2017 Texas Pharmacy Law Update and Board Forum

Gay Dodson, R.Ph.
Executive Director/Secretary

Texas Pharmacy Association’s Annual Meeting
San Antonio

July 7, 2017

Goals and Objectives

- Review recent changes in Texas Pharmacy rules and laws;
- Update Drug Therapy Management Activity of Pharmacists under Physician’s Protocol; and
- Review the “New” Prescription Monitoring Program.

Disclosure

This program is accredited by ACPE for pharmacists and technicians and has been assigned the following ACPE #s
- Pharmacists – 0154-0000-17-007-L03-P
- Pharmacy Technicians – 0154-0000-17-007-L03-T

Gay Dodson has no financial or conflicts of interest in relation to this activity.
Board of Pharmacy Members

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Recently Adopted Rules
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)

Board Action

- At the February 2, 2017, meeting, the Board approved use of the ExCPT examination for pharmacy technician registration beginning:
  - September 1, 2017; or
  - When staff has established procedures for electronic transfer of information between ExCPT and the Board.

Drug Therapy Management
Dr. Therapy Management Update

- As of 5/12/2017, TSBP has 214 RPhs providing DTM under 3,540 protocols.
- The majority of DTM is occurring in:
  - Hospital;
  - Hospital Clinic; or
  - Academic Health Care Institution.

Drug Therapy Management Update

- The most common disease states covered under DTM protocols are:
  - Anticoagulation;
  - Asthma;
  - COPD;
  - Diabetes;
  - Hypertension;
  - Hyperlipidemia; and
  - Thyroid Disorders.

Texas Prescription Monitoring Program

AWARXE
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.

Timeline for Transfer of the PMP Program (cont.)

- **February 2016** – Board adopted new Chapter 315 to implement PMP and provisions related to prescriptions in the Controlled Substances Act.
  - The rules became effective on 9/1/2016.
- **May – August 2016** – Testing program.
- **September 1, 2016** – PMP AWARxE is live.

PMP AWARxE

Go to the PMP Website:  
texas.pmpaware.net

OR

Go to the TSBP Website:  
www.pharmacy.texas.gov
Data from the PMP from 1/16 through 2/17 (1 ½ Year)

<table>
<thead>
<tr>
<th>Controlled Substance Dispensed</th>
<th># Rx's Dispensed</th>
<th>% of the 4 Controlled Substances Dispensed</th>
<th>% of ALL Controlled Substances Dispensed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Barbiturates</td>
<td>292,669</td>
<td>0.71%</td>
<td>0.49%</td>
</tr>
<tr>
<td>Benzodiazepines</td>
<td>12,318,202</td>
<td>30.5%</td>
<td>20.54%</td>
</tr>
<tr>
<td>Carisoprodol</td>
<td>898,270</td>
<td>2.19%</td>
<td>1.5%</td>
</tr>
<tr>
<td>Opioids</td>
<td>27,487,686</td>
<td>67.05%</td>
<td>45.83%</td>
</tr>
<tr>
<td>Total of Above Controlled Substance Dispensed</td>
<td>40,996,857</td>
<td></td>
<td>68.36%</td>
</tr>
<tr>
<td>Total of Other Controlled Substance Dispensed</td>
<td>18,978,281</td>
<td></td>
<td>31.64%</td>
</tr>
<tr>
<td>Grand Total of All Controlled Substance Dispensed</td>
<td>59,975,138</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

BARBITURATES, BENZODIAZEPINES, CARISOPRODOL AND OPIOIDS REPRESENT 68.36% OF ALL CONTROLLED SUBSTANCES DISPENSED DURING THIS 1½ YEAR PERIOD

Still valid prescription forms!
Pharmacy Related Legislation
Passed by the 2017 Texas Legislature

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.

Sunset Review Time Line

- August 2015.
  - Sunset staff reviews the agency.
- Late March 2016.
  - Sunset's confidential report issued followed by a meeting with TSBP to discuss recommendations, and Sunset's formal request for agency written response.
Sunset Review Time Line (cont.)

- April 2016.
  - Sunset staff report published.
- August 22, 2016.
  - Sunset Commission public hearing make decisions on the review of the agency.
  - 2017 Legislative Session – Sunset Bill introduced.

Sunset Report

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.

Sunset Report (cont.)

Sunset 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.
The “Sunset” Bill (HB 2561
Effective Date:  9/1/17.

Texas State Board of Pharmacy

The “Sunset” Bill (HB 2561
Effective Date:  9/1/17.

Texas State Board of Pharmacy

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

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.
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.

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.

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

**Amends** the Pharmacy Act to require the ED to:
- Create a Board member training manual;
- Distribute a copy of the manual yearly to each Board member. On receipt of the manual, each Board member must sign and submit to the ED a statement acknowledging receipt of the manual.
- Publish a copy of each signed statement on the Board's website.

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

**Amends** the training requirements for Board members to include:
- The law governing the TSBP's operations;
- The scope of and limitations on the rulemaking authority of the Board;
- The laws relating to Board members disclosing conflicts of interest;
- Other laws applicable to Board members in performing their duties; and

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

**Amends** the training requirements for Board members to include:
- The types of rules, interpretations, and enforcement actions that may implicate federal antitrust law by limiting competition or impacting prices charged by persons engaged in a profession or business the Board regulates, including rules, interpretations, and enforcement actions **that**:
HB 2561 by Rep. Senfronia Thompson/Sen. Van Taylor (cont.)

- Regulate the scope of practice of persons in a profession or business the board regulates;
- Restrict advertising by persons in a profession or business the board regulates;
- Affect the price of goods or services provided by persons in a profession or business the board regulates; and
- Restrict participation in a profession or business the board regulates.

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

- Amends the Pharmacy Act to require TSBP to develop a policy to encourage the use of:
  - Negotiated rulemaking procedures (NRP) for the adoption of Board rules; and
  - Appropriate alternative dispute resolution (ADR) procedures to assist in the resolution of internal and external disputes under the Board’s jurisdiction.

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

- Amends the Pharmacy Act to specify that TSBP shall:
  - Coordinate the implementation of the NRP or ADR;
  - Provide training as needed to implement or NRP or ADR; and
  - Collect data concerning the effectiveness of those procedures.
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.

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

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

**Amends** the Pharmacy Act to add the following definitions:
- "Provider pharmacy" – a Class A pharmacy that provides pharmacy 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 pharmacy through a telepharmacy system to store and dispense Rx drugs/devices including dangerous drugs and controlled substances.

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.

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.
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.

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

- The Board must adopt rules specifying licensing and operating requirements, including a requirement that:
  - Remote dispensing site license identify the provider pharmacy that will provide pharmacy services at the remote dispensing site;
  - Provider pharmacy be allowed to provide pharmacy services at no more than 2 remote sites;

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

- The Board must adopt rules that require:
  - A RPh employed by a provider pharmacy 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;
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;

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

The Board must adopt rules that require:
- All pharmacy techs at a remote site be counted when establishing the RPh/pharmacy tech ratio of the provider phcy, which, may not exceed 3 pharmacy techs for each RPh;

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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 tech 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;

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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.

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.

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.
The Act specified that the Board by rule shall require and develop a process for a remote site to apply for a Class A pharmacy license if the average number of Rx's dispensed each day the remote dispensing site is open for business is more than 125, as calculated each calendar year.

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.

The bill adds a new Sec. 481.0764 to the Texas Controlled Substances Act (TCSA) titled “Reports of Wholesale Pharmaceutical Distributors” to require wholesalers to report to TSBP the sale of a controlled substance made by the distributor to a person in this state.

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.

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.

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

The bill amends the TCSA to require a regulatory agency that issues a license to a prescriber to periodically access the PMP to determine whether a prescriber is engaging in potentially harmful prescribing patterns or practices.
The bill amends the TCSA to specify that in determining if a potentially harmful pattern is occurring, the regulatory agencies, at a minimum, shall consider the:

- **# of times a prescriber prescribes opioids**, benzodiazepines, barbiturates, or carisoprodol; and
- **Patterns of prescribing combinations** of these drugs and other dangerous combinations of drugs identified by TSBP.

The bill amends the TCSA to specify that if, during a periodic check, a regulatory agency finds evidence that a prescriber may be engaging in potentially harmful prescribing patterns or practices, the regulatory agency may notify that prescriber.

The bill amends the TCSA to specify that a regulatory agency may open a complaint against a prescriber if the agency finds evidence during a periodic check under this section that the prescriber is engaging in conduct that violates the TCSA or any other statute or rule.
HB 2561 by Rep. Senfronia Thompson/Sen. Van Taylor (cont.)

The bill amends the TCSA to specify that a regulatory agency that issues a license, to a prescriber or dispenser shall provide TSBP with any necessary information, including contact information for the notifications and to register the prescriber or dispenser with the PMP.

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

The bill amends the TCSA to specify that after 9/1/2019, a RPh 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.

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.
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.

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.

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 Rx record that the patient has been diagnosed with cancer or is receiving hospice care.
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.

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).

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.
The bill establishes a joint interim committee to conduct an interim study on the monitoring of the prescribing and dispensing of controlled substances in this state.

The interim committee is composed of:
- 3-Senators appointed by the Lt. Governor; and
- 3-members of the House appointed by the speaker.

Not later than November 1, 2017, the Lt. Governor and Speaker shall appoint the members of the joint interim committee.

The Lt. Governor and Speaker shall each designate a co-chair from among the joint interim committee members.

The joint interim committee shall convene at the joint call of the co-chairs.

The interim study must:
- Include the # of prescribers and dispensers registered to receive information from the PMP;
- Evaluate the accessing of information by regulatory agencies to monitor licensees;
- Address any complaints, technical difficulties, or other issues with the PMP;
The interim study must:
- Examine controlled substance prescribing and dispensing trends that may be affected by the passage and implementation of HB 2561;
- evaluate the use and effectiveness of electronic notifications sent to prescribers and dispensers;
- evaluate the use and effectiveness of identifying geographic anomalies in comparing delivery and dispensing data;
- Evaluate the integration of any new data elements required to be reported;
- Evaluate the existence and scope of diversion of controlled substances by animal owners to whom the substances are dispensed by veterinarians;
- Explore the best methods for preventing the diversion of controlled substances by animal owners; and
- Determine how any future reporting by dispensing veterinarians might best be tailored to fit the practice of veterinary medicine.
The committee shall:
- Solicit feedback from regulatory agencies, prescribers, dispensers, and patients.
- Submit a report to the legislature on the results of the interim study, including any legislative recommendations for improvements to information access and controlled substance prescription monitoring, no later than January 1, 2019.

Other Pharmacy Related Bills Passed by the Texas Legislature


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.
HB 1178

- **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.

HB 1296

- **Effective Date:** 9/1/2017. Applies only to an insurance plan that is delivered, issued for delivery, or renewed on or after 1/1/2018.
- **Amends** the Insurance Code **to add coverage for prescription drug synchronization.**

HB 1296
by Rep. Frullo/Sen. Buckingham (cont.)

- **Applies only to a Rx that:**
  - Is covered by the person's health benefit plan;
  - Meets the prior authorization criteria on the date the request for synchronization is made;
  - Is used for a chronic illness;
  - May be prescribed with refills;
  - Can be effectively dispensed within the medication synchronization plan; and
HB 1296  
by Rep. Frullo/Sen. Buckingham (cont.)

- **Applies only to a Rx that is NOT a:**
  - Schedule II controlled substance; or
  - Schedule III controlled substance containing hydrocodone.

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HB 1296  
by Rep. Frullo/Sen. Buckingham (cont.)

- **The plan must prorate amount charged for a partial fill of a Rx IF** the phcy/prescriber notifies the plan that the:
  - Quantity dispensed is to synchronize the dates that the phcy. dispenses the Rx; and
  - Synchronization is in the best interest of the enrollee; and
  - Patient agrees to the synchronization.

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HB 1296  
by Rep. Frullo/Sen. Buckingham (cont.)

- The proration must be based on the number of days’ supply of the drug actually dispensed.

- **A health benefit plan** that prorates a cost-sharing amount **may not prorate the fee paid to the pharmacy** for dispensing the drug.
SB 1107

**Effective Date:** 9/1/2017. (Except the amendments to the Insurance Code take effect 1/1/2018).

- Amends the Medical Practices Act to outline provision of Telemedicine and Telehealth Services. (Note: Mental Health Services are excluded.)

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SB 1107

- The bill defines "Telemedicine medical service" as a health care service delivered by a physician, or a health professional acting under the delegation and supervision of a physician, to a patient at a different physical location than the physician or health professional using telecommunications or information technology.

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SB 1107

- The bill specifies that a health professional providing a health care service or procedure as a telemedicine medical service or a telehealth service is subject to the standard of care that would apply to the provision of the same health care service or procedure in an in-person setting.
SB 1107

- The bill adds a new Section to Medical Practices Act that requires the:
  - Texas Medical Board
  - Board of Nursing;
  - Physician Assistant Board; and
  - the Board of Pharmacy to:
- **Jointly adopt rules that establish the determination of a valid prescription.**

SB 1107

- **The bill specifies** that TMB, BON, TPAB, and TSBP must **jointly develop and publish on each respective Internet website responses to frequently asked questions** relating to the determination of a valid prescription issued in the course of the provision of telemedicine medical services.

SB 584 by Royce West/Rep. Rose

- **Effective Date:** Applies only to an offense committed on or after September 1, 2017
- **The bill amends** the Medical Practices Act to require TMB to **adopt guidelines for the prescribing opioid antagonists.**
SB 584 by Royce West/
Rep. Rose (cont.)

The guidelines must address:
- **Prescribing an opioid antagonist** to a patient to whom an opioid medication is also prescribed; and
- **Identifying patients at risk of an opioid-related drug overdose and prescribing an opioid antagonist** to that patient or to a person in a position to administer the opioid antagonist to that patient.

Specifies that in adopting guidelines under this section, the Medical Board shall consult:
- With the Texas State Board of Pharmacy: Materials published by the Substance Abuse and Mental Health Services Administration of the US Dept of Health and Human Services; and
- May consult other materials, including medical journals subject to peer review and publications by medical professional associations.

Specifies that a physician who acts in good faith and with reasonable care, regardless of whether the physician follows the guidelines adopted by TMB, is not subject to criminal/civil liability or any professional disciplinary action for:
- Prescribing or failing to prescribe an opioid antagonist; or
SB 584 by Royce West/ Rep. Rose (cont.)

A physician is **not subject to criminal/civil liability or any professional disciplinary action** for:
- Any outcome resulting from the eventual administration of an opioid antagonist prescribed by the physician.


**NOTE:** The provisions in this bill are also contained in the HB 2561 (TSBP Sunset Legislation).
- Effective Date: 9/1/2017.
- The Board must adopt rules no later than 1/1/2018.


**The Bill adds** the following definitions to the Pharmacy Act:
- "**Provider pharmacy**" – a Class A phcy that provides phcy services through a telephcy system at a remote dispensing site.
- "**Remote dispensing site**" – a location licensed as a telephcy that is authorized by a provider phcy through a telephcy system to store and dispense Rx drugs and devices, including dangerous drugs and controlled substances.
SB 1633

**The Bill adds** the following definition 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.

SB 1633

**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.

SB 1633

**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.
**SB 1633**

- **Specifies that the Board** must adopt rules specifying licensing and operating requirements, including a requirement that a:
  - Remote dispensing site license identify the provider phcy that will provide phcy services at the remote dispensing site;
  - Provider phcy be allowed to provide phcy services at **no more than 2 remote sites**;

- **SB 1633**

- **Specifies that 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 dispensing site **must be reconciled monthly** by a RPh employed by the provider phcy;

- **SB 1633**

- **Requires the Board to adopt rules** that require:
  - A RPh employed by a provider phcy 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;
SB 1633

Specifies that the Board must adopt rules that require:
- All pharmacy techs at a remote site be counted when establishing the RPh/pharmacy tech ratio of the provider phcy, which, may not exceed 3 pharmacy techs for each RPh.

SB 1633

Amends the Pharmacy Act to specify that the Board must adopt rules that require:
- Before working at a remote site, a pharmacy tech 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.

SB 1633

Amends the Pharmacy Act to specify that the Board must adopt rules that require:
- 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 Pharmacy Law Update
Texas Pharmacy Association’s Annual Meeting

July 7, 2017

SB 1633

Amends the Pharmacy Act to specify that a telepharmacy system at a remote dispensing site may not:
- Dispense a CII controlled substances.
- Be located within 25 miles, by road, of a Class A phcy.
  - 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.

SB 1633

Amends the Pharmacy Act to specify that a telepharmacy system located at a remote dispensing 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 site that is currently operating, the remote site may continue to operate at that location.

SB 1633

Specifies that the Board by rule shall require and develop a process for a remote dispensing 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.
SB 1633

Specifies that a provider pharmacy may not provide remote pharmacy 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.

Q & A

Thank You!