Sunset Advisory Commission

Staff Report

Texas State Board of Pharmacy

2016–2017
85th Legislature

Sunset Advisory Commission

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Appointment Pending

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LTC Allen B. West, (US Army Ret.)

Ken Levine
Director

Cover Photo: The iron perimeter fence was installed in the 1890s, a few years after the completion of the Texas State Capitol. The fence surrounds approximately 22 acres of the Capitol Grounds but only on the east, west, and south sides due to the addition of the Capitol Extension to the north in the early 1990s. Photo Credit: Janet Wood

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How to Read Sunset Reports

Each Sunset report is issued *three times*, at each of the three key phases of the Sunset process, to compile all recommendations and action into one, up-to-date document. Only the most recent version is posted to the website. (**The version in bold is the version you are reading**.)

1. Sunset Staff Evaluation Phase

   Sunset staff performs extensive research and analysis to evaluate the need for, performance of, and improvements to the agency under review.

   First Version: The *Sunset Staff Report* identifies problem areas and makes specific recommendations for positive change, either to the laws governing an agency or in the form of management directives to agency leadership.

2. Sunset Commission Deliberation Phase

   The Sunset Commission conducts a public hearing to take testimony on the staff report and the agency overall. Later, the Commission meets again to vote on which changes to recommend to the full Legislature.

   Second Version: The *Sunset Staff Report with Commission Decisions*, issued after the decision meeting, documents the Sunset Commission's decisions on the original staff recommendations and any new issues raised during the hearing, forming the basis of the Sunset bills.

3. Legislative Action Phase

   The full Legislature considers bills containing the Sunset Commission's recommendations on each agency and makes final determinations.

   Third Version: The *Sunset Staff Report with Final Results*, published after the end of the legislative session, documents the ultimate outcome of the Sunset process for each agency, including the actions taken by the legislature on each Sunset recommendation and any new provisions added to the Sunset bill.

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Summary of Sunset Staff Recommendations

Summary

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. Created in 1907 to examine and certify pharmacists, the board's mission has expanded over time to adapt to the increasingly complex and growing practice of pharmacy. The board now licenses more than 90,000 pharmacists and pharmacy technicians, and licenses and inspects nearly 8,000 pharmacies. Beginning in 2013, the Legislature required the board to place additional scrutiny on high-risk sterile compounding pharmacies, following several deaths nationally from tainted drugs distributed by a Massachusetts compounding pharmacy. During the Sunset review, staff looked carefully at the board's progress to catch up with resulting inspection backlogs and cover its regulatory mandates and found no critical concerns with its core licensing, inspection, and enforcement functions.

With the prescription drug abuse epidemic facing the country, now is the time to ensure Texas' prescription monitoring program offers the most robust data and reporting possible.

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. 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. Most states have similar databases collecting and reporting information from pharmacies to give drug prescribers and dispensers the information they need to prevent abuse before the patients taking these drugs wind up in emergency care or worse. Unfortunately, Texas' program lags behind national best practices, lacking a number of basic tools needed to maximize its effectiveness, such as ensuring data is timely entered into the system and that pharmacists actually look at the information before dispensing highly addictive prescriptions. As the board takes over the program from the Department of Public Safety (DPS) on September 1, 2016, and makes adjustments under its new authority, now is the time to ensure Texas' system offers the most robust data and reporting possible. While Texas has fared better than some other states nationally in this crisis, these changes are needed to ensure the high cost of prescription drug abuse does not grow further in Texas. While prescribers such as doctors also have an important role to play in curbing the problem, this report focuses narrowly on the role of the pharmacy board and postpones evaluation of prescriber best practices to the upcoming Sunset review of the Texas Medical Board.

Staff also explored the potential benefits of transferring the board's functions to an alternative organizational structure, such as the Texas Department of Licensing and Regulation or another healthcare licensing agency. While an

umbrella agency can provide benefits, Sunset staff found transferring the board's functions provides no benefits significant enough to justify such a major change. However, a contributing factor to the board's success in meeting its mission within its current structure is the long-tenured, professional staff that has guided the agency through its evolution over the last 20 years. Several high-ranking staff, including the executive director, are about to retire, creating a management risk requiring a proactive succession plan to guide the agency through coming leadership changes. Finally, Sunset staff also identified a few elements of the board's practices that do not conform to common licensing and enforcement standards and made related recommendations to ensure the continued fair and effective regulation of pharmaceutical services in Texas.

The following material summarizes Sunset staff recommendations on the Texas State Board of Pharmacy.

Issues and Recommendations

Issue 1

Texas Lacks Key Tools Needed to Ensure Safe Dispensing of Dangerous, Highly Addictive Drugs to Patients.

The abuse and misuse of highly addictive prescription medications, particularly painkillers such as Vicodin and OxyContin, have reached epidemic levels across the country. Texas keeps track of the large volume of these drugs, known as controlled substances, by collecting dispensing information from all pharmacies in a database called the Prescription Monitoring Program. Reflecting a desire to improve the system's usability and better use the information for public health purposes, the Legislature transferred responsibility for the program from DPS to the board effective September 1, 2016.

Sunset staff evaluated the current status of the program operated by DPS and identified several national best practices the board should implement as it transitions the program. States are increasingly using these databases as key front-line tools to give healthcare practitioners information needed to protect the public from the harm that can be caused by improper use of these drugs. Implementing the following changes would improve the program's effectiveness and help ensure Texans receive only necessary prescriptions that do not pose a threat to their safety. The recommendations below focus narrowly on the board's authority over the program and the pharmacies it regulates, and pends evaluation of the important role of prescribers to the upcoming Sunset review of the Texas Medical Board.

Key Recommendations

- Beginning in 2018, require pharmacists to search the Prescription Monitoring Program database before dispensing certain controlled substances.
- Require pharmacists to enter dispensing information in the Prescription Monitoring Program database within one business day of dispensing controlled substances.
- Authorize the board to send push notifications and to set related thresholds.
- Direct the board to create delegate accounts for pharmacy technicians, work to integrate the program with pharmacy software systems, and make trend data on dispensing publicly available.

Issue 2

Key Elements of the Texas State Board of Pharmacy's Statute Do Not Conform to Common Licensing Standards.

Since 1977, Sunset staff has completed more than 100 reviews of occupational licensing agencies. In doing so, the staff has identified standards that are common practices throughout state agency statutes, rules, and procedures. The Sunset review compared the board's regulatory framework to these model licensing standards to identify variations. Based on these variations, staff identified several changes needed to bring the board in line with model standards, with a goal to better protect the public and ensure fair, consistent regulation for the pharmacy industry.

Key Recommendations

- Require the board to create a system of graduated penalties for late renewal of pharmacy technician registration.
- Authorize the board to deny renewal applications for licensees and registrants who are noncompliant with an existing board order.
- Direct the board to remove burdensome requirements that pharmacy licensure renewal forms be notarized.
- Direct the board to query a national disciplinary database before license renewal.

Issue 3

The State Has a Continuing Need to Regulate the Practice of Pharmacy.

The Board of Pharmacy regulates the practice of pharmacy by licensing individuals and pharmacies that provide pharmaceutical services, and regulating the operation of pharmacies and the distribution of prescription drugs. Sunset staff found that Texas has a continuing need to regulate the practice of pharmacy to ensure Texans receive safe and quality pharmaceutical care, and that no significant benefits would justify an alternative organization to the current independent agency structure. However, in light of impending retirements in the agency's top management positions, the board needs a more proactive succession plan to ensure continued effective oversight.

Key Recommendations

- Continue the Texas State Board of Pharmacy for 12 years.
- The board should develop and implement a succession plan to prepare for impending retirements.

Fiscal Implication Summary

Overall, the recommendations in this report would not have a significant fiscal impact, since most either clarify current practice or change procedures in ways that do not require additional resources. One recommendation, summarized below, would result in a small loss to the General Revenue Fund.

Issue 2 — Making the late renewal penalty structure for pharmacy technicians consistent with that of pharmacists would result in an annual loss to the General Revenue of about $36,000 because pharmacy technicians renewing within 90 days of expired registrations would pay reduced penalties.

Texas State Board of Pharmacy

Fiscal Year	Loss to the General Revenue Fund
2018	$36,000
2019	$36,000
2020	$36,000
2021	$36,000
2022	$36,000

Agency at a Glance

Agency at a Glance

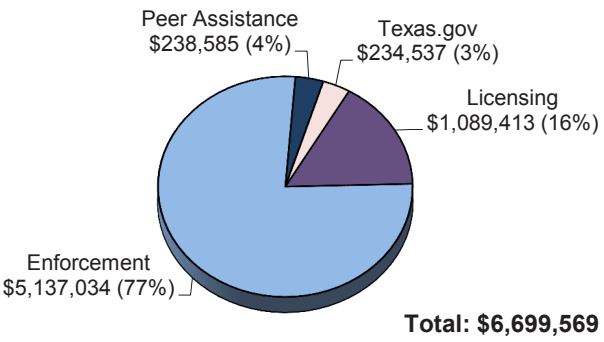
In 1907, the Legislature established the Texas State Board of Pharmacy to examine and certify pharmacists. Since that time, the Legislature has expanded the board's authority to include oversight of pharmacies and others involved in delivering pharmaceutical care. To achieve its mission of protecting public health, safety, and welfare by fostering the provision of quality pharmaceutical care, the board carries out the following key activities:

- Licensing pharmacies and pharmacists
- Registering pharmacy technicians, pharmacy technician trainees, interns, and preceptors, who are licensed pharmacists registered by the board to instruct interns
- Setting standards for the practice of pharmacy and operation of pharmacies
- Investigating and resolving complaints against licensees and registrants, and taking disciplinary action when necessary

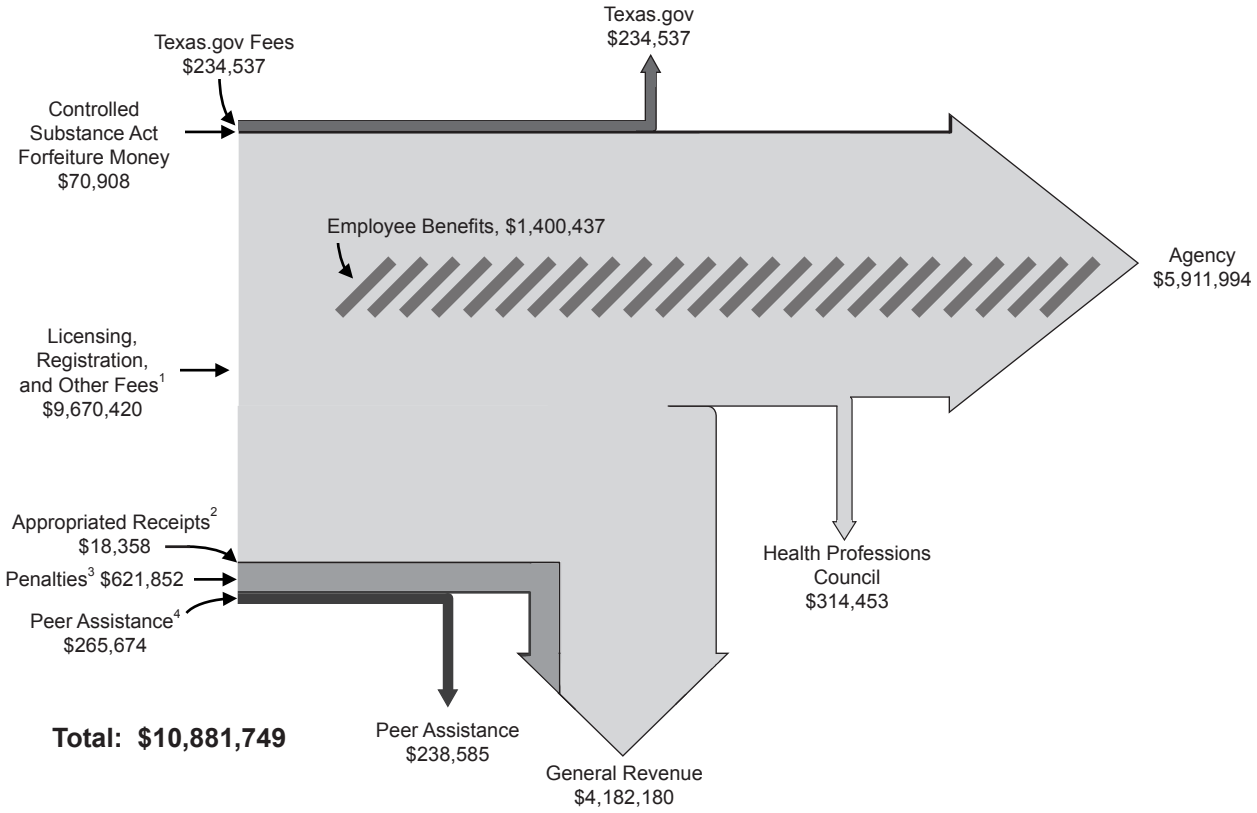
Key Facts

- **Texas State Board of Pharmacy.** The agency's governing board consists of 11 governor-appointed members who serve staggered six-year terms. Seven members are licensed pharmacists, one is a registered pharmacy technician, and three members represent the public. Appendix A, *Texas State Board of Pharmacy*, shows the board's current composition.
- **Funding.** The board spent about $6.7 million in fiscal year 2015. The pie chart, *Board of Pharmacy Expenditures*, provides a breakdown of expenditures by program area. The board collected fees totaling more than $9.6 million, including about $4.4 million in pharmacist licensing fees, $2 million in pharmacy licensing fees, and $1.9 million in pharmacy technician registration fees. In fiscal year 2015, the board transferred nearly $4.2 million generated in excess of the agency's appropriation to the General Revenue Fund. The chart on the following page, *Flow of Texas State Board of Pharmacy Revenue and Expenditures*, shows the overall impact of board revenue and expenditures in fiscal year 2015. Appendix B, *Historically Underutilized Businesses Statistics*, describes the board's use of historically underutilized businesses in purchasing goods and services for fiscal years 2013–2015.

Board of Pharmacy Expenditures
FY 2015



Flow of Texas State Board of Pharmacy Revenue and Expenditures FY 2015



[1] Includes fees such as duplicate license and change of name or location, and the Office of Patient Protection surcharge.

[2] Includes copying fees, third party reimbursement, and sale of vehicles.

[3] Includes delinquent penalties, administrative penalties, and probation penalties.

[4] $27,089 of Peer Assistance revenue goes to General Revenue.

- **Staffing.** In fiscal year 2015, the board employed 88 staff, with 67 based in Austin and 21 working remotely throughout the state conducting inspections and investigations. Additionally, the board is a member of the Health Professions Council, which provides supplementary information technology staffing for the board and other health professional licensing agencies. Appendix C, *Equal Employment Opportunity Statistics*, compares the board's workforce composition to the percentage of minorities in the statewide civilian labor force for the past three fiscal years.

- **Licensing.** To operate as a pharmacy, or to work as a pharmacist, intern, preceptor, pharmacy technician, or technician trainee in Texas, a facility or individual must be licensed or registered by the board. The board completes background checks on all applicants, including pharmacy owners and officers. The board renews all licenses and registrations on a two-year rolling basis.

  Pharmacies. The state regulates pharmacies to ensure quality patient care and control the distribution of dangerous drugs and controlled substances. The textbox on the following page, *Prescription Medications*, explains the two classes of medications dispensed at pharmacies. The board licenses pharmacies in 11 different classes, including sub-classes for pharmacies that compound sterile preparations,

which are customized injectable medications that pose a higher risk of infection than other drugs. Appendix D, *Licensed Pharmacies*, details the classes of pharmacies and number of pharmacies licensed in each class in fiscal year 2015. The application materials and pre-inspection requirements vary depending on the class of pharmacy, with sterile compounding pharmacies receiving the highest level of scrutiny. In fiscal year 2015, the board licensed 7,914 pharmacies.

Prescription Medications

- A controlled substance is a drug that has the potential for abuse. Controlled substances are ranked in five schedules depending on the drug's addictive nature and potential for abuse. Controlled substances include prescriptions such as pain medications.
- A dangerous drug is any medication for which a prescription is required that is not a controlled substance. Dangerous drugs include prescriptions such as antibiotics.

Pharmacists. Pharmacists review prescriptions, dispense drugs, counsel patients, administer certain immunizations, and supervise pharmacy technicians and technician trainees. Each pharmacy must have a designated pharmacist-in-charge, who must ensure the pharmacy complies with board regulations. The board licensed 31,807 pharmacists in fiscal year 2015. All applicants seeking a pharmacist license must first graduate from a board-approved doctor of pharmacy program. Applicants must complete 1,500 internship hours and usually begin their internships in their first year of school. Interns can perform any task delegated to them by a supervising pharmacist who must receive a special preceptor license designation from the board. In fiscal year 2015, the board registered 3,725 interns and 9,593 preceptors. After completing the educational and internship requirements, the applicant must pass the national pharmacist licensure exam and a state-specific pharmacy jurisprudence exam before licensure.

Pharmacy technicians and technician trainees. Pharmacy technicians perform technical tasks that do not require professional judgment, such as counting and labeling medications, and must work under the supervision of a pharmacist. Texas began regulating pharmacy technicians more recently, in 2004, due to concerns about theft and loss of drugs. All applicants seeking a pharmacy technician license must have a high school diploma or equivalency and pass a board-approved national certifying exam. Prospective pharmacy technicians may choose to first apply for technician trainee status, which allows the trainee to gain experience for up to two years before taking and passing the certifying exam. In fiscal year 2015, the board registered 41,990 pharmacy technicians and 18,777 technician trainees.

- **Inspections.** The board employs 12 inspectors in nine regions to conduct inspections before licensure, routine compliance inspections, and inspections in response to complaints. Appendix E, *Map of Inspection Regions*, shows the regions in which inspectors work and the number of inspectors assigned to each region. The Pharmacy Act requires the board to inspect all sterile compounding pharmacies before initial licensure and before renewal every two years following. The board inspects all other pharmacies depending on staff availability, with the goal of inspecting each pharmacy at least once every four years. When inspectors identify violations of pharmacy regulations, they may note areas that need improvement, issue a warning notice, or refer a violation to the board's legal department. In fiscal year 2015, the board completed 2,992 inspections and issued 1,293 warning notices for minor violations.

- **Investigations.** The board employs eight commissioned peace officers as investigators who conduct in-depth investigations, often undercover, of pharmacies that have been the subject of serious complaints, including reported theft or loss of drugs or suspected improper dispensing. Investigators also audit drug inventory and gather evidence for board enforcement proceedings.

Board Enforcement Data
FY 2015

Complaints Disposed	
From the Public	697
From Staff	5,258
Total Complaints Disposed	***5,955***
Subject of Complaints*	
Pharmacy	1,915
Pharmacist	693
Intern	109
Pharmacy Technician	1,208
Technician Trainee	1,990
Non-Licensee	40
Total	***5,955***
Resolved Complaints by Disposition	
No Action	245
Dismissed**	1,341
Referred to Another Agency	31
Registration Expired	184
Pharmacy Closed	42
Verbal Warning	87
Application Withdrawn	219
Investigation, No Disciplinary Action	2,128
Disciplinary Order or Remedial Plan	700
Other	978
Total	***5,955***
Disciplinary Orders	
Probation	146
Administrative Penalty	229
Formal Reprimand	91
Suspension	50
Revocation	95
Other***	16
Total*	***627***

* Includes licensees/registrants and applicants.

** Includes inspections or investigations closed with a dismissal/warning letter, preliminary notice letters with application withdrawn, preliminary notice letters closed with a dismissal letter, and informal settlement conferences resulting in dismissal.

*** Includes modifications of existing board orders and license restrictions.

**** Some disciplinary orders resolve multiple complaints.

- **Enforcement.** The board investigates complaints against licensees and registrants and takes disciplinary action for violations of board statute or rule. The board may impose administrative penalties, a probation period, or monitoring requirements, or may suspend or revoke a license or registration for serious violations. The board also monitors pharmacists, interns, pharmacy technicians, and technician trainees found to be impaired in order to ensure they address substance abuse issues and are able to work safely in a pharmacy. At the end of fiscal year 2015, the board was monitoring 167 impaired licensees and registrants. The table, *Board Enforcement Data*, details the number, subject, and disposition of complaints in fiscal year 2015.

- **Prescription Monitoring Program.** In 2015, the Legislature transferred the operation of the state's Prescription Monitoring Program from the Department of Public Safety to the board, effective September 1, 2016. The program monitors the prescribing and dispensing of controlled substances in order to protect patient safety and prevent drug abuse and theft. Under the program, the board will manage a statewide database of prescribers and individuals receiving prescriptions for controlled substances, and print and distribute the special, higher-security prescription pads on which the most addictive controlled substance prescriptions must be written.

Issues

Issue 1

Texas Lacks Key Tools Needed to Ensure Safe Dispensing of Dangerous, Highly Addictive Drugs to Patients.

Background

The Texas State Board of Pharmacy plays an important role in protecting the public from improper dispensing of prescription drugs by setting standards for the practice of pharmacy, including the dispensing of drugs to patients. By their very nature, all prescription drugs are considered dangerous, but a special class known as controlled substances carry greater potential for abuse and, therefore, are subject to greater regulatory control. The textbox, *Controlled Substances*, provides more information on this class of drugs. While the decision to distribute a prescription drug necessarily starts with a prescriber such as a doctor, pharmacists have an important gate-keeping role. State law and standards of professional practice describe this duty as a pharmacist's "corresponding responsibility" to ensure a prescription is valid before dispensing medications to a patient, and authorize a pharmacist to refuse to dispense suspicious prescriptions.[2]

Controlled Substances

What are controlled substances?

- Highly addictive medications with increased potential for abuse — addiction can occur from taking just one valid prescription[1]
- Commonly prescribed for pain relief or sedation
- Examples include opioid drugs such as Vicodin (hydrocodone) and OxyContin (oxycodone) and benzodiazepine drugs such as Xanax (alprazolam)

What additional regulations govern controlled substances?

- The federal Drug Enforcement Agency registers and monitors prescribers, pharmacists, and drug distributors of controlled substances
- In Texas, prescriptions for particularly addictive controlled substances must be written on registered, secure prescription pads
- The Texas Medical Practice Act defines four classes of controlled substances carrying higher risk and places additional requirements on pain management clinics that prescribe these drugs (opioids, benzodiazepines, barbiturates, and carisoprodol)
- The state's Prescription Monitoring Program requires all Texas pharmacies to enter information about controlled substance prescriptions into a statewide database within seven days of dispensing

Over the last decade, dispensing of painkillers and other highly addictive medications has skyrocketed, and these drugs are now some of the most prescribed in the country.[3] While often needed for legitimate medical purposes, the euphoric effects of medications such as Vicodin and OxyContin have contributed to a rise in associated problems such as addiction, overdoses, and illicit activity such as doctor-shopping and diversion of drugs for illegal sale on the street.[4] In 2013, nearly 23,000 people died in the United States from overdoses related to either opioid pain medications or sedative drugs.[5] Drug overdose deaths from prescription painkillers and sedatives have more than quadrupled since the late 1990s.[6] These statistics have led many public health experts and policymakers to declare an epidemic facing the country relating to prescription drug abuse.[7]

The state's primary method for keeping track of prescriptions for these highly addictive medications is the Prescription Monitoring Program, a statewide database collecting information from pharmacies on every controlled substance dispensed in the state. Statute allows prescribers, pharmacists, and related regulatory agencies to check the database. The database provides prescribers and dispensers information on the patient's controlled substance prescription history that can help inform prescribing and dispensing

decisions. In addition, regulatory agencies can use the database to investigate potential illicit behavior by licensees such as overprescribing or improper dispensing. In 2015, the Legislature transferred responsibility for the Prescription Monitoring Program from the Department of Public Safety to the pharmacy board, reflecting a desire to improve the system's usability and better use the information for public health purposes.[8] The board has been working to transition to a new vendor, with a goal to improve features, streamline reporting, and make it easier to monitor and identify potential invalid prescriptions. The board's new system will begin operating on September 1, 2016.

Findings

Millions of highly addictive prescriptions are dispensed in Texas each year, posing a significant risk for abuse and public harm.

In fiscal year 2015, Texas pharmacies dispensed more than 11 million prescriptions for five highly addictive, frequently abused controlled substances, or about one of these prescriptions for every 2.4 Texans, as shown in the chart below. Hydrocodone is the most prescribed controlled substance in Texas, and the most abused opioid in the United States.[9] Texas pharmacies purchased more than 500 million pills of this highly addictive drug for dispensing to Texas patients in 2015.[10] In total, Texas pharmacies dispensed nearly 38.6 million prescriptions for all types of controlled substances that year, each of which carries a risk of abuse.[11]

Texas pharmacies purchased more than 500 million hydrocodone pills in 2015.

While many patients need these drugs for legitimate medical purposes including severe pain, the potential for abuse and harm is great. In 2013, more than 5,700 people called the Texas Poison Center Network due to prescription opioid exposure.[12] In addition, nearly 1,000 Texans died from prescription drug overdoses in 2013, according to the Centers for Disease Control.[13] While Texas' reported number of prescription drug overdose deaths is lower than those of other states, the inherent danger of taking these drugs and the volume at which they are dispensed pose an ongoing, high public health risk.[14]

Commonly Abused Prescription Drugs Dispensed by Texas Pharmacies — FY 2015[15]

Controlled Substance	Prescriptions Dispensed
Vicodin (Hydrocodone)*	6,160,127
Xanax (Alprazolam)*	3,251,977
OxyContin (Oxycodone)	764,731
Soma (Carisoprodol)*	677,809
Promethazine with codeine (Cough syrup with codeine)	344,305
Total	**11,198,949**

* Many drug abusers seek prescriptions for hydrocodone, alprazolam, and carisoprodol, a combination referred to as "the Houston cocktail" that creates a heroin-like effect.[16]

Texas' Prescription Monitoring Program lacks key best practices needed for the state to understand and respond to prescription drug abuse.

A strong prescription monitoring program is a clear best practice for states, but Texas has lagged behind in recent years. Forty-nine states have programs similar to Texas, and these systems have become powerful tools for prescribers, pharmacists, and regulatory agencies to understand trends and identify problem areas within their communities. While Texas was initially in the vanguard when it created a statewide database in 1982, its placement at the Department of Public Safety focused its use for law enforcement purposes, and features to help prescribers and dispensers use the information never fully developed. These and other concerns about the system's usability for public health purposes prompted the Legislature's decision to transfer the program to the Pharmacy Board in 2015.[17]

Concerns about the system's usability for public health purposes prompted the Legislature's decision to transfer the program to the board in 2015.

The Prescription Drug Monitoring Program Center of Excellence at Brandeis University identifies best practices and provides analysis to assist states in maximizing these programs, drawing on the expertise of national specialists in addiction, pain treatment, and public health. In 2012, the Center published an assessment of best practices, identifying specific areas where states often underutilize their programs.[18] These best practices aim to identify potential drug abuse, but not preemptively limit patient access to needed medication. While the board plans to make improvements to the program when it transfers, some improvements require changes in law to fully implement. Sunset staff compared Texas' current program operated by the Department of Public Safety with national best practices, and identified the following gaps where the current system fails to meet best practices.

- **Unacceptably low use by pharmacists.** By creating prescription drug monitoring programs, states have decided tracking controlled substances is an important public safety measure and have invested millions of dollars in these databases. However, pharmacists' efforts to gather the data are somewhat in vain if pharmacists do not check the information to inform dispensing decisions. The Center of Excellence emphasizes increasing the use of the database as an important best practice since this simple step can help determine whether dispensing certain drugs could cause a patient harm. Increased use can be achieved through voluntary efforts such as promotional campaigns, user education, and making the system easy to access, or by simply requiring users to look at the system before dispensing certain drugs.

  Texas' voluntary approach for pharmacist use of the system has not worked well, representing a major lost opportunity to enhance patient safety and protect public health. The textbox on the following page, *Texas Pharmacist Usage of the Prescription Monitoring Program*, shows the low usage rate of the program. In fiscal year 2015, at least 74 percent of pharmacists did not use the system at all, and 98 percent of controlled substance prescriptions were dispensed without being checked in the database. As a result, tens

98 percent of controlled substance prescriptions were dispensed without being checked in the database in fiscal year 2015.

Texas Pharmacist Usage of the Prescription Monitoring Program — FY 2015[19]

Number of searches by pharmacists	833,654
Total controlled substances dispensed	38,562,564
Percent of controlled substance prescriptions searched by pharmacists before dispensing	2.1%
Pharmacists using the database at least once	8,279
Percent of total pharmacists using the database at least once	26%

of thousands of Texans obtained prescriptions for addictive, potentially harmful drugs without a pharmacist using the best tool available to check the validity of the prescription.

Other states mandate use of prescription monitoring programs with positive results. Currently, 11 states require pharmacists to check the database before dispensing a controlled substance in certain circumstances.[20] Ohio requires pharmacists to check the system when a prescription has certain "red flag" indicators such as a new controlled substance prescription, a prescriber or patient outside of the pharmacy's geographic area, or a patient exhibiting signs of obtaining the drugs for illegal purposes.[21] Tennessee similarly requires pharmacists to check the system if they have reason to believe a prescription is fraudulent or medically unnecessary.[22] In Texas, the board has identified "red flags" for pharmacists that indicate a prescription may be invalid, but these do not trigger a requirement to check the database.[23]

Mandating use of the database has greatly reduced doctor and pharmacy shopping in other states.

In both Ohio and Tennessee, mandatory use requirements for both prescribers and pharmacists have helped reduce the number of patients who shop for doctors or pharmacies to obtain additional prescriptions. In Ohio, the number of patients receiving prescriptions from five or more prescribers in one month declined by 77 percent between 2009 and 2015 since the mandatory use requirement was put into effect.[24] In Tennessee, patients receiving prescriptions from more than five doctors or pharmacies in a three-month-period declined by 50 percent between 2011 and 2015.[25]

Texas law already singles out certain controlled substances as posing the greatest risk for abuse or addiction, and imposes increased scrutiny on pain clinics that prescribe these medications. Medical facilities that primarily prescribe opioids, benzodiazepines, barbiturates, and carisoprodol must register as pain clinics with the Texas Medical Board, triggering additional regulatory requirements such as searching the database before prescribing drugs to treat chronic pain.[26] Requiring pharmacists to also place increased scrutiny on these drugs would better ensure informed decisions for safe dispensing. Mandating use of the database by pharmacists would also ensure the state's significant investment in this program can achieve its intended purpose. As the board is currently working to make the new system more user friendly, this requirement could easily be phased in to give time for pharmacists to adjust their practices.

- **No delegate accounts.** Pharmacists often work in busy, fast-paced settings. The Center of Excellence encourages states to make the database easier to use through the creation of delegate accounts for pharmacy technicians, who perform much of the day-to-day work in pharmacies under the

supervision of a licensed pharmacist. Delegate accounts allow pharmacy technicians to access the system to pull a patient report the pharmacist can then quickly review. Thirty-eight states currently authorize delegate accounts. In Texas, statute already authorizes the board to create delegate accounts, but the Department of Public Safety has not set up this feature. Ensuring the board makes this enhancement to the new system would help busy pharmacists use the Prescription Monitoring Program more frequently and reduce the burden of any additional requirements to check the database for certain high-risk prescriptions.

- **Delayed reporting.** Up-to-date information helps prescribers, pharmacists, and regulatory agencies better identify potentially dangerous prescription drug activity. The Center of Excellence recommends real-time data entry into prescription monitoring databases, or as close to real time as possible. Requiring pharmacies to enter data quickly improves the quality of the information and ensures other users are able to access up-to-date prescription information. Without viewing the most recent prescription data for a patient, pharmacists and prescribers do not have the best information about whether giving a controlled substance to a patient may be harmful.

  About half of all state prescription monitoring programs require pharmacists to enter dispensing information within one day, and Oklahoma requires real time reporting within five minutes of dispensing a controlled substance. However, Texas' timeframe is much longer, allowing a lag time of up to one week for pharmacists to enter dispensing information. This window can allow patients who abuse drugs to obtain additional prescription medications without any information available to track their activity. Requiring pharmacists to enter dispensing information within one business day would make the already required data more useful for public protection purposes, without creating a new or overly burdensome reporting requirement on pharmacies.

Texas pharmacists can take as long as one week to enter dispensing information.

- **No proactive alerts about suspicious activity.** The Center of Excellence recommends states send automated push notifications to flag prescriptions meeting pre-determined thresholds that could indicate questionable prescribing or dispensing activity. Push notifications proactively engage prescribers and pharmacists, encourage use of the system to improve care, and help draw attention to potentially unsafe or invalid prescriptions. Forty-four states have authority to send push notifications to end users, typically triggered when a patient has visited a set number of prescribers or pharmacies in a short time period to obtain controlled substances. Users then receive an alert directing them to view the patient's profile for further analysis. States where prescribers and pharmacists receive push notifications have noted positive changes in prescribing and dispensing behavior, with users more likely to discuss the report with the patient, refer patients for substance abuse treatment, or call pharmacists who have dispensed controlled substances to the patient.[27]

In Texas, many patients meet indicators for potential doctor or pharmacy shopping, as shown in the textbox below. However, very little is done with this information within the current system. In addition to visiting numerous prescribers and pharmacies, many Texas patients have multiple prescriptions for pain medications, with nearly 842,000 patients receiving prescriptions for five or more painkillers concurrently in fiscal year 2015.[28] These drugs have a high potential for abuse and illicit activity, and can also have potentially harmful interactions for legitimate patients who receive valid prescriptions from multiple prescribers. Flagging cases of obvious concern would help pharmacists and prescribers ensure patients only receive safe and valid prescriptions.

Patients With Potential Indicators for Doctor or Pharmacy Shopping — FY 2015[29]

Patients with controlled substance prescriptions from more than five prescribers	180,783
Patients with controlled substance prescriptions from more than 10 prescribers	8,020
Patients with controlled substance prescriptions from more than 15 prescribers	1,180
Patients with controlled substance prescriptions from more than five pharmacies in a three-month period	13,139
Patients with five or more concurrent pain medication prescriptions	841,915

Software integration would streamline use of the program, allowing pharmacists to easily access patient profiles.

- **Lack of software integration.** Integrating the Prescription Monitoring Program with dispensing software streamlines its use, allowing pharmacists to easily access patient profiles without switching between software programs. States are increasingly seeking to integrate their databases with common pharmacy dispensing software. Ohio recently began a project to integrate the system with dispensing software and electronic medical records throughout the state.[30] Additionally, some chain pharmacies have opted to voluntarily integrate state databases with their software as a matter of good business practice since encouraging pharmacists to use the available information leads to better dispensing decisions.[31] Texas' program is not currently integrated with dispensing software, but the pharmacy board reports that the new database has the capability to work with many of the most commonly used products. The board should pursue software integration to help make it easier for all pharmacies to regularly use database information.

- **No public information available.** State prescription drug monitoring programs hold the best source of data for understanding trends in prescribing and dispensing of controlled substances. Making aggregate, de-identified information available online and in reports is a best practice recommended by the Center of Excellence, and some states make extensive data and analyses available for public purposes. Texas lags far behind in this regard,

and while the Department of Public Safety provides information about Texas prescribing or dispensing activity upon request, the department has not proactively published such information. State law currently requires a work group of regulatory and law enforcement agencies involved in monitoring controlled substances to submit a biennial report to the Legislature but does not require publication of any data or analysis of dispensing trends.[32] Providing better access to this information would help the Legislature, pharmacists, prescribers, and the public stay informed about the prescription drug abuse problem.

Best practices for prescribers should be considered in the context of the Medical Board's authority over pain clinics and prescribers.

The important role of prescribers to the future success of Texas' Prescription Monitoring Program should continue to be evaluated as part of the upcoming Sunset review of the Texas Medical Board.

While the role of prescribers is a critical part of monitoring prescription drug abuse, this report does not make recommendations to change requirements on prescribers related to the Prescription Monitoring Program. Instead, this report focuses narrowly on the role of the pharmacy board to operate the program and its authority over the pharmacies and pharmacists it regulates.

However, the review identified additional best practices relating to prescriber use of the program that will be further evaluated as part of the upcoming Sunset review of the Texas Medical Board, scheduled for completion in fall 2016. For example, Texas statute authorizes prescribers to register with the program and search the database before prescribing controlled substances but only requires prescribers working in pain management clinics to search the information before writing high-risk prescriptions. This and other potential best practices related to prescribers are best considered in the full context of the Medical Board's authority over pain clinics and prescribers overall.

Recommendations

Change in Statute

1.1 Beginning in 2018, require pharmacists to search the Prescription Monitoring Program database before dispensing certain controlled substances.

Statute would require pharmacists to search the database and review a patient's prescription history before dispensing opioids, benzodiazepines, barbiturates, or carisoprodol, in line with drugs already identified in the Medical Practice Act as carrying the highest risk of abuse. Statute would also authorize the board to define any additional "red flag" circumstances in which pharmacists must search the database before dispensing controlled substances. Requiring pharmacists to search before dispensing the most addictive controlled substances would increase usage and efficiency of the system, and would help pharmacists meet their corresponding responsibility to dispense only valid prescriptions.

This recommendation would not go into effect until January 1, 2018, to allow the board to finish transitioning the program and to give pharmacists time to adjust their practices to the new requirements.

1.2 Require pharmacists to enter dispensing information in the Prescription Monitoring Program database within one business day of dispensing controlled substances.

This recommendation would require pharmacists to enter dispensing information for all controlled substances within one business day of dispensing these drugs. Requiring dispensing information be entered within one business day would ensure prescribers, pharmacists, and regulatory agencies have access to the timely, complete data necessary to protect patients and prevent prescription drug abuse.

1.3 Authorize the board to send push notifications and to set related thresholds.

This recommendation would allow the board to send push notifications to prescribers and pharmacists alerting them to prescriptions meeting thresholds for potentially questionable activity, helping to inform users before deciding whether to prescribe or dispense. The board would set thresholds for these alerts in board policy, with the input of regulatory and enforcement agencies involved in monitoring controlled substances. Sending push notifications would encourage use of the database and ensure that the board proactively notifies users when patients or prescriptions have clear "red flag" indicators for doctor or pharmacy shopping.

Management Action

1.4 Direct the board to create delegate accounts for pharmacy technicians.

Under this recommendation, the board would create delegate accounts for registered pharmacy technicians linked to supervising pharmacists' accounts, allowing technicians, if so assigned, to search and send reports for their delegating pharmacists. Creating delegate accounts would facilitate use of the Prescription Monitoring Program, further encouraging increased use of the database and minimizing the impact on pharmacists' workloads from enhanced requirements.

1.5 Direct the board to work with vendors and stakeholders to integrate the Prescription Monitoring Program with pharmacy dispensing software.

Under this recommendation, the board would work with vendors and stakeholders to explore opportunities for integrating the state's database with pharmacy dispensing software. Integration would allow pharmacists to access patient reports within their existing software programs, streamlining systems and making it easier for pharmacists to check whether a prescription is valid before dispensing.

1.6 Direct the board to make trend data about controlled substance prescriptions in Texas publicly available.

This recommendation would require the board to make aggregate, de-identified trend data and information regarding the impact of the Prescription Monitoring Program available on the board's website and in an existing biennial report to the Legislature.[33] Making this information more easily available would keep the public and the Legislature aware of the scope of prescription drug issues in Texas and would assist future evaluations of the program's impact on prescription drug abuse and overdose.

Fiscal Implication

These recommendations would not have a fiscal impact to the State. For fiscal year 2017, the board is appropriated about $800,000 in dedicated user fees to cover the cost of administering the program, which includes the cost of the database and program staff. Integrating the database with pharmacy dispensing software is possible under the current contract but may incur a cost in the future, which would require

that the board raise user fees to cover such costs, as already required by statute.[34] The board's existing contract for the database also allows for implementation of all of the other features recommended with no additional cost.

1 "Injury Prevention & Control: Prescription Drug Overdose," Centers for Disease Control and Prevention, last modified October 28, 2015, http://www.cdc.gov/drugoverdose/epidemic/index.html.

2 All citations to Texas statutes are as they appear on http://www.statutes.legis.state.tx.us/. Section 562.056, Texas Occupations Code.

3 "Injury Prevention & Control: Prescription Drug Overdose," Centers for Disease Control and Prevention, last modified January 12, 2016, http://www.cdc.gov/drugoverdose/data/index.html; Troy Brown, "Top 10 Most Prescribed Generic Drugs Through September," Medscape, November 6, 2014, http://www.medscape.com/viewarticle/834578.

4 National Institute on Drug Abuse, *The Science of Drug Abuse and Addiction: The Basics*, accessed March 11, 2016, https://www.drugabuse.gov/publications/media-guide/science-drug-abuse-addiction-basics; Randy Sansone and Lori Sansone, "Doctor Shopping: A Phenomenon of Many Themes," Innovations in Clinical Neuroscience 9 (November-December 2012): 42–46.

5 "Prescription Drug Overdose Data," Centers for Disease Control and Prevention, last modified October 16, 2015, http://www.cdc.gov/drugoverdose/data/overdose.html.

6 "Injury Prevention & Control: Prescription Drug Overdose," Centers for Disease Control and Prevention, last modified January 12, 2016, http://www.cdc.gov/drugoverdose/data/index.html; Roni Caryn Rabin, "More Overdose Deaths From Anxiety Drugs," *The New York Times*, February 25, 2016, http://well.blogs.nytimes.com/2016/02/25/more-overdose-deaths-from-anxiety-drugs/.

7 "Injury Prevention & Control: Prescription Drug Overdose," Centers for Disease Control and Prevention, last modified October 28, 2015, http://www.cdc.gov/drugoverdose/epidemic/index.html; Haeyoun Park and Matthew Bloch, "How the Epidemic of Drug Overdose Deaths Ripples Across America," *The New York Times*, January 19, 2016, http://www.nytimes.com/interactive/2016/01/07/us/drug-overdose-deaths-in-the-us.html.

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[9] "Drug Fact Sheet: Hydrocodone," Drug Enforcement Administration, accessed March 23, 2016, http://www.dea.gov/druginfo/drug_data_sheets/Hydrocodone.pdf.

[10] Based on Drug Enforcement Administration data.

[11] Based on Texas Department of Public Safety (DPS) data.

[12] Based on Texas Department of State Health Services data.

[13] Mary Ann Roser, "Flawed numbers mask scope of Texas' prescription drug problem," *Austin American-Statesman*, April 25, 2015, http://www.mystatesman.com/news/news/flawed-numbers-mask-scope-of-texas-prescription-dr/nk3pj/.

[14] Niraj Chokshi, "America's drug overdose problem — and what states can do to help fight it — in four charts and maps," *The Washington Post*, June 17, 2015, https://www.washingtonpost.com/blogs/govbeat/wp/2015/06/17/americas-drug-overdose-problem-and-what-states-can-do-to-help-fight-it-in-4-charts-and-maps/.

[15] Based on DPS data.

[16] The Associated Press, "Houston area tops Texas in prescriptions for 'heroin high' drug cocktail," *The Dallas Morning News*, June 1, 2010, http://www.dallasnews.com/news/state/headlines/20100601-Houston-area-tops-Texas-in-prescriptions-1341.ece.

[17] House Research Organization, Bill Analysis: S.B. 195.

[18] Thomas Clark, John Eadie, Peter Kreiner, and Gail Strickler, *Prescription Drug Monitoring Programs: An Assessment of the Evidence for Best Practices*, September 20, 2012, accessed March 1, 2016, http://www.pdmpexcellence.org/sites/all/pdfs/Brandeis_PDMP_Report_final.pdf.

[19] Based on DPS data.

[20] "PDMP Mandatory Query by Prescribers and Dispensers," Prescription Drug Monitoring Program Training and Technical Assistance Center, last modified February 29, 2016, http://www.pdmpassist.org/pdf/Mandatory_Query.pdf.

[21] Ohio Administrative Code 4729-5-20.

[22] Tennessee Code Annotated Section 53-10-310.

[23] 22 T.A.C. Section 291.29; "Red Flags' Checklist for Pharmacies," Texas State Board of Pharmacy, accessed March 7, 2016, https://www.pharmacy.texas.gov/files_pdf/You_might_be_a_pill_mill_if.pdf.

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[27] Clark, Eadie, Kreiner, and Strickler, *Prescription Drug Monitoring Programs: An Assessment of the Evidence for Best Practices*.

[28] Based on DPS data.

[29] Ibid.

[30] "Empowering Prescribers & Pharmacists to Prevent Opiate Abuse," Office of John R. Kasich, Governor, State of Ohio, last modified October 26, 2015, https://www.ohiopmp.gov/Portal/Documents/FactSheet.pdf.

[31] "PMP InterConnect Integration Projects Bring Data Into Pharmacy Workflow, Ohio Supports Additional Deployments With $1.5 Million in Funding," National Association of Boards of Pharmacy, November 3, 2015, https://www.nabp.net/news/pmp-interconnect-integration-projects-bring-data-into-pharmacy-workflow-ohio-supports-additional-deployments-with-1-5-million-in-funding.

[32] Section 481.354, Texas Health and Safety Code.

[33] Ibid.

[34] Section 554.006(b), Texas Occupations Code.

Issue 2

Key Elements of the Texas State Board of Pharmacy's Statute Do Not Conform to Common Licensing Standards.

Background

The Texas State Board of Pharmacy's mission is to protect public health, safety, and welfare by ensuring the provision of quality pharmaceutical care. Under the Pharmacy Act, only a licensed pharmacist working in a licensed pharmacy can dispense prescription drugs. The board accomplishes its mission by licensing pharmacies and pharmacists, registering pharmacy technicians and trainees, enforcing board regulations, and taking disciplinary action when necessary. In fiscal year 2015, the board regulated 7,914 pharmacies, 31,807 pharmacists, 3,725 interns, 41,990 pharmacy technicians, and 18,777 technician trainees.

The Sunset Advisory Commission has a historic role in evaluating licensing agencies, as the increase of occupational licensing programs served as an impetus for the creation of the commission in 1977. Since then, the Sunset Commission has completed more than 100 licensing agency reviews. Sunset staff has documented standards in reviewing licensing programs to guide future reviews of licensing agencies. While these standards provide a guide for evaluating a licensing program's structure, they are not intended for blanket application. The following material highlights areas where the board's statute and rules differ from these model standards, and describes the potential benefits of conforming to standard practices.

Findings

Licensing provisions of the board's statute do not follow model licensing practices and could potentially affect the fair treatment of licensees and registrants.

- **Subjective qualification for licensure and registration.** Qualifications for licensure or registration should not overburden applicants or unreasonably restrict entry into practice. Currently, statute requires applicants for licensure or registration be of "good moral character."[1] Good moral character is a subjective, vague requirement that may be determined inconsistently. The board recognizes the good moral character requirement is subjective and overly broad, and instead reviews applicants' criminal history, only denying licensure or registration for criminal history related to the practice of pharmacy in accordance with Chapter 53 of the Occupations Code, which governs how licensing agencies should use criminal history information.[2] Removing the statutory requirement that applicants be of good moral character would be in line with the board's current practice of reviewing criminal history before granting a license or registration and would ensure that, going forward, all qualifications for licensure or registration remain related to the practice of pharmacy and do not unreasonably restrict entry into practice.

Qualifications for licensure should not unreasonably restrict entry into practice.

- **Unnecessary renewal form requirements.** Renewal forms should be simple, straightforward, and only require information necessary for the

board to determine the applicant's eligibility for renewal. The board's renewal forms for pharmacy licenses require a notarized signature, an unnecessary burden to license renewal that adds no value to the renewal process. State law already prohibits a person from knowingly making a false entry in a government record.[3] Removing the requirement that a licensee obtain a notarized signature for renewal would lessen the burden on licensees without reducing the board's ability to determine a licensee's eligibility for renewal.

Currently, the board's late fees are more punitive for pharmacy technicians than pharmacists.

- **Inconsistent, overly punitive late renewal penalties.** Penalties for late renewal of registration should provide an incentive to renew on time but should not be overly punitive. Currently, the board's late fees are more punitive for pharmacy technicians than pharmacists. While pharmacists may pay graduated late fees based on how many days late they submit their renewal, pharmacy technicians receive no such flexibility and must pay twice the registration fee, regardless of how late they renew.[4] Assessing a graduated penalty for pharmacy technicians who renew their registration late would encourage timely renewal and ensure equal treatment of all regulated individuals.

- **Insufficient statutory authority for the board to delegate tasks.** An agency's enabling legislation should be consistent with the agency's actual operations. The board's statute does not explicitly authorize the policymaking body to delegate tasks to the executive director, but the board delegates some routine activities to the director, including signing consent orders, a practice that improves efficiency. Other healthcare professional licensing agencies, including the Texas Medical Board and the Texas State Board of Dental Examiners, have explicit statutory authority to delegate certain tasks to the executive director. Allowing the board to delegate the signing of certain disciplinary orders to the director would increase the board's efficiency and ensure consistency between statutory authority and agency practices.

- **Insufficient statutory authority for continuing education requirements for pharmacy technicians.** To adequately protect the public, practitioners must have a working knowledge of recent developments and techniques in their profession. Continuing education provides a proven means of ensuring practitioners remain competent. Statute requires the board to develop continuing education requirements for pharmacists, but not for pharmacy technicians.[5] Board rules require pharmacy technicians to complete a set number of continuing education hours before renewing their registration every two years, but the board lacks clear statutory authority for these rules.[6] Clearly requiring the board to develop continuing education requirements for pharmacy technicians in statute would ensure technicians remain educated on changing developments in their field and would create consistency between board statute and rules.

The board lacks clear statutory authority for its technician continuing education rules.

- **No statutory authority to deny renewal applications for noncompliant licensees or registrants.** The authority to deny license renewals based

on the applicant's failure to comply with previous board orders bolsters agencies' efforts and ensures that disciplined licensees have fulfilled their responsibilities regarding safe practices. While the board issues more than 600 disciplinary orders in a typical year, it does not have such authority. Authorizing the board to deny renewal for noncompliant licensees or registrants would allow the board to more effectively protect the public.

A nonstandard board enforcement practice could reduce the agency's effectiveness in protecting the public.

- **Underutilization of national disciplinary database.** Licensing agencies should make use of enforcement information shared with national or federal data banks. All state boards of pharmacy, including the Texas board, are members of the National Association of Boards of Pharmacy, which requires that each board enter disciplinary actions against licensees into the association's national database. The board has authority to query the database for actions taken against pharmacists by other state boards but does not currently check the database before renewal. Instead, the board requires that renewal applicants self-report such actions. Without checking the database, the board cannot ensure pharmacists are not subject to enforcement action in another state related to an action that would inhibit their ability to practice pharmacy. Statute already requires that the board deny a pharmacist's application for renewal if the pharmacist's license in another state has been suspended, revoked, canceled, or subject to an action that prohibits the person from practicing pharmacy.[7] Requiring the board to search the database before renewing pharmacist licenses would ensure that the board fulfills its statutory obligation to deny renewal in such cases and would better protect the public by ensuring that licensees meet the requirements for continued licensure.

The board should use a national disciplinary database to ensure licensees meet requirements for continued licensure.

Recommendations

Change in Statute

2.1 Remove unnecessary qualifications required of applicants for licensure or registration.

This recommendation would remove the subjective requirement that applicants be found to have good moral character, ensuring that qualifications for licensure and registration do not overburden applicants or unreasonably restrict entry into practice. The board would continue to review an applicant's criminal history to determine the applicant's eligibility for licensure or registration according to requirements in Chapter 53, Occupations Code and in line with the board's current rules.

2.2 Require the board to create a system of graduated penalties for late renewal of pharmacy technician registration.

This recommendation would incentivize timely renewal by requiring the board to create a graduated late renewal penalty structure for pharmacy technicians similar to how pharmacists are currently treated. Technicians would be charged one and one-half of the normally required renewal fee for renewing

up to 90 days late and twice the normally required renewal fee for renewing 91 days to one year late. This recommendation would also promote fairness by ensuring the board applies late fees equally to technicians and pharmacists.

2.3 Clarify statute to authorize the board to delegate tasks to the executive director.

This recommendation would clearly allow the current practice of the executive director entering into consent orders on the board's behalf. This best practice improves efficiency by allowing the executive director to handle routine enforcement matters that do not require the board's attention.

2.4 Clarify statute to require the board to develop continuing education standards for pharmacy technicians.

This recommendation would ensure the board has proper statutory authority for existing rules creating a system of continuing education requirements for pharmacy technicians, and would protect the public by ensuring pharmacy technicians remain competent.

2.5 Authorize the board to deny renewal applications from noncompliant applicants.

This recommendation would authorize the board to deny renewal for licensees and registrants who are noncompliant with an existing board order, giving the board a standard tool to better protect the public.

Management Action

2.6 The board should remove requirements that renewal forms be notarized.

Under this recommendation, the board would no longer impose the burdensome requirement that pharmacy license renewal forms be notarized. Current provisions of the Penal Code that make falsifying a government record a crime would continue to apply to license renewals.

2.7 Direct the board to query a national disciplinary database before license renewal.

This recommendation would direct the board to verify that a pharmacist has not had a license suspended, revoked, canceled, or subject to an action that prohibits the person from practicing pharmacy in another state by searching the National Association of Boards of Pharmacy database, allowing the board to better protect the public by ensuring licensees are not subject to disciplinary orders in other states. The board would have flexibility in implementing this recommendation to ensure checking the database does not unduly disrupt the online license renewal process.

Fiscal Implication

Overall, these recommendations would not have a significant fiscal impact to the state. All but one recommendation either clarify current practice or change procedures in ways that do not require additional resources. However, the modification of the late renewal penalty structure for pharmacy technicians would result in a small loss of revenue to General Revenue. Based on the number of technicians who renewed late in fiscal year 2015, requiring a decreased late renewal fee would result in a loss of approximately $36,000 annually.

Texas State Board of Pharmacy

Fiscal Year	Loss to the General Revenue Fund
2018	$36,000
2019	$36,000
2020	$36,000
2021	$36,000
2022	$36,000

[1] All citations to Texas statutes are as they appear on http://www.statutes.legis.state.tx.us/. Sections 558.101(a)(2), 558.051(a)(2)(B), 568.002(c)(1), Texas Occupations Code.

[2] 22 T.A.C. Section 281.63.

[3] Section 37.10(a)(1), Texas Penal Code.

[4] Section 559.003(b), (c), Texas Occupations Code; 22 T.A.C. Section 297.3(d)(4).

[5] Sections 559 and 568, Texas Occupations Code.

[6] 22 T.A.C. Section 297.8(b).

[7] Section 559.003(e), Texas Occupations Code.

Issue 3

The State Has a Continuing Need to Regulate the Practice of Pharmacy.

Background

The Legislature created the Texas State Board of Pharmacy in 1907 as an independent regulatory board to protect the public by ensuring that Texans receive safe and quality pharmaceutical care. The board accomplishes its mission by regulating the practice of pharmacy, the operation of pharmacies, and the distribution of prescription drugs. In fiscal year 2015, the board regulated nearly 32,000 pharmacists, 8,000 pharmacies, and 42,000 pharmacy technicians. In fiscal year 2015, the board resolved 5,955 complaints, which resulted in 627 disciplinary orders against licensees and registrants. In addition to investigating complaints, the board inspects pharmacies to ensure compliance with state law. In fiscal year 2015, the board completed 2,992 inspections. In fiscal year 2017, the board will begin administering the Prescription Monitoring Program, a database that tracks the prescribing and dispensing of controlled substances within Texas to protect patient safety and prevent drug abuse and theft.

Findings

The Texas State Board of Pharmacy has a necessary role to protect the public by licensing and enforcing standards for the practice of pharmacy.

Prescription drug use continues to increase in Texas and across the United States. In 2002, when the board was last under Sunset review, Americans spent nearly $141 billion and averaged a little less than 12 prescriptions per person.[1] In 2014, spending on prescription drugs rose to nearly $374 billion, a 13 percent increase over the previous year and more than 2.5 times as much as was spent in 2002.[2] In addition, in 2014 Americans averaged 12.7 prescriptions per person, filling nearly 4.3 billion prescriptions for the year.[3]

Americans averaged 12.7 prescriptions per person in 2014.

While prescription drugs are able to cure and treat an ever increasing number of conditions, they also pose significant risks if not taken correctly and under proper supervision. The board regulates individuals to ensure their competence to provide pharmacy services to the public. The board helps ensure patient safety by requiring counseling for all new prescriptions, so that patients understand how to properly take their prescriptions and the potential side effects or interactions with other medications.

In addition, as discussed in Issue 1, the over-prescribing and over-dispensing of highly addictive drugs such as opioids poses great risk to the public. A license from the board is a serious responsibility as it allows a pharmacy to obtain a DEA permit to purchase these controlled substances. Prescription opioid drugs are extremely addictive, in demand, and have a high street value, all of which incentivize illicit activities around pharmacies, such as theft and illegal reselling of prescribed drugs. The board's oversight role remains critical

to public health efforts to ensure the state is doing everything possible to limit diversion of drugs for illegitimate purposes.

The board also develops and enforces rules and regulations to ensure that licensees engage in safe practices for increasingly specialized and technical pharmacy operations. For example, sterile compounding pharmacies, which prepare customized injectable medications that pose a higher risk of infection than other drugs, have been subject to increased legislative interest following the deaths of 64 people nationally who took drugs compounded by the New England Compounding Center in Massachusetts in 2012.[4] In 2013, the Legislature added a requirement that the board inspect sterile compounding pharmacies before initial licensure and every two years on renewal to ensure that these pharmacies continue to meet sterility requirements. In fiscal year 2015, the board inspected 273 sterile compounding pharmacies, issuing 171 warning notices for violations of board rules.

The board revoked 95 licenses and registrations for serious violations of the rules in fiscal year 2015.

Finally, the public needs an agency that can resolve complaints about pharmacy service providers and, when warranted, discipline those who violate the laws to bring them into compliance or expel them from the profession when necessary. The board has taken this role seriously, revoking 95 licenses and registrations for serious violations of the rules in fiscal year 2015. The board also pays special attention to pharmacists and pharmacy technicians suffering from chemical dependency issues, performing comprehensive monitoring of 167 licensees and registrants with these issues in fiscal year 2015.

No substantial benefits would result from transferring the board's functions to another agency at this time.

- **Independent agency structure.** The state has regulated the practice of pharmacy through an independent regulatory agency since its creation in 1907. This independent structure reflects the common approach for some significant health licensing activities in Texas, especially larger agencies such as the Medical and Nursing boards. These agencies oversee complex medical activities that pose a significant risk to public health and safety and generate significant regulatory activity such as complaint investigations, inspections, and action to correct or discipline bad actors.

  The board takes its duty to protect the public seriously, performing thousands of inspections and complaint investigations and disciplining hundreds of practitioners each year.

  The board takes its duty to protect the public seriously, performing thousands of inspections and complaint investigations and disciplining hundreds of practitioners each year. In addition, having the board operate as an independent agency with the singular focus of regulating the practice of pharmacy allows the Legislature to readily identify where responsibility lies when problems arise.

  This independent structure offers benefits in terms of focusing regulatory attention on protecting patient health. This structure provides for a dedicated staff focused exclusively on regulating the practice of pharmacy that is easily identifiable and accessible to practitioners and the public alike.

The board also benefits from colocation with other health regulatory agencies currently in the Hobby Building in downtown Austin. It also shares administrative functions with these agencies through the Health Professions Council. Colocation and shared administrative services enable the agency to easily access best practices from neighboring agencies and to achieve administrative efficiencies among similar state regulatory programs.

- **Umbrella agency structure.** An alternative approach to having an independent agency is the consolidation of needed regulatory programs under an umbrella structure. The state has long regulated various trades under the umbrella of the Texas Department of Licensing and Regulation (TDLR). However, the only comparable effort for health regulatory programs at the Department of State Health Services (DSHS) was ineffective and largely dismantled in 2015, with numerous programs moved to TDLR or the Texas Medical Board, while others were deregulated. The rationale for this change was to focus DSHS on its important public health mission while still improving needed regulation.

  This umbrella structure can offer distinct advantages compared to an independent agency structure. By having staff specialize along functional lines, umbrella agencies can provide benefits of long-term efficiency over smaller, independent agencies. Umbrella oversight agencies can also provide a more objective regulatory approach because their broad responsibilities typically require them to have oversight boards comprising public members that rely on advisory committees of practitioners for expertise about the regulated field. This separation helps promote the broader public interest, minimizing the potential for the regulated community to promote its own interest when it controls these oversight boards. The review considered the following structural alternatives but ultimately concluded the potential benefits of organizational change were not great enough to justify such an upheaval.

  The potential benefits of an organizational change were not great enough to justify such an upheaval.

  Texas Department of Licensing and Regulation. In 2015, through the Sunset review of DSHS, the Legislature transferred 13 health-related programs to TDLR over the next three years. While this experience has engaged TDLR in the regulation of health professions, none of the programs transferred require the kind of technical expertise needed to regulate the practice of pharmacy, especially from an inspection and enforcement standpoint. In addition, the large expansion of authority may well have brought TDLR to the limits of its ability — at least its ability to take on a larger, more complex regulatory program with the level of risk associated with pharmacy.

  Texas Medical Board. While the Texas Medical Board is not a traditional umbrella agency, it regulates a number of health licensing programs including four health-related programs transferred to the Medical Board through the Sunset review of DSHS. However, the Medical Board's focus is on regulation of providers of health-related services, particularly physicians and physician assistants who have prescribing authority. While

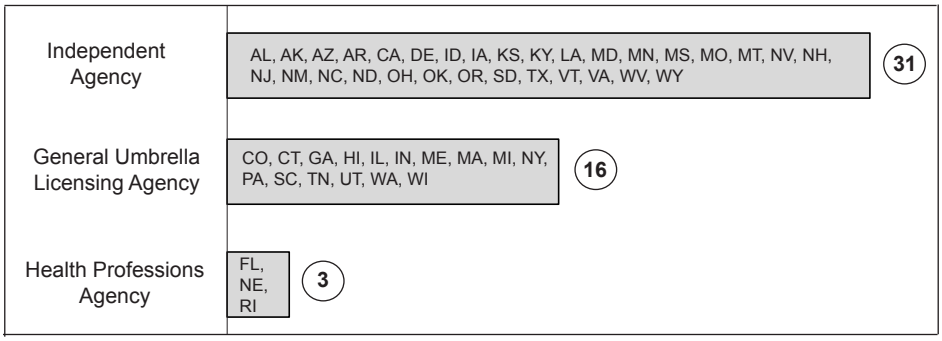
this is somewhat linked to the Board of Pharmacy's mission to regulate the practice of pharmacy, the regulation of practitioners with prescribing authority is significantly different than the regulation of the dispensing of pharmaceuticals. In addition, the Medical Board's structure would require significant adjustment to accommodate a healthcare practice such as pharmacy.

The majority of states, including Texas, regulate the practice of pharmacy through independent agencies overseen by independent pharmacy boards.

Most states regulate pharmacies, pharmacists, and pharmacy technicians through independent agencies, like Texas.

All states regulate the practice of pharmacy and pharmacy facilities. The chart, *Regulation of Pharmacy in the United States*, describes the organizational approach to pharmacy regulation in the 50 states. A large majority of states — 31 including Texas — regulate the practice of pharmacy through independent state agencies overseen by independent pharmacy boards. Fifteen states regulate pharmacy through general umbrella licensing agencies, and only three states regulate pharmacies through health professions regulatory agencies. In addition, 44 states, including Texas, also regulate pharmacy technicians.

Regulation of Pharmacy in the United States



The board's statute does not reflect standard language typically applied across-the-board during Sunset reviews.

The Sunset Commission has developed a set of standard recommendations that it applies to all state agencies reviewed unless an overwhelming reason exists not to do so. These across-the-board recommendations (ATBs) reflect an effort by the Legislature to place policy directives on agencies to prevent problems from occurring, instead of reacting to problems after the fact. ATBs are statutory administrative policies adopted by the Sunset Commission that contain "good government" standards for state agencies. The ATBs reflect review criteria contained in the Sunset Act designed to ensure open, responsive, and effective government.

The board's statute does not include a standard provision relating to alternative rulemaking and dispute resolution that the commission routinely applies to agencies under review. This provision helps improve rulemaking and dispute resolution through more open, inclusive, and conciliatory processes designed to solve problems by building consensus rather than through contested cases.

The board faces the likely retirement of top-level management employees in the near future but lacks a formal plan to deal with impending staff losses.

All agencies should plan for succession of senior level staff. Such planning is especially important for agencies where major retirements may soon affect agency operations. In the case of the Board of Pharmacy, potential impending retirements could result in a significant loss of experienced staff in key management positions. The board employs six top-level managers, three of whom are eligible or will be eligible to retire in the next four years. This includes the directors of enforcement and licensing who have been with the agency for decades and represent a wealth of institutional knowledge. In addition, the executive director has announced her retirement in 2017, and the board has publicly discussed the potential difficulty in attracting a qualified replacement as statute requires the executive director be a licensed pharmacist and the current pay is below what a pharmacist would make in the private sector.

The board has not developed a formal succession plan that trains and develops employees to move into key positions.

Although the board recognizes the impending loss of key staff, it has not developed a formal succession plan that trains and develops employees to move into key positions. The purpose of succession planning is to ensure that there are experienced and capable employees who are prepared to assume strategic organizational roles as they become open. However, the board has not formally documented what skill sets are critical to meeting agency objectives, identified experienced and capable staff to fill vacancies, or prepared staff to assume top-level management roles by providing additional training and development opportunities.

Recommendations

Change in Statute

3.1 Continue the Texas State Board of Pharmacy for 12 years.

This recommendation would continue the Texas State Board of Pharmacy for the standard 12-year period as an independent agency responsible for regulating the practice of pharmacy.

3.2 Apply the standard Sunset across-the-board requirement for the board to develop a policy regarding negotiated rulemaking and alternative dispute resolution.

This recommendation would ensure that the board develops and implements a policy to encourage alternative procedures for rulemaking and dispute resolution. The board would also coordinate implementation of the policy, provide training as needed, and collect data concerning the effectiveness of these procedures. Because the recommendation only requires the board to develop a policy for this alternative approach to solving problems, it would not require additional staffing or other expenses.

Management Action

3.3 The board should develop and implement a succession plan to prepare for impending retirements.

With the expected turnover of top-level management positions, the board should implement a succession plan no later than January 2017, before anticipated retirement-eligibility dates of key staff. As part of the succession planning process, the board should identify key positions at risk of becoming vacant, identify the skills needed to fill these vacancies, identify experienced and capable staff to fill vacancies, and prepare staff to assume top-level management roles by providing additional training and development opportunities.

Fiscal Implication

If the Legislature continues the current functions of the board, the agency's annual appropriation of $6.7 million would be required for its operation. This appropriation is entirely paid for by the licensing and registration fees the agency collects. The state would also continue to receive approximately $4.2 million from fees collected by the agency in excess of its appropriation. Applying the standard Sunset provision relating to alternative rulemaking and dispute resolution would not have a fiscal impact. Preparing for future staff needs is an essential agency function and should be handled with existing resources. In addition, providing training, including internal training for positions at risk of becoming vacant, can be accomplished within the agency's existing budget.

1 The Henry J. Kaiser Family Foundation, *Prescription Drug Trends, Fact Sheet* (Menlo Park, CA: The Henry J. Kaiser Family Foundation, May 2003).

2 Alexandra Sifferlin, "Americans Spent a Record Amount on Medicine in 2014," *Time*, April 14, 2015, http://time.com/3819889/medicine-spending/.

3 Ibid.; The Henry J. Kaiser Family Foundation, *Retail Prescription Drugs Filled at Pharmacies (Annual Per Capita*), accessed January 18, 2016, http://kff.org/other/state-indicator/retail-rx-drugs-per-capita/.

4 "State Regulation of Compounding Pharmacies," National Conference of State Legislatures, last modified October 1, 2014, http://www.ncsl.org/research/health/regulating-compounding-pharmacies.aspx; Jess Bidgood and Sabrina Tavernise, "Pharmacy Executives Face Murder Charges in Meningitis Deaths," *The New York Times*, December 17, 2014, http://www.nytimes.com/2014/12/18/us/new-england-compounding-center-steroid-meningitis-arrests.html.

APPENDICES

Appendix A

Texas State Board of Pharmacy

Member	City	Qualification	Term Expiration
Jeanne D. Waggener, R.Ph. President	Waco	Registered Pharmacist	2017
Buford T. Abeldt, Sr., R.Ph. Treasurer	Lufkin	Registered Pharmacist	2019
Christopher M. Dembny, R.Ph.	Richardson	Registered Pharmacist	2017
L. Suzan Kedron	Dallas	Public Member	2019
Alice G. Mendoza, R.Ph.	Kingsville	Registered Pharmacist	2017
Bradley A. Miller, Ph.T.R.	Austin	Registered Pharmacy Technician	2019
Phyllis A. Stine	Abilene	Public Member	2017
Chip Thornsburg	Helotes	Public Member	2021
Suzette Tijerina, R.Ph.	Castle Hills	Registered Pharmacist	2021
Dennis F. Wiesner, R.Ph.	Austin	Registered Pharmacist	2019
Jenny Downing Yoakum, R.Ph.	Kilgore	Registered Pharmacist	2021

Appendix B

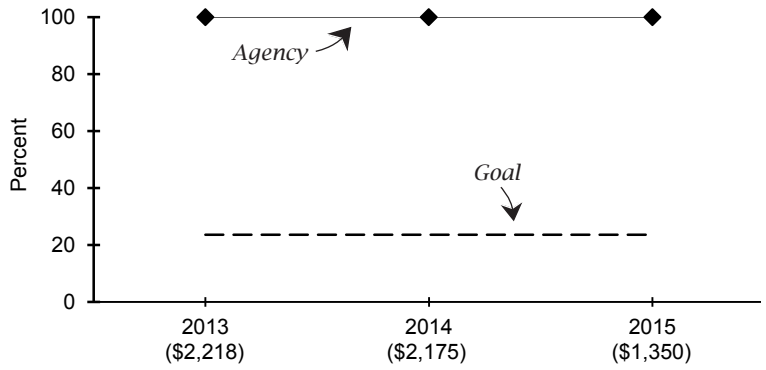
Historically Underutilized Businesses Statistics 2013 to 2015

The Legislature has encouraged state agencies to increase their use of historically underutilized businesses (HUBs) to promote full and equal opportunities for all businesses in state procurement. The Legislature also requires the Sunset Commission to consider agencies' compliance with laws and rules regarding HUB use in its reviews.[1]

The following material shows trend information for the Texas State Board of Pharmacy's use of HUBs in purchasing goods and services. The agency maintains and reports this information under guidelines in statute.[2] In the charts, the dashed lines represent the goal for HUB purchasing in each category, as established by the comptroller's office. The diamond lines represent the percentage of agency spending with HUBs in each purchasing category from 2013 to 2015. Finally, the number in parentheses under each year shows the total amount the agency spent in each purchasing category.

The Board of Pharmacy has complied with most HUB program requirements but has had difficulty meeting statewide HUB purchasing goals, particularly in the category of other services, and has not participated in the HUB forum program or established a HUB mentor-protégé program.

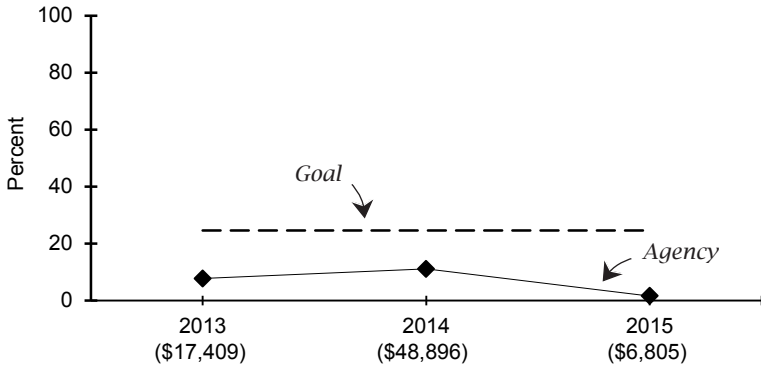
Professional Services



In the professional services category, the board has used only HUBs, exceeding the statewide goal in each of the last three fiscal years.

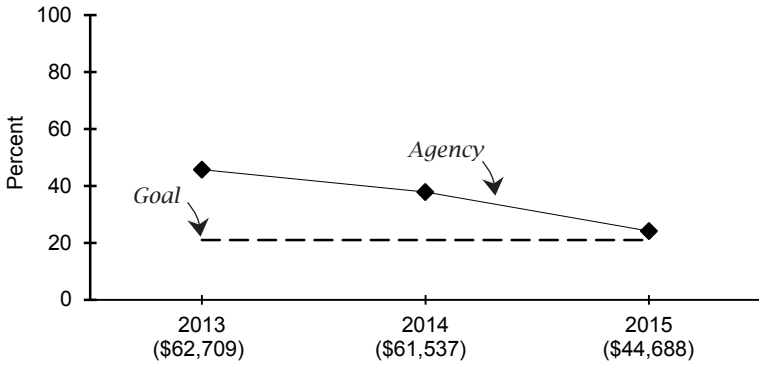
Appendix B

Other Services



The board failed to meet the statewide goal for other services during the last three fiscal years. The board uses contracts available through Texas Council on Competitive Government and Texas Department of Information Resources for some of these services and many of the vendors that can provide the services needed are not HUB vendors. One of the board's primary vendors in this category lost HUB certification in fiscal year 2015, which significantly impacted the board's HUB percentage.

Commodities



The board met or exceeded the statewide goal for commodities during the last three fiscal years.

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1 All citations to Texas statutes are as they appear on http://www.statutes.legis.state.tx.us/. Section 325.011(9)(B), Texas Government Code.

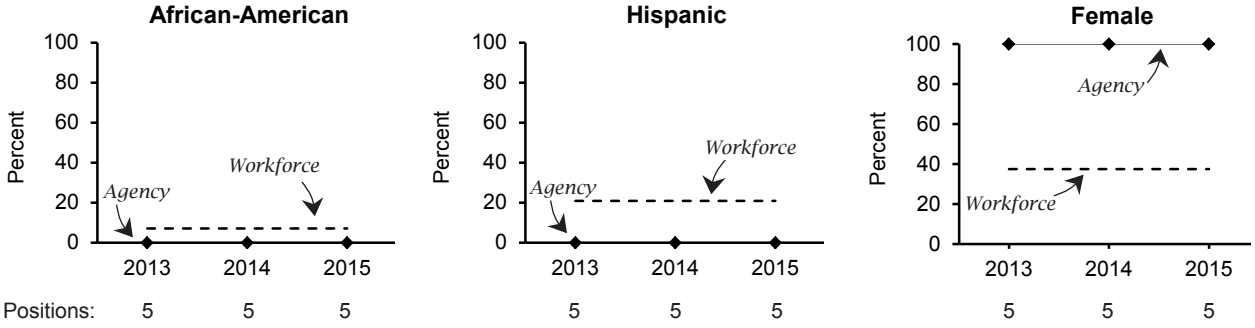
2 Chapter 2161, Texas Government Code.

Appendix C

Equal Employment Opportunity Statistics 2013 to 2015

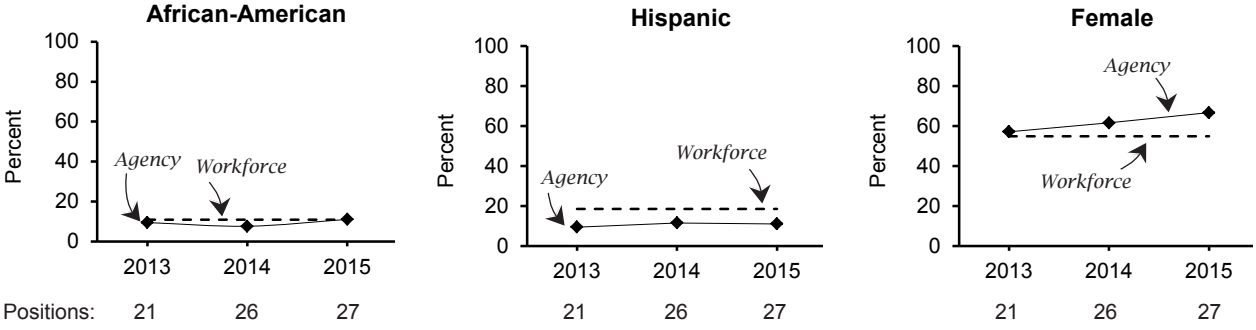
In accordance with the requirements of the Sunset Act, the following material shows trend information for the employment of minorities and females in all applicable categories by the Texas State Board of Pharmacy.[1] The agency maintains and reports this information under guidelines established by the Texas Workforce Commission.[2] In the charts, the dashed lines represent the percentages of the statewide civilian workforce for African-Americans, Hispanics, and females in each job category.[3] These percentages provide a yardstick for measuring agencies' performance in employing persons in each of these groups. The diamond lines represent the agency's actual employment percentages in each job category from 2013 to 2015. The board met or exceeded many statewide civilian workforce percentages for fiscal years 2013 to 2015, but fell short on its employment of minorities in administration.

Administration



The board met or exceeded the statewide civilian workforce percentage of administrators for women. However, the board did not meet the statewide percentage for African-American and Hispanic employees in administrative positions.

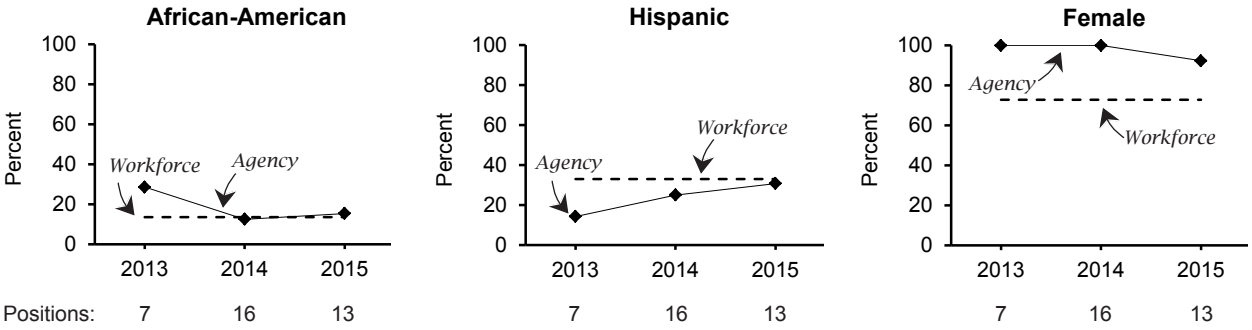
Professional



The board's workforce percentages for professionals met or exceeded the statewide civilian workforce for women and were within a few points of the statewide civilian workforce for African-Americans. However, the board's percentage of Hispanic professionals fell below the statewide percentage.

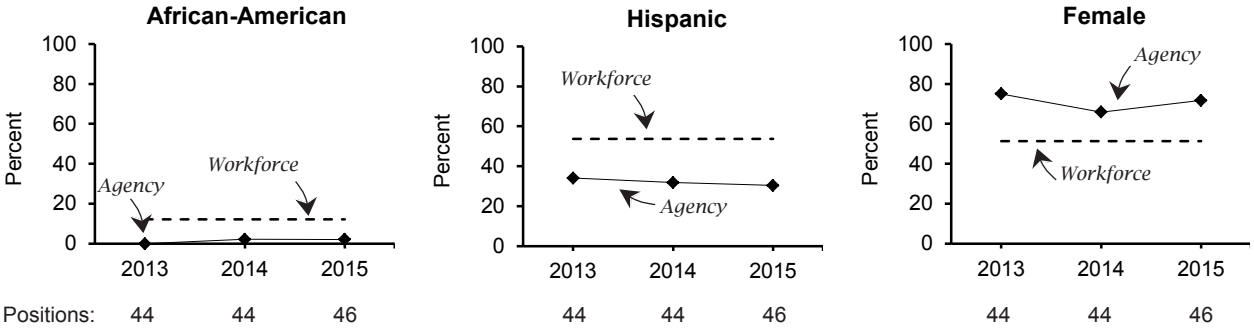
Appendix C

Administrative Support



The board met or exceeded the statewide civilian workforce percentage for African-Americans and women in administrative support positions. The board fell below the statewide workforce percentage for Hispanics in administrative support, but the percentage has increased in each of the last three fiscal years.

Service/Maintenance



The board met or exceeded the statewide civilian workforce percentage for women in service and maintenance positions. However, the board fell below the statewide percentage for African-Americans and Hispanics in these positions.

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1 All citations to Texas statutes are as they appear on http://www.statutes.legis.state.tx.us/. Section 325.011(9)(A), Texas Government Code.

2 Section 21.501, Texas Labor Code.

3 Based on the most recent statewide civilian workforce percentages published by the Texas Workforce Commission.

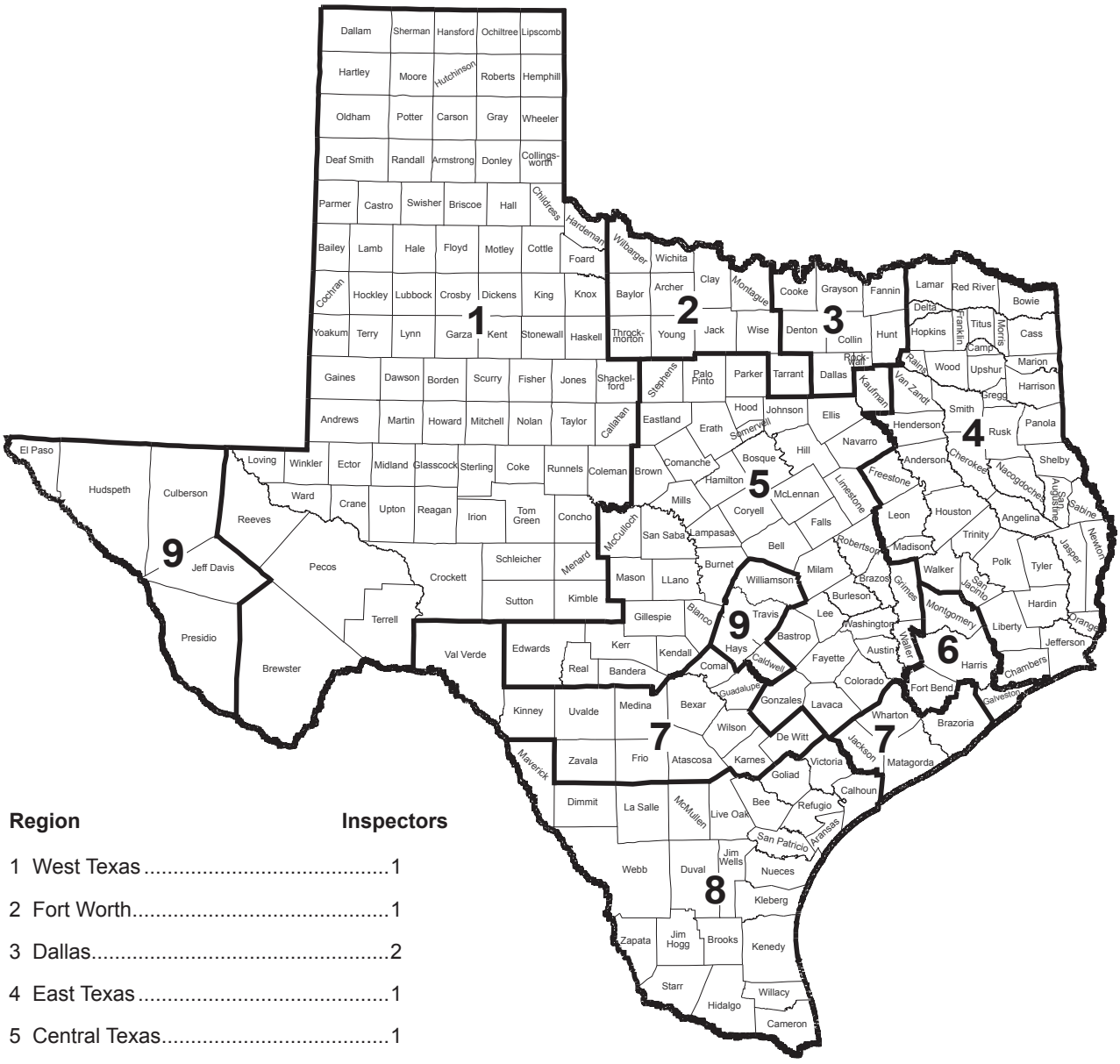
Appendix D

Licensed Pharmacies FY 2015

Class of Pharmacy	Number
Class A (Community/Retail) Typical independent or chain pharmacy filling routine prescriptions, but not conducting any sterile compounding	4,935
Class A-S (Sterile Compounding Community Pharmacy) Typical independent or chain pharmacy filling routine and sterile compounded prescriptions	321
Class B (Nuclear) Highly specialized pharmacy preparing radioactive prescriptions used in medical imaging tests such as CT scans	37
Class C (Institutional/Hospital) Pharmacy in a hospital, hospice facility, or outpatient surgery center filling prescriptions for the facility's patients	732
Class C-S (Sterile Compounding Institutional Pharmacy) Pharmacy in a hospital, hospice facility, or outpatient surgery center filling prescriptions and compounding sterile preparations for the facility's patients	459
Class D (Clinic) Clinic pharmacy filling a limited set of dangerous drugs such as anti-infective drugs, vitamins, and vaccines related to the clinic's objectives, such as rural, school-based, and indigent care clinics	375
Class E (Non-Resident) Out–of–state pharmacy filling and shipping prescriptions to Texas, but not conducting any sterile compounding	658
Class E-S (Sterile Compounding Non-Resident Pharmacy) Out-of-state pharmacy filling and shipping prescriptions to Texas, including sterile compounded preparations	148
Class F (Freestanding Emergency Medical Center) Pharmacy in an urgent, emergency care center that is not part of a hospital filling prescriptions for the center's patients	222
Class G (Central Processing) Pharmacy entering data and processing prescriptions that are usually dispensed at another location to streamline chain pharmacy processing	26
Class H (Limited Prescription Delivery) Prescription pick-up location in a remote area not served by a traditional pharmacy	1
Total	**7,914**

Appendix E

Map of Inspection Regions



Region	Inspectors
1 West Texas	1
2 Fort Worth	1
3 Dallas	2
4 East Texas	1
5 Central Texas	1
6 Houston	3
7 San Antonio	1
8 South Texas/Rio Grande Valley	1
9 Austin/El Paso	1

Appendix F

Staff Review Activities

During the review of the Texas State Board of Pharmacy, Sunset staff engaged in the following activities that are standard to all Sunset reviews. Sunset staff worked extensively with agency personnel; attended board meetings and met with board members; met with staff from key legislative offices; conducted interviews and solicited written comments from interest groups and the public; reviewed agency documents and reports, state statutes and rules, federal statutes, legislative reports, previous legislation, and literature; researched the organization and functions of similar state agencies in other states; and performed background and comparative research.

In addition, Sunset staff also performed the following activities unique to this agency:

- Observed inspections of six pharmacies in Austin, Houston, and Dallas, including retail, hospital, and sterile compounding pharmacies
- Interviewed board field inspectors working in four of the board's nine regions
- Toured a nuclear pharmacy and central processing pharmacy
- Attended numerous informal settlement conferences and hearings to observe agency enforcement actions against pharmacies, pharmacists, pharmacy technicians, and technician trainees
- Conducted an online survey of board stakeholders and staff and evaluated the approximately 100 responses
- Attended a meeting of the Interagency Prescription Monitoring Program Work Group
- Interviewed staff from state agencies including the State Office of Administrative Hearings, Department of Public Safety, Health and Human Services Commission Office of Inspector General, Health Professions Council, Department of State Health Services, and Texas Medical Board
- Interviewed staff from the National Association of Boards of Pharmacy, Prescription Drug Monitoring Program Center of Excellence, U.S. Drug Enforcement Agency, and other states about best practices for prescription monitoring programs

Sunset Staff Review of the *Texas State Board of Pharmacy*

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