JOINT INTERIM COMMITTEE ON PRESCRIBING & DISPENSING CONTROLLED SUBSTANCES

INTERIM REPORT
TO THE
86TH LEGISLATURE

December 2018

JOINT INTERIM COMMITTEE ON
PRESCRIBING & DISPENSING CONTROLLED SUBSTANCES

SENATOR CHARLES SCHWERTNER
Co- Chair
SENATOR DAWN BUCKINGHAM
SENATOR KIRK WATSON

REPRESENTATIVE J.D. SHEFFIELD
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REPRESENTATIVE DEWAYNE BURNS
REPRESENTATIVE DONNA HOWARD

Dear Lieutenant Governor, Speaker, and Members,

Please find the report from the Joint Interim Committee on Prescribing & Dispensing Controlled Substances enclosed.

Respectfully submitted,

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Senator Charles Schwertner, Co-Chair

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Representative J.D. Sheffield, Co-Chair

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Senator Dawn Buckingham

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Representative DeWayne Burns

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Senator Kirk Watson

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Representative Donna Howard

Charge Language: *The interim study conducted by the Joint Interim Committee must*
- *Include the number of prescribers and dispensers registered to receive information electronically under Section 481.076, Health and Safety Code, as amended by this Act;*
- *Evaluate the accessing of information under Section 481.076, Health and Safety Code, as amended by this Act, by regulatory agencies to monitor persons issued a license, certification, or registration by those agencies;*
- *Address any complaints, technical difficulties, or other issues with electronically accessing and receiving information under Section 481.076, Health and Safety Code, as amended by this Act;*
- *Examine controlled substance prescribing and dispensing trends that may be affected by the passage and implementation of this Act;*
- *Evaluate the use and effectiveness of electronic notifications sent to prescribers and dispensers under Sections 481.0761(i) and (k), Health and Safety Code, as added by this Act;*
- *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 under this Act;*
- *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.[i]*

Background

In 2015, the 84th Legislature voted to transfer the Prescription Monitoring Program (PMP) from the Department of Public Safety (DPS) to the Texas State Board of Pharmacy (TSBP).[ii] The TSBP launched a new and more user friendly system on September 1, 2016.

Prior to the 85th Legislative Session, statute required pharmacists to enter data on controlled substances within seven days of filling the prescription, but did not require them to search the PMP database prior to dispensing. In Fiscal Year (FY) 2017, 74 percent of pharmacists did not use the system in any capacity and 98 percent of controlled substances were dispensed without utilizing the PMP.[iii]

Citing a lack of use of the PMP by prescribers and dispensers, the Sunset Commission (Sunset) made a recommendation to the 85th Legislature to require pharmacists to check the PMP prior to dispensing certain controlled substances. Additionally, the Commission recommended requiring pharmacists to enter dispensing information within one day of filling a controlled substance prescription.

In response to Sunset's recommendations, the Legislature passed House Bill 2561 (Thompson/V. Taylor). Regarding the PMP, the bill:
- Requires pharmacists or their delegates to enter dispensing information in the PMP database within one business day of dispensing controlled substances;

- Requires all prescribers and dispensers (except veterinarians) to search the PMP database before prescribing or dispensing opioids, benzodiazepines, barbiturates, or carisoprodol beginning September 1, 2019;
- Requires prescriber licensing boards to provide licensee information to TSBP, and requires TSBP to use this information to automatically register practitioners to use the PMP;
- Authorizes TSBP to highlight potentially dangerous prescribing and dispensing patterns through proactive electronic notifications to system users; and
- Requires a joint interim study of changes to the Prescription Monitoring Program, to include the extent of drug diversion by animal owners, by January 1, 2019 to understand the impacts of the PMP on controlled substance abuse and guide potential future changes.[iv]

Registered Users FY 2018

As of August 31, 2018, 92,232, or 51.6 percent, of licensed prescribers and dispensers were registered to use the PMP.[v]

License Type	Registered Users 2017	Registered Users 2018	Total Number Licensed 2018	Percentage Registered 2018
Advanced Practice Registered Nurse	6,786	10,107	36,446	38.4%
Dentist	3,291	8,596	17,683	48.6%
Medical Resident with Prescriptive Authority	191	324	N/A	N/A
Optometrist	16	625	4,037	15.5%
Pharmacist	18,460	24,702	34,012	72.6%
Pharmacy Technician (Pharmacist Delegate)	918	2,663	N/A	N/A
Physician (MD, DO)	22,737	35,601	78,088	45.6%
Physician Assistant	2,989	4,437	9,056	49.0%
Podiatrist	221	442	1,143	38.7%
Prescriber Delegate	1,642	3,883	N/A	N/A
Other Prescriber	86	256	N/A	N/A
Veterinarian	109	596	8,389	7.1%
TOTAL	**57,584**	**92,232**	**178,744**	**51.6%**

## Prescriber and Pharmacist Notifications/Threshold alerts: "5-5-5"

The PMP sends monthly alerts to prescribers and pharmacies when a patient receives:
- five or more controlled substance prescriptions
- written by five prescribers; and
- had the prescriptions filled at five or more pharmacies
- all within the past three months.

This pattern could indicate "doctor-shopping" behavior; however, it is not known how many of these individuals can be characterized as doctor-shoppers and how many are chronically ill patients with legitimate controlled substance needs, a distinction decisions makers need to keep in mind as utilization of the PMP increases. The number of threshold notifications peaked in January 2017 and has since been on the decline. Approximately 40 threshold notifications were sent in July 2018.[vi] A downward trend in these notifications could suggest an overall decrease in doctor-

shopping, but could also indicate patients have become aware of the existence of 5-5-5 notifications and have adjusted their patterns to avoid triggering a notification.[vii]

Threshold Notifications (5-5-5)
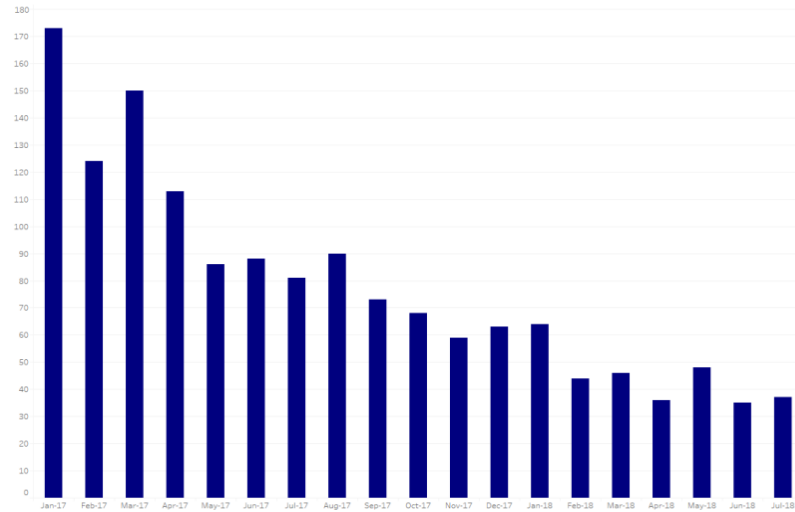
Prescribing Trends

In FY 2018, 39,592,102 dispensations were reported to the PMP.[viii] The chart below shows the top 15 controlled substances dispensed in Texas in FY 2018.[ix]

Controlled Substance	Number of Prescriptions
Hydrocodone	5,505,045
Tramadol	4,715,668
Codeine	4,643,658
Alprazolam	3,180,656
Zolpidem	2,544,216
Dextroamphetamine	2,523,588
Clonazepam	1,982,864
Methylphenidate	1,593,968
Lorazepam	1,436,935
Amphetamine	1,419,921
Phentermine	1,330,533
Testosterone	1,184,185
Pregabalin	979,483
Oxycodone	935,174
Diazepam	765,826

There are significant differences in prescribing across age groups and geographic areas of Texas. The rate of opioid prescriptions dispensed across age groups in Texas is quite concentrated. The

population of 65 and older are prescribed opioids at a much higher rate than any other age group, while individuals between the ages of 18-34 are prescribed opioids at a significantly lower rate.[x]

Rate of Opioid Prescriptions Dispensed in Texas, by Age Group: 2015-2017
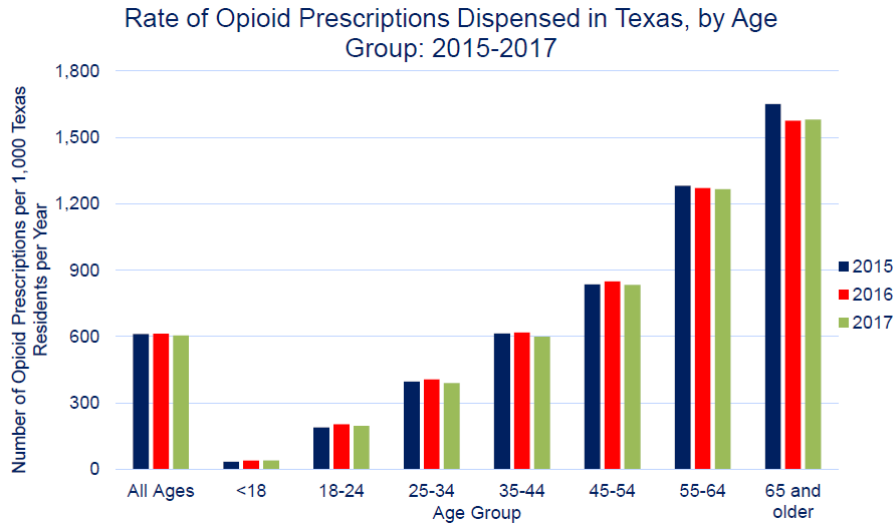
The benzodiazepine prescribing rate is on a slight decline; however, the combined use of opioids and benzodiazepines has proven to be a risk factor for opioid overdose. In 2015, 37 percent of accidental overdose deaths in Texas involving prescription opioids also involved benzodiazepines.[xi]

Additionally, the prescribing rate of stimulants is an emerging concern. Data gathered thus far from the PMP has hinted that risky opioid prescribing may be declining but stimulant prescribing is increasing. The rate of stimulant prescriptions has increased since 2015, and continues to rise. The most prescribed stimulants are[xii]:

- Adderall (amphetamine-dextroamphetamine)
- Vyvanse (lisdexamfetamine)
- Concerta (methylphenidate)

Rate of Opioid, Stimulant, and Benzodiazepine Prescriptions Dispensed in Texas, by Drug Class: 2015-2017
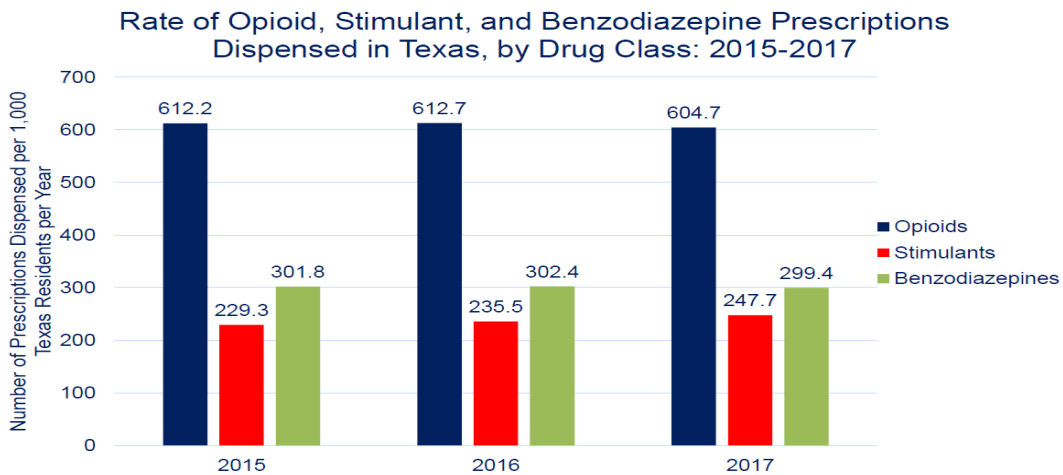
Enhancing the PMP

The TSBP is requesting a $2.5 million per fiscal year Exceptional Item for electronic enhancements to the PMP. Enhancements would include statewide integration of the PMP into prescribers' and dispensers' Electronic Health Record (EHR) systems, the purchase of the NarxCare program, and clinical alert notifications.

Electronic Health Record Integration

As of August 2018, just under one-third of EHR systems were integrated with the state's PMP.[xiii] Numerous provider groups testified that the lack of PMP integration into an EHR creates care interruption. According to the TSBP's Legislative Appropriations Request, "providing integration of the system into the prescribers' & dispensers' electronic medical record systems would dramatically increase the efficiency with which providers have access to the PMP data."[xiv]

NarxCare

NarxCare analyzes PMP data, patient health history, and provides risk scores and an interactive visualization of usage patterns to help identify risk patterns.[xv] Additionally, the program:
- Provides full access to state of the art tools and assessments regardless of integration status
- Sets the stage for incremental data addition determined by the State. Examples include non-fatal overdose, drug court participation, naloxone administration data, etc.
- NarxCare messaging and care notes would allow for provider to provider messaging within the system as well as auto-generated messages based on input from the Texas PMP.

Clinical alerts

Clinical alerts would provide increased notification to the prescribers and pharmacists when their patients meet certain thresholds. Examples include:
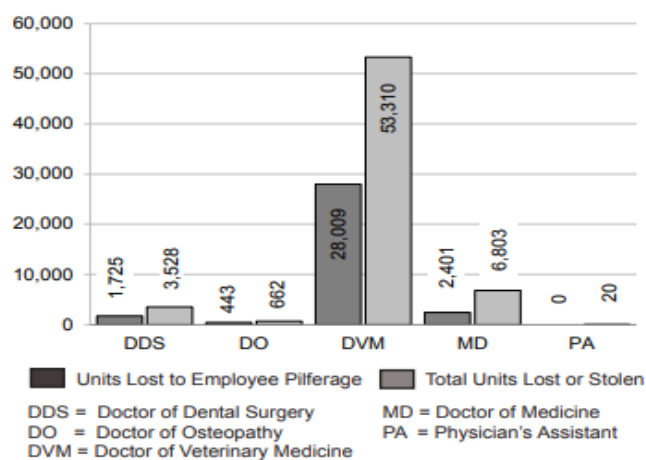- The number of consecutive days a patient receives opioids
- A patient received both an opioid and a benzodiazepine
- Data reflecting the percentage of the maximum morphine equivalent that a patient receives on a daily basis

This data would support practitioners in making medically appropriate prescribing and dispensing decisions and assist in assessing risk of potential abuse and overdose.

Veterinarians

Unlike other practitioners, veterinarians have the authority to both prescribe and dispense drugs, and can keep a fully stocked inventory of most controlled substances in their clinics. Texas veterinarians have been shown to have a high risk of drug diversion, and in 2016, Sunset found that the state has "an ineffective and inconsistent approach to monitoring potential diversion of controlled substances by veterinarians."[xvi] The figure below shows dosage units of Tramadol reported lost or stolen from Veterinary Clinics compared to other prescribers, based on U.S. Drug Enforcement Agency (DEA) data.[xvii] Veterinarians do not report drugs dispensed to the PMP and Sunset found that the State of Board of Veterinary Medical Examiners' inspection process "does not adequately identify or prevent diversion of controlled substances."[xviii]

Dosage Units of Tramadol Reported Lost or Stolen

In response to these findings, Sunset recommended requiring veterinarians to report dispensing information of all Schedule II-V controlled substances to the PMP and requiring the State Board of Veterinary Medical Examiners to "collect and track relevant data to establish a risk-based approach to onsite inspections."[xix] However, these recommendations were not included in House Bill 2561 (85R) and were not written into statute elsewhere.

Seventeen states require veterinarians to report dispensing information to their PMPs.[xx] The DEA data regarding veterinary drug diversion rates in Texas indicate that the state has a need to collect its own data to understand the extent of the problem.

Recommendations

1. **Fund TSBP's Exceptional Item request for enhancements to the PMP, including the integration of the system into electronic health record systems. The state should pursue opportunities for federal funding for these items.** The enhancements will drastically increase the efficiency of the system.

2. **Delay the effective date for requiring prescribers and dispensers to check the PMP prior to prescribing for Schedules III-V, but maintain the September 1, 2019 effective date for schedule II prescriptions.** This will allow prescribers and dispensers time to adjust to using the system, and will allow TSBP time to integrate the system with electronic health record systems, if the Exceptional Item is funded.

3. **Appoint an advisory committee to TSBP comprised of prescribers and dispensers.** This advisory committee would examine data accuracy, data integrity, best practices, and address system weaknesses and workflow challenges.

4. **The Legislature and veterinarian stakeholders should continue to collaborate to ensure veterinarian dispensing of controlled substances is incorporated appropriately into the PMP within 30 days of dispensing.**

5. **Establish legal penalties for wrongful access and misuse of the PMP and direct TSBP to increase financial penalties.** Current penalties for inappropriate use of the PMP are in the form of fines ranging from $1,000 to $2,500.

6. **Continue integrating Texas's PMP with other states' systems.** Texas's system is currently integrated with the following states: Alabama, Arizona, Arkansas, Connecticut, Georgia, Idaho, Kansas, Louisiana, Maine, Massachusetts, Minnesota, Mississippi, Montana, New Mexico, New York, North Carolina, North Dakota, Ohio, Oklahoma, Oregon, Pennsylvania, South Carolina, Tennessee, and Virginia.

7. **Make PMP data available to a minor patient's parent/guardian on behalf of the minor child.** Texas is one of eight states that currently does not have a process for this.

8. **Provide legal immunity to practitioners not submitting data or accessing the PMP.** Thirty other states have legal immunity in place to protect practitioners from civil lawsuits.

9. **Allow a state entity that is also a Centers for Medicare & Medicaid Services (CMS) Qualified Entity (QE) to access the PMP data for research and analysis.** QEs are entities certified by CMS to meet the highest standards in analysis of health data, including protected health information. Currently, only TSBP has the ability to analyze PMP data. This recommendation would allow the data to be analyzed in relation to claims data to study rates and patterns.

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[i] House Bill 2561, 85th Regular Session (Thompson, S./Taylor, V.), 2017.
[ii] Senate Bill 195, 84th Regular Session (Schwertner/Crownover), 2015.
[iii] Sunset Advisory Commission. *Texas State Board of Pharmacy: Staff Report with Final Results.* June 2017.
[iv] *Supra* note 1.
[v] Texas State Board of Pharmacy, *Testimony before the Senate Committee on Health and Human Services.* October 3, 2018.
[vi] *Supra* note 3.
[vii] *Supra* note 3.
[viii] *Supra* note 3.
[ix] *Supra* note 3.
[x] *Supra* note 3.
[xi] *Supra* note 3.
[xii] *Supra* note 3.
[xiii] *Supra* note 3.

[xiv] Texas State Board of Pharmacy, *Legislative Appropriations Request for Fiscal Years 2020 and 2021.* August 10, 2018.

[xv] *Supra* note 14.

[xvi] Sunset Advisory Commission. *State Board of Veterinary Medical Examiners: Staff Report with Final Results.* June 2017.

[xvii] *Supra* note 16.

[xviii] *Supra* note 16.

[xix] *Supra* note 16.

[xx] Texas Veterinary Medical Association, *Testimony before the Senate Committee on Health and Human Services.* October 3, 2018.