



Newsletter

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SUMMER 2013

PRESIDENT'S COLUMN

by

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Summary of Legislation Passed by the 83rd Legislature That Impacts the Practice of Pharmacy

This President's Column will be devoted to summarizing the legislation passed by the 83rd Regular Session of the Texas Legislature that will impact the practice of pharmacy in Texas. The effective date of the legislation is noted for each bill. Text of the bills is available through the Texas Legislature Online website at: www.capitol.state.tx.us.

S.B. 316 **Effective Date: 6/14/2013**

This bill amends the Texas Pharmacy Act is to:

- require the Board to develop a continuing education (CE) program regarding opioid drug abuse and the delivery, dispensing, and provision of tamper-resistant opioid drugs after considering input from interested persons; and
- allow the Board to adopt a rule that will require a license holder to take this CE program as a part of their CE requirement for renewal.

The bill also directs the Senate Health and Human Services committee to conduct an interim study regarding opioid abuse and the provision of tamper-resistant opioids. The study must include an examination of:

- matters relating to prescription opioid abuse; and
- the use and effectiveness of tamper-resistant opioids.

The committee report is due December 1, 2014.

S.B. 404 **Effective Date: 9/1/2013**

This bill amends the Texas Pharmacy Act to:

- prohibit the Board from considering or acting on a complaint if the violation occurred more than 7-years before the date of the complaint; and
- allow the Board to:
 - issue a remedial plan to resolve a complaint; and
 - assess a fee against a license holder participating in a remedial plan in an amount necessary to recover the costs of administering the plan.

The bill specifies that a remedial plan may not be imposed to resolve a complaint concerning:

- a death;

- a hospitalization;
- the commission of a felony;
- a matter designated by board rule; or
- a matter in which the appropriate resolution may involve a restriction on the manner in which a license holder practices pharmacy.

If a license holder complies with and successfully completes the terms of a remedial plan, the board is required to remove all records of the remedial plan on the 5th anniversary of the date the license holder successfully completes the remedial plan.

S.B. 406 **Effective Date: 11/1/2013**

The Texas Medical Practices Act is amended to allow advanced practice registered nurses (APRN) and physician assistants (PA) to "prescribe or order a drug or device." The Act is also amended to allow APRNs and PAs to prescribe Schedule II controlled substances:

- in a hospital facility-based practice in accordance with policies approved by the facility's medical staff;
- as part of the plan of care for the treatment of a person that:
 - has executed a written certification of a terminal illness;
 - has elected to receive hospice care; and
 - is receiving hospice treatment from a qualified hospice provider.

The combined number of APRNs and PAs with whom a physician may enter into a prescriptive authority agreement may not exceed:

- seven APRNs and PAs; or
- the full-time equivalent of seven APRNs and PAs.

This limit does not apply to a:

- practice serving medically underserved populations; or
- hospital facility-based practice in a hospital.

The bill also gives the Texas Medical Board (TMB) the authority to inspect and audit any records at a site where a party to a prescriptive authority agreement practices, if TMB is notified of a complaint filed against a APRN or PA by their respective board.

S.B. 500 **Effective Date: 9/1/2013**

This bill increases the size of the Board of Pharmacy to eleven members by adding one pharmacist and one pharmacy technician. The composition of the Board will be:

- 7 pharmacists;
- 1 pharmacy Technician; and
- 3 public Members.

The pharmacy technician board member must, at the time of appointment:

- be a resident of Texas;

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- have been registered as a pharmacy technician for the five years preceding appointment;
- be in good standing to act as a pharmacy technician in Texas; and
- be practicing as a pharmacy technician in Texas.

S.B. 566 **Effective Date: 6/14/2013**

This bill authorizes the University of Texas at Tyler to establish a school of pharmacy.

S.B. 869 **Effective Date: 9/1/2013**

This bill makes numerous "clean-up" amendments to the Texas Pharmacy Act. The amendments:

- add a definition of a pharmacy technician trainee;
- clarify the provisions of the Act that are applicable to pharmacy technician trainees;
- clarify that the Board may impose any of the sanctions listed in the Act on a "pharmacist-intern;"
- allow the Board to receive/spend gifts and grants;
- prohibit a pharmacist or pharmacy from renewing a license if the license has been suspended, revoked in another state;
- delete the requirement for pharmacists to notify a practitioner when they substitute a dosage form;
- allow the Board to disclose information about an investigation to an "entity that administers a board-approved pharmacy technician certification examination;"
- replace the requirement for a pharmacy to post the licenses and renewals of pharmacists working at the pharmacy with a requirement for the pharmacy to:
 - post the license and renewal of the PIC; and
 - maintain proof and make such proof available to the public on request that each pharmacist, pharmacy technician/trainee and pharmacist intern has a current license/registration.

S.B. 1100 **Effective Date: 9/1/2013**

This bill amends the Texas Pharmacy Act to:

- give the Board the authority to inspect out-of-state sterile compounding pharmacies;
- require out-of-state sterile compounding pharmacies to reimburse the Board for travel expenses related to the inspection;
- require an inspection prior to opening a sterile compounding pharmacy; and
- specify that a pharmacy that compounds sterile preparations may not renew a pharmacy license unless the pharmacy:
 - has been inspected as provided by Board rule; and
 - if the pharmacy is located in another state, has reimbursed the Board for all expenses, including travel, incurred by the Board in inspecting the pharmacy during the term of the expiring license.

The bill also specifies that a pharmacy that compounds a sterile preparation must notify the Board:

- immediately of any adverse effects reported to the pharmacy or that are known by the pharmacy to be potentially attributable to a sterile preparation compounded by the pharmacy; and
- not later than 24 hours after the pharmacy issues a recall for a sterile preparation compounded by the pharmacy.

S.B. 1643 **Effective Date: 9/1/2013**

This bill amends the Texas Controlled Substances Act to:

- add a freestanding emergency medical care facility licensed under Chapter 254 to the definition of a hospital. (Note: this will allow these facilities to obtain a "hospital" registration from DPS).
- allow pharmacy technician working under the supervision of a pharmacist to query the Prescription Access in Texas (PAT) Program for the recent Schedule II-V prescription history of a particular patient;
- allow a person authorized to receive information from the PAT to access it through a health information exchange (HIE), subject to proper security measures to ensure against disclosure to unauthorized persons;
- allow a person authorized to receive information from PAT to include that information in any form in the medical or pharmacy record of the patient who is the subject of the information. (e.g. a physician may print-out the report and place it in a patient's file);
- increase the time DPS can maintain the information in PAT from 12-months to 36-months;
- establish an Interagency Prescription Monitoring Work Group to:
 - evaluate the effectiveness of PAT program; and
 - offer recommendations to improve the effectiveness and efficiency of recordkeeping and other functions related to the regulation of dispensing controlled substances by prescription.

The Interagency Prescription Monitoring Work Group is composed of the following individuals or their designee:

- Director of DPS;
- Commissioner of State Health Services;
- Executive Director of the Board of Pharmacy;
- Executive Director of the Medical Board;
- Executive Director of the Board of Nursing; and
- Executive Director of the Physician Assistant Board.

The Interagency Prescription Monitoring Work Group must:

- meet at least quarterly;
- proactively engage stakeholders and solicit and take into account input from the public; and
- submit to the legislature its recommendations relating to prescription monitoring not later than December 1 of each even-numbered year.

H.B. 1675 **Effective Date: 6/14/2013**

This bill requires the Sunset Advisory Commission to:

- conduct a study concerning the self-directed semi-independent (SDSI) status of state agencies; and
- send a report of the findings and recommendations of the study to the Governor, Lt. Governor, and each member of the Legislature by December 31, 2014.



CELEBRATING 50 YEARS

The Texas State Board of Pharmacy has proudly presented a Citation of Achievement to the following pharmacists who completed fifty years of service from September 2012 through August 2013 as a licensed pharmacist in Texas.

GEORGIA SAFFORD LEECH
FRANCIS P. SUTTON
S. RAY JOHNSON
EDWARD ALAN ROBINSON
ARTURO ACUNA
CHARLES D. BAKER
PAUL STANLEY BARRENTINE
JAMES WILLIAM BLACK
PAUL DON BORSELLINO
JAMES T. COLEMAN
DOUGLAS C. COPELAND
NOEL THOMAS CURB
HAROLD A. GARBER
J.B. HENSLER
WILLIAM ARLYN KLOESEL
KEN MELVIN KWAN
LAMBERT LABAY
MARY LUCILLE LADAY
RAY LEE
JOEL NELSON LIPSCOMB
CHARLIE T. NOVOSAD
JOSE ROLANDO OLVERA
DAYTON E. PARKER
DARRELL DAVID RAYBURN
DONALD N. RIDGWAY
BILL R. SPAIN
DAVID A. WALKER
BILLY WAYNE WOODWARD
CAMILLE KLACH AMORUSO
LONNIE RAY NUNLEY
JEANNE MCCAREN OSTEN
CARL VINCENT ACCARDO
HERMAN NELSON BARNES
MARGARET BEAULIEU NOVOSAD
SUZAN BENBOW TAFF
MAX DEWAYNE BERRY
THOMAS DAVID BRIDGES
JOLI KATO ALKER
DAVID DAVIS
ROBERT CECIL DAVIS

BEN MARION DYER
JULIA E. CONNOR
RONNIE JOE ELLIOTT
JERRY DON EVANS
HAROLD R. FISHER
THOMAS LLOYD GARDNER
GERALD ALLEN GARZA
JOE E. GIAMFORTONE
HARRY L. GORDON
RONALD LEE HALL
BENJAMIN MARK HARRISON
EARL C. HARVEY
RICHARD PAUL HATLEY
BENTLEY FRED HAWLEY
SANTIAGO RIOS HERNANDEZ
DANIEL HRNA
DELL IRVIN
JERRY JEREL JONES
KENNETH WAYNE JORDAN
RAYMA WATSON KARACOSTAS
STEVEN MICHAEL KING
RONNY GERALD LEACH
JOE DON LIVINGSTON
JAMES CHARLES MAASS
BILLIE MARIE MCMILLER
ANNIS M. MINYARD HARRISON
ORAN KENNETH MOBLEY
WILLIAM HARVEY MORGAN
WELDON ANTON NEUENDORFF
BRENDA JOYCE OBEY
ORVILLE NEIL ODOM
JAMES SMITH OLIVE
DOUGLAS BRYAN PAIR
BOBBY LEE PAYNE
ROY M. PHILP
WILLIAM ELMORE PIERCE
HAROLD DEAN PORTER
SHELBY W RASH
JAMES CHARLES RIVERS
JERRY WAYNE RUDLOFF
CAROLYN SCHROETER MIERS

RICHARD W SCHULTZ
JOSEPH WILLIAM SEALE
EMMA JEAN SEEKER
LEAH RAYE SEXTON
ROGER WAYNE SMITH
LARRY JOE SQUIRES
JOHN F. SVOBODA
B.E. SWEET
WAYNE T. THOMPSON
JAMES VERA
CLINTON J. VOELKEL
RICHARD LLOYD WAGNER
DONALD TYNDALL YAAP
ELUTERIO MORALES
RUBIN WAYNE MATHEWS
JAMES CAREY PROSPERIE
GORDON SMITH RICHARDS
EARL WELDON ANDERSON
RODNEY O. BEATY
FRANK A. DALEO
DANIEL GEORGE DROZD
GUADALUPE ANTONIO GARZA
NORMAN ALFORD GOUND
JOHN ARTHUR HRUSKA
ENRIQUE DELEON JIMENEZ
JOEL EDWARD JOHNSON
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LAWRENCE SEMANDER
ERNESTO NICOLAS SOTO
WARREN ALBERT THIBEAUX
DOUGLAS CHARLES WEISE
JOHN THOMAS WILLET

S.B. 227 VETOED BY THE GOVERNOR

Senate Bill 227 would have allowed physicians to dispense the following “aesthetic pharmaceuticals:”

- Bimatoprost (Latisse);
- Hydroquinone (Lustra, Claripel);and
- Tretinoin (Retin A).

Governor Rick Perry vetoed the bill on June 14, 2013, with the following veto proclamation:

“SB 227 would circumvent existing safeguards for the dispensing of certain prescription cosmetic drugs by allowing physicians and optometrist to sell these medications directly. It is the role of the pharmacists – who are trained specifically in drug interactions, side effects and allergies – to dispense the medications. Additionally, the State Board of Pharmacy has the authority to inspect pharmacies to ensure drugs are stored securely and at safe temperatures.”

LICENSURE STATISTICS

This data is based on current licenses, as of July 2013.

PHARMACIES			
	2012	2013	% Change
Number of Pharmacies	7,184	7,292	1.5%
CLASSIFICATION BY CLASS			
Class A (Community)	4,909	4,938	<1%
Class B (Nuclear)	39	35	-10.3%
Class C (Institutional)	1,119	1,136	1.5%
Class D (Clinic)	376	374	<-1%
Class E (Non Resident)	675	701	3.9%
Class F (Free Standing EMCC)	58	93	60.3%
Class G (Central Processing)	8	15	87.5%
CLASSIFICATION BY OWNERSHIP			
Corporation	4,386	4,348	<-1%
Government	385	388	<1%
Individual	264	240	-9.1%
Partnership	1,451	1,417	-2.3%
Other	698	899	28.8%
PHARMACISTS			
	2012	2013	% Change
Number of Pharmacists	27,714	29,128	5.1%
Residing in Texas	22,264	23,126	3.9%
Residing out-of-state	5,450	6,002	10.1%
TEXAS RESIDENTS ONLY			
CLASSIFICATION BY FIELD			
Community (Independent)	2,636	2,965	13.2%
Community (Multiple/Chain)	8,256	8,680	5.1%
Community (Government)	254	245	-3.5%
Hospital (Non-Government)	3,887	4,207	8.2%
Hospital (Government)	1,140	1,235	8.3%
HMO	77	77	0%
Long Term Care	514	555	8.0%
Mail Service	778	796	2.3%
Nuclear	121	119	1.7%
Sterile Compounding	90	110	22.2%
Armed Services	30	37	23.3%
Education	255	237	-7.1%
Government	222	240	8.1%
Manufacturer or Wholesaler	127	143	12.6%
Pharmacy Management	290	346	19.3%
Unemployed	775	673	-13.2%
Retired	709	675	-4.8%
Home Health	119	117	-1.7%
OTHER	1,980	1,669	-15.7%
CLASSIFICATION BY REGISTRATION METHOD			
Examination	18,116	18,816	3.8%
Reciprocity	4,148	4,310	3.9%
PHARMACY TECHNICIANS/TRAINEES			
	2012	2013	% Change
Pharmacy Technicians/ Trainees	52,822	56,088	6.2%

BOARD CALENDAR FY2014

SEPTEMBER 2013

2 LABOR DAY - STATE HOLIDAY - Office Closed

NOVEMBER 2013

5 TSBP BOARD BUSINESS MEETING, Austin

11 VETERAN'S DAY - STATE HOLIDAY - Office Closed

28-29 THANKSGIVING HOLIDAYS - STATE HOLIDAY - Office Closed

DECEMBER 2013

24-26 CHRISTMAS HOLIDAY - STATE HOLIDAY - Office Closed

JANUARY 2014

1 NEW YEAR'S DAY - STATE HOLIDAY - Office Closed

20 M.L. KING JR. DAY - STATE HOLIDAY - Office Closed

FEBRUARY 2014

11 TSBP BOARD BUSINESS MEETING, Austin

17 PRESIDENT'S DAY - STATE HOLIDAY - Office Closed

MAY 2014

6 TSBP BOARD BUSINESS MEETING, Austin

26 MEMORIAL DAY - STATE HOLIDAY - Office Closed

JULY 2014

4 INDEPENDENCE DAY - STATE HOLIDAY - Office Closed

AUGUST 2014

7-8 TSBP BOARD BUSINESS MEETING, Austin

COMPLIANCE REMINDERS

COMMON WARNING NOTICES ISSUED DURING COMPLIANCE INSPECTIONS

In Fiscal Year 2012, the Texas State Board of Pharmacy's Compliance Field Staff completed approximately 2,135 inspections. During these inspections, written warning notices were issued to approximately 511 pharmacies (23% of inspected pharmacies). A total of 860 violations of Texas Pharmacy rules and laws were cited in the Warning Notices (more than one violation may be cited per Warning Notice). See chart below for the most common violations. Take a few moments to review your pharmacy operation and see if you can spot these violations. Correcting these issues now may reduce the stress of being issued a Warning Notice.

TOP 10 CONDITIONS WHICH RESULT IN A WARNING NOTICE BEING ISSUED DURING A COMPLIANCE INSPECTION			
Violation		Applicable Law/Rules	
		Class A	Class C
1	Licenses not Posted (e.g., Pharmacy, Pharmacist and Technicians)*	Texas Pharmacy Act §562.051, §562.103 Board Rule 297.9(a)	
2	Improper Documentation of Training (e.g., incomplete or no initial and in-service training)	Board Rule 291.133(c)(4) and 297.6	
3	Counseling (e.g., no verbal counseling by R.Ph.; offer to counsel made by technician; no written notice)	Board Rule 291.33(c)(1)	
4	Computer Records Incomplete	Board Rule 291.34	Board Rule 291.75
5	Prescription Label Incorrect	Board Rule 291.33(c)(7)	
6	Inadequate Library	Board Rule 291.33(e)	Board Rule 291.74(d)
7	Outdated Drug Stock (e.g., expired products on shelf)	Board Rule 291.33(f)(2)	Board Rule 291.74(f)(1)(E) and (F)
8	No Annual Inventory	Board Rule 291.17(a) and (c)	
9	Improper Dispensing	Board Rule 291.33(c)	
10	No/Incomplete Sterile Preparation Policy & Procedure Manual	Board Rule 291.133	

*Note: S.B. 869, passed during the 2013 Legislative Session, modifies the posting requirements. See President's Column for more information.

If you have questions regarding compliance with the laws or rules governing the practice of pharmacy, contact the Compliance/Enforcement staff at 512-305-8070 or rxlaw@tsbp.state.tx.us

ATTENTION: PHARMACIST-IN- CHARGE You Are Responsible!

The pharmacist-in-charge is responsible for the legal operation of the pharmacy. This includes ensuring the individuals working in the pharmacy are authorized by the Texas State Board of Pharmacy (TSBP) to work in the pharmacy.

Pharmacy technicians, pharmacist-interns, pharmacy technician trainees, and pharmacists all receive documentation from TSBP indicating that the individual is appropriately licensed or registered with TSBP. An individual who cannot provide appropriate credentials should not be allowed to work in the pharmacy until the information is verified. Registration and licensure status should be periodically verified on the TSBP web page at the following link:

**[http://www.tsbp.state.tx.us/
dbsearch/default.asp](http://www.tsbp.state.tx.us/dbsearch/default.asp)**

Allowing an individual to work in the pharmacy without an active registration or license could lead to disciplinary and legal consequences for the individuals involved and the pharmacy where the activity occurred.

The NEWSLETTER is published in an attempt to keep pharmacists, pharmacy technicians, and pharmacy owners informed about laws and rules relating to the practice of pharmacy in Texas. Unless otherwise noted, permission to quote from or reproduce items in this publication is granted when due acknowledgment is made. Guest articles do not necessarily express the views of the Texas State Board of Pharmacy. Comments and/or suggestions should be addressed to:

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The Importance of Drug Utilization Reviews

During the FY2012, the Texas State Board of Pharmacy entered 24 disciplinary orders, resulting from 14 incidents, against pharmacists and pharmacies that could have been prevented through a proper Drug Utilization Review or DUR. In all of these cases the pharmacist failed to identify a clinically significant high dosage or clinically significant reasonable directions for use. After reviewing the orders entered in 2012, the following statistics are applicable:

- 43% of the errors were mistakes between milliliters and teaspoons
- 93% of the errors allegedly involved pediatric prescriptions
- 29% of the errors allegedly caused negative patient outcomes
- 21% of the orders, a pharmacist allegedly failed to provide proper patient counseling

Examples of these errors include the following:

DRUG	MISTAKE	RESULT
Zantac	Directions read 1 ½ tsp by mouth twice daily instead of 1 ½ ml by mouth twice daily.	A two month old infant was given 5 times the prescribed daily dose for approximately one month before the error was discovered.
Amoxicillin	Direction read 1 ½ tsp by mouth twice daily instead of 1.5 ml by mouth twice daily.	A seven week old infant was given the medication for three days and experienced adverse effects including diarrhea and abdominal pains.
Zoloft	The prescription was data entered as zolpidem 10 mg tablets instead of Zoloft 25 mg tablets.	The patient ingested the incorrect medication and experienced adverse effects requiring treatment at an emergency room.
Tamiflu	Directions read 1 ¼ tsp twice a day for 5 days instead of 1 ½ ml twice a day for 5 days.	A seven month old infant was given the incorrect dosage which was five times the prescribed dosage.
Levothyroxine	The prescription was dispensed as levothyroxine 200 mcg tablets instead of levothyroxine 25 mcg tablets.	The patient ingested the medication and experienced adverse effects.
Premarin	The prescription was incorrectly dispensed as Permethrin instead of Premarin .	The patient's agent identified the error before applying the incorrect medication to the patient, a one-year old child.

Approximately 64% of the 14 errors were caused by incorrect directions and of these errors, one-third may have been detected through proper patient counseling. The other 36% of the 14 errors were a result of an incorrect drug strength or incorrect drug being dispensed. These errors should have been detected by conducting a DUR. Twenty-nine percent of the errors allegedly caused adverse effects including one patient going to the emergency room.

The Board encourages pharmacists to understand the value of a drug utilization review. Suggestions for avoiding these particular errors are as follows:

- Be especially careful when reviewing prescriptions for pediatric patients, as these patients are the most susceptible to dosing errors.

- Use clinical judgment and investigate any dose that seems unusual, high, or questionable. Don't forget you are the drug expert!

- To confirm correct data entry, pharmacists must check the label on a new prescription against the original prescription and NOT against a document prepared by the computer.

- Always remember to counsel patients! Not only is it the law but it may also help you catch an error you might have missed.

- Review errors that have occurred in your pharmacy and make necessary changes to prevent errors in the future.

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Summer 2013

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2013 Texas State Board of Pharmacy Continuing Education Webcast Schedule

Texas Pharmacy Laws and Rules Update

Approved for 1 hour of continuing education

These free programs will review recent changes to pharmacy rules and review the most common deficiencies found during inspections of pharmacies. Registration space is limited.

August 22, 2013 10:00 a.m.

November 14, 2013 10:00 a.m.

Pharmacist-in-Charge Training

Approved for 1 hour of continuing education

Are you a new pharmacist-in-charge (PIC) or just need a refresher on the requirements and responsibilities as PIC? This program is for individuals interested in learning about the responsibilities of the PIC, primarily in community pharmacy settings. The same information will be covered during each webcast; please only register for one session. Registration space is limited.

October 10, 2013 10:00 a.m.

For more information on continuing education programs offered by the Texas State Board of Pharmacy and to register, visit:

www.tsbp.state.tx.us/ce_program.htm

After registering you will receive a confirmation email containing information about joining the training.

Connect with the Texas State Board of Pharmacy on Facebook, Twitter, and YouTube. You can find links to these pages at www.tsbp.state.tx.us

