

EXECUTIVE SUMMARY

Texas State Board of Pharmacy

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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