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An Audit Report on

The Prescription Monitoring Program at the Board of Pharmacy

December 2021

Report No. 22-010

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Overall Conclusion

The Board of Pharmacy (Board) administers the Prescription Monitoring Program (PMP), which is designed to help prescribers and pharmacists identify, deter, or prevent potential prescription drug misuse, diversion, and overdose. The PMP provides prescribers and pharmacists access to patients' controlled-substance prescription history.

The Board has implemented processes and controls to help ensure that the data submitted to the PMP was sufficiently complete[1]. However, the Board should strengthen certain controls to confirm that PMP data continues to be complete, reported within the required timeframe, and secured.

Background Information

The Prescription Monitoring Program (PMP) was implemented on January 1, 1982, under the Department of Public Safety. As of September 1, 2016, the Board of Pharmacy (Board) became the agency responsible for managing the PMP.

PMP collects outpatient prescription data for Schedules II through V controlled substances that a pharmacy in Texas dispensed or a pharmacy in another state dispensed to a Texas resident. From September 1, 2018, through March 31, 2021, approximately 95.2 million prescriptions were recorded in PMP AWARxE, the system used to manage PMP data. Prescribers and pharmacists with access to PMP AWARxE can use this information as a patient care tool to address potential prescription drug misuse and diversion. Licensing agencies also can monitor their licensees' prescribing practices through the PMP AWARxE system.

Source: The Board.

Data validation and reporting. The Board's PMP process has controls for validating the data when prescription records are submitted. Overall, pharmacists are satisfactorily submitting required prescription information. However, the Board should strengthen its processes for following up with pharmacies not submitting controlled-substance prescription records as required to PMP AWARxE, the system used to manage PMP data.

Clinical alerts and communication. The Board implemented clinical alerts to notify prescribers and pharmacists when activity may indicate a harmful prescribing pattern or identify a patient at risk of substance abuse. However, the Board should develop processes to (1) provide immediate notice of those alerts to the relevant licensing agencies as required by statute and (2) verify that pharmacists review patients' history prior to dispensing certain controlled substances.

Fiscal controls. The Board implemented sufficient fiscal controls to ensure that payments tested, totaling almost $9.0 million, were supported, properly approved, and did not exceed the contracted amounts. However, it should maintain all

[1] The analysis focused on the completeness of the information required by statute that dispensing pharmacies submitted to PMP. Auditors did not assess the accuracy of the data because the original prescription information resides at dispensing pharmacies.

This audit was conducted in accordance with Texas Government Code, Section 321.013.

For more information regarding this report, please contact Cesar Saldivar, Audit Manager, or Lisa Collier, State Auditor, at (512) 936-9500.

contract documentation in accordance with its records retention policy and report vendor performance as required by statute.

IT controls. The Board had significant weaknesses in selected information technology controls that reduced its ability to safeguard its data, which contains sensitive and confidential information. To minimize security risks, auditors communicated details about the identified weaknesses separately to the Board's management in writing.

Pursuant to Standard 9.61 of the U.S. Government Accountability Office's Generally Accepted Government Auditing Standards, certain information was omitted from this report because that information was deemed to present potential risks related to public safety, security, or the disclosure of private or confidential data. Under the provisions of Texas Government Code, Section 552.139, the omitted information is also exempt from the requirements of the Texas Public Information Act.

Table 1 presents a summary of the findings in this report and the related issue ratings. (See Appendix 2 for more information about the issue rating classifications and descriptions.)

Table 1

Summary of Chapters and Related Issue Ratings		
Chapter	**Title**	**Issue Rating [a]**
1	Background Information on the Prescription Monitoring Program	Not Rated
2	PMP AWARxE Data Is Sufficiently Complete; However, the Board Should Continue to Strengthen Its Processes for Monitoring Pharmacies Not Submitting Prescription Records as Required	Medium
3	While the Board Implemented a Clinical Alert to Help Identify Patients at Risk of Potential Drug Abuse, It Does Not Monitor to Determine Whether Pharmacists Reviewed Patients' History as Required	Medium
4	The Board Had Sufficient Contract Fiscal Controls; However, It Should Comply with Its Records Retention Policy and Vendor Performance Reporting Requirements	Medium
5	The Board Should Strengthen Controls Over the PMP AWARxE System to Help Safeguard Its Data	Priority

[a] A chapter is rated **Priority** if the issues identified present risks or effects that if not addressed could critically affect the audited entity's ability to effectively administer the program(s)/function(s) audited. Immediate action is required to address the noted concern and reduce risks to the audited entity.

A chapter is rated **High** if the issues identified present risks or effects that if not addressed could substantially affect the audited entity's ability to effectively administer the program(s)/function(s) audited. Prompt action is essential to address the noted concern and reduce risks to the audited entity.

A chapter is rated **Medium** if the issues identified present risks or effects that if not addressed could moderately affect the audited entity's ability to effectively administer the program(s)/function(s) audited. Action is needed to address the noted concern and reduce risks to a more desirable level.

A chapter is rated **Low** if the audit identified strengths that support the audited entity's ability to administer the program(s)/function(s) audited or the issues identified do not present significant risks or effects that would negatively affect the audited entity's ability to effectively administer the program(s)/function(s) audited.

Auditors communicated other, less significant issues separately in writing to Board management.

Summary of Management's Response

At the end of Chapters 2, 3, and 4 in this report, auditors made recommendations to address the issues identified during this audit. The Board agreed with the recommendations in those chapters.

The Board disagreed with the Priority rating assigned to Chapter 5. Auditors used professional judgment to rate the weaknesses in the Board's information technology controls and stands by its conclusion.

Audit Objective and Scope

The objective of this audit was to determine whether the Board has processes and related controls to help ensure that it administers the PMP and related contract management functions in accordance with applicable requirements.

The scope of this audit covered PMP activities from September 1, 2018, through March 31, 2021. For contract oversight, the scope included selected internal controls related to the Board's contract monitoring activities and all payments for PMP services from January 15, 2016, through August 31, 2021. The scope also included a review of significant internal control components related to PMP management activities.

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Detailed Results

Chapter 1

Background Information on the Prescription Monitoring Program

Controlled Drugs

A controlled (scheduled) drug is one whose use and distribution is tightly controlled because of its abuse potential or risk. Controlled drugs are rated in the order of their abuse risk and placed in Schedules I through V by the U.S. Drug Enforcement Administration.

Schedule I: Drugs with a high abuse risk (such as heroin) with NO safe and accepted medical use.

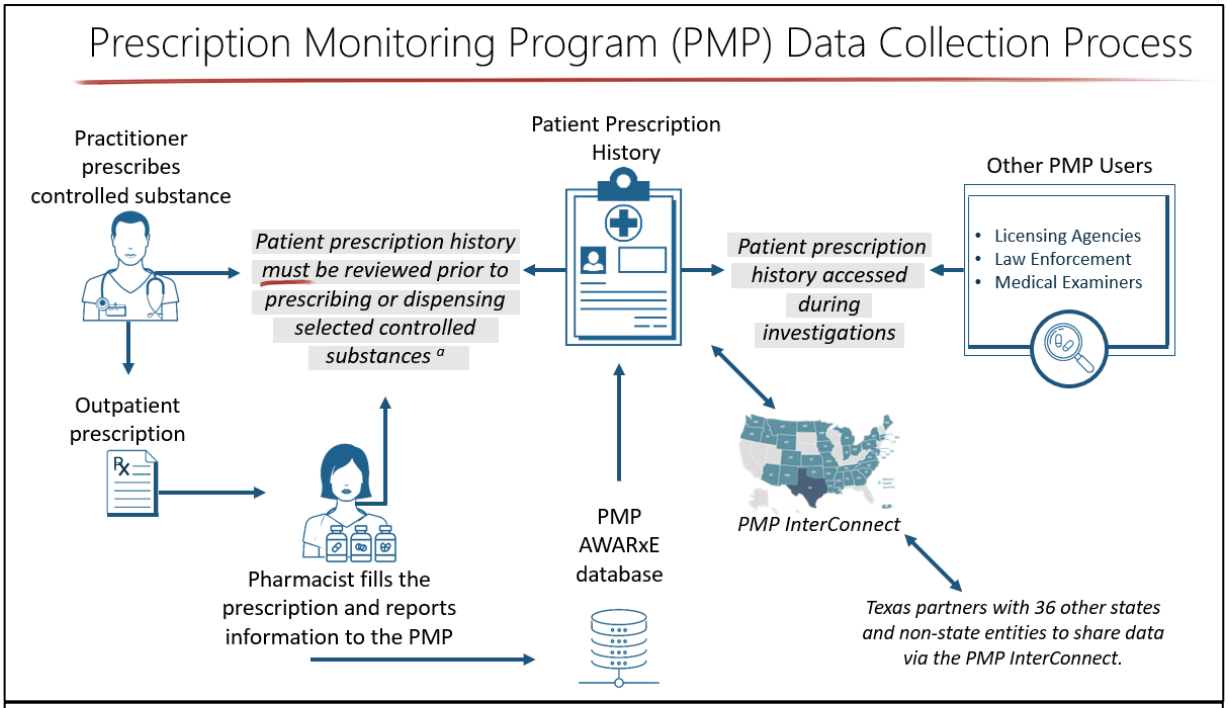
Schedule II: Drugs with a high abuse risk (such as morphine) but with safe and accepted medical uses.

Schedules III, IV, or V: Drugs with an abuse risk that is less than Schedule II.

Source: The Board of Pharmacy.

The Prescription Monitoring Program (PMP) provides prescribers and pharmacists access to a patient's controlled-substance prescription history. PMP is designed to help prescribers and pharmacists identify, deter, or prevent potential prescription drug misuse, diversion, and overdose. PMP collects outpatient prescription data on all Schedule II through Schedule V controlled substances that pharmacies dispense in Texas or that pharmacies in another state dispense to a Texas resident (see text box for more information about controlled drugs). Pharmacies are required to report all dispensed controlled substance information to PMP AWARxE, the system used to manage PMP data. To strengthen patient prescription history, Texas shares PMP data with other states/entities to help monitor prescriptions dispensed to Texas patients across state lines (see Appendix 4 for a list of those states and entities). Figure 1 shows PMP's data collection process.

Figure 1

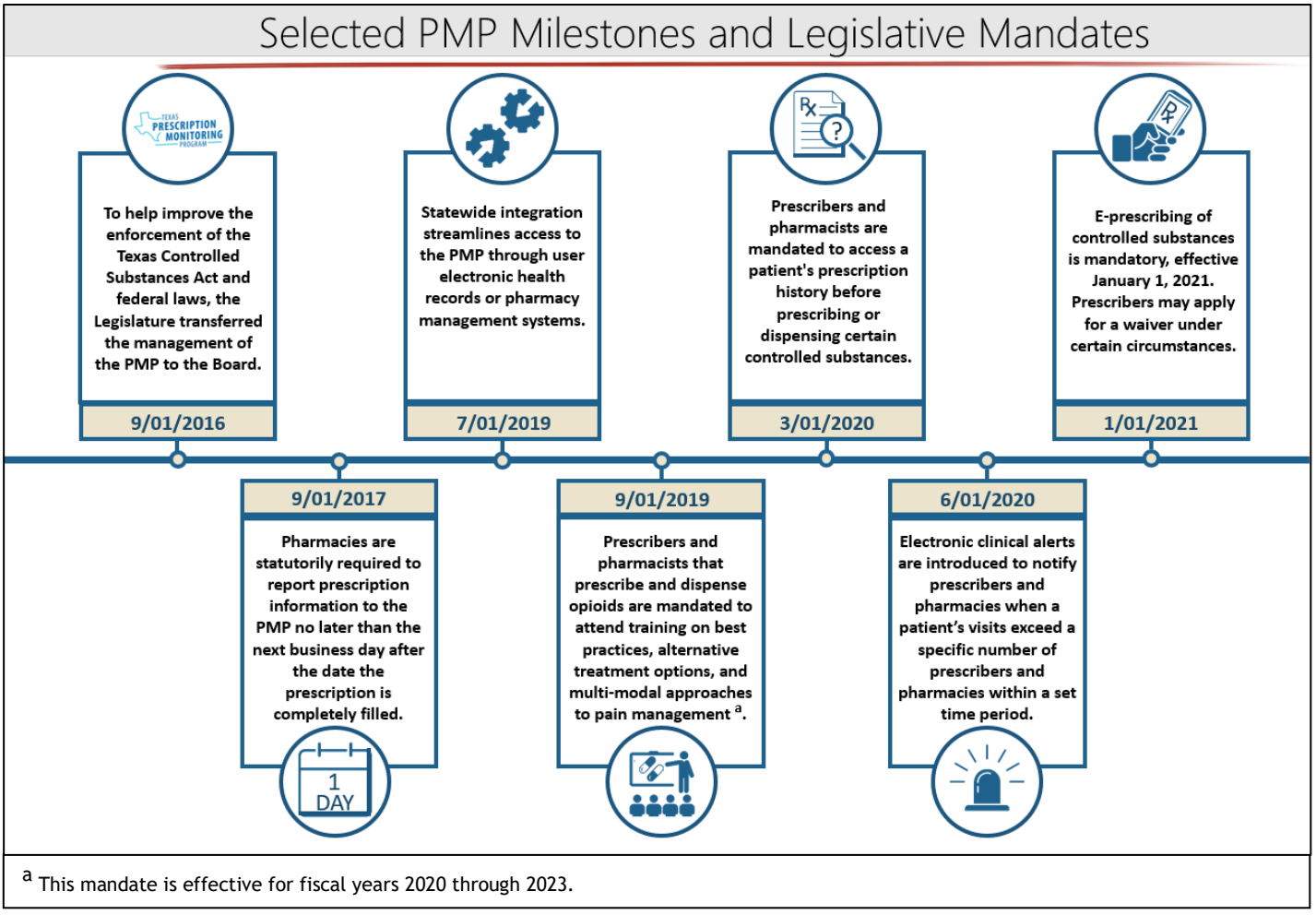


[a] Prescribers, other than veterinarians, and pharmacists are required to access a patient's prescription history only when the prescription involves opioids, benzodiazepines, barbiturates, or carisoprodol; this requirement is waived when the prescription clearly identifies the patient as diagnosed with sickle cell disease or cancer or receiving hospice care.

Source: Based on information from the Board of Pharmacy.

As of September 1, 2016, the Board of Pharmacy (Board) is the agency responsible for managing the PMP. Since then, the Board has coordinated the implementation of certain legislative mandates to help improve the timeliness and accuracy of the prescription data. For example, pharmacies are now required to report dispensed information no later than the next business day after the prescription is completely filled and E-prescribing is mandatory to help eliminate handwriting errors and reduce the use of fraudulent prescriptions. In addition, the PMP AWARxE system issues electronic clinical alerts[2] to prescribers and pharmacists whose prescription records may suggest potential prescription drug abuse or diversion. Figure 2 shows selected PMP milestones and legislative mandates.

Figure 2



[a] This mandate is effective for fiscal years 2020 through 2023.

Sources: Based on information from the Texas Health and Safety Code, Chapter 481, and the Board.

[2] Prior to electronic clinical alerts, the Board mailed to prescribers push notifications that contained information similar to clinical alerts. The Board reports that Push Notifications were active from May 2017 through March 2020.

Chapter 2

PMP AWARxE Data Is Sufficiently Complete; However, the Board Should Continue to Strengthen Its Processes for Monitoring Pharmacies Not Submitting Prescription Records as Required

Chapter 2 Rating:

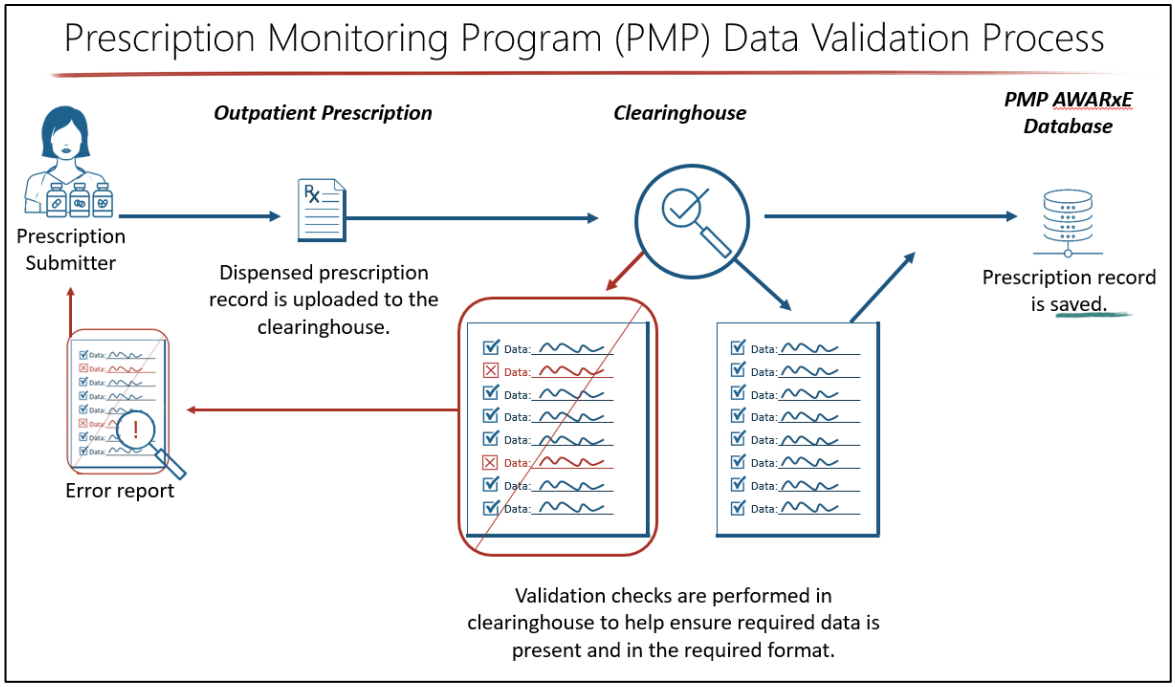
Medium [3]

The Board implemented processes that ensured the information pharmacies reported to the Prescription Monitoring Program (PMP) was sufficiently complete. However, it should strengthen its processes for following up with pharmacies not submitting controlled-substance prescription records to PMP AWARxE as required.

The Board has established controls that ensure the records submitted to AWARxE are sufficiently complete.

The PMP process has application controls for validating the data when prescription records are submitted. Pharmacies are required to report to the PMP clearinghouse the records for all controlled-substance prescriptions completely filled not later than the next business day. The clearinghouse system compares those records against the established validation standards, such as data completeness and formatting, and generates an error report for the submitting pharmacy, if applicable, to facilitate error corrections. Figure 3 illustrates the PMP data validation process.

Figure 3



Source: Based on information from the Board of Pharmacy.

[3] The risk related to the issues discussed in Chapter 2 is rated as Medium because they present risks or effects that if not addressed could moderately affect the audited entity's ability to effectively administer the program(s)/function(s) audited. Action is needed to address the noted concern and reduce risks to a more desirable level.

Data analysis. Pharmacists overall are satisfactorily submitting required prescription information. Specifically, auditors performed data analysis on statutorily required data fields for approximately 95.2 million prescription records submitted to PMP AWARxE from September 1, 2018, through March 31, 2021, and determined that nearly all the records contained the required prescription information[4] (see text box for statutorily required prescription data fields included in the analysis). Auditors identified certain data entry controls that should be strengthened to increase compliance with verification standards and statutory requirements. For example, the U.S. Drug Enforcement Administration (DEA) registration number entered did not always meet required format, the last-name field accepted a single space as an entry, and the drug quantity field allowed zero to be entered as a quantity.

Required Prescription Data Fields

- Patient name, address, and date of birth.
- Prescriber name, address, and U.S. Drug Enforcement Administration registration number.
- Date prescription is issued and date it is filled.
- Drug name and quantity.

Source: Texas Health and Safety Code, Sections 481.074 and 481.075.

PMP Review process. During January 2020, the Board reports that it initiated a PMP Review process with the goal of examining 5,403 pharmacies authorized to dispense controlled substances as of that date. The process consists of a detailed review of each pharmacy's data, focusing on completeness in terms of the statutorily required prescription information referenced above. The Board reported that 74 PMP reviews were in progress as of March 31, 2021. The Board also reported that the PMP Review policies and procedures were in progress.

The completeness of data is critical to help ensure that (1) AWARxE users can rely and make informed decisions based on available prescription information and (2) clinical alerts, which identify potentially harmful prescription patterns that may suggest drug diversion or drug abuse, are triggered when criteria is met. See Chapter 3 for additional detail on clinical alerts.

Prescription Reporting and Waiver Requirements

Texas Health and Safety Code, Section:

- 481.074(q)-requires prescription information to be reported to the Board not later than the next business day after the date the prescription is completely filled.
- 481.075(i)(4)-states that if the pharmacy does not dispense any controlled-substance prescriptions during a period of seven consecutive days, it is to send a report to the Board indicating as such, unless the pharmacy has obtained a waiver or permission to delay reporting to the Board.

The Board should continue to strengthen its processes for monitoring pharmacies not submitting prescription records as required.

PMP AWARxE generates a "Delinquent Dispenser" report that lists pharmacies that are not compliant with statutory reporting requirements (see text box for those requirements). During January 2021, the Board implemented a process to monitor and help bring into compliance the pharmacies listed in that report. The process included verifying operational status and determining whether a Notice of Delinquency was needed. As of March 31, 2021, the Board had

[4] The analysis focused on the completeness of information required by statute. Auditors did not assess the accuracy of data because the original prescription information resides at the dispensing pharmacies and was unavailable for such a comparison.

completed 26 reviews. For the six completed reviews auditors tested, the Board sent a Notice of Delinquency to the pharmacy.

However, the Board has not established procedures for following up on these notices or a protocol for referring these pharmacies to the Enforcement Division for non-compliance (see text box for the penalties that the Enforcement Division may initiate). Five of the 6 pharmacies that received a Notice of Delinquency between January 28, 2021, and March 17, 2021, remained on the list of 258 non-compliant pharmacies as of March 31, 2021.

Enforcement

A dispenser that fails to provide required information is subject to an administrative penalty or a civil penalty of not more than $5,000 for each act.

Sources: Texas Health and Safety Code, Section 481.128; and Title 22, Texas Administrative Code, Section 281.65.

In addition, the Board's process did not proactively address pharmacies' non-compliance. For example, while pharmacies are required to report prescription information within 1 business day of complete dispensation, the 6 pharmacy reviews tested were of pharmacies that had been delinquent between 73 and 545 days. The Board also reported that policies and procedures to monitor pharmacies that are delinquent with reporting requirements were in progress.

The Board also does not have a process to verify that it has entered all pharmacies with a DEA registration number, which authorizes them to dispense controlled substances, into the PMP AWARxE system. If the pharmacy is not entered into the system, its compliance with reporting requirements cannot be tracked in the Delinquent Dispenser report. Auditors identified 7 pharmacies with a DEA registration number that the Board had not entered into PMP AWARxE; as of March 31, 2021, those seven pharmacies had neither reported any prescription data to PMP AWARxE nor obtained a Board-approved prescription reporting waiver.

Lack of fully developed and implemented monitoring processes to help ensure that prescription data is reported to PMP AWARxE as required by statute impacts the timeliness and completeness of prescription information. Prescribers and pharmacists rely on this data to make an informed decision when considering prescribing or dispensing a controlled substance to a patient.

Recommendations

The Board should:

- Strengthen PMP clearinghouse controls by refining the field entry requirements to require complete and correctly formatted entries.
- Fully develop, document, and implement data completeness and monitoring procedures to promptly identify and correct inconsistencies in data submitted and bring into compliance delinquent pharmacies.
- Develop, document, and implement (1) a process to identify pharmacies with a DEA registration number that need to be added to PMP AWARxE and (2) policies and procedures to monitor pharmacies not submitting prescription records as required, including procedures for referring pharmacies to the Enforcement Division for further action.

Management's Response

TSBP agrees to continue strengthening processes, including policies and procedures, for monitoring pharmacies not submitting prescription records as required.

- *TSBP will continue to strengthen PMP clearinghouse controls by refining the field entry requirements to require complete and correctly formatted entries.*
- *TSBP further developed and implemented data completeness and monitoring procedures in July 2021 and procedures for referring pharmacies to Enforcement in May 2021. Additionally, an automatic delinquency notice email to pharmacies was implemented in November 2021.*
- *TSBP further developed and implemented a process to identify pharmacies with a DEA registration number that need to be added to PMP AWARxE in September 2021. However, TSBP notes that the seven pharmacies the auditors identified that the agency had not entered into PMP AWARxE accounted for only 0.1% of the 5,449 pharmacies that obtained a DEA registration number between April 2016 and December 2020.*

Responsible Party: PMP Manager

Target Date: March 2022

Chapter 3

While the Board Implemented a Clinical Alert to Help Identify Patients at Risk of Potential Drug Abuse, It Does Not Monitor to Determine Whether Pharmacists Reviewed Patients' History as Required

Chapter 3 Rating:

Medium[5]

The Board implemented a clinical alert notification process to help prescribers and pharmacists identify potentially harmful prescribing practices and to help mitigate the risk of controlled-substance misuse or abuse by patients. However, the Board did not immediately provide clinical alert notifications to the licensing agencies responsible for monitoring prescribers' activity as required by statute. In addition, the Board had not implemented a monitoring process to verify that pharmacists reviewed patients' prescription histories prior to dispensing certain controlled substances.

The Board implemented an electronic clinical alert in accordance with statutory requirements.

Texas Health and Safety Code, Chapter 481, Subchapter C, requires the Board to identify prescribing practices that may be potentially harmful and patient prescription patterns that may suggest drug diversion or drug abuse. In addition, if prescription data submitted to the Board indicates a potentially harmful prescribing pattern, practice, or drug abuse, the Board may send an electronic notification to the prescriber or pharmacist. A clinical alert is an electronic notification sent to a pharmacist or a prescriber when prescriptions entered in PMP AWARxE meet certain criteria established by the Board, in consultation with the licensing agencies that have access to PMP AWARxE.

In June 2020, the Board activated the Prescriber and Dispenser alert, which is triggered when a patient receives a prescription from a specified number of prescribers and that prescription is dispensed by a specified number of dispensers (pharmacies) within a set time period[6]. The alert does not consider the amount or type of controlled substances dispensed.

[5] The risk related to the issues discussed in Chapter 3 is rated as Medium because they present risks or effects that if not addressed could moderately affect the audited entity's ability to effectively administer the Program(s)/function(s) audited. Action is needed to address the noted concern(s) and reduce risks to a more desirable level.

[6] To protect the integrity of the clinical alert process, auditors are not disclosing the thresholds used to trigger this alert type.

The Board should improve its notification process by providing licensing agencies with immediate notice of clinical alerts issued to their prescribers.

Licensing Agencies Whose Prescribers Access PMP AWARxE

- Board of Veterinary Medical Examiners.
- Optometry Board.
- Texas Medical Board.
- Texas Board of Nursing.
- Texas State Board of Dental Examiners.
- Texas Department of Licensing and Regulation (podiatrists).

Source: Texas Health and Safety Code, Section 481.076(a)(1).

Texas Health and Safety Code, Section 481.0762(c), states that if the Board sends a prescriber an electronic notification, the Board shall immediately send an electronic notification to the appropriate licensing agency (see text box for a list of licensing agencies). For all three months that auditors tested, the Board provided clinical alert notifications to licensing agencies on a monthly basis instead of immediately as required by statute. The Board asserted that licensing agencies do not have the capacity to process clinical alerts more often than on a monthly basis. Not providing the immediate notifications required by statute increases the risk that a licensing agency delays corrective action when a prescriber's behavior may indicate a harmful prescribing pattern.

The Board should implement a process to monitor pharmacists' compliance with patient history review requirements.

Exceptions to Patient History Review Requirement

Pharmacists are not required to review a patient's record if:

- The prescription record clearly notes that the patient has been diagnosed with cancer or sickle cell disease or is receiving hospice care.
- Despite a good-faith attempt to comply, the pharmacists are unable to access the information because of circumstances beyond their control.

Source: Texas Health and Safety Code, Section 481.0765.

As of March 1, 2020, Texas Health and Safety Code, Section 481.0764(a), requires a pharmacist, or a pharmacist's delegate, to access a patient's prescription history prior to dispensing opioids, benzodiazepines, barbiturates, or carisoprodol (see text box for exceptions to this requirement). However, the Board had not developed or implemented any processes to monitor whether pharmacists are complying with that requirement. The purpose of the checks is to help pharmacists to identify any duplicate prescriptions from multiple prescribers[7] or the over prescription of drugs before dispensing additional controlled substances.

For 13 (52.0 percent) of the 25 records tested, the pharmacist did not access the record to review a patient's prescription history prior to dispensing opioids, benzodiazepines, barbiturates, or carisoprodol. While there may have been a valid reason for not reviewing the 13 patient history records, lack of a monitoring process increases the possibility that a patient with a substance abuse disorder will not be identified.

[7] Obtaining prescriptions from multiple doctors, also known as doctor shopping, is a practice among users with a controlled substance use disorder.

Recommendations

The Board should:

- Implement a process to send clinical alert notifications to the appropriate licensing agency immediately upon their being issued to prescribers as required by statute.
- Implement a monitoring process to determine whether pharmacists perform the statutorily required reviews of patients' prescription histories.

Management's Response

TSBP agrees to implement a process to send clinical alert notifications to the appropriate licensing agency as soon as possible following issuance to prescribers. However, TSBP continues to find concern with the feasibility of immediate notifications that currently require a manual process and with the other licensing boards' capacity to process these alerts on an immediate basis.

TSBP agrees that state law requires a pharmacist, or pharmacist delegate, to access a patient's prescription record prior to dispensing opioids, benzodiazepines, barbiturates, or carisoprodol unless a statutory exception applies. However, state law does not require TSBP to actively monitor PMP data to determine whether pharmacists, or pharmacist delegates, are performing this review. TSBP finds concern with the feasibility of monitoring the approximately 1.5 million prescriptions each month that potentially require a mandatory pharmacist review, particularly given that the PMP AWARxE vendor does not currently offer a feature that could perform this monitoring of pharmacists' reviews automatically. Nevertheless, TSBP agrees to implement a process to confirm that a pharmacist, or a pharmacist delegate, performed the required review of patients' prescription history.

Responsible Party: PMP Manager

Target Date: May 2022

Chapter 4

The Board Had Sufficient Contract Fiscal Controls; However, It Should Comply with Its Records Retention Policy and Vendor Performance Reporting Requirements

Chapter 4 Rating:

Medium [8]

The Board had sufficient fiscal controls in place to process PMP AWARxE contract payments. However, it should maintain all contract documentation in accordance with records retention policy and report vendor performance as required by statute.

Fiscal oversight. The Board ensured that all contract payments tested, totaling $8,967,525 for PMP AWARxE services received from September 1, 2016, through August 31, 2021[9], were supported, properly approved, and did not exceed the contracted amounts. The Board's policy requires it to retain all contract documentation for the term of the contract plus seven years. However, the Board did not retain documentation for the first payment of $250,000 for PMP AWARxE contract services received from January 15, 2016, through August 31, 2016. As a result, auditors could not test whether that payment was supported and properly approved. Table 2 lists the contracted services related to those payments.

Table 2

Contract Payments and Services for Fiscal Years 2016 Through 2021		
Date	**Contracted Services**	**Total Contract Payments**
January 15, 2016, through August 31, 2016	PMP AWARxE implementation and testing.	$ 250,000 [a]
September 1, 2016, through August 31, 2017	PMP AWARxE services for year 1.	625,000
September 1, 2017, through August 31, 2018	PMP AWARxE services for year 2.	700,000
October 5, 2017	Creation of batch user accounts to facilitate PMP AWARxE user registration.	8,400
September 1, 2018, through August 31, 2019	PMP AWARxE services for year 3.	700,000
July 1, 2019, through August 31, 2021	PMP Gateway - An integration service that streamlines access to PMP and other states' PMP data.	4,550,000
July 1, 2019, through August 31, 2021	NarxCare - A patient tool that includes information such as a patient's use of narcotics, sedatives, and stimulants.	868,292
July 1, 2019, through August 31, 2021	Clinical Alerts - A notification service to prescribers and pharmacists that may indicate a potential harmful prescribing pattern, drug diversion, or drug abuse may be occurring.	50,833

[8] The risk related to the issues discussed in Chapter 4 is rated as Medium because issues identified present risks or effects that if not addressed could moderately affect the audited entity's ability to effectively administer the program(s)/function(s) audited. Action is needed to address the noted concern(s) and reduce risks to a more desirable level.

[9] The PMP AWARxE contract requires service fees to be paid in advance.

Contract Payments and Services for Fiscal Years 2016 Through 2021		
Date	Contracted Services	Total Contract Payments
October 1, 2019	A service that allows prescribers to monitor the prescribing activity of individuals to whom they have delegated prescribing authority.	65,000
September 1, 2019, through August 31, 2020	PMP AWARxE Services for year 4.	700,000
September 1, 2020, through August 31, 2021	PMP AWARxE Services for year 5.	700,000
	Total Payments	**$ 9,217,525**

[a] Payment was not tested because supporting documentation was destroyed.

Source: PMP AWARxE contract.

Vendor performance reporting. The Board did not report vendor performance as required for its PMP AWARxE contract to the Office of the Comptroller of Public Accounts' (Comptroller's Office) Vendor Performance Tracking System prior to extending the contract. As of September 1, 2019, Texas Government Code, Section 2155.089, required state agencies to review vendor performance for contracts that exceed $5 million at least once each year during the term of the contract, at each contract key milestone, and before extending the contract.

As of June 13, 2019, the PMP AWARxE contract exceeded $5 million and the Board extended the contract for an additional year on August 21, 2020. The Board asserted that, as of May 28, 2021, it had not reported any vendor performance to the Comptroller's Office. By not reporting vendor performance as required by statute, the Board creates the risk that other users of the Vendor Performance Tracking System may not have sufficient information to make contracting decisions.

Recommendation

The Board should:

- Maintain all contract documentation in accordance with policy.
- Implement procedures to report vendor performance to the Comptroller's Office as required.

Management's Response

TSBP acknowledges that a good faith misinterpretation of the record retention policy that applied to documentation of the first payment for PMP AWARxE contract services occurred. Moving forward, the agency will apply the correct record retention policy to this type of payment documentation.

TSBP acknowledges the failure to report vendor performance for the PMP AWARxE contract prior to extending the contract. However, TSBP notes that the agency experienced technical issues with the Comptroller's Office Vendor Performance Tracking System and contacted the Comptroller's Office regarding these technical issues. TSBP submitted the vendor performance report on September 30, 2021. Additionally, TSBP updated purchasing procedures in October 2021 to include specific references to vendor performance reporting.

Responsible Party: Director of Finance

Target Date: October 2021

Chapter 5

The Board Should Strengthen Controls Over the PMP AWARxE System To Help Safeguard Its Data

Chapter 5 Rating:

Priority[10]

The Board had significant weaknesses in the controls to protect its data, which contains sensitive medical and other confidential information. To minimize security risks, auditors communicated details separately to the Board's management in writing.

Pursuant to Standard 9.61 of the U.S. Government Accountability Office's Generally Accepted Government Auditing Standards, certain information was omitted from this report because that information was deemed to present potential risks related to public safety, security, or the disclosure of private or confidential data. Under the provisions of Texas Government Code, Section 552.139, the omitted information is also exempt from the requirements of the Texas Public Information Act.

[10] The risk related to the issues discussed in Chapter 5 is rated as Priority because they present risks or effects that if not addressed could critically affect the audited entity's ability to effectively administer the program(s)/function(s) audited. Immediate action is essential to address the noted concern(s) and reduce risks to the audited entity.

Appendices

Appendix 1

Objective, Scope, and Methodology

Objective

Determine whether the Board of Pharmacy (Board) has processes and related controls to help ensure that it administers the Prescription Monitoring Program (PMP) and related contract management functions in accordance with applicable requirements.

Scope

The scope of this audit covered PMP activities from September 1, 2018, through March 31, 2021. For contract oversight, the scope included selected internal controls related to the Board's contract monitoring activities and all payments for PMP services from January 15, 2016, through August 31, 2021. The scope also included a review of significant internal control components related to PMP management activities (see Appendix 3 for more information about internal control components).

Methodology

The audit methodology included reviewing and analyzing the PMP's prescription data; conducting interviews; reviewing the PMP's contract and amendments; and performing selected tests and other procedures. The audit methodology also included testing selected general and application controls over PMP AWARxE, the Board's information technology system used to collect information for dispensed controlled substances and manage PMP.

Data Reliability and Completeness

PMP AWARxE. Auditors obtained the following data populations from PMP AWARxE to analyze prescription data and determine whether all pharmacies authorized to dispense a controlled substance were reporting prescription information to PMP AWARxE:

- Prescription data, which includes information such as pharmacy, patient full name, prescribed drug name and quantity, and dispensed date, from September 1, 2018, through March 31, 2021.
- List of pharmacies that have submitted prescription data as of June 25, 2021.
- List of pharmacies with an approved waiver as of May 14, 2021.

- Clinical alerts issued from June 6, 2020, through March 31, 2021.

Auditors also obtained active user access accounts as of May 6, 2021, for the following user roles:

- Investigator role.
- Pharmacist role.
- Licensees from a selected licensing agency[11].

To assess the reliability of the data obtained from PMP AWARxE, auditors performed procedures including (1) observing data extracts, (2) reviewing SQL or standard report parameters used to extract the data, (3) performing data analysis to identify missing data or outliers, and (4) reviewing key data fields for completeness and reasonableness. Auditors also evaluated the effectiveness of certain general and application controls over PMP AWARxE.

Auditors determined that the data obtained from PMP AWARxE was sufficiently reliable for purposes of this audit.

Uniform Statewide Accounting System (USAS). Auditors downloaded all PMP contract payments from USAS for services provided from January 15, 2016, through August 31, 2021. To assess the reliability of the data, auditors reconciled USAS information to the approved contract, contract amendments, invoices, and the Board's internal system. Auditors determined that USAS contract payments data was sufficiently reliable for purposes of this audit.

List of Licensees. To test the appropriateness of user access to PMP AWARxE based on a licensee's license status (for example, active, revoked, retired, etc.), auditors downloaded selected licensees' information from the public websites of the Board and another licensing agency[12]. To assess the completeness of that licensee information, auditors reviewed key data fields. Auditors determined that the information was of undetermined reliability because there were instances in which the expiration date was blank. However, this was the most complete population to assess user access appropriateness.

Delinquent Pharmacies. Auditors obtained from PMP AWARxE a list of pharmacies that were delinquent with PMP reporting requirements that were subject to the Board's delinquent pharmacies review process. To assess

[11] In addition to the Board users, prescribers from six other licensing agencies have access to PMP AWARxE information.

[12] To test the Board's processes for monitoring user access to PMP AWARxE, auditors sampled licensee information from one of the six other licensing agencies that have access to that system.

the reliability of delinquent pharmacies subject to the Board's review process, auditors reviewed key data fields for completeness and reasonableness. Auditors determined that the population was of undetermined reliability because the completeness of the population could not be verified because it was established based on Board's staff notations. However, it provided the most complete population to pull a sample to determine if the Board follows its process to bring pharmacies into compliance with PMP reporting requirements.

Closed Pharmacies. Auditors obtained from Board staff a list of pharmacies with a closed status as of March 31, 2021, from the Board's licensing system. To assess the reliability of the information, auditors verified that each record included a unique license number. Auditors determined that the population of closed pharmacies was of undetermined reliability because the completeness of the population could not be verified because the underlying query language to generate the report was not available for review. However, this was the most complete population to determine if it was appropriate for a pharmacy to not be registered in PMP AWARxE.

U.S. Drug Enforcement Administration (DEA) Registration Numbers. Auditors obtained from Board staff a list of pharmacies with a DEA registration number, which allows those pharmacies to dispense controlled substances, as of March 31, 2021. Auditors obtained additional lists with prescriber DEA registration numbers for selected dates between September 7, 2017, and November 6, 2019. To assess the reliability of the information, auditors reviewed key data fields for completeness, reasonableness, and duplicates. Auditors determined that the population of DEA registration numbers was of undetermined reliability because the completeness of the population could not be verified because the information was third-party data. However, this was the most complete information related to DEA registration numbers to determine (1) whether all pharmacies that can dispense a controlled substance were registered in the PMP AWARxE and (2) if prescribers' DEA registration numbers agreed with the information in PMP AWARxE.

Official Prescription Form. Auditors obtained from Board staff a list of official prescription forms that prescribers reported as lost, stolen, or destroyed from September 1, 2018, through March 31, 2021. To assess the reliability of the information, auditors observed Board staff retrieve the information and determined that the population was of undetermined reliability because the information was self-reported by prescribers and the completeness of the population could not be verified. However, this was the most complete information available to determine if official prescription forms reported as lost, stolen, or destroyed were inappropriately used to obtain a controlled substance prescription.

Sampling Methodology

Auditors selected nonstatistical samples for (1) clinical alerts and (2) patients' prescription history records, primarily through random selection. The sampling design was selected to provide auditors with sufficient evidence to meet the audit objectives. The following sample items were not necessarily representative of the population; therefore, it would not be appropriate to project the test results to the population:

- To determine if notifications were sent to other licensing agencies, auditors randomly selected all clinical alerts issued for 2 of the 10 months within the audit scope. Auditors also selected one additional month based on risk to ensure the sample included a representative section of all clinical alerts issued.

- To determine if pharmacists were reviewing patients' prescription history records prior to dispensing certain controlled substances, auditors randomly selected a sample of 25 records as follow: 3 records per month from June 2020 through January 2021, and 2 records from February 2021 (which included one replacement record) from a total of 181,241 clinical alerts associated with a patient. The sample was designed to ensure that it included a cross section of patient records from clinical alerts issued from June 6, 2020, through February 28, 2021.

In addition, to determine if the Board followed its process to address pharmacies delinquent with reporting requirements, auditors selected a nonstatistical sample through random selection of 6 of 26 delinquent pharmacies reviews the Board performed. The test results may be projected to the population, but the accuracy of the projection cannot be measured.

To determine if the official prescription forms that prescribers reported as lost, stolen, or destroyed were inappropriately used to obtain a controlled substance, auditors selected a nonstatistical sample through random selection of 25 forms from 2,880 forms submitted. The test results may be projected to the population, but the accuracy of the projection cannot be measured.

To determine if the information in PMP AWARxE matched (1) a prescriber's DEA registration number from the list provided by Board staff and (2) a prescriber's professional license number from licensing board data, auditors selected a nonstatistical sample through random selection of 25 prescriber DEA registration numbers from 14,062 prescribers' DEA registration numbers. The test results may be projected to the population, but the accuracy of the projection cannot be measured.

In addition, auditors selected one of six other licensing agencies whose prescribers use PMP AWARxE to test the Board's processes for managing user access to that system. This was a risk-based sample that was not necessarily representative of the population; therefore, it would not be appropriate to project those test results to the population.

Information collected and reviewed included the following:

- PMP information including prescription data, clinical alerts, Patient History Results reports and Patient Reports (full prescription details).
- Pharmacies with an approved reporting waiver.
- Pharmacies with an active DEA registration number.
- PMP contract and amendments.
- Board policies and procedures.
- The professional license numbers and license status for licensees of the Board and one other licensing agency that has access to PMP AWARxE.

Procedures and tests conducted included the following:

- Interviewed Board's management and staff, as well as staff at the vendor that provides PMP AWARxE services for the Board.
- Reviewed the Board's processes for monitoring whether pharmacies submitted complete and timely data to the PMP.
- Analyzed the PMP's data for completeness and compliance with American Society for Automation in Pharmacy standards and PMP vendor-implemented validation requirements.
- Performed tests to assess if (1) the Board timely notified other licensing boards when their prescribers received a clinical alert as required by statute and (2) pharmacists reviewed a patient's prescription history prior to dispensing certain controlled substances.
- Tested PMP payments to determine whether they were properly supported and approved, and did not exceed the contract amount.
- Reviewed policies and procedures for, and tested selected general and application controls over, the Board's PMP AWARxE system.

Criteria used included the following:

- Texas Health and Safety Code, Chapter 481.
- Department of Information Resources' *Security Control Standards Catalog*, version 1.3.
- Title 1, Texas Administrative Code, Chapter 202.
- Title 1, Texas Administrative Code, Chapter 315.
- Board policies and procedures.
- American Society for Automation in Pharmacy standards and PMP AWARxE vendor-implemented validation requirements.

Project Information

Audit fieldwork was conducted from February 11, 2021 through November 2021. We conducted this performance audit in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objective(s). Those standards also require independence in both fact and appearance. During the audit, legislative funding was vetoed. This condition could be seen as potentially affecting our independence in reporting results related to this agency. However, we proceeded with this audit as set forth by the annual state audit plan, operated under the Legislative Audit Committee. We believe this condition did not affect our audit conclusions.

The following members of the State Auditor's staff performed the audit:

- Ileana Barboza, MBA, CGAP (Project Manager)
- Michael Bennett (Assistant Project Manager)
- Nicholas Dufour, M.S. Accounting
- Ashlie Garcia, MBA, CFE
- Elijah Marchlewski
- Brenda Zamarripa, CGAP

- Mary Ann Wise, CPA, CFE (Quality Control Reviewer)
- Cesar Saldivar, CIA, CFE, CGAP (Audit Manager)

Appendix 2

Issue Rating Classifications and Descriptions

Auditors used professional judgment and rated the audit findings identified in this report. Those issue ratings are summarized in the report chapters/sub-chapters. The issue ratings were determined based on the degree of risk or effect of the findings in relation to the audit objective(s).

In determining the ratings of audit findings, auditors considered factors such as financial impact; potential failure to meet Program/function objectives; noncompliance with state statute(s), rules, regulations, and other requirements or criteria; and the inadequacy of the design and/or operating effectiveness of internal controls. In addition, evidence of potential fraud, waste, or abuse; significant control environment issues; and little to no corrective action for issues previously identified could increase the ratings for audit findings. Auditors also identified and considered other factors when appropriate.

Table 3 provides a description of the issue ratings presented in this report.

Table 3

Summary of Issue Ratings	
Issue Rating	**Description of Rating**
Low	The audit identified strengths that support the audited entity's ability to administer the Program(s)/function(s) audited or the issues identified do not present significant risks or effects that would negatively affect the audited entity's ability to effectively administer the Program(s)/function(s) audited.
Medium	Issues identified present risks or effects that if not addressed could moderately affect the audited entity's ability to effectively administer the Program(s)/function(s) audited. Action is needed to address the noted concern(s) and reduce risks to a more desirable level.
High	Issues identified present risks or effects that if not addressed could substantially affect the audited entity's ability to effectively administer the Program(s)/function(s) audited. Prompt action is essential to address the noted concern(s) and reduce risks to the audited entity.
Priority	Issues identified present risks or effects that if not addressed could critically affect the audited entity's ability to effectively administer the Program(s)/function(s) audited. Immediate action is required to address the noted concern(s) and reduce risks to the audited entity.

Appendix 3

Internal Control Components

Internal control is a process used by management to help an entity achieve its objectives. The U.S. Government Accountability Office's *Government Auditing Standards* require auditors to assess internal control when internal control is significant to the audit objectives. The Committee of Sponsoring Organizations of the Treadway Commission established a framework for 5 integrated components and 17 principles of internal control, which are listed in Table 4.

Table 4

Internal Control Components and Principles		
Component	**Component Description**	**Principles**
Control Environment	The control environment sets the tone of an organization, influencing the control consciousness of its people. It is the foundation for all other components of internal control, providing discipline and structure.	▪ The organization demonstrates a commitment to integrity and ethical values. ▪ The board of directors demonstrates independence from management and exercises oversight of the development and performance of internal control. ▪ Management establishes, with board oversight, structures, reporting lines, and appropriate authorities and responsibilities in the pursuit of objectives. ▪ The organization demonstrates a commitment to attract, develop, and retain competent individuals in alignment with objectives. ▪ The organization holds individuals accountable for their internal control responsibilities in the pursuit of objectives.
Risk Assessment	Risk assessment is the entity's identification and analysis of risks relevant to achievement of its objectives, forming a basis for determining how the risks should be managed.	▪ The organization specifies objectives with sufficient clarity to enable the identification and assessment of risks relating to objectives. ▪ The organization identifies risks to the achievement of its objectives across the entity and analyzes risks as a basis for determining how the risks should be managed. ▪ The organization considers the potential for fraud in assessing risks to the achievement of objectives. ▪ The organization identifies and assesses changes that could significantly impact the system of internal control.
Control Activities	Control activities are the policies and procedures that help ensure that management's directives are carried out.	▪ The organization selects and develops control activities that contribute to the mitigation of risks to the achievement of objectives to acceptable levels. ▪ The organization selects and develops general control activities over technology to support the achievement of objectives. ▪ The organization deploys control activities through policies that establish what is expected and procedures that put policies into action.

Internal Control Components and Principles		
Component	**Component Description**	**Principles**
Information and Communication	Information and communication are the identification, capture, and exchange of information in a form and time frame that enable people to carry out their responsibilities.	▪ The organization obtains or generates and uses relevant, quality information to support the functioning of internal control. ▪ The organization internally communicates information, including objectives and responsibilities for internal control, necessary to support the functioning of internal control. ▪ The organization communicates with external parties regarding matters affecting the functioning of internal control.
Monitoring Activities	Monitoring is a process that assesses the quality of internal control performance over time.	▪ The organization selects, develops, and performs ongoing and/or separate evaluations to ascertain whether the components of internal control are present and functioning. ▪ The organization evaluates and communicates internal control deficiencies in a timely manner to those parties responsible for taking corrective action, including senior management and the board of directors, as appropriate.

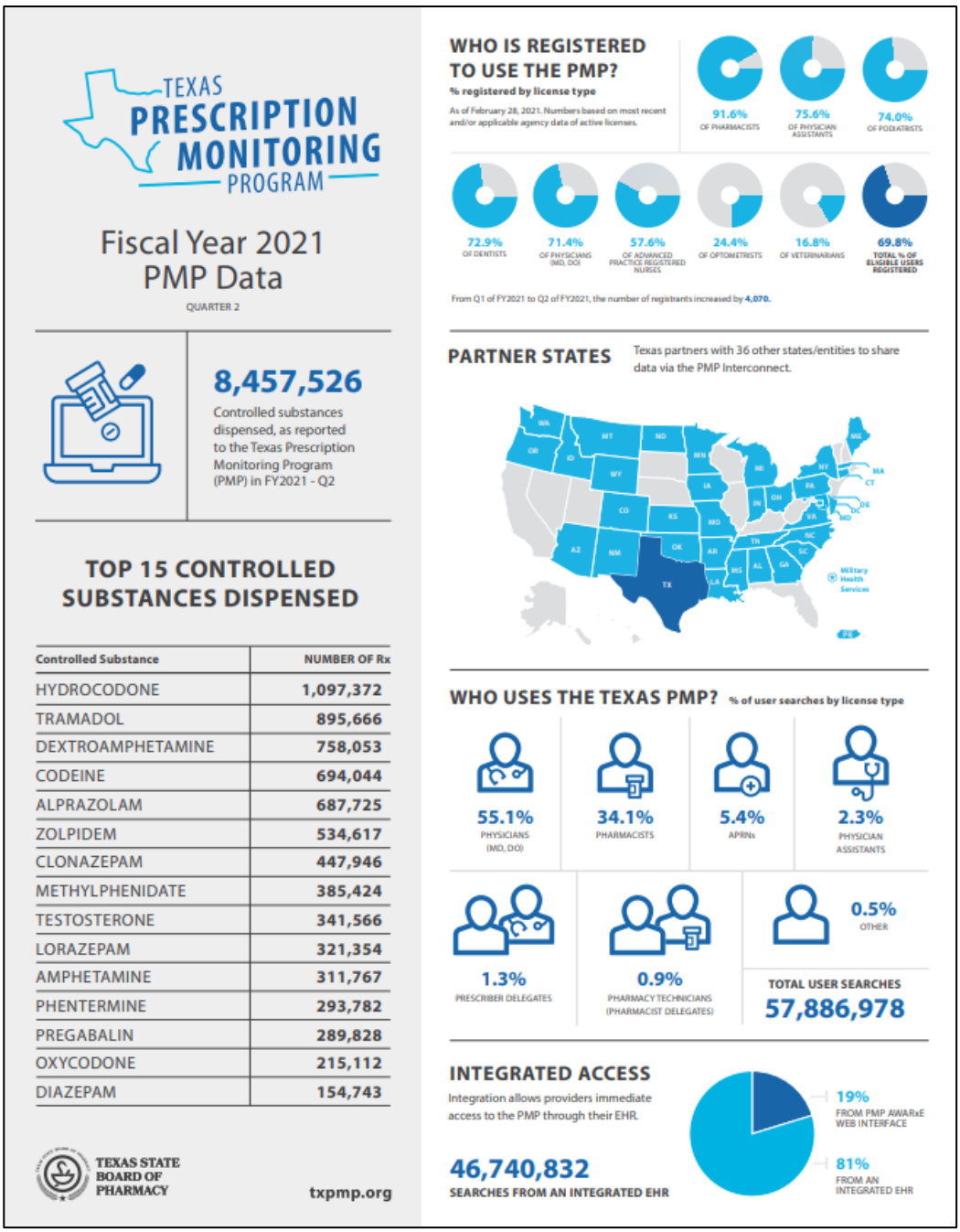
Source: Internal Control – Integrated Framework, Committee of Sponsoring Organizations of the Treadway Commission, May 2013.

Appendix 4

Prescription Monitoring Program Statistics

Figure 5 shows information related to the data collected by the Prescription Monitoring Program (PMP). From December 1, 2020, through February 28, 2021, approximately 8.5 million prescriptions for controlled substances were dispensed in Texas, according to PMP data collected. Of that amount, the opioid hydrocodone accounted for 1.1 million, or 13 percent.

Figure 5



Source: The Board.

Copies of this report have been distributed to the following:

Legislative Audit Committee

The Honorable Dan Patrick, Lieutenant Governor, Joint Chair
The Honorable Dade Phelan, Speaker of the House, Joint Chair
The Honorable Jane Nelson, Senate Finance Committee
The Honorable Robert Nichols, Member, Texas Senate
The Honorable Greg Bonnen, House Appropriations Committee
The Honorable Morgan Meyer, House Ways and Means Committee

Office of the Governor

The Honorable Greg Abbott, Governor

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- Mr. Rick Tisch
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Dr. Timothy L. Tucker, Executive Director/Secretary