texas.gov



Final Reminders (Part I)

- If you have additional compliance-related questions, please call the TSBP Compliance Line at 512-305-8070.
- If you would like a copy of today's presentation slides, they are currently posted in your Lifelong Learning Account.

Trouble accessing your Lifelong Learning Account?

Call the help desk:

1-800-215-0641

Select Option 1



Final Reminders (Part II)

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.**





Thank you for your attendance!

**If you have any additional questions about the
content presented today,
please email us at:**

educationcoordinator@pharmacy.texas.gov



TEXAS STATE BOARD OF PHARMACY