



Texas State Board of Pharmacy

Agency at a Glance

The Texas State Board of Pharmacy protects the public by ensuring that Texans receive safe and quality pharmaceutical care. The Board accomplishes this mission by regulating the practice of pharmacy, the operation of pharmacies, and the distribution of prescription drugs.

The State of Texas began regulating pharmacists more than a century ago, when the Legislature established district boards of pharmaceutical examiners to certify pharmacists. In 1907, the Legislature passed the Texas Pharmacy Act and established the Texas State Board of Pharmacy as an independent state regulatory board. The Board's main functions include:

- licensing qualified individuals to practice pharmacy or operate a pharmacy, and registering pharmacist-interns, preceptors, and pharmacy technicians;
- regulating the delivery or distribution of prescription drugs or devices;
- setting standards regarding the practice of pharmacy, including recognizing and approving pharmacy school degree requirements;
- investigating and resolving complaints against pharmacists and pharmacies; and
- enforcing the Texas Pharmacy Act and taking disciplinary action when necessary.

Key Facts

- **Funding.** In fiscal year 2004, the Board operated with a budget of about \$3.2 million. All costs are covered by licensing fees collected from the industry.
- **Staffing.** The Board has a staff of 48, with 38 based in Austin and the remaining 10 in the field across the state.
- **Licensing.** The Board regulated 22,111 pharmacists, 6,014 pharmacies, and 1,579 pharmacist-interns in fiscal year 2004. The Board also registered 22,164 pharmacy technicians in fiscal year 2004, the first full year of regulation.
- **Enforcement.** The Board received 4,436 jurisdictional complaints in fiscal year 2004, and resolved 2,982. Of the resolved complaints, 466 resulted in disciplinary action, with the largest category of complaints relating to dispensing errors. The remaining complaints were dismissed or referred to another board, such as the Medical Board.



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Recommendations

1. Strengthen the Board's Ability to Regulate Out-of-State Pharmacies.
2. Update the Board's Enforcement Authority to Address Needs Created by Changes in the Pharmacy Industry.
3. Authorize the Board to Access Sales and Pricing Data During Investigations That Resulted From a Complaint or Previously Failed Inspection.
4. Conform Key Elements of the Board's Licensing and Regulatory Functions to Commonly Applied Licensing Practices.
5. Allow for a Greater Range of Disciplinary Sanctions for Pharmacy Technicians.
6. Authorize the Board to Register and Discipline Pharmacy Technician Trainees.
7. Give Pharmacists the Option of Making Their Home Address Confidential.
8. Continue the Texas State Board of Pharmacy for 12 Years.

The Board's Authority to Regulate Out-of-State Pharmacies Has Not Kept Pace With Changes in Technology.

Key Findings

- Technology has changed how consumers buy their prescription drugs and how regulators do their job.
- Buying drugs online can harm consumers, who may not be aware of the legitimacy of an Internet pharmacy.
- Minimal regulation of out-of-state pharmacies creates an environment for illegal activity.
- The Board cannot hold out-of-state pharmacies to the same licensing standards as Texas-based pharmacies.
- The Board has limited ability to discipline out-of-state pharmacies that violate state law.

Texas established its framework for regulating the pharmacy profession at a time when most consumers purchased their prescription drugs at a pharmacy around the corner. Today, however, many consumers' prescriptions are filled by pharmacies across the country. Although technological strides, such as the Internet, offer great benefits to consumers, they also pose hazards. Without adequate regulation of these distant pharmacies, consumers are at risk of getting unsafe or inappropriate medications, not receiving appropriate oversight from healthcare professionals, or having illegal access to prescription drugs. The Texas Pharmacy Act has not kept pace with recent technological advancements, limiting the Board's ability to regulate out-of-state pharmacies – including Internet pharmacies – that provide prescription drugs to Texans.

Recommendations

Change in Statute

1.1 Require out-of-state pharmacies to meet the same standards for licensure as Texas-based pharmacies.

Under this recommendation, a pharmacy located outside of Texas would have to meet comparable standards as Texas-based pharmacies to receive a license from the Board. The Board would adopt rules outlining the requirements for licensure, which should include proof of credit worthiness and an inspection report that is no more than two years old. In addition, to maintain the license, a pharmacy must have on file with the Board an inspection report that is no more than three years old at any time. The Board should adopt rules that allow for a pharmacy located out of state to submit an inspection report conducted by an entity other than the pharmacy board in the pharmacy's state of physical location. This would ensure that should another state not have comparable inspection procedures to those in Texas, an out-of-state pharmacy would still be able to meet Texas' licensing requirements.

1.2 Clarify that the grounds for disciplinary action for out-of-state pharmacies include the same grounds as for Texas-based pharmacies.

The disciplinary grounds for out-of-state pharmacies would mirror those outlined in the Texas Pharmacy Act for in-state pharmacies, in addition to the grounds that already exist for out-of-state

pharmacies. For example, the Board would have authority to discipline an applicant for or holder of an out-of-state – or Class E – pharmacy license for allowing an employee who is not a pharmacist to practice pharmacy or for failing to establish effective controls against drug diversion.

1.3 Authorize the Board to take disciplinary action on a pharmacy's license based on the action of another state board of pharmacy.

This recommendation would allow the Board to take disciplinary action against a pharmacy licensed in Texas when that pharmacy has been subject to disciplinary action by another jurisdiction's regulatory agency. As a result, the Board would be able to take disciplinary action without having to independently prove the merits of the case, based on the due process the pharmacy owner received in another state, as long as the violation is also a violation of Texas law. This change would make disciplinary grounds for pharmacies more consistent with those for pharmacists.

1.4 Authorize the Board to initiate disciplinary action against an out-of-state pharmacy at any time.

This recommendation would remove the time frames that the Board must adhere to before initiating disciplinary action against an out-of-state pharmacy that allegedly violated the Texas Pharmacy Act. As a result, the Board would not have to wait to see if the regulatory board in the state in which the pharmacy is located takes disciplinary action against the pharmacy first. The Board would still be required to notify the other state pharmacy board about the alleged action, but action by the Texas Board would not be dependent on the other state's action.

1.5 Require pharmacies that use an Internet site to post information on filing a complaint with the Board.

A pharmacy that sells or distributes prescription drugs or devices through an Internet site would be required to include information about how to file a complaint with the Board on the site. The site would specifically mention complaints, so that consumers would be able to easily discern how to contact the Board. The online pharmacy would be able to include a general statement about filing complaints on its home page, but specific information about contacting the Texas Board would be no more than two links from the home page. At a minimum, the information would include the Board's phone number, address, and Web address.

1.6 Establish that a pharmacist or pharmacy may only distribute a prescription drug or device if a valid practitioner-patient relationship exists.

This recommendation would codify the Board's current requirement that pharmacists and pharmacies may not dispense prescription drugs or devices if a valid practitioner-patient relationship does not exist. Because the Texas State Board of Medical Examiners has jurisdiction over physicians, the Pharmacy Board would base any decisions or actions on the definition of practitioner-patient relationship established by the Medical Board.

1.7 Require the Board to list Internet pharmacies licensed in Texas on its Web site.

To provide consumers with simple, easy-to-obtain information about Internet pharmacies licensed in Texas, the Board would post a list of those pharmacies on the agency's Web site. The list should include the pharmacy's name, license number, and state of physical location. This list would be in addition to the Board's licensure verification database.

The Texas Pharmacy Act Does Not Give the Board Adequate Authority to Fully Protect the Public.

Key Findings

- The grounds for disciplining a licensee under the Texas Pharmacy Act do not account for changes in the pharmacy environment.
- Certain statutory restrictions on the Board's sanction authority prevent it from rapidly responding to changes in the pharmacy industry.
- The Board's authority to find violations and sanction licensees is inconsistent with other Texas health-care practitioners and other states' pharmacy laws.

The Board seeks to protect the public through its enforcement efforts. However, current statutory constraints do not permit the Board to address emerging enforcement needs created by changes and advancements in the pharmacy industry. Industry forces create an evolving pharmacy environment requiring enforcement measures responsive to these changes. To continue protecting the public from unsafe pharmacy practices, the Board's statutory enforcement authority must also change to address new threats to public safety.

Recommendations

Change in Statute

2.1 Hold pharmacists accountable for oversight of activities delegated to technicians.

This recommendation would add disciplinary grounds to the Texas Pharmacy Act for inadequate pharmacist supervision of a pharmacy technician, ensuring that a pharmacist who delegates tasks to a technician oversees the work appropriately. If a pharmacist fails to adequately supervise delegated activities or delegates inappropriately, the Board would have grounds to take disciplinary action against the pharmacist. This recommendation would not change the supervisory relationship between pharmacists and technicians, which is already in statute. It also would not affect existing grounds for taking disciplinary action against pharmacy technicians, such as for fraud in becoming registered and violation of drug laws.

2.2 Clarify that a pharmacist or pharmacy that does not comply with a Board rule or order is in violation of the Texas Pharmacy Act and is subject to disciplinary action by the Board.

This recommendation would clarify that the Board may take disciplinary actions against a licensee who does not comply with Board rules or orders. Specifically, rule violations would be subject to the full range of sanctions available to the Board, allowing it to impose more significant sanctions, such as revocation, for serious rules violations. Violations of Board orders would be subject to penalties to provide the Board with needed authority to ensure sanctioned licensees comply with orders. This recommendation would also include clarification that Board orders include the confidential orders or contracts entered into through the Pharmacy Recovery Network peer assistance program.

2.3 Permit the Board to discipline a pharmacist or pharmacy owner who receives deferred adjudication for any felony or for a misdemeanor under any statute governing the practice of pharmacy.

This recommendation would permit the Board to discipline a pharmacist who receives deferred adjudication for any felony or for misdemeanors involving moral turpitude or that relate to statutes affecting the practice of pharmacy, including the Controlled Substances Act, the Dangerous Drug Act, and the federal Comprehensive Drug Abuse Prevention and Control Act of 1970. This change would cover offenses such as forging or altering a prescription and misdemeanor drug possessions. It would also bring the Board's ability to discipline pharmacists and pharmacy owners in line with the Medical Board's authority to discipline practitioners who receive deferred adjudication for relevant offenses.

2.4 Permit the Board to take action against a pharmacist license based on any action of another state board.

Under this recommendation, the Board would be able to apply sanctions to a Texas licensee who violates Texas pharmacy law based on a sanction or order in another state. The Board would be able to impose the full range of sanctions on the licensee without having to prove a case already prosecuted in another state.

2.5 Expand the Board's authority to discipline a pharmacy owner or pharmacist to include drug shortages.

The Board would be able to hold a pharmacist or pharmacy owner accountable for the more significant offense of drug audit shortages, rather than the currently available finding of inadequate record keeping. The Board could determine whether the licensee is accountable for the loss of controlled substances and apply a more severe penalty in cases where the public may be at greater risk.

Issue 3

The Board Does Not Have Access to Key Sales and Pricing Information Needed to Prosecute Illegal Activity.

Key Findings

- The Board investigates complaints alleging violation of pharmacy laws and Board policies.
- The Board's lack of access to sales and pricing data hampers its ability to enforce state law and prosecute illegal activity.
- Other states have access to a pharmacy's sales and pricing data, which enhances their enforcement activities.

The Board uses inspections as a tool to ensure that pharmacies and pharmacists comply with state laws. While most inspections are routine checks, some result from complaints received by the Board or problems discovered during previous inspections. During any inspection, the Board is prohibited from accessing sales and pricing information, even though such information may be crucial to proving a complaint the Board is investigating or confirming a violation found during a previous inspection. As a result, the Board is unable to aggressively pursue cases against pharmacists and pharmacies that commit fraud or dispense drugs illegally.

Recommendation

Change in Statute

3.1 Authorize the Board to access sales and pricing data during investigations that resulted from a complaint or previously failed inspection.

This recommendation would remove the limitation on the Board's access to sales and pricing data, enabling the Board to more effectively enforce state laws and prosecute pharmacies engaged in illegal activity. However, the Board would be authorized to access this information only when the Board has reasonable cause to investigate a pharmacy or pharmacist for illegally dispensing drugs or for violating a provision of the Texas Pharmacy Act or Board rules, such as fraud cases. To protect a pharmacy's business practices, any sales and pricing data collected by the Board would remain confidential during an investigation and in cases where no violation is found. The data would be subject to public information only if it is used in a disciplinary action by the Board.

Issue 4

Key Elements of the Board's Licensing and Regulatory Functions Do Not Conform to Commonly Applied Licensing Practices.

Key Findings

- Licensing provisions of the Board's statute do not follow model licensing practices and could potentially affect the fair treatment of licensees and consumer protection.
- Nonstandard enforcement provisions of the Board's statute could reduce the agency's effectiveness in protecting the consumer.
- Certain administrative provisions of the Board's statute could reduce the Board's efficiency and flexibility to adapt to changing circumstances.

Various licensing, enforcement, and administrative processes in the Texas Pharmacy Act do not match model licensing standards developed by the Sunset Commission from experience gained through more than 80 occupational licensing reviews over the last 25 years. For example, the lack of a full range of penalties may affect the agency's ability to protect the public from practitioners who violate the law and Board rules. A comparison of the Board's statute, rules, and practices with model licensing standards identified variations from these standards and the needed changes to bring the Board in line with other agencies.

Recommendations

Licensing

Change in Statute

4.1 Require the Board to adopt procedures to ensure that its exams are accessible to persons with disabilities in accordance with the Americans with Disabilities Act.

Ensuring that the Board makes reasonable accommodations for its licensing exams would provide equal opportunity and access to all qualified applicants. The Board would need to work with the national testing organization to ensure that these rules are followed.

4.2 Authorize the Board to establish policies regarding nonrefundable testing fees.

The Board would have the authority to retain all or part of examination processing fees should an applicant withdraw from an exam without reasonable advance notice or a satisfactory excuse, such as an emergency.

4.3 Simplify the process for a pharmacist who holds an active license in another state to be licensed in Texas.

This recommendation would provide for the Board to issue a license to a pharmacist who has passed any exams required by the Board, is licensed in good standing as a pharmacist in another state that has licensing requirements substantially equivalent to Texas, and meets other statutory requirements. The Board would no longer require a pharmacist to provide proof of an active license from the state in which the pharmacist was originally licensed.

4.4 Base delinquent license renewal fees on the Board's normally required renewal fee.

The renewal fee for pharmacists and pharmacies who are delinquent in renewing their license would be based on the normal renewal rate set by the Board, not the examination fee. To renew a license that has been expired for 90 days or less, the renewal fee would equal 1-1/2 times the standard renewal fee. If the license has been expired for more than 90 days, but less than one year, the renewal fee would equal two times the standard renewal fee.

Enforcement

Change in Statute

4.5 Authorize staff to dismiss baseless cases.

Under this recommendation, staff would have the ability to dismiss cases if the investigation shows no violation occurred or if the complaint does not fall under the Board's jurisdiction. Staff would regularly report administratively dismissed complaints to Board members at the Board's public meetings.

4.6 Increase the amount of the Board's administrative penalty authority and require the Board to adopt an administrative penalty matrix in rule.

The amount of an administrative penalty the Board would be able to impose on an individual who violates the Texas Pharmacy Act or Board rule would be increased from \$2,500 to \$5,000 per violation per day. The Board would also be required to adopt an administrative penalty matrix in rule to ensure that sanctions appropriately relate to violations, and that the public would have the opportunity to comment.

4.7 Remove the requirement that a majority of Board members must approve temporary suspension of a license and provide for the temporary suspension of pharmacies' licenses.

Under this recommendation, a panel of three Board members – and not a majority of five members – would be required to temporarily suspend a pharmacist or a pharmacy license. In addition, temporary suspension authority would be extended to include pharmacies, filling a gap in the Board's enforcement authority. The disciplinary panel would be authorized to hold a meeting by telephone conference call

if immediate action is required and convening of the panel at one location is inconvenient for any member of the panel.

4.8 Authorize the Board to use cease-and-desist orders with regard to practicing pharmacy without a license.

Allowing the Board to issue cease-and-desist orders would enable it to move more quickly to stop unlicensed activity that threatens the public's health and safety. The Board should consider unauthorized practice cases as jurisdictional, and direct investigators to pursue and follow up with unlicensed individuals to ensure compliance. The Board could also assess administrative penalties against violators of these orders. In addition, the Act would be clarified to state that the Attorney General, not the Board, petitions district court for an injunction.

Policy Body

Change in Statute

4.9 Allow pharmacy faculty members to be eligible to serve on the Board.

This recommendation would remove the statutory prohibition against salaried faculty members at a college of pharmacy from serving on the Board as a pharmacist member. To be eligible to serve in one of the six pharmacist positions on the Board, a faculty member would have to meet the qualifications outlined in the Texas Pharmacy Act, including being actively practicing pharmacy.

4.10 Authorize Board members to receive reimbursement for travel expenses.

This recommendation would remove the conflict between the Texas Pharmacy Act and the General Appropriations Act. As a result, Board members would have clear statutory authority to receive reimbursement for all travel expenses, including transportation, meals, and lodging expenses, incurred while conducting Board business.

4.11 Require the Board to establish guidelines for Board subcommittees.

This recommendation would direct the Board to establish formal policies outlining the structure, role, and responsibilities of subcommittees consisting of Board members, thus ensuring the committees operate consistently.

4.12 Eliminate the Pharmacy Board Operating Account.

Under this recommendation, the Board's dedicated account would be removed. The Board would deposit all funds into and receive appropriations from the General Revenue Fund.

Issue 5 _____

The Board Does Not Have a Full Range of Sanctions Available for Disciplining Pharmacy Technicians.

The Board registers pharmacy technicians, who perform tasks related to the preparation of a prescription under the direct supervision of a pharmacist. Duties include preparing and packaging drug orders, affixing labels to prescription containers, and reconstituting medications. Currently, the Texas Pharmacy Act allows the Board to deny, suspend, or revoke a pharmacy technician's registration based on various disciplinary grounds. However, the Act outlines eight actions the Board can take

against a pharmacist's license. The lack of a broader range of sanctions for pharmacy technicians forces the Board to treat pharmacists and pharmacy technicians differently even when similar violations have occurred.

Recommendation

Change in Statute

5.1 Allow for a greater range of disciplinary sanctions for pharmacy technicians.

Under this recommendation, the Board would have a broader range of sanctions available when disciplining pharmacy technicians. In addition to the Board's current authority to refuse to issue or renew, suspend, or revoke a pharmacy technician's license, the Board would also be authorized to restrict, reprimand, and retire a pharmacy technician's license, impose an administrative penalty against a pharmacy technician, and place the pharmacy technician's license on probation. Doing so would bring the range of disciplinary sanctions for pharmacy technicians in line with those for pharmacists.

Issue 6

The Board Does Not Have Authority to Regulate Pharmacy Technician Trainees.

To become registered as a pharmacy technician, an individual must pass a Board-approved pharmacy technician certification exam. Most pharmacy technician trainees work in a pharmacy while studying to take this exam. The time for the trainee to study, take the exam, and receive exam results may be up to one year. During this time, the pharmacy technician trainee has access to prescription drugs and controlled substances in the pharmacy, and the Board believes that pharmacy technician trainees have been responsible for stealing controlled substances during this period. However, the Board has no authority to discipline pharmacy technician trainees until after they have passed the certification exam and become registered pharmacy technicians.

Recommendation

Change in Statute

6.1 Require registration for pharmacy technician trainees and authorize the Board to take disciplinary action.

Under this recommendation, the Board would be authorized to register individuals while they are working in a pharmacy as a pharmacy technician-in-training, similar to the registration method the Board currently uses for pharmacist-interns. This would allow the Board to identify pharmacy technician trainees and refuse to issue a license or restrict, suspend, or revoke their license if they violate state laws or Board rules.

Issue 7

Disclosing a Pharmacist's Home Address Serves No Valuable Purpose.

The Board collects a pharmacist's home address in addition to a pharmacist's business address because the home address provides the agency an alternate means of contacting the licensee. Also, because a pharmacist may change employment, the home address provides a more consistent means for agency staff to communicate with the licensee. However, state law does not allow the Board to withhold a licensee's home address from public disclosure. Disclosing this information, though, could affect a pharmacist's safety and serves no valuable purpose, as a pharmacist's business address is public information.

Recommendation

Change in Statute

7.1 Give pharmacists the option of making their home address confidential.

Under this recommendation, pharmacists would have the option of making their home address confidential, and the Board would be prohibited from releasing the information under the Texas Public Information Act. As a result, the Board would not post a pharmacist's or pharmacy owner's home address on its Web site or in its licensure verification database. Instead, the Board would be able to maintain an address of record or business address that would be subject to public disclosure.

Issue 8

Texas Has a Continuing Need for the Texas State Board of Pharmacy.

Key Findings

- Texas has a continuing interest in licensing and regulating the practice of pharmacy.
- The Texas State Board of Pharmacy protects the public by ensuring that qualified individuals practice pharmacy.

Although prescription drugs cure and treat an increasing number of ailments in the population, they also pose a risk if not taken correctly and under proper supervision. Pharmacists counsel patients about new prescriptions, an important service given the expanding number of new drugs and the heightened risk of adverse outcomes from interactions of different drugs. High-cost drugs create incentives for illegal activities around pharmacy, such as theft and counterfeiting, creating another critical area of oversight for the Board.

Recommendation

Change in Statute

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

This recommendation would continue the Board as a separate, stand-alone agency for the standard 12-year period.

Fiscal Implication Summary

One recommendation regarding the Texas State Board of Pharmacy would have a fiscal impact to the State. The fiscal impact of the recommendation is summarized below.

- **Issue 4** – Eliminating the Pharmacy Board Operating Account would result in about \$4.8 million being available in the General Revenue Fund, instead of within a dedicated account in General Revenue.