

Sunset Advisory Commission



**Texas State Board
of Pharmacy**

Staff Report
February 2004

TEXAS STATE BOARD OF PHARMACY

SUNSET STAFF REPORT

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SUMMARY

Texas State Board of Pharmacy

Texas has regulated pharmacy since 1907, when the Legislature passed the Texas Pharmacy Act and created the Texas State Board of Pharmacy to ensure that Texans receive safe pharmaceutical care. Since that time, the pharmacy environment has changed dramatically. Where once pharmacists themselves prepared and dispensed a limited number of drugs, pharmacists now dispense an ever expanding array of medications prepared by pharmaceutical manufacturers. Factors such as the increased number of prescription drugs available for treatment, the growing demand for pharmaceutical therapy, technological advances, and new lucrative incentives for illegal behavior have changed the pharmacy industry and the practice of pharmacy.

The Sunset staff examined the Board's ability to license and regulate pharmacy service providers to ensure public health and safety, and concluded that the Board's statute has not kept pace with this rapidly changing environment. To help the Board adapt to this changing landscape, the Texas Pharmacy Act needs to provide additional authority for regulating both in-state and out-of-state pharmacies, such as Internet pharmacies. While the State should continue to regulate pharmacies and pharmacists, the decision on the specific organizational structure for the agency should be made after the Sunset reviews of other health licensing agencies have been completed.

A summary of the recommendations in this report is provided in the following material.



*The Board's statute
has not kept pace with
the rapidly changing
pharmacy
environment.*

Issues/Recommendations

Issue 1

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

Key Recommendations

- Provide the same protections to Texans who fill their prescriptions out of state as those who use a local pharmacy.
- Authorize the Board to take disciplinary action on a pharmacy's license based on the action of another state board of pharmacy.
- Ensure that consumers who use online pharmacies receive information on the pharmacy's Web site about filing a complaint with the Board.
- Require Internet pharmacies to ensure that a valid practitioner-patient relationship exists before distributing a prescription drug.

Issue 2

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

Key Recommendations

- Clarify the Board's authority to take enforcement action against a pharmacist for delegated duties and to take enforcement action for violations of Board orders or rules.
- Expand the Board's authority to discipline a pharmacy owner or pharmacist for drug shortages and to discipline a pharmacist receiving deferred adjudication for a misdemeanor under certain state and federal drug laws.
- Permit the Board to take action against a pharmacist or pharmacy license based solely on the action of another state board.

Issue 3

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

Key Recommendation

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

Issue 4

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

Key Recommendations

- Standardize the Board's licensing functions by streamlining the licensing by reciprocity process, requiring the Board to ensure its exams are accessible to persons with disabilities, and changing the basis for assessing late renewal fees.
- Improve the Board's ability to protect the public by allowing a panel of the Board to temporarily suspend a license, increasing the administrative penalty amount, authorizing staff to dismiss complaints, and granting the Board authority to issue cease-and-desist orders.
- Update elements related to the policy body, such as allowing pharmacy faculty members to serve on the Board and requiring the Board to define the roles and responsibilities of Board subcommittees.

Issue 5

Decide on Continuation of the Board After Completion of Sunset Reviews of Other Health Licensing Agencies.

Key Recommendation

- Decide on continuation of the Texas State Board of Pharmacy as a separate agency upon completion of upcoming Sunset reviews of other health-profession licensing agencies.

Fiscal Implication Summary

This report contains one recommendation that would have a fiscal impact to the State. The fiscal impact of the recommendation is summarized below.

- **Issue 4** – Eliminating the dedicated Pharmacy Board Operating Account would result in a one-time gain to the General Revenue Fund of about \$4.4 million at the end of 2006.

ISSUES

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

Summary

Key Recommendations

- Provide the same protections to Texans who fill their prescriptions out of state as those who use a local pharmacy.
- Authorize the Board to take disciplinary action on a pharmacy's license based on the action of another state board of pharmacy.
- Ensure that consumers who use online pharmacies receive information on the pharmacy's Web site about filing a complaint with the Board.
- Require Internet pharmacies to ensure that a valid practitioner-patient relationship exists before distributing a prescription drug.

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.

Conclusion

Texas established its framework for regulating the pharmacy profession at a time when most consumers purchased their prescription drugs at the neighborhood pharmacy. 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 pharmacies, consumers are at risk of getting unsafe or inappropriate medications, not receiving appropriate oversight from health-care professionals, or having illegal access to prescription drugs.

The borderless nature of the Internet poses regulatory difficulties, not just for Texas, but for other states and the nation as a whole. As a result, problems arising from Internet pharmacies and other pharmacies located outside of a state's jurisdiction cannot be addressed in a vacuum. Although the Texas State Board of Pharmacy alone cannot solve the problems, the Board can take steps to strengthen its regulation of out-of-state pharmacies. Holding nonresident pharmacies to the same licensing standards and expanding the grounds for disciplinary action for out-of-state pharmacies would provide better public protection.

Support

Technology has changed how consumers buy their prescription drugs and how regulators do their job.

- Advancements in technology have had a significant impact on the pharmacy profession. With the introduction of Internet pharmacies and an increase in the number of mail-order pharmacies, consumers no longer are relegated to buying their prescription drugs and devices from a traditional brick-and-mortar pharmacy. In fact, the number of consumers purchasing drugs through these nontraditional methods has skyrocketed in recent years.

While the precise number of Internet pharmacies is impossible to identify, the number appears to be increasing, with some estimates as high as 8,000. In fact, health concerns are the sixth most common reason people go online.¹ Industry experts predict that prescription drugs will account for \$15 billion in Internet sales in 2004.² Legitimate online and mail-order pharmacies can provide tremendous benefits to consumers, particularly the elderly and those who live in rural areas, where access to a pharmacy may not be convenient. For information on why more consumers are using the Internet to purchase pharmaceuticals, see the textbox, *Getting Prescriptions Online*.

Getting Prescriptions Online

For some people, buying prescription drugs and devices online offers advantages compared to purchasing from a local drugstore, including:

- the privacy and convenience of ordering medications from their homes;
- greater availability of drugs for shut-in people or those who live in rural areas or areas far from a pharmacy;
- lower prices through increased competition among licensed sellers;
- the ease of comparative shopping among many sites to find the best prices;
- greater convenience and variety of products; and
- easier access to written product information and references to other sources than in traditional storefront pharmacies.

- Regulation of pharmacies, including those that dispense drugs across state lines, falls primarily under the jurisdiction of the state boards of pharmacy. Authority is mainly exercised by the pharmacy board of the state in which the pharmacy is physically located. However, because an Internet or mail-order pharmacy's operations may cross multiple state lines, federal oversight is more frequently becoming a factor in regulation of pharmacies. The chart on page 7, *Who Regulates Prescription Drugs?*, outlines the roles of state and federal regulators.
- The Texas State Board of Pharmacy licenses five types of pharmacies, most of which are in-state community and institutional pharmacies. The Board also licenses nonresident – or Class E – pharmacies, which are located outside of the state, but dispense prescription drugs and devices to Texas residents. Class E pharmacies primarily consist of mail-order and Internet pharmacies. Because Class E pharmacies operate out of another state's jurisdiction, licensing requirements vary.


Prescription drugs will account for \$15 billion in Internet sales in 2004.

Who Regulates Prescription Drugs?	
Agency	Role
State Boards of Pharmacy	Licenses and regulates pharmacists and pharmacies.
State Medical Boards	Licenses and regulates physicians.
State Attorneys General	Prosecutes pharmacies illegally selling or advertising prescription drugs to residents of the state.
U.S. Food & Drug Administration	Regulates sale, importation, and distribution of prescription drugs, including those sold on the Internet.
U.S. Drug Enforcement Administration	Registers pharmacies, health professionals, and businesses who dispense, administer, prescribe, manufacture, or distribute controlled substances. Also, monitors and investigates diversion of drugs across U.S. borders.
Federal Trade Commission	Regulates false and deceptive practices by pharmacies, including on the Internet.
U.S. Department of Justice	Prosecutes pharmacies illegally selling prescription drugs.
U.S. Customs Service	Inspects packages, including prescription drugs, shipped to the United States from foreign countries.
National Association of Boards of Pharmacy	Maintains voluntary verification system for Internet pharmacies.

To receive a Class E license, a pharmacy must submit the information listed in the textbox, *Licensing Out-of-State Pharmacies*.

Mirroring national trends, the number of out-of-state pharmacies dispensing pharmaceuticals to Texans has mushroomed. In fiscal year 2003, the Board licensed 306 out-of-state pharmacies, more than double the number from 1997.³

- The U.S. government, state governments, the National Association of Boards of Pharmacy, the Federation of State Medical Boards, and other national and state organizations have expressed concern about regulation of Internet and mail-order pharmacies. Given the borderless nature of the Internet and the multiple jurisdictions involved in online and mail-order pharmacies, federal and state administrators recognize that successfully regulating these types of pharmacies will require multiple entities working together. As such, oversight of Internet pharmacies has become an increasingly frequent topic of federal and state hearings and legislation, as well as studies, reports, and task forces.

Licensing Out-of-State Pharmacies
<p>To receive a license as a nonresident, or Class E, pharmacy, the pharmacy owner must submit:</p> <ul style="list-style-type: none"> • an application provided by the Board; • evidence that the pharmacy is licensed in the state in which it's located; • the name of the owner and pharmacist-in-charge; • evidence of the pharmacy's ability to provide to the Board a record of a prescription drug order dispensed by the pharmacy to a Texas resident within 72 hours of the Board's request to do so; • a copy of the most recent inspection conducted by the pharmacy board in the state where the pharmacy is located; and • an affidavit that the pharmacist-in-charge has read and understands Texas laws and rules relating to Class E pharmacies.

★

*A growing number of
rogue pharmacies
sidestep consumer
protections.*

Buying drugs online can harm consumers, who may not be aware of the legitimacy of an Internet pharmacy.

- Although many out-of-state pharmacies offer legitimate services and products, a growing number of rogue pharmacies either sell unapproved products or sidestep procedures meant to protect consumers. As a result, significant public health and consumer safety issues have arisen.
- Consumers who purchase pharmaceuticals from an illegal out-of-state pharmacy risk receiving a contaminated or counterfeit product, the wrong product, an incorrect dose, or no product at all.⁴ Taking an unsafe or inappropriate medication puts consumers at risk for dangerous drug interactions and other serious health consequences.
- By purchasing drugs online, consumers may not receive adequate medical supervision, such as through a face-to-face physical examination or an established physician-patient relationship. Without a proper practitioner-patient relationship, sufficient information may not exist to determine if a drug is safe for the consumer, if another treatment is more appropriate, or if an underlying medical condition exists that could cause use of that drug to be harmful.⁵
- Consumers who buy their prescription drugs through an out-of-state pharmacy may get shortchanged on proper patient counseling from a pharmacist.⁶ To optimize drug therapy and ensure consumer safety, pharmacists at both Texas-based and out-of-state pharmacies are required to provide patients with information about the prescription drug or

**Verified Internet Pharmacy
Practice Sites**

In response to public concern of the safety of pharmacy practices on the Internet, the National Association of Boards of Pharmacy (NABP) developed the Verified Internet Pharmacy Practice Sites (VIPPS) program in the spring of 1999. To be accepted into the voluntary program, an online pharmacy must agree to stringent conditions, including:

- maintaining all state licenses in good standing;
- allowing information about the pharmacy to be posted and maintained on the VIPPS Web site;
- allowing an NABP-sanctioned team to inspect its operations, given reasonable notice; and
- displaying and maintaining the VIPPS seal with a link to the VIPPS Web site. By clicking on the seal, a visitor is linked to NABP's VIPPS site, where verified information about the pharmacy is maintained.

device, including dosage and common severe side effects.⁷ Out-of-state pharmacies are required to provide patient counseling in written format as well as offer a toll-free telephone number for patient questions.⁸ However, illegal pharmacies may omit the patient counseling step altogether, potentially to the detriment of both the pharmacist and the consumer.

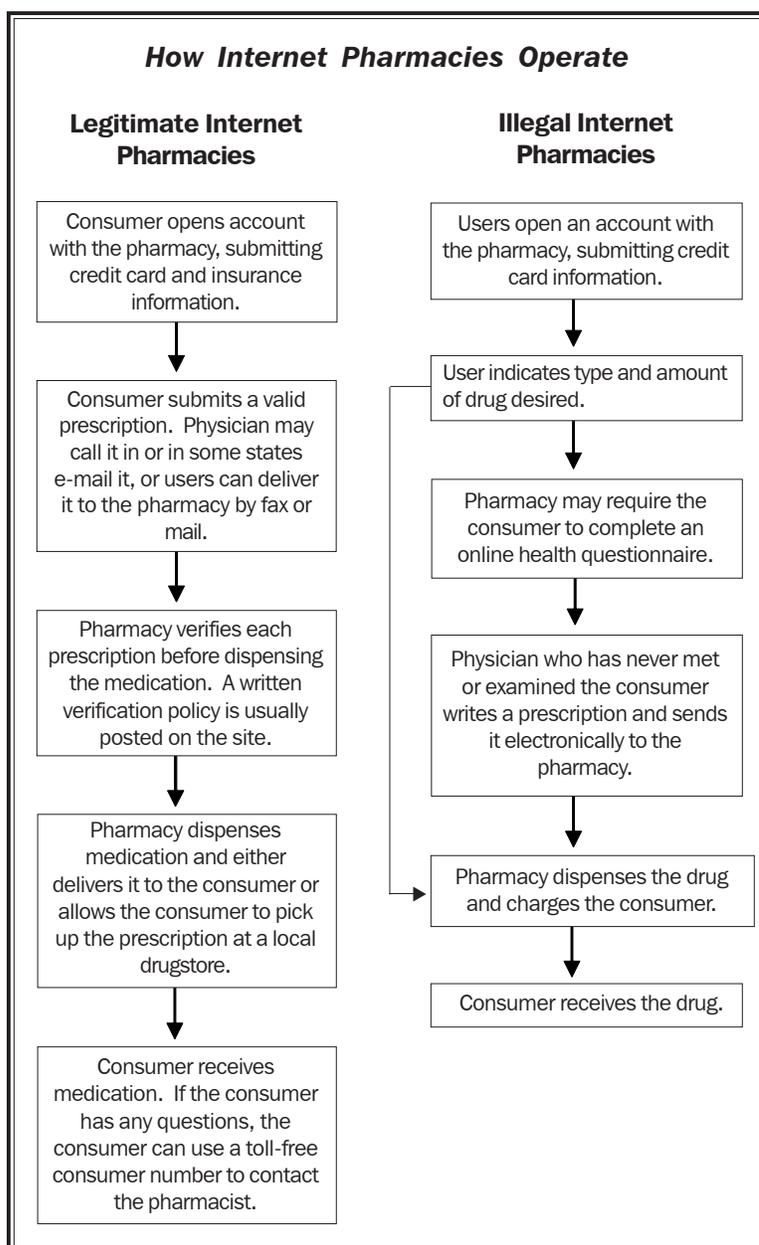
- Consumers may not be able to distinguish whether an Internet pharmacy is a legitimate operation.⁹ Pharmacy Web sites may be professionally designed and appear authentic to the average consumer. To help the public identify valid Internet pharmacies, the National Association of Boards of Pharmacy developed the Verified Internet Pharmacy Practice Sites (VIPPS) program. Legitimate pharmacy sites display a VIPPS seal indicating they are appropriately licensed and have met certain standards. As of December 2003, NABP had verified 14 pharmacies through the program, a minute fraction of the number of Internet pharmacies estimated to exist. Requirements for the program are outlined in the textbox, *Verified Internet Pharmacy Practice Sites*. However, the program is voluntary and concerns are emerging that some online pharmacies post counterfeit copies of the VIPPS seal.

Minimal regulation of out-of-state pharmacies creates an environment for illegal activity.

- Out-of-state pharmacies can bypass the normal checks and balances in the practitioner-patient relationship, putting consumers at risk. Illegal pharmacies may dispense prescription drugs – including narcotics – based on a brief, general questionnaire that the consumer fills out online. A physician or other health-care provider who has never examined or even met the consumer will then write a prescription based on the consumer’s responses to the questionnaire. State and federal entities have determined that the practice of prescribing medications based solely on an online questionnaire or telephone consultation does not constitute a valid practitioner-patient relationship and is generally substandard or unethical medical care.¹⁰ Indeed, taking prescription drugs without proper medical oversight poses serious health risks, such as harmful drug interactions, allergic reactions, contraindications, or improper dosing.

Some Internet pharmacies dispense drugs without a prescription at all, which is illegal in the United States. An investigation done by the U.S. General Accounting Office found that to receive drugs from some online pharmacies, the consumer merely had to indicate the type and amount of the drug needed and provide credit card information.¹¹ The chart, *How Internet Pharmacies Operate*, illustrates the differences in how legitimate and illegal online pharmacies may work.

- The opportunity for illegal activity is also illustrated by a recent Board investigation of an Internet pharmacy in Texas. In the investigation, the Board’s chief investigator purchased 100 hydrocodone tablets from the online pharmacy, despite having an invalid prescription and no medical need. A physician located in Tennessee conducted a telephonic evaluation with the Board’s investigator, after which the invalid prescription drug order was issued. The investigator never met face to




*One Internet
pharmacy dispensed
narcotics illegally to
an undercover Board
investigator.*

face with the physician, did not receive a physical examination, and underwent no diagnostic or laboratory tests. The pharmacist, who was licensed in Texas, dispensed drugs – including narcotics – to the Board investigator and other patients in 19 states based on the invalid prescriptions.¹²

In another case, the Board found that a pharmacist dispensed Viagra tablets to a patient without authorization of a practitioner. Pharmacy records indicated that the prescribing practitioner was “no doctor.”¹³ Concern that the Internet would encourage drug-seeking behavior and sidestep the traditional physician-patient relationship led the Texas State Board of Medical Examiners – the state agency that licenses and regulates physicians in Texas – to adopt a policy maintaining that it is unprofessional conduct for a physician to initially prescribe any dangerous drugs or controlled substances without first establishing a proper physician-patient relationship.¹⁴ The Medical Board developed minimum standards for what constitutes an appropriate physician-patient relationship.¹⁵ These standards are highlighted in the textbox, *What Is a Physician-Patient Relationship?*

In March 2003, the Medical Board adopted rules regarding online evaluations for the purpose of medical treatment, including prescribing drugs. The Medical Board’s rules provide that treatment and consultation recommendations made online – including issuing a prescription via electronic means – will be held to the same standards of appropriate practice as those in traditional face-to-face settings.¹⁶

What Is a Physician-Patient Relationship?

Physicians who treat over the Internet must ensure a proper physician-patient relationship is established that at a minimum includes:

- establishing that the person requesting the treatment is in fact who the person claims to be;
- establishing a diagnosis through the use of acceptable medical practices such as patient history, mental status examination, physical examination, and appropriate diagnostic and laboratory testing to establish diagnoses and identify underlying conditions and/or contraindications to treatment recommended/provided;
- discussing with the patient the diagnosis and the evidence for it, the risks and benefits of various treatment options; and
- ensuring the availability of the physician or coverage of the patient for appropriate follow-up care.

- The Pharmacy Board also has established rules regarding use of the Internet for prescribing drugs.¹⁷ Pharmacists are prohibited from dispensing a prescription drug if the pharmacist knows or should have known that the prescription was issued on the basis of an Internet-based or telephonic consultation without a valid patient-practitioner relationship.¹⁸ Because the Pharmacy Board has no jurisdiction over physicians, the rule relies on the definition of the Medical Board’s definition of patient-practitioner relationship. However, these rules apply only to pharmacists working in Texas-based pharmacies.

- Illegal online pharmacies contribute to substance abuse problems. Prescription drug abuse accounts for about one-third of all drug abuse in the United States.¹⁹ The National Institute on Drug Abuse estimates that 9 million people use prescription drugs for nonmedical – and primarily recreational – purposes.²⁰ About one-third of these abusers are between the ages of 12 and 17 years old.²¹ Federal officials say that the key factor for the skyrocketing abuse of prescription drugs – from painkillers to sedatives to stimulants – is the Internet, which provides unparalleled access to drugs.

For example, in January 2003, a Nevada-based Internet pharmacy relinquished its license after the Nevada State Board of Pharmacy took disciplinary action against the pharmacy for, among other violations, dispensing dangerous drugs without a valid practitioner-patient relationship. About 90 percent of the pharmacy's prescriptions were for controlled substances, compared to a typical share of 15 percent in the average pharmacy. Also, in October 2003, a federal jury convicted a Texas pharmacist on six felony accounts, including conspiracy to dispense a controlled substance. The Texas Board provided assistance to the federal government in this case. An Oklahoma-based Internet pharmacy owned by the pharmacist dispensed controlled substances to an 18-year-old California student, who died after overdosing on the drugs.

The Board cannot hold out-of-state pharmacies to the same licensing standards as Texas-based pharmacies.

- Out-of-state pharmacies, including online and mail-order pharmacies, do not have to adhere to the same rigorous inspection requirements as Texas-based pharmacies to receive and maintain a license in Texas. Before receiving a license, in-state pharmacies must undergo a pre-inspection conducted by Board compliance officers. Among other things, compliance officers check to see that drugs are stored properly, that the pharmacists and pharmacy technicians working in the pharmacy hold current licenses or certificates, and that the pharmacy is clean and orderly. After receiving a license, a pharmacy is subject to unannounced inspections. Each pharmacy in Texas is inspected at least once every two to 2-1/2 years.²²

No comparable pre-inspection procedures exist for out-of-state, or Class E, pharmacies. The Board requires the Class E pharmacy owner or managing officer to attach a copy of the most recent pharmacy inspection conducted by the pharmacy board in the state in which the pharmacy is located. The Board does not specify how recent the inspection must be or what must be included in the inspection. As a result, an out-of-state pharmacy may apply for and receive a Texas license despite not having a recent inspection or an inspection that is comparable to the inspections required of Texas-based pharmacies. In addition, out-of-state pharmacies do not have to submit updated inspection information to the Board when renewing their license. Therefore, as long as an out-of-state pharmacy renews its Texas license on time, it does not ever have to undergo another inspection to maintain the Texas license.



Prescription drug abuse accounts for one-third of all drug abuse in the United States.



Out-of-state pharmacies do not undergo regular inspections, as with Texas-based pharmacies.



Internet pharmacies do not have to alert consumers on how to file a complaint with the Board.

- The Texas Pharmacy Act does not require an out-of-state pharmacy that dispenses drugs to Texans to provide consumers with information about how to file a complaint with the Board on the pharmacy's Web site. Pharmacies that serve walk-in customer must either post a sign provided by the Board or provide information about filing a complaint with each dispensed prescription. Although Internet pharmacies are required to provide a link to the Board's Web site, nothing requires an Internet pharmacy to delineate that the link provides an avenue for filing a complaint.²³
- The Board requires more detailed information about a pharmacy's operations from in-state pharmacies than it does from those located outside of Texas' borders. For example, the Board requires Texas-based community (Class A) and institutional (Class C) pharmacies to submit copies of an approved credit application from a primary wholesaler or other documents showing credit worthiness. However, the Board does not ask for such information from out-of-state pharmacies, even though it could help the Board determine if the pharmacy is legitimate.

The Board has limited ability to discipline out-of-state pharmacies that violate state law.

- Before initiating disciplinary action against an out-of-state pharmacy, the Board must first file a complaint against the pharmacy with the regulatory agency of the state in which the pharmacy is located. However, this requirement does not support the Board's efforts to take disciplinary action against the Texas license of an out-of-state pharmacy, as the Board does not have authority to take disciplinary action against a pharmacy license based on the action of another state.
- The Board cannot quickly pursue complaints involving out-of-state pharmacies. The Texas Pharmacy Act permits the Board to initiate action against an out-of-state pharmacy licensed in Texas, but only after giving the pharmacy board in the state where the pharmacy is physically located 60 days to initiate action or 180 days to resolve the complaint. Although, according to Board staff, other states rarely meet these deadlines, the Board's delayed ability to discipline out-of-state pharmacies can allow dangerous and harmful practices to continue. Further, because out-of-state pharmacies – particularly Internet pharmacies – can open and close at a moment's notice, requiring the Board to wait at least six months before pursuing a complaint could derail an investigation.
- The grounds for which the Board can discipline an out-of-state pharmacy are much less rigorous than those for in-state pharmacies. When a violation of the Texas Pharmacy Act takes place in Texas, the Board has authority to hold the pharmacist as well as the pharmacy accountable. However, the grounds for disciplining an out-of-state pharmacy primarily relate to the action of the pharmacist, who may not be licensed in Texas. For example, a Texas-based pharmacy can be disciplined for allowing an employee who is not a pharmacist to practice pharmacy or for fraud or deceit, while an out-of-state pharmacy cannot be disciplined



Requiring the Board to wait six months before pursuing a complaint could derail an investigation.

for either. Examples of the types of grounds on which the Board can discipline an in-state pharmacy, but not an out-of-state pharmacy, are outlined in the textbox, *Disciplining Pharmacies*.

Disciplining Pharmacies

Examples of grounds for which the Board can discipline Texas-based – but not out-of-state – pharmacies include the following.

- Allowing an employee who is not a pharmacist to practice pharmacy.
- Advertising a prescription drug or device in a misleading or fraudulent manner.
- Failing to maintain required records.
- Being convicted of a misdemeanor involving moral turpitude or a felony under the laws of this state, another state, or the United States.
- Failing to establish effective controls against drug diversion.

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. As a result, this recommendation would make the grounds for disciplining out-of-state pharmacies, including Internet pharmacies, consistent with those for Texas-based pharmacies.

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 help the Board to more effectively discipline pharmacies, particularly those whose operations cross multiple jurisdictions. In addition, the disciplinary grounds for pharmacies would be 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.

Impact

These recommendations are intended to update the Texas Pharmacy Act to reflect changes in how prescription drugs and devices are purchased and received. Given that online pharmacy operations often cross multiple jurisdictions, the problems that result from Internet and out-of-state pharmacies cannot be solved solely by one agency. Still, the Board's ability to regulate these pharmacies can be enhanced.

Because a pharmacy that dispenses drugs to Texans may be located in another state, requiring all pharmacies – including Internet pharmacies – to submit the same information when applying for a

Texas license would ensure that all pharmacies licensed to do business in Texas meet the same standards. Likewise, expanding the Board's enforcement authority over out-of-state pharmacies licensed in Texas would allow the Board to appropriately discipline nonresident pharmacies in the same way as the Board can discipline Texas-based pharmacies. Authorizing the Board to take disciplinary action on a pharmacy's license based on another state's action, and permitting the Board to pursue complaints against out-of-state pharmacies immediately, would protect consumers from pharmacies whose operations cross multiple jurisdictions. Requiring out-of-state pharmacies to post information about filing a complaint with the Board, and listing all Internet pharmacies licensed to dispense drugs in Texas on the Board's Web site, would provide more information about out-of-state pharmacies to consumers.

Fiscal Implication

These recommendations would have no fiscal impact to the State. Requiring out-of-state pharmacies to comply with the same licensing standards as Texas-based pharmacies may result in additional review of licensure applications, but the amount should be insignificant and would be absorbed by existing staff. Authorizing the Board to take disciplinary action on a pharmacy's license based on the action of another state board of pharmacy would free up enforcement staff, who no longer would have to duplicate efforts by the other state.

¹ U.S. Food and Drug Administration, “Buying Drugs Online: It’s Convenient, but Beware of ‘Rogue Sites,’” www.fda.gov/fdac/features/2000/100_online.html. Accessed: November 18, 2003.

² Paul A. Greenberg, “Report: Online Pharmacy Sales Top \$1.9 Billion,” *E-Commerce Times* (January 13, 2000). Online. Available: www.ecommercetimes.com/perl/story/2206.html. Accessed: November 24, 2003. Also, Glenn Wachter, “‘Fly-by-Night’ Internet Pharmacies: The Crackdown Begins,” *Telemedicine Information Exchange* (November 2002). Online. Available: tie.telemed.org/legal/other/internet_pharmacies02.asp. Accessed: December 15, 2003.

³ Texas State Board of Pharmacy, “Licensure Statistics,” *Newsletter* (Fall 2003), p.10.

⁴ U.S. Food and Drug Administration, *Buying Medicines and Medical Products Online*, www.fda.gov/oc/buyonline/default.htm. Accessed: November 2, 2003.

⁵ *Ibid.*

⁶ The definition of the practice of pharmacy includes providing patient counseling. Texas Occupations Code, sec. 551.003(33).

⁷ Texas Administrative Code, Title 22, part 15, rule 291.33(c)(1) and rule 291.104(b)(3). Pharmacists must provide this patient counseling with each new prescription drug order, annually on maintenance medications, and – if the pharmacist deems appropriate – with prescription drug refills.

⁸ Texas Administrative Code, Title 22, part 15, rule 291.104(b)(3)(B)(iv); and rule 291.104(b)(3)(D).

⁹ Judy Foreman, “No one’s watching online druggists,” *The Boston Globe* (February 15, 1999), p. E-1. Online. Available: www.boston.com/globe/search/stories/health/health_sense/021599.htm. Accessed: December 5, 2003.

¹⁰ The Texas State Board of Medical Examiners has established that “an online or telephonic evaluation by questionnaire does not constitute an acceptable standard of care.” Texas Administrative Code, Title 22, part 9, rule 174.17(b).

¹¹ U.S. General Accounting Office, *Internet Pharmacies: Adding Disclosure Requirements Would Aid State and Federal Oversight*, report no. GAO-01-69 (Washington, D.C., October 2000) p. 11. Online. Available: www.gao.gov/new.items/d0169.pdf. Accessed: November 24, 2003.

¹² Texas State Board of Pharmacy, Agreed Board Order #J-00-013-A (May 8, 2002). The Board revoked the pharmacist’s license.

¹³ Texas State Board of Pharmacy, Agreed Board Order #J-99-002-A (May 3, 2002).

¹⁴ Texas State Board of Medical Examiners, *Internet Prescribing*, www.tsbme.state.tx.us/guidelines/ipp.htm. Accessed: December 4, 2003.

¹⁵ Texas Administrative Code, Title 22, part 9, rule 174.17(a).

¹⁶ Texas Administrative Code, Title 22, part 9, rule 174.17(b).

¹⁷ Texas Occupations Code, sec. 554.055, requires the Board to adopt rules regarding the sale and delivery of drugs by use of electronic media, including the Internet.

¹⁸ Texas Administrative Code, Title 22, part 15, rule 291.34(b)(1)(B).

¹⁹ U.S. Substance Abuse and Mental Health Services Administration, Center for Substance Abuse Prevention, *Prevention Alert*, “Trouble in the Medicine Chest(I): Rx Drug Abuse Growing” (newsletter), vol. 6, no. 4 (March 7, 2003). Online. Available: samhsa_search.samhsa.gov/cgi-bin/MsmGo.exe?grab_id=7&EXTRA_ARG=&CFGNAME=MssFind%2Ecf&host_id=42&page_id=8741632&query=people+abuse+prescription+drugs&chiword=people+drugs+prescription+abuse+. Accessed: December 4, 2003.

²⁰ National Institute on Drug Abuse, *Prescription Drugs: Abuse and Addiction*, www.drugabuse.gov/ResearchReports/Prescription/Prescription.html. Accessed: December 4, 2003.

²¹ Alexandra Marks, “Steep Rise in Abuse of Legal Drugs,” *The Christian Science Monitor*. Online. Available: abcnews.go.com/sections/living/Business/CSM_drugabuse_031006.html. Accessed: December 15, 2003.

²² Board compliance officers inspect pharmacies that received a warning notice during a previous inspection, changed owners, or were the subject of a disciplinary order more frequently than once every two years.

²³ Texas Occupations Code, sec. 562.1045.

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

Summary

Key Recommendations

- Clarify the Board's authority to take enforcement action against a pharmacist for delegated duties and to take enforcement action for violations of Board orders or rules.
- Expand the Board's authority to discipline a pharmacy owner or pharmacist for drug shortages and to discipline a pharmacist receiving deferred adjudication for a misdemeanor under certain state and federal drug laws.
- Permit the Board to take action against a pharmacist or pharmacy license based solely on the action of another state board.

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.

Conclusion

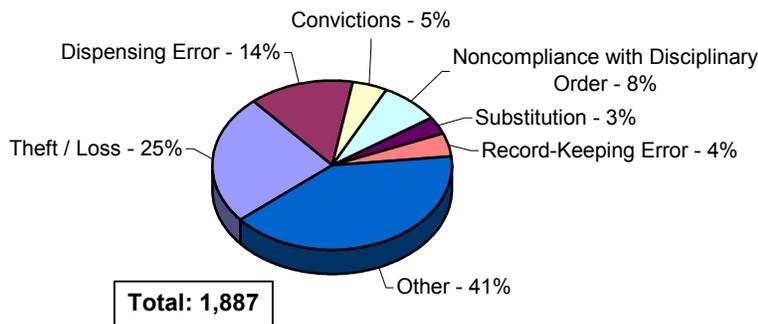
The Texas State Board of Pharmacy seeks to protect the public through enforcement, however current statutory constraints do not permit the Board to address emerging enforcement needs created by changes and advancements in the pharmacy industry. Industry forces create an evolving pharmacy environment 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. The ability to sanction licensees and the range of disciplinary penalties available should enable the Board to address these new enforcement challenges and protect the public. To ensure adequate public health and safety in pharmaceutical care, the Board should be able to hold its licensees accountable for safe practices.

Support

The Board is responsible for enforcing the Texas Pharmacy Act in an evolving pharmacy environment.

- The Board regulates 21,570 pharmacists, 3,445 preceptors, 1,495 pharmacist-interns, and 5,794 pharmacies. To regulate these licensees, the Board is charged with enforcing the Texas Pharmacy Act and the Texas Dangerous Drug Act; and working in concert with various other regulatory bodies, such as the Texas Department of Public Safety and Texas Department of Health, to ensure licensees comply with the Texas Controlled Substances Act and the Texas Food, Drug, and Cosmetic Act.
- In 2003, the Board resolved nearly 1,900 complaints. As the pie chart, *Allegations in Pharmacy Board Complaints*, shows, the two largest single categories of complaints were for alleged theft and loss (469) and dispensing errors (267), representing 25 and 14 percent respectively of all complaints resolved.

Allegations in Pharmacy Board Complaints



Of the complaints, 220 were resolved with disciplinary orders against 213 licensees. After investigation, the remaining complaints were dismissed because no violation occurred or the allegation was not jurisdictional and was referred to another state or federal agency, such as the Texas State Board of Medical Examiners.

- Increasingly, the Board faces enforcement cases resulting from changes in the pharmacy environment in recent years, especially the dramatic increase in prescription drug use. In the United States, spending for prescription drugs has more than tripled since 1990, reaching \$140.6 billion in 2001.¹ Similarly, the number of prescriptions purchased in 2002 increased 74 percent from 1992 – a jump from 1.9 billion to 3.3 billion. On average, the number of prescriptions per person per year increased from seven to nearly 12 in this same time period.²
- To meet increasing consumer demands for prescription drugs, pharmacies have begun to employ pharmacy technicians to assist in pharmacist duties. Nationwide, the number of certified technicians has increased nearly fivefold in the past three years.³ Recognizing the increasing role of technicians in pharmacies, the Legislature made the Board responsible for registering an estimated 26,500 technicians by July 2004.
- The advent of high-cost drugs creates growing incentives for illegal activities around pharmacy, such as theft and counterfeiting. Further, new technology, especially the Internet, and the increased mobility of society permit pharmacists to be licensed and practice in more than one

state. These changes have placed increasing pressure on the pharmacy industry and the Board to regulate the industry.

The Board's grounds for disciplining a licensee do not account for recent changes that have affected the pharmacy industry.

- With most retail and hospital pharmacies employing from one to five technicians per pharmacist to meet the higher demand for prescription drugs, pharmacists may delegate to technicians nonjudgmental, technical duties, such as preparing a medication for dispensing, that must be performed under the pharmacist's direct supervision. The textbox, *Pharmacy Technician Duties*, outlines some of the tasks once carried out by a pharmacist that are increasingly performed by technicians.

Pharmacy technicians have vastly different educational requirements from pharmacists. Technicians typically complete a year-long course to receive national certification, pharmacists undergo six years of higher education followed by a national licensure exam.⁵ The result of the increased use of technicians is that many pharmacist duties have shifted from performing traditional prescription tasks to overseeing the quality of these tasks now delegated to pharmacy technicians.

The grounds currently listed in the Board's statute for disciplining a pharmacist do not account for this change to include inadequate oversight of pharmacy technician duties. While the Board has adopted rules to address this issue, and currently does discipline pharmacists for inadequate oversight, the absence of statutory authority confuses the accountability of pharmacists for these delegated activities.⁶ Because of risk to patients from errors, the pharmacist is ultimately responsible for the medication that the patient receives, even when the pharmacist delegates preparation for dispensing to a technician.

- The Board cannot take enforcement action against pharmacists or pharmacy owners on the basis of deferred adjudication for misdemeanor offenses under state and federal laws, such as marijuana possession or forging or altering a prescription. While convictions for these offenses are punishable by the Board, deferred adjudication is not. Courts increasingly offer deferred adjudication for offenses such as drug abuse – 29 percent of all drug related-felonies in Texas for 2002, up from 22 percent in 1988.⁷ The gravity of these drug offenses by practitioners responsible for others' health care warrants the Board having the ability to take disciplinary action. Without Board authority to sanction licensees who engage in risky behaviors that could have a direct negative impact on their practice, public safety could be compromised.

<p style="text-align: center;">Pharmacy Technician Duties⁴</p> <p>Tasks that a pharmacy technician may perform include:</p> <ul style="list-style-type: none">• initiating and receiving refill authorization requests;• entering prescription data into a data processing system;• preparing and packaging drug orders (i.e., counting tablets and capsules, measuring liquids, and placing them in the container);• affixing the label to the prescription container;• reconstituting medications;• prepackaging and labeling prepackaged drugs; and• stocking an automated pharmacy system.
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The grounds for disciplining a pharmacist do not include inadequate oversight of pharmacy technicians.



The Board has limited ability to punish licensees for drug theft.

- The Board is also limited in its ability to sanction pharmacies and pharmacists responsible for stolen or diverted drugs. Currently, when a pharmacy is found to be missing drugs that were not proven to be stolen it can only be cited for failing to maintain required records – a minor finding for a potentially dangerous offense. Although the potential for public harm from missing drugs varies greatly, shortages are often of controlled drugs, such as narcotics, or expensive drugs to be diverted to the black market.

Advances in pharmaceutical development, and the resulting high-cost drugs, have created a lucrative market for illegal activities, such as pilfering medications and counterfeiting. For example, Epogen, an injectable drug used to treat anemia often caused by cancer treatment, can legally sell for up to \$500 per vial, making it a lucrative drug for theft or counterfeiting. Because the Board is unable to take stronger disciplinary action than just for a record-keeping violation, it cannot impose sanctions sufficient to deter this activity.

- Technology has changed the way consumers get their drugs, particularly with the development of Internet pharmacies. As discussed in Issue 1, the ability to purchase prescription drugs from pharmacies located in other states raises concerns about the Pharmacy Board's ability to protect Texans. Pharmacists based in Texas may also dispense drugs to patients in other states, but the Board is unable to discipline them based on the actions of the other state's licensing board, even when the violation is punishable in Texas as well.

The Board may discipline a pharmacist based on another state's action only if the other state takes a severe action against a license, such as suspension or revocation. In 2001, only 13 states suspended 10 or more pharmacists' licenses and only one state other than Texas revoked more than 10 licenses.⁸ Limited disciplinary actions in other states, combined with statutory limits, prevent the Board from adequately disciplining Texas pharmacists without gathering evidence and building its own case, even when a punishable offense has been proven in another state. These limits add undue burden on the Board to sanction a Texas-licensed pharmacist who violates Texas law and is sanctioned accordingly in another state.



The Board cannot properly sanction licensees who fill illegal prescriptions.

Certain statutory restrictions on the Board's sanction authority prevent it from rapidly responding to changes in the pharmacy industry.

- Although given authority to develop rules to govern the practice of pharmacy, the Texas Pharmacy Act limits the Board's authority to sanction a pharmacist or pharmacy in violation of those rules. The Board is limited to suspending or restricting a license, imposing an administrative penalty, placing the license on probation, or reprimanding the licensee, regardless of the potential danger to the patient from the violation.⁹ For example, Board rules prohibit a pharmacist from knowingly filling a prescription illegally obtained through an improper patient-practitioner relationship. Even if a pharmacist repeatedly fills such prescriptions, the Board cannot revoke or refuse to renew the pharmacist's license.

- The statute is completely silent on whether a licensee can be sanctioned for violating a Board order. To enforce orders, the Board has adopted a rule that defines unprofessional conduct to include violating the terms of a disciplinary order.¹⁰ Although to date the Board has effectively enforced its orders, it lacks the full force of statute to raise the level of the offense to a violation of the Texas Pharmacy Act subject to revocation.

The Board's authority to discipline licensees is inconsistent with other Texas health-care practitioners and other states' pharmacy laws.

- A review of other Texas health profession licensing laws revealed that the Board is unique in that it is not directed to apply the full range of sanctions for a rule violation. The boards of Medical Examiners, Nurse Examiners, Dental Examiners, and Optometry permit licensees to receive a full range of sanctions, including revocation, for violating a Board rule.
- The boards governing physicians, nurses, dentists, chiropractors, and optometrists all have statutory authority to impose, at a minimum, administrative penalties for violating a board order. The Board of Nurse Examiner's statute goes as far as to permit the full range of sanctions for violating an order. Similarly, violations of peer assistance contracts for physicians are violations of the Medical Practice Act. However, the Pharmacy Act has no similar provision for taking disciplinary action for violating a board order or a contract with the Pharmacist Recovery Network, the peer assistance program for pharmacists with substance abuse problems. Authorizing the Board to impose sanctions for violating Board orders and peer assistance contracts would enable the Board to take further action against a licensee who does not comply with Board-ordered sanctions and other requirements.
- Licensing boards for the physicians, nurses, and dentists are not restricted in their ability to discipline or deny a licensee based on the actions of another state, as is the Pharmacy Board. These boards may impose the full range of sanctions on a licensee in violation of Texas law based solely on the action of another state, regardless of the degree of action. These boards may also apply lesser sanctions, such as reprimands or fines, based on other states' actions, while the Pharmacy Board may not.
- The Board of Medical Examiners received authority last session to discipline doctors who receive deferred adjudication for punishable offenses. Similar authority for the Pharmacy Board to discipline licensees who receive deferred adjudication for drug-related offenses under the purview of a pharmacist would strengthen the Board's ability to control the licensee population.



Other agencies have more authority to discipline violators of board rules or orders.

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 a felony or misdemeanor under any statute governing the practice of pharmacy.

This recommendation would permit the Board to discipline a pharmacist who receives deferred adjudication for misdemeanor offenses under 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 more in line with new authority of the Board of Medical Examiner 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.

Impact

Each of the recommended changes to the Board's enforcement authority would enable it to respond more appropriately to violations of regulations governing the practice of pharmacy in Texas. These recommendations take into account recent changes in the pharmacy industry and provide the Board more authority to adapt enforcement to meet the continuing changes in the industry.

Fiscal Implication

These recommendations will not have a fiscal impact to the State. The Board may incur some costs as a result of increased enforcement efforts, but these costs could not be estimated for this report.

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

² IMS Health, "IMS Reports 8% Growth in Retail Pharmacy Drug Sales for the 12 Months to November 2003," www.imshealth.com/ims/portal/front/articleC/0,2777,6599_41382715_44532480,00. Accessed: December 2003.

³ Pharmacy Technician Certification Board, July 2003 Actively Certified Technicians Nationwide, (Washington, D.C., 2003).

⁴ Texas Administrative Code, Title 22, part 15, rule 291.32(2)(c).

⁵ Texas Administrative Code Title 22. Part 15, rule 291.32 (d)(1)(A).

⁶ Texas Administrative Code Title 22. Part 15, rule 291.32 (c).

⁷ Office of Court Administration (OCA), *Texas Judicial System Annual Report, 1988-2002*.

⁸ National Association of Boards of Pharmacy, *Survey of Pharmacy Law* (ParkRidge, Ill., 2002).

⁹ Texas Occupations Code 565.051 (b).

¹⁰ Texas Administrative Code Title 22. Part 15, rule 281.7(a)(191).

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

Summary

Key Recommendation

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

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.

Conclusion

The Board is prohibited from accessing a pharmacy's 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 an inspection. As a result, the Board is unable to aggressively pursue cases against pharmacists and pharmacies that commit fraud or dispense drugs illegally. Authorizing the Board to access financial data in certain enforcement situations would enable the Board to more effectively enforce state laws and prosecute pharmacies engaged in illegal activity.

Support

The Board investigates complaints alleging violations of pharmacy laws and Board policies.

- In regulating the practice of pharmacy in Texas, the Board enforces the Texas Pharmacy Act and plays a role in enforcing other state and federal laws relating to pharmacy and prescription drugs and devices. Among other things, these laws charge the Board with ensuring that pharmacies and pharmacists properly dispense prescription drugs and do not commit fraud.
- The Board investigates allegations of violations of state pharmacy laws and Board rules, and sanctions pharmacies and pharmacists who violate these laws. When conducting investigations, the Board inspects relevant documents that state and federal laws require a pharmacy to maintain, such as dispensing records, prescriptions, inventory logs, and forms used to order controlled substances.¹


Crucial information needed to prosecute illegal pharmacies is off limits to the Board.

The Board's lack of access to sales and pricing data hampers its ability to enforce state law and prosecute illegal activity.

- While the Board has access to most of a pharmacy's records, certain financial information is off limits. The Board may not access financial data, sales data other than shipment data, or pricing data, unless the pharmacy owner, pharmacist, or person in charge of the pharmacy consents in writing.² This limitation applies even if the Board is inspecting the pharmacy as the result of a complaint. Without authority to access financial data, the Board has referred many cases to another agency or taken other action, such as assisting another agency in the investigation.
- The Board has difficulty obtaining information crucial to prosecuting pharmacies and pharmacists that illegally dispense drugs. Illegal pharmacies, particularly unlicensed Internet pharmacies, will sell drugs – including narcotics and highly abusable drugs such as hydrocodone – without prescriptions or without ensuring that a valid practitioner-patient relationship exists. Many of these pharmacies significantly inflate the price of the drugs they sell because consumers who are trying to obtain drugs without a prescription or physician involvement are willing to pay the marked-up prices to circumvent state and federal laws. Showing a substantial increase in the price of drugs sold by a pharmacy would strengthen the Board's ability to prove that a pharmacy or pharmacist is operating illegally and violating state laws. However, without the ability to access pricing data, the Board cannot effectively establish such a violation.
- The Board is not able to rigorously pursue fraud – including Medicaid fraud cases – without obtaining financial information. The Board is authorized to discipline a pharmacist or pharmacy owner engaged in fraud, deceit, or misrepresentation.³ However, the Board typically has to rely on another entity, such as the U.S. Food and Drug Administration or the Texas Health and Human Services Commission's Medicaid Program, to build a case proving that a pharmacist or pharmacy owner


Illegal pharmacies may inflate drug prices for consumers wanting to circumvent state and federal laws.

committed financial fraud. As a result, the Board may not be able to take swift, effective action against a licensee that it has reason to believe is committing financial fraud.

For example, in one case currently at the Board, a patient learned that a pharmacy had billed the patient's insurance company for more than 20 prescriptions, totaling about \$1,500, that the patient had not received. In fact, the patient had never been to that pharmacy. Also, in billing the insurance company, the pharmacy claimed that the patient had paid a \$20 copay for each prescription, even though the patient had not. A pharmacist who financed the pharmacy currently is on probation and is under investigation for other serious violations. Because the Board cannot inspect financial information, however, staff investigators have had difficulty investigating the complaint. The Board is hampered in its ability to pursue this case as well as insurance fraud the Board believes the pharmacist conducted at other pharmacies and involving other insurance companies.

- Limiting the Board's access to financial data prevents the Board from disciplining pharmacists who overcharge patients. Pharmacists are prohibited from billing a patient or third-party payer for a treatment the pharmacist knows was improper, unreasonable, or medically or clinically unnecessary, and are subject to disciplinary action – including revocation or suspension of their license – if they do so.⁴ State law authorizes the Board to audit a pharmacist's records if the Board receives a complaint alleging that the pharmacist overcharged a patient.⁵ However, under restrictions in the Texas Pharmacy Act, the Board does not have the authority to obtain financial data, which would be required to properly investigate an overcharging complaint.
- Without obtaining a pharmacy's sales and pricing information, the Board cannot determine whether a pharmacist appropriately substituted a generic drug. To ensure that consumers receive appropriate medications at an appropriate price, the Texas Pharmacy Act mandates that a pharmacist may not select a generically equivalent drug unless that drug costs the consumer less than the prescribed drug.⁶ In addition, a pharmacist may not charge a higher price for a generic drug than the fee the pharmacist customarily charges for dispensing the brand-name drug.⁷ However, because the Board is prohibited from accessing sales and pricing data, the Board cannot prove whether the pharmacy or pharmacist violated generic-substitution laws, including if a pharmacist dispensed a generic drug, but charged the patient for the more expensive brand-name drug.

Other states' pharmacy boards have access to a pharmacy's sales and pricing data, which enhances their enforcement activities.

- Many states do not limit the access of their boards of pharmacy to financial, sales, and pricing data. In fact, as states address the issues of drug reimportation and Internet pharmacies, they are contemplating how access to sales and pricing data can help their pharmacy boards verify the legitimacy of a pharmacy.⁸



Without obtaining financial information, the Board cannot adequately pursue insurance fraud or violations of generic substitution laws.

- Oklahoma recently used pricing data to bring enforcement action against a pharmacist for illegally dispensing drugs – including hydrocodone, Valium, Fioricet, and Xanax – and providing prescriptions through the Internet pharmacy he owned. The Oklahoma State Board of Pharmacy showed that the pharmacist was selling drugs at a 1,000-percent markup, which led to the successful prosecution and revocation of the individual's pharmacist and pharmacy licenses in Oklahoma. The case received national attention, as the pharmacist illegally dispensed drugs to customers in many other states – including Texas – through his Web site. At least one person – an 18-year-old Californian – died after illegally purchasing drugs from the illegal pharmacy site.

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. 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. 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.

Impact

Granting the Board access to financial, sales, and pricing data in situations involving a complaint or failed inspection would allow the Board to more effectively enforce state laws that relate to illegally dispensing prescription drugs, overcharging, and generic substitution. As such, the Board would be able to more quickly and resolutely resolve complaint cases.

Fiscal Implication

This recommendation will not have a fiscal impact to the State.

¹ Texas Occupations Code, sec. 556.053. The Board may inspect and copy documents, including records or reports, required to be kept under the Texas Pharmacy Act, the Texas Controlled Substances Act, the Texas Dangerous Drug Act, or the U.S. Comprehensive Drug Abuse Prevention and Control Act of 1970.

² Texas Occupations Code, sec. 556.054.

³ Texas Occupations Code, sec. 565.001 (pharmacists) and Texas Occupations Code, sec. 565.002 (pharmacy).

⁴ Texas Health and Safety Code, sec. 311.0025. Texas Occupations Code, sec. 101.203, requires healthcare professionals, including pharmacists, to comply with this section of the Health and Safety Code.

⁵ Texas Health and Safety Code, sec. 311.0025(b).

⁶ Texas Occupations Code, sec. 562.011(a).

⁷ Texas Occupations Code, sec. 562.011(b).

⁸ National Association of Boards of Pharmacy (Park Ridge, Ill., November 17, 2003).

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

Summary

Key Recommendations

- Standardize the Board's licensing functions by streamlining the licensing by reciprocity process, requiring the Board to ensure its exams are accessible to persons with disabilities, and changing the basis for assessing late renewal fees.
- Improve the Board's ability to protect the public by allowing a panel of the Board to temporarily suspend a license, increasing the administrative penalty amount, authorizing staff to dismiss complaints, and granting the Board authority to issue cease-and-desist orders.
- Update elements related to the policy body, such as allowing pharmacy faculty members to serve on the Board and requiring the Board to define the roles and responsibilities of Board subcommittees.

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.

Conclusion

Over the past 25 years, Sunset staff has reviewed more than 80 occupational licensing agencies. In doing so, the staff has identified standards that are common practices throughout the agencies statutes, rules, and procedures. In reviewing the State Board of Pharmacy, staff found that various licensing, enforcement, and administrative processes in the Texas Pharmacy Act do not match these model licensing standards. The Sunset review compared the Board's statute, rules, and practices to the model licensing standards to identify variations. Based on these variations, staff identified the recommendations needed to bring the Board in line with the model standards.

Support

Regulating occupations, such as pharmacy, requires common activities that the Sunset Commission has observed and documented over more than 25 years of reviews.

- The mission of the Texas State Board of Pharmacy is to protect the public by ensuring that Texans receive safe and high-quality pharmaceutical care. To provide this protection, the Board regulates the practice of pharmacy, the operation of pharmacies, and the distribution of prescription drugs in Texas. In fiscal year 2003, the Board regulated 21,570 pharmacists, 5,794 pharmacies, 1,495 pharmacist-interns, and 3,445 preceptors. In fiscal year 2004, the Board will begin registering an estimated 26,500 pharmacy technicians. The Board also regulates the pharmacy profession by enforcing the Texas Pharmacy Act, investigating and resolving complaints alleging violations of the Act or Board rules, and taking disciplinary action when necessary.
- The Sunset Advisory Commission has a historic role in evaluating licensing agencies, as the increase of occupational licensing programs served as an impetus behind the creation of the Commission in 1977. Since then, the Sunset Commission has completed more than 80 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 statutes and rules differ from these model standards, and describes the potential benefits of conforming with their standard practices.

Unfair treatment of licensees and inadequate consumer protection may result from outdated statutory provisions.

- *Access to exams.* Agency rules should reflect exam procedures that accommodate all qualified applicants regardless of any existing disabilities. Although the Board follows Americans with Disabilities Act guidelines and works with the National Association of Boards of Pharmacy (NABP) to accommodate disabled applicants, it has not formalized its process through rule to ensure future applicants with disabilities are not excluded from sitting for the exams. Referencing the Americans with Disabilities Act in the Board's statute would clarify the Board's responsibility to establish accessibility policies in rule and ensure that future applicants with disabilities are not excluded from taking exams.
- *Testing fees.* Fees for both initial exams and retakes of the exams should not be refundable, except in cases of emergencies and reasonable advance notice of withdrawal. The agency incurs administrative costs for processing exam applications, which should be covered by the examinee. Currently, the Board refunds the entire \$50 exam processing fee and the \$250 reciprocity fee if the Board receives written notification no later than six weeks before the scheduled exam date.¹ Because staff

may have already begun processing an application, the Board should keep a portion of the exam fee to cover its costs if an applicant cancels an examination appointment. Authorizing the Board to determine what portion of exam fees to refund balances the needs of both the agency and the applicant.

- ***Reciprocity.*** An agency should establish a fair and equitable procedure for licensing applicants from other states. This procedure should protect the safety of Texans without being unduly burdensome on the licensee. Currently, the Board issues a reciprocal pharmacist license to any applicant who holds an active, unrestricted license from the original licensing state, passes the jurisprudence exam, and pays a fee. Adhering to a policy suggested by NABP, the Board will not issue a reciprocal pharmacist license based on a license in any state other than the original licensing state, no matter how long it has been since the applicant practiced in the original state. This requirement burdens the applicant, who must maintain a license in a state that the applicant may never intend to practice in again.

The Texas Pharmacy Act does not require that an applicant hold an active original license, but merely that the applicant show proof of initial licensure by exam.² In addition, despite NABP's preferred policy, the organization accepts that some states will allow licensure by reciprocity based on a license other than the original license. Clarifying that the Board may issue a license if a pharmacist provides proof that the applicant passed the required exams, holds a current, unencumbered license in another state, and complies with other licensing requirements in the Texas Pharmacy Act would maintain the Board's standards for issuing a license while allowing qualified pharmacists to receive a Texas license hassle-free.

- ***Late renewal penalties.*** Penalties for delinquent renewal should be set at a level that is reasonable to ensure timely payment and that provides comparable treatment for all licensees. Under the Texas Pharmacy Act, late renewal penalties for pharmacist licenses are based on the cost of the examination required for licensure. For the purpose of calculating delinquent penalties, the Board set the examination fee at \$300 – the cost of the national exam at the time – although the current cost of the national exam is \$430.³ The requirements for renewing a delinquent pharmacy license should be equally fair. Although the Act does not address penalties for late renewals of a pharmacy license, the Board has established fees in rule. An expired pharmacy license can be renewed by paying the pharmacy licensing fee – currently \$278 – plus the renewal fee – \$225.

A fairer, more consistent practice would be to require delinquent licensees – both pharmacists and pharmacies – to pay 1-1/2 to two times the standard renewal fee. Doing so will bring the Board's renewal time frames and delinquent renewal fees in line with other licensing agencies and ensure that the Board's licensees are treated the same as other individuals licensed by the state.



Authorizing the Board to retain a portion of exam fees would offset costs incurred.



The Texas Pharmacy Act does not address penalties for late renewals of a pharmacy license.

The Board's ability to protect consumers is hampered by nonstandard enforcement provisions.


Allowing for administrative dismissal of complaints would expedite the enforcement process.

- **Complaint dismissal.** Agency staff should have the authority to dismiss complaints without having to involve the Board, although the Board should be informed of all such dismissals. This approach saves Board time in considering each complaint while still providing Board members information on staff actions. Currently, the Board annually approves a procedure for how staff should handle complaints. However, the Texas Pharmacy Act does not grant clear authority for the administrative dismissal of complaints. Allowing staff to dismiss complaints and requiring staff to report such dismissals to the Board would expedite the complaint process while ensuring that Board members are aware of staff actions.
- **Administrative penalties.** An agency's administrative penalty authority should authorize penalty amounts that reflect the severity of the violation and serve as a deterrent to violations of the law. The Board has authority to impose administrative penalties of up to \$2,500 per violation per day; for violations that involve the diversion of a controlled substance, the amount of the penalty is limited to \$5,000 per day per violation. Given the significant harm that can result from illegal activity related to pharmaceuticals and the large amounts of money often involved in illegal activity, such as drug diversion, the current administrative penalty amount may not be adequate to deter illegal behavior. Other health licensing agencies are authorized to impose a penalty amount of up to \$5,000 per violation per day for violations of state law.⁴ Increasing the administrative penalty amount to \$5,000 per violation per day for any violation of the Act or Board rules would give the Board flexibility to address the potentially severe nature of deviant behavior.

Agencies that use administrative penalties should also use a penalty matrix to establish penalties for specific violations in a way that is fair and consistent for all violators. The matrix should be adopted by an agency's policymaking body in rule so that opportunity exists for public awareness and debate. Currently, the Board has no penalty matrix, although staff does research to ensure that the Board applies penalty consistently. Requiring the Board to adopt a penalty matrix would facilitate fair treatment of all violators.


Authority to suspend a license without an initial hearing is useful in cases of substantial harm.

- **Temporary suspension.** Granting an agency authority to summarily suspend a license without an initial hearing is useful in situations, such as dispensing dangerous drugs without a prescription, where substantial harm can result if an activity is not stopped immediately. The Board has authority to temporarily suspend a pharmacist's license, but only if a majority of the Board determines that a threat to public welfare exists.⁵ The Board does not have any authority to temporarily suspend a *pharmacy* license, even if a dangerous situation arises concerning a pharmacy that constitutes a threat to the public.

Because its members live across the state, the Board has difficulty getting a quorum – which is five members – present on little notice to vote on temporarily suspending a license. Other health licensing agencies in

Texas have the authority to temporarily suspend a license based on a panel or committee of Board members, not a majority of the Board. For example, a three-member disciplinary panel consisting of members of the Texas State Board of Medical Examiners has authority to determine whether a person's license to practice medicine should be temporarily suspended.⁶ In addition, the disciplinary panel may 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.⁷

Authorizing a panel of the Board to temporarily suspend a pharmacist or a pharmacy license, and to meet by telephone conference call if necessary, would allow the Board to better protect the public in situations where the continued practice constitutes a threat to public welfare.

- ***Cease-and-desist orders.*** A licensing agency should have enforcement authority not only over its licensees, but over those who engage in the unlicensed activity of the profession. Two tools for taking action against unlicensed violators include injunctive relief and cease-and-desist orders. Currently, the Board has injunctive authority, but the statute provides for the Board, instead of the Attorney General, as is more customary, to petition in district court.⁸ The Board does not have cease-and-desist authority, which serves as an interim step before an injunction that the Board may take on its own to stop unlicensed activity. Further, making violations of cease-and-desist orders subject to additional sanctions, such as administrative penalties, would help make them more enforceable. Because illegally distributing prescription drugs and devices can have a detrimental effect on public health and safety, giving the Board cease-and-desist authority would allow the Board to better protect the public.

Certain policy body and administrative provisions of the Board's statute could reduce the Board's efficiency and flexibility to adapt to changing circumstances.

- ***Policy body composition.*** Unless conflicts of interest exist, a member of the regulated profession who meets statutory qualifications should be eligible to serve on the Board. The Texas Pharmacy Act prohibits faculty members of a college of pharmacy from serving on the Board as pharmacist members. This restriction prevents qualified members of the pharmacy profession from serving on the policy body. Allowing a licensed pharmacist who is on the faculty of a college of pharmacy to serve on the Board would increase the pool of individuals with relevant expertise from which appointments are made and provide the Board with valuable input from the academic sector of the pharmacy profession.
- ***Compensation.*** Board members should be subject to reasonable standards for travel reimbursement, which should be reflected in statute. While the General Appropriations Act indicates that reimbursement for policy body members includes transportation, meals, lodging, and incidental expenses, the Texas Pharmacy Act prohibits reimbursement of some travel expenses, such as meals and lodging.⁹ Although Board members receive reimbursement according to the General Appropriations Act, the Texas Pharmacy Act conflicts with this provision.



*Cease-and-desist
authority would give
the Board another
tool to stop unlicensed
activity.*


The use of dedicated accounts, such as the Pharmacy Board's, has largely been eliminated by the Legislature.

Eliminating this prohibition on travel reimbursement would make the Texas Pharmacy Act consistent with the General Appropriations Act.

- **Board committees.** Board committees allow boards to divide their workload and take advantage of specialization or expertise among the members. Board committees typically focus on issues and forward their recommendations to the full board for final action. The Act allows the Board to appoint committees from its members, and currently the Board has established one committee. The Executive Committee, which consists of the Board President, Vice President, and Treasurer, makes recommendations regarding the agency's proposed operating budget before the full Board's review and approval. However, the Board has not adopted rules or written guidelines outlining the structure and purpose of this committee. Requiring the Board to adopt rules describing the makeup and responsibilities of the Executive Committee – and any other committees the Board forms – would give committee members clear direction and ensure that the committees are properly structured and operate consistently.
- **Funding structure.** A licensing agency typically should deposit licensing fees in the General Revenue Fund and receive appropriations from that fund. The use of funds dedicated to an agency's use, either within or outside General Revenue, has largely been eliminated in the Legislature. The Board is an exception to this standard, as the agency deposits revenue – except for administrative penalties – into and receives appropriations from a dedicated account.¹⁰ At the end of fiscal year 2003, the Pharmacy Board Operating Account had a cash balance of \$4 million. Removing the dedicated account would allow any remaining cash balances to accrue to the General Revenue Fund and would result in administrative savings to the state from administration of fewer dedicated accounts.

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.

Under this recommendation, the Board's statute would be amended to ensure that testing accommodations for the pharmacist licensing exams are in accordance with the Americans with Disabilities Act. The Board would need to adopt procedures regarding accessibility accommodations and work with the National Association of Boards of Pharmacy 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. In determining its refund policies, the Board should work to ensure that its policies do not conflict with NABP's policies.

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

This recommendation would clarify the statutory provision that permits a pharmacist to receive a license if the pharmacist holds an active, unencumbered license in another state and complies with other statutory licensing requirements. The Texas Pharmacy Act would be clarified to provide for the Board to issue a license by reciprocity 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 to \$5,000 per violation per day from \$2,500 per violation per day. The provision that each day a violation continues or occurs is a separate violation for purposes of imposing the penalty would continue to apply. The amount for violations that involve controlled substances would remain the same, at \$5,000 per violation. This recommendation reflects the significant amounts of money that can be involved in pharmaceutical-related violations, and would pose as a larger deterrent than the existing penalty amount. The Board would also be required to adopt an administrative penalty matrix in agency rules to ensure that the Board develops administrative penalty sanctions that appropriately relate to different violations of the Board's Act or rules. By requiring the Board to adopt the matrix in rule, 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. Extending temporary suspension authority to include pharmacies would fill a gap in the Board's enforcement authority. In addition, to the extent it complies with Chapter 551 of the Government Code concerning open meetings, 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. These provisions would not change the existing provisions for a hearing on the suspension before the Board and a second hearing before the State Office of Administrative Hearings.

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

The Board would issue cease-and-desist orders when it receives a complaint or otherwise hears of an individual or entity practicing pharmacy without a license. It could also assess administrative penalties against violators of these orders. The Board would still be authorized to refer these cases to local law enforcement agencies or the Attorney General for prosecution. However, the Board should count unauthorized practice cases as jurisdictional, and direct investigators to pursue and follow up with unlicensed individuals to ensure compliance. In addition, the Act would be clarified to state that the Attorney General, not the Board, petitions district court for an injunction. The Board would refer such cases to the Attorney General.

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 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 committees consisting of Board members. Doing so would ensure that each committee's duties are clearly outlined, thus allowing the committees to 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.

Impact

The application of these recommendations to the Board would result in efficiency and consistency from fairer processes for licensees, additional protection for consumers, and standardization of Board procedures. The chart, *Benefits of Recommendations*, categorizes the recommendations according to their greatest benefits.

Benefits of Recommendations				
Recommendations	Efficiency of Operation	Administrative Flexibility	Fairness to Licensee	Public Protection
Licensing				
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.			✓	
4.2 Authorize the Board to establish policies regarding nonrefundable testing fees.		✓	✓	
4.3 Simplify the process for a pharmacist who holds an active license in another state to be licensed in Texas.	✓	✓	✓	
4.4 Base delinquent license renewal fees on the Board's normally required renewal fee.	✓		✓	
Enforcement				
4.5 Authorize staff to dismiss baseless cases.	✓	✓		
4.6 Increase the amount of the Board's administrative penalty authority and require the Board to adopt an administrative penalty matrix in rule.	✓	✓		✓
4.7 Remove the requirement that a majority of Board members must approve temporary suspension of a license.	✓	✓		✓
4.8 Authorize the Board to use cease-and-desist orders with regard to practicing pharmacy without a license.		✓		✓
Policy Board				
4.9 Allow faculty members to be eligible to serve on the Board.		✓	✓	
4.10 Authorize Board members to receive reimbursement for travel expenses.	✓	✓		
4.11 Require the Board to establish guidelines for Board subcommittees.		✓	✓	✓
4.12 Eliminate the Pharmacy Board Operating Account.	✓	✓		✓

Fiscal Implication

Eliminating the dedicated Pharmacy Board Operating Account would result in a one-time gain to the General Revenue Fund equal to the remaining balance in the account after operating expenses, which is projected to be about \$4.4 million at the end of fiscal year 2006. Other recommendations are procedural improvements that would not require additional resources.

Fiscal Year	Gain to General Revenue
2006	\$4,400,000
2007	\$0
2008	\$0
2009	\$0
2010	\$0

¹ Refunds for fees charged by NABP for the administration of the NAPLEX and MPJE are in accordance with NABP policy and are not handled by the Board.

² Texas Occupations Code, sec. 558.101.

³ Texas Administrative Code, Title 22, part 15, rule 283.9(d) sets the exam fee at \$300 for the purpose of calculating delinquent pharmacist license fees. The cost of NAPLEX, the exam required of all applicants, is set by NABP. Currently, the fee for NAPLEX is \$430. National Association of Boards of Pharmacy, NAPLEX/MPJE Registration Bulletin, Park Ridge, Ill. (2002), p. 1.

⁴ The State Board of Medical Examiners, State Board of Physician Assistant Examiners, and State Board of Dental Examiners each have a \$5,000 per day per violation administrative penalty amount.

⁵ Texas Occupations Code, sec. 565.059.

⁶ Texas Occupations Code, sec. 164.059. In addition to the Texas State Board of Medical Examiners, other health licensing agencies that have authority to temporarily suspend a license based on a determination by a panel of Board members include the Chiropractic Examiners, Dental Examiners, Nurse Examiners, Examiners of Psychologists, Examiners of Professional Counselors, and Veterinary Medical Examiners boards.

⁷ Texas Occupations Code, sec. 164.059(d).

⁸ Texas Occupations Code, sec. 566.051.

⁹ House Bill 1, General Appropriations Act, 78th Legislature (2003), Article IX, Sec. 4.04.

¹⁰ Texas Occupations Code, sec. 554.007. The Board deposits funds into and receives appropriations from Pharmacy Board Operating Account No. 523.

Decide on Continuation of the Board After Completion of Sunset Reviews of Other Health Licensing Agencies.

Summary

Key Recommendation

- Decide on continuation of the Texas State Board of Pharmacy as a separate agency upon completion of upcoming Sunset reviews of other health-profession licensing agencies.

Key Findings

- The Texas State Board of Pharmacy protects the public by licensing and enforcing standards for pharmacy services providers.
- Texas has a continuing need for regulating the practice of pharmacy.
- Different organizational options for regulating licensed health-care practitioners offer advantages and disadvantages to the Board.
- Most states regulate pharmacies and pharmacists through independent agencies, like Texas.
- A complete study of organizational options should consider the results of the Sunset Commission's reviews of other health-care professional licensing agencies this review cycle.

Conclusion

The Sunset review evaluated the continuing need for regulation of the pharmacy industry in Texas, as well as the need for the Texas State Board of Pharmacy as the agency to provide these functions. While the review found that the State should continue to regulate pharmacies and pharmacists, several options exist for how to structure this regulatory effort, including continuing the Board as an independent agency, enhancing coordination of administrative functions through a council like the Health Professions Council, and consolidating the Board with other health-profession agencies. The review concluded that the decision on the appropriate structure of the agency responsible for these regulations should be delayed until the Sunset reviews of other health-profession licensing agencies are completed later this year, to draw on insights gained from those reviews.

Support

The Texas State Board of Pharmacy protects the public by licensing and enforcing standards for pharmacy services.

- The Board's main purpose is to protect 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 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. To accomplish its goal, the Board licenses pharmacists and pharmacies, and regulates their activities through enforcement. In fiscal year 2003, the Board regulated more than 21,000 pharmacists and nearly 6,000 pharmacies. It will begin registering an estimated 26,500 pharmacy technicians in 2004.
- In 2003, the Board received nearly 1,900 complaints against licensees. In that same year, the Board resolved 1,850 complaints, of which 220 resulted in disciplinary action against 213 licensees.



Prescription drug use has more than tripled since 1990, reaching \$140.6 billion in 2001.

Texas has a continuing need for regulating the practice of pharmacy.

- Prescription drug use is increasing in Texas and across the country. In the United States, spending for prescription drugs has more than tripled since 1990, reaching \$140.6 billion in 2001.¹ In fact, the number of prescriptions purchased in 2002 increased 74 percent from 1992 – a jump from 1.9 billion to 3.3 billion. On average, the number of prescriptions per person increased from seven to nearly 12 in this same period.²
- 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. For example, pharmacists counsel patients about new prescriptions, and the expanding number of new drugs creates a greater need that the Board ensure that patients receive counseling. In addition, as newly developed drugs treat more and more conditions and the demand for prescriptions increases each year, the potential risk to individuals increases as well. High-cost drugs create incentives for illegal activities around pharmacy, such as theft and counterfeiting, creating another critical area of oversight for the Board.
- The Board licenses individuals to ensure their competence to provide pharmacy services to the public. The Board also develops and implements rules and regulations to ensure that licensees engage in safe practices. The Texas Pharmacy Act is designed to protect clients and give them recourse if laws are violated. Further, the public needs an agency that can receive and investigate complaints about pharmacy service providers and, if necessary, to discipline those who violate the laws to bring them into compliance, or to expel them from licensed practice.



Prescription drugs treat an increasing number of ailments, but pose a risk if not taken correctly.

Different organizational options for regulating licensed health-care practitioners offer advantages and disadvantages to the Board.

- The regulation of health-care practitioners, including pharmacy licensees, could occur through several organizational structures – an independent board, a coordinating council similar to the Health Professions Council, or a consolidation of similar licensing agencies. The advantages and disadvantages of each of these organizational structures are described in the chart, *Organizational Structure Options*.
- Traditionally, Texas has approached the regulation of most health-care professions, including pharmacy, through an independent agency that pays for itself through licensing and professional fees, focuses on good

Organizational Structure Options			
Type of Organization	Description	Advantages	Disadvantages
Independent Agency	Board appointed by Governor to represent pharmacists and pharmacy practitioners and make final decisions for regulation with own staff and budget.	<ul style="list-style-type: none"> • Expertise in pharmacy applied to regulation of licensees. • Better accountability for licensing and enforcement decisions. • Improved customer service by Board and staff dedicated to single profession. 	<ul style="list-style-type: none"> • Duplication of effort with other licensing agencies performing common functions. • Limited coordination with agencies with similar responsibilities.
Coordinating Council	Board appointed by Governor to make final decisions for regulation with own staff for licensing and enforcement. Receives some or all administrative support from coordinating council composed of comparable agencies, such as Health Professions Council, which may rely on staff from member agencies or may employ own staff.	<ul style="list-style-type: none"> • Administrative efficiency from standardizing functions among member agencies. • Better focus of limited resources on core licensing and enforcement functions. 	<ul style="list-style-type: none"> • Less autonomy for Board in meeting administrative program needs. • Fracturing of administrative services among agencies, with some favored more than others. • Duplication of effort with other licensing agencies performing common functions.
Consolidation of Similar Agencies	Advisory Board that makes recommendations to consolidated licensing oversight board, either for regulation of certain health-care practitioners specifically, or as part of unified regulation of all health professions.	<ul style="list-style-type: none"> • Single point of contact for consumers to obtain information or lodge complaints. • Improved coordination and standardization of rules and policies, especially among similar professions. • Improved economy of scale for administrative, licensing, and enforcement functions. • Reduced potential for regulated profession to dominate regulations. 	<ul style="list-style-type: none"> • Neglect of individual professions in favor of larger, more powerful groups. • Diminished customer service and accountability, resulting in increased response times for licensing and enforcement actions. • Lack of staff expertise in a specific profession.

customer service, and provides expertise for the regulation of its licensees. The Board currently operates as an independent agency, with 48 staff to regulate the pharmacy industry. In the last few years, the Board has generally had a good history of meeting all of its performance measures relating to licensing and enforcement.

★

The Pharmacy Board is currently a net contributor to the Health Professions Council.

- The Health Professions Council (HPC) currently functions as a coordinating council for 15 health-care professional licensing agencies representing 35 professional licensing boards and programs. Member agencies collocate in one state office building to facilitate resource sharing, including shared board and conference rooms, an imaging system, courier services, and information technology staff. HPC is currently making plans to coordinate human resources and financial activities among member agencies. The Legislature augmented the activities of HPC in 2003 by establishing the Office of Patient Protection, which will assist consumers with complaints about HPC member agencies. While currently the Pharmacy Board is a net contributor of administrative services to HPC, additional authority could be given to HPC to perform member agencies' administrative functions, leaving them to perform only licensing and enforcement functions.
- A single umbrella health licensing agency could regulate all of the health professions currently regulated under 35 separate boards and programs. A public board would oversee all regulation, assisted by advisory committees that could provide expertise in the regulation of the various health-care professions. The structure of the agency could be modeled after the Texas Department of Licensing and Regulation, which has a structure for occupational and professional examination, licensing, and enforcement for more than 20 regulatory programs. The agency's public board receives assistance from statutorily created advisory committees, composed of regulated trades, businesses, industries, and occupations.

★

Most states regulate pharmacy through independent licensing boards.

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

- The chart, *Regulation of Pharmacy in the United States*, describes the organizational structure of agencies responsible for regulating pharmacy in the 50 states. A large majority, 32 states, including Texas, regulate pharmacy through independent agencies overseen by independent

Regulation of Pharmacy in the United States		
Structure	Number of States	States
Independent Agency	32	AL, AK, AZ, AR, CA, DE, ID, IA, KS, KY, LA, MD, MN, MS, MO, MT, NV, NH, NJ, NM, NC, ND, OH, OK, OR, SD, TX, VT, VA, WA, WV, WY
Health Professions Agency	4	FL, IN, NE, RI
General Umbrella Licensing Agency	14	CO, CT, GA, HI, IL, ME, MA, MI, NY, PA, SC, TN, UT, WI

pharmacy boards with final policymaking authority. Fourteen states regulate pharmacy through general umbrella licensing agencies, with nine of these having pharmacy boards with final policy making authority. Three states regulate pharmacies through health professions regulatory agencies.

A complete study of organizational options should also consider the results of the Sunset Commission's reviews of other health-profession licensing agencies during this review cycle.

- Sunset reviews of other health-profession licensing agencies are scheduled for completion in the fall of 2004, after the completion of this agency's review. The textbox, *Health Boards Under Sunset Review*, lists the professional licensing agencies that will undergo a Sunset review by the fall of 2004.
- The results of these reviews may indicate that further administrative efficiencies could be gained among these agencies. Opportunities may also exist to provide for greater coordination and consistent regulation across Texas' health-profession licensing agencies. Delaying decisions on continuation of the Board until that time will allow Sunset staff to finish its work on all the professional licensing agencies. Thus, the Sunset Commission can then base its recommendations on the most complete information.

Health Boards Under Sunset Review 2003-2005*
State Board of Acupuncture Examiners
Texas Board of Chiropractic Examiners
Texas State Board of Examiners of Dietitians
Texas State Board of Examiners of Marriage and Family Therapists
Texas State Board of Medical Examiners
Texas Midwifery Board
Texas Optometry Board
Texas State Board of Examiners of Perfusionists
Texas State Board of Pharmacy
State Board of Physician Assistant Examiners
State Board of Podiatric Medical Examiners
Texas State Board of Examiners of Professional Counselors
Texas State Board of Examiners of Psychologists
State Board of Social Work Examiners
State Board of Veterinary Medical Examiners
* All the above boards are members of HPC or are attached to the Texas Department of Health, which is an HPC member.

Recommendation

Change in Statute

5.1 Decide on continuation of the Texas State Board of Pharmacy as a separate agency upon completion of upcoming Sunset reviews of other health-profession licensing agencies.

This recommendation would postpone the Sunset Commission's decision on the status of the Board as a separate agency until completion of the Sunset reviews of other health-profession licensing agencies being reviewed this biennium.

Impact

Though the State should continue to regulate pharmacies and pharmacists, Sunset staff recommends that the Sunset Commission delay its decision on continuation of the Board as a separate agency until the Sunset reviews of other health-care professional licensing agencies are completed. At that time, Sunset staff will make recommendations to the Commission regarding continuing the Board.

The results of each agency review should be used to determine if administrative efficiencies and greater coordination can be achieved in the organization of the State's separate health-care professional licensing agencies.

Fiscal Implication

This recommendation will not have a fiscal impact to the State.

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

² IMS Health, "IMS Reports 8% Growth in Retail Pharmacy Drug Sales for the 12 Months to November 2003," www.imshealth.com/ims/portal/front/articleC/0,2777,6599_41382715_44532480,00. Accessed: December 2003.

ACROSS-THE-BOARD RECOMMENDATIONS

Texas State Board of Pharmacy

Recommendations	Across-the-Board Provisions
Already in Statute	1. Require public membership on the agency's policymaking body.
Update	2. Require provisions relating to conflicts of interest.
Already in Statute	3. Require unbiased appointments to the agency's policymaking body.
Apply	4. Provide that the Governor designate the presiding officer of the policymaking body.
Already in Statute	5. Specify grounds for removal of a member of the policymaking body.
Update	6. Require training for members of the policymaking body.
Already in Statute	7. Require separation of policymaking and agency staff functions.
Already in Statute	8. Provide for public testimony at meetings of the policymaking body.
Update	9. Require information to be maintained on complaints.
Already in Statute	10. Require the agency to use technology to increase public access.
Already in Statute	11. Develop and use appropriate alternative rulemaking and dispute resolution procedures.

AGENCY INFORMATION

Agency Information

Agency at a Glance

The Texas State Board of Pharmacy's main purpose is to protect 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. To accomplish its goal, the Board licenses pharmacists and pharmacies, and regulates their activities through enforcement. 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.



*On the Internet:
Visit the Texas State
Board of Pharmacy at
www.tsbp.state.tx.us.*

Key Facts

- **Funding.** In fiscal year 2003, the Board operated with a budget of about \$4 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 regulates 21,570 pharmacists, 3,445 preceptors, 1,495 pharmacist-interns, and 5,794 pharmacies. In fiscal year 2004, the Board will begin registering an estimated 26,500 pharmacy technicians.
- **Enforcement.** The Board received 1,893 jurisdictional complaints in fiscal year 2003, and resolved 1,850. Of the resolved complaints, 220 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 Board of Medical Examiners.

Organization

Policy Body

The Texas State Board of Pharmacy consists of nine voting members appointed by the Governor: six Registered Pharmacists who have been actively practicing pharmacy for the five previous years and three public members. The Board elects a president, vice president, treasurer, and other appropriate officers from its members for one-year terms. The chart, *Texas State Board of Pharmacy*, identifies current Board members.

Texas State Board of Pharmacy			
Member	City	Qualification	Term Expires
Doyle E. High, R.Ph., President	Haskell	Registered Pharmacist	2007
Oren M. Peacock, Jr., R.Ph., Vice President	Sachse	Registered Pharmacist	2005
Rosemary Forester Combs, Treasurer	El Paso	Public Member	2005
Roger W. Anderson, R.Ph., Dr. P.H.	Houston	Registered Pharmacist	2005
Juluette F. Bartlett-Pack, Ph.D.	Houston	Public Member	2007
W. Michael Brimberry, R.Ph., M.B.A.	Austin	Registered Pharmacist	2007
Kim A. Caldwell, R.Ph.	Plano	Registered Pharmacist	2003
Wiki Erickson, M.A.	Waco	Public Member	2003
Donna Burkett Rogers, R.Ph., M.S.	San Antonio	Registered Pharmacist	2003

Board duties fall primarily into three categories: setting pharmacy standards, licensure and registration, and enforcing the standards. Within the scope of these duties, the Board establishes qualifications for pharmacist licensure, including degree requirements of colleges of pharmacy in Texas, and standards for the operation of pharmacies.

To assist in developing standards, the Board forms task forces to provide additional expertise and advice on rules development. Recent examples include the task force on technician registration, which included six pharmacists and three certified technicians, and the task force on pharmacy drug compounding, which had nine members. Other task forces have advised the Board on pharmacists' working conditions, remote pharmacy services, peer review guidelines, and generic substitution.

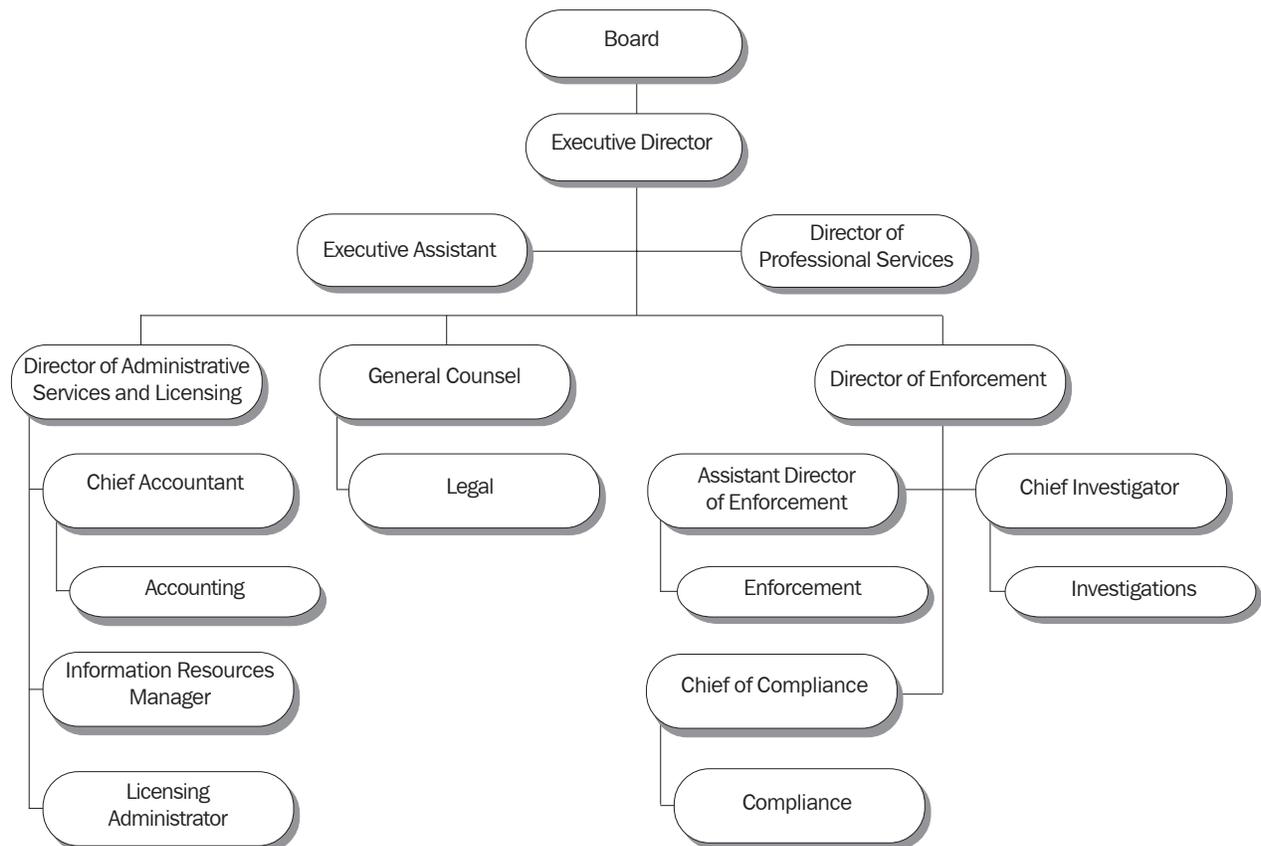
In addition to these main functions, the Board employs an Executive Director and approves the agency's operating budget and its legislative appropriations request.

Staff

The Board is allocated 48 full-time staff equivalents, and currently has a staff of 47. Of these staff, five investigators and five compliance officers work in the field; the rest work in Austin. The Executive Director, under the direction of the Board, manages the agency's day-to-day operations, and serves as the Board's secretary and a nonvoting ex officio Board member. Board employees work in five divisions: Office of the Executive Director, Professional Services, Administrative Services and Licensing, Enforcement, and Legal. The *Texas State Board of Pharmacy Organizational Chart* shows the agency's divisions with the number of full-time positions assigned to each.

The Board is a member of the Health Professions Council, which coordinates functions among various health care licensing agencies. The Council provides services to the Board, such as a copy center, mail and courier services, and access to imaging equipment.

Texas State Board of Pharmacy Organizational Chart



Appendix A compares the agency's workforce composition to the minority civilian labor force. Generally, where it does not exceed the standard, the agency comes close to meeting most of the civilian workforce standards. For example, in the area of agency administration, the Board falls below the civilian workforce for Hispanics in administration; however it far exceeds the civilian workforce in the number of women in administration.

Funding

Revenues

In fiscal year 2003, the regulation of pharmacies and the pharmacy profession generated revenue of almost \$4 million through various fees and assessments. As a licensing agency, the Board covers its administrative costs through licensing, renewal, and examination fees, and through

<i>Pharmacy Board Fees¹</i>	
License	Fee
Pharmacist – new license by exam	\$278
Pharmacist – new license by reciprocity	\$478
Pharmacist – renewal	\$225
Pharmacies	\$368
Pharmacies - renewal	\$365
Pharmacy Technicians	\$56
Pharmacy Technician - renewal	\$53

appropriated receipts for charges for services, such as providing copies of the Board's statutes and rules. In fiscal year 2003, revenue generated through these licensing and service charges totaled about \$3.9 million, which was deposited into a dedicated account for the Board in the State's General Revenue Fund. The Board adjusts licensing fees every two years to keep the revenues generated through fees consistent with expenditure needs. The Board's current licensing and examination fees are outlined in the chart, *Pharmacy Board Fees*.

In addition, the agency assesses administrative penalties against licensees. In fiscal year 2003, these penalties totaled \$94,150. The Board also collects a \$10 fee from pharmacists and pharmacy licenses for the Texas Online

System. The revenue from these penalties and fees, which totaled \$225,848 in fiscal year 2003, is not used to cover the agency's operating costs, but goes to the General Revenue Fund to be spent for other state purposes.

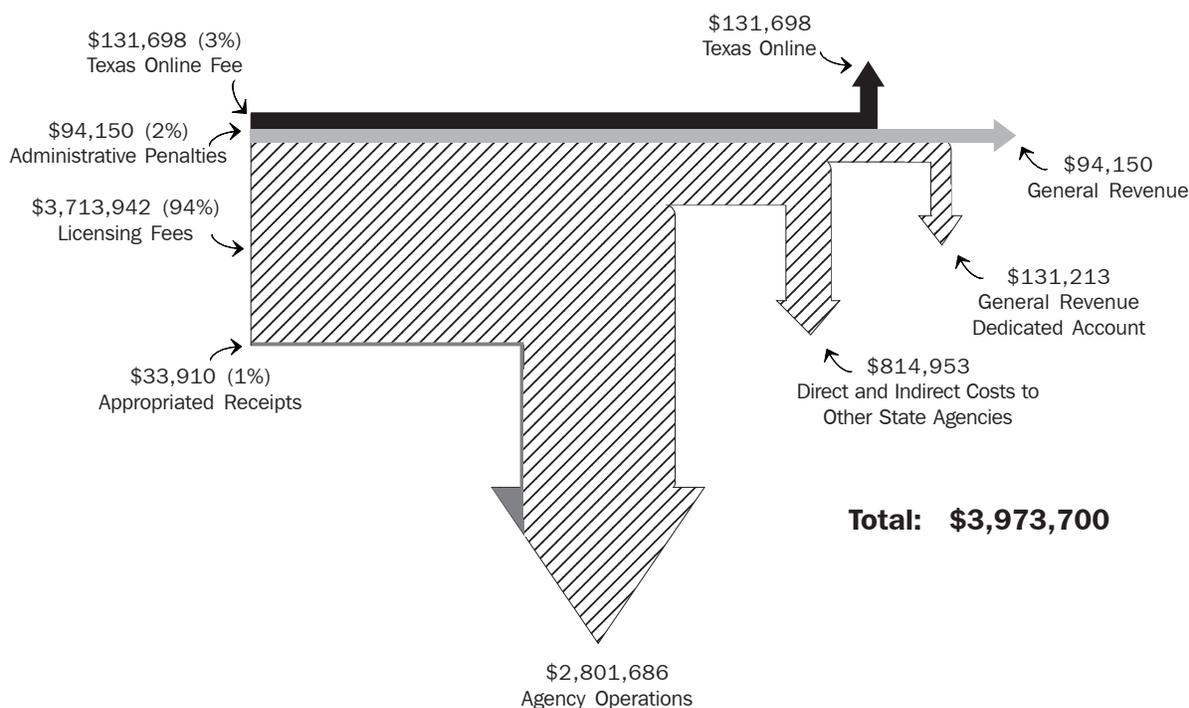
Because the Board consistently raises more than it spends and is in the unique position of having a dedicated General Revenue account, the Board's fund carries an unexpended balance of about \$4 million. These funds are not appropriated to the agency and, as a result, the Board cannot spend the funds. The Legislature has not swept this dedicated account since 1987.

Expenditures

In fiscal year 2003, the Board spent about \$2.9 million on three strategies: maintain standards, enforce regulations, and indirect administration. In addition, the Legislature has directed the Board and other licensing agencies that pay the costs of regulatory programs with fees levied on licensees to also cover direct and indirect costs appropriated to other agencies. Examples of these costs include rent and utilities paid by the State Building and Procurement Commission and employee benefits paid by the Employees Retirement System. In fiscal year 2003, these direct and indirect costs for the Board totaled \$814,953.

The chart, *Flow of Agency Revenue and Expenditures*, shows the overall impact of revenues and expenditures in fiscal year 2003. After subtracting the agency's operating expenses and the direct and indirect costs incurred by other agencies from the total of licensing fee revenue, \$131,213 went into the Board's dedicated account in the General Revenue Fund. Administrative penalties, amounting to \$94,150, were deposited directly into General Revenue to be used for other state purposes.

Flow of Agency Revenue and Expenditures FY 2003



Appendix B describes the Board's use of Historically Underutilized Businesses (HUBs) in purchasing goods and services for fiscal years 1999 to 2003. The Board uses HUBs in the categories of special trade, professional services, commodities, and other services. Although the agency fell short of the State's goal for the other services category, it has consistently surpassed the goal for commodities spending by a large margin. The Board must use a sole-source provider for information technology, which tends to skew the agency's purchases in the other services category.

Agency Operations

The Texas State Board of Pharmacy differs from most health-care licensing agencies in Texas in that it regulates both the professionals who dispense drugs and the facilities in which they practice. To ensure that only competent individuals dispense medications in a safe environment, the Board licenses pharmacists and pharmacies, registers pharmacist-interns, preceptors, and pharmacy technicians, and sanctions licensees who violate the law.



*The Board is fairly
unique in that it
regulates individuals
and facilities.*

Licensing and Examination

Pharmacies

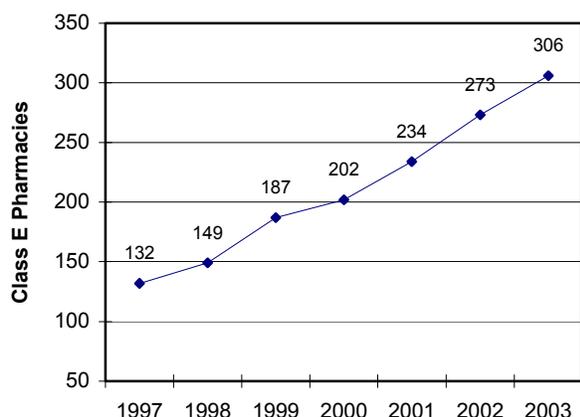
The Board licenses five types of pharmacies. The textbox, *Pharmacies in Texas*, describes each type of pharmacy licensed to dispense drugs in Texas and reflects the number of each type licensed in fiscal year 2003. While the Legislature previously created all classes of pharmacies, in 2003, through Senate Bill 1315, it delegated the authority to the Board to create new classes in rule.

★

The number of out-of-state pharmacies licensed in Texas has more than doubled since 1997 – an increase greater than any other class.

Pharmacies in Texas	
Class (# Licensed)	Description
A – Community (4,131)	Fill prescriptions for individuals in the community, including local individually owned, nationwide chain, and Texas-based Internet pharmacies. Some perform compounding services.
B – Nuclear (37)	Dispense radioactive drugs or devices to people who administer radiation therapy or nuclear testing, for example. Some nuclear pharmacies are located in hospitals, while others are stand-alone and contract with facilities.
C – Institutional (875)	Located in hospitals, long-term care facilities, ambulatory care centers, or the like.
D – Clinic (445)	Located in outpatient clinics and dispense drugs to both health-care providers and patients. These pharmacies do not typically have a pharmacist on duty at all times and have a limited formulary specific to the services they provide, such as family planning. Do not stock controlled substances.
E – Nonresident (306)	Located outside of the state, such as mail-order and Internet pharmacies, but dispense prescription drugs to Texas residents.

Out-of-State Pharmacy Growth



In 2003, the Board licensed 5,794 pharmacies, including issuing new licences to 508 pharmacies. The majority of licensed pharmacies are community, or Class A, pharmacies. However, in recent years, the number of out-of-state, or Class E, pharmacies has dramatically increased, as mail-order and Internet pharmacies become more prevalent. From 1997 to 2003, the number of Class E pharmacies more than doubled. This growth trend is reflected in the chart, *Out-of-State Pharmacy Growth*.

A pharmacy does not have to be owned by a pharmacist; however, each pharmacy must designate a pharmacist-in-charge, who is responsible for the legal operation of the pharmacy

along with the owner. To operate any class of pharmacy in Texas, applicants must provide extensive ownership information, including documentation of property ownership and lease information; and an approved credit application from a primary pharmacy wholesaler, or other proof of credit worthiness. Prospective pharmacy owners also undergo a criminal background check through the Texas Department of Public Safety (DPS). For corporate-owned pharmacies, the Board extends the criminal background check to the top four corporate officers.

Before issuing a pharmacy license, the Board conducts a pre-inspection of the pharmacy facility. The inspection includes assurance that the facility has adequate space for the scope of proposed services, adequate fixtures for storage and preparation, a sink with hot and cold water exclusive of restroom facilities, necessary reference library materials, and sufficient security to prevent inappropriate access to drugs. In addition to traditional brick-and-mortar pharmacies, the Board regulates remote pharmacies that operate under the oversight of a licensed pharmacist and include automated pharmacies, emergency medication kits in nursing homes, or telepharmacy systems.

Pharmacists

Only individuals licensed by the Board may practice pharmacy – including dispensing or distributing prescription drugs – in Texas. In fiscal year 2003, the Board licensed 21,570 pharmacists; 855 licenses were issued to new pharmacists.² To become a Registered Pharmacist, applicants must satisfy a criminal history background check conducted by DPS and meet education, examination, and experience requirements specified in the Texas Pharmacy Act and Board rules. Appendix C, *The Practice of Pharmacy*, describes some of the significant laws that shape the pharmacy profession.

Education. An applicant must graduate from a pharmacy school accredited by the Accreditation Council for Pharmacy Education and approved by the Board. Texas has five pharmacy schools:

- The University of Texas at Austin College of Pharmacy;
- Texas Tech Health Science Center School of Pharmacy;
- University of Houston College of Pharmacy;
- Texas Southern University College of Pharmacy and Health Sciences; and
- Texas A&M Kingsville School of Pharmacy.

Pharmacy schools, including those in Texas, offer a Doctor of Pharmacy – or PharmD – degree. This six-year program includes two years of prepharmacy and four years of pharmacy. Forty-one percent of the new pharmacists licensed by the Board each year graduated from a Texas college of pharmacy.³

The Board also approves applicants who have graduated from a foreign college of pharmacy and have obtained full certification from the National Association of Boards of Pharmacy's (NABP's) Foreign Pharmacy Graduate Examination Committee, which ensures that the applicant's pharmacy education meets United States standards.



*Texas has five
accredited schools of
pharmacy.*



*Forty-one percent of
new pharmacists
licensed by the Board
graduate from a
Texas college of
pharmacy.*

Experience. To be eligible for licensure, an applicant must complete 1,500 internship hours covering competency objectives determined by the Board. Typically, applicants participate in a student internship program while in pharmacy school. In fact, the Board annually reviews and approves internship programs designed by each of the pharmacy colleges in Texas.

Examination. Once an applicant has graduated from pharmacy school and fulfilled the internship requirement, the applicant is eligible to take the two exams required for licensure as a pharmacist in Texas. The North American Pharmacist Licensure Examination (NAPLEX) covers topics such as chemistry, mathematics, pharmacy, pharmacology, and the practice of pharmacy, and is used by all 50 states as part of their assessment of competence to practice pharmacy.⁴

Applicants also must pass the Multistate Pharmacy Jurisprudence Examination, which tests knowledge of federal and state pharmacy laws. The jurisprudence exam is based on a national blueprint of pharmacy jurisprudence competencies; however, the questions are tailored to the specific laws in each state.

Both NAPLEX and the jurisprudence exam are computer-based and are developed by NABP, based on input from the Board. Applicants take the exams on their own schedule at any contracted local testing center in Texas or nationwide. About 90 percent of test-takers pass both exams on their first try.⁵

Pharmacist Continuing Education

Pharmacists must complete 30 hours of continuing education every two years to renew their license. The Board accepts the following types of continuing education programs:

- any live or home-study program presented by a provider who is accredited by the American Council on Pharmaceutical Education (ACPE);
- courses that are part of a professional degree program or an advanced pharmacy degree program offered by a college of pharmacy which has a professional degree program accredited by ACPE;
- cardiopulmonary resuscitation (CPR) certification obtained through either the American Red Cross or the American Heart Association;
- attendance at a full, public Board business meeting in its entirety; and
- completion of an Institute for Safe Medication Practices' Medication Safety Self-Assessment for Hospital or for community/ambulatory pharmacies.

Because of the similarity of licensing requirements, pharmacists licensed in another state can receive a Texas license by satisfying the same educational requirements as a Texas applicant, passing NAPLEX and the jurisprudence exam specific to Texas laws, undergoing the criminal background check, and having a clean compliance history in the other states where licensed. About 68 percent of pharmacists in Texas are licensed by exam; 32 percent are licensed by reciprocity.

Pharmacists renew their licenses every two years and must have completed 30 hours of continuing education within that time. The types of acceptable continuing education programs are detailed in the textbox, *Pharmacist Continuing Education*.⁶

Pharmacists in good standing can complete their renewals through the Texas Online system. Approximately 32 percent of pharmacists now renew their licenses online.

Preceptors

Licensed pharmacists can obtain a certification from the Board that allows them to supervise pharmacist-interns. To be eligible for preceptorship, a pharmacist must have at least one year of experience and be free of disciplinary and enforcement actions for the previous three years. A pharmacist with disciplinary history in the previous three years may petition the Board for an exception to serve as a

preceptor. Preceptors then complete at least three hours of specialized preceptor course work. Preceptors are recertified every two years with their pharmacy licence renewal. In fiscal year 2003, 3,445 pharmacists acted as preceptors for pharmacist-interns – approximately two preceptors for every intern.

Pharmacist-Interns

Pharmacy students working on a Board-approved internship program must register with the Board as a student pharmacist-intern. Student pharmacist-interns have completed the first 30 hours of professional pharmacy school. The Board also registers extended pharmacist-interns, who have graduated from pharmacy school in another state or country and met the examination requirements for licensure, but lack the 1,500 internship hours needed to receive a pharmacist license.

Working under the guidance of a Board-approved pharmacist preceptor, interns may perform any duty of a pharmacist. When not under the supervision of a preceptor pharmacist, an intern may perform the duties of and function as a pharmacy technician, provided the intern is under the direct supervision of a pharmacist, and meets other training requirements. The ratio of pharmacists to interns must be 1-to-1 when the intern performs pharmacist duties.

Pharmacist-interns are subject to the same criminal background check as pharmacists. Registration as a pharmacist-intern remains in effect while students complete study and until they receive their examination results. In fiscal year 2003, the Board registered 1,495 pharmacist-interns.

Pharmacy Technicians

As a result of legislation from 2003, the Board now registers pharmacy technicians. Pharmacy technicians perform nonjudgmental tasks directly related to the preparation of a prescription under the direct supervision of, and are responsible to, a pharmacist. Examples of tasks that may be performed by a pharmacy technician are outlined in the textbox, *Pharmacy Technician Duties*.

To become registered, a pharmacy technician must have graduated from high school and passed an exam administered by the Pharmacy Technician Certification Board, a national organization with a Board-recognized certification. Pharmacy technicians will be required to complete 20 hours of continuing education biennially. While the Board has not fully implemented this program, staff anticipates registering approximately 26,500 technicians.

Most pharmacies operate with a ratio of no more than five technicians for every pharmacist. However, in 2003, the Legislature provided for pharmacies with a formulary limited to 20 or fewer drugs that does not produce injectable drugs to have a five-to-one ratio.



*In fiscal year 2003,
the Board registered
two preceptors for
every pharmacist
intern.*

Pharmacy Technician Duties

Tasks that a pharmacy technician may perform under the direct supervision of a pharmacist include:

- initiating and receiving refill authorization requests;
- entering prescription data into a data processing system;
- preparing and packaging drug orders (i.e., counting tablets and capsules, measuring liquids and placing them in the container);
- affixing the label to the prescription container;
- reconstituting medications; and
- prepackaging and labeling prepackaged drugs.


*Sixty-eight percent of
 the Board's staff works
 in the area of
 enforcement.*

Enforcement

Enforcement is key to the Board's ability to protect the public from the potential dangers associated with pharmaceuticals. Of its 48 employees, 32 – or 68 percent – work in the area of enforcement. To ensure safety for the public, the Board promotes voluntary compliance through inspections and by educating pharmacists and pharmacy owners about pharmacy laws and rules. In this vein, the Board adopts a philosophy of prevention. However, for pharmacies and pharmacists who do not comply with the law, the Board uses a range of sanctioning tools.

Inspections

To ensure an ongoing environment of safety in pharmacies, the Board conducts routine, unannounced pharmacy inspections on a two- to 2-1/2-year cycle. Inspectors also inspect pharmacies in response to complaints, and conduct pre-inspections for applicants seeking a license for a new pharmacy. To accomplish this, the Board employs six inspectors – most of whom are pharmacists. One works in the Austin office and five work out of their homes conducting field inspections in regions as described in the table, *Pharmacy Inspectors*.

When an inspector finds a pharmacy is not in compliance with Board regulations, the pharmacy generally receives a written warning notice identifying the violations and giving the pharmacy a detailed corrective action plan and due date. The inspector then follows up with another unannounced inspection to ensure that the pharmacy corrected the problems. If the pharmacy has not corrected

the problem to the satisfaction of the Board staff, the Board files a complaint against the pharmacy or pharmacist and an investigation ensues. Occasionally an inspector may find a serious violation, which is immediately referred to the Board's Legal Division for possible disciplinary action.

Pharmacy Inspectors	
Location	Region
<i>San Antonio</i>	San Antonio, South Texas
<i>Houston</i>	West Houston and surrounding areas, North Central and Central Texas
<i>Houston</i>	East Houston, East Texas, Southeast Texas
<i>Dallas</i>	Dallas, Fort Worth, Northeast Texas
<i>Breckenridge</i>	West Texas, Panhandle, El Paso and surrounding areas
<i>Austin</i>	Austin, Travis and surrounding counties

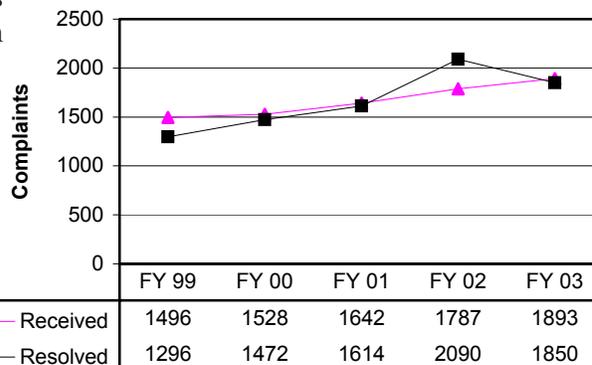
Complaints

In addition to inspecting pharmacies, the Board investigates complaints filed by the public. The Board accepts complaints by mail, Internet, or telephone (although staff asks that telephone complaints be subsequently submitted in writing), and typically investigates anonymous complaints as well. Since the Board began accepting Web-based complaints in 2001, the number of complaints filed online has increased considerably, with the Board receiving 19 in 2001, 261 in 2002, and 344 in fiscal year 2003. The Board

also may initiate complaints on its own, as it does with inspection findings or failure to provide required continuing education. Most complaints are generated by the public.

The chart, *Complaint Trends*, shows the growth in the number of complaints received and resolved by the Board over the last five years. These numbers differ because complaints may not be resolved in the same year that they were filed.

**Complaint Trends
FY 1999 - 2003**



Once a complaint is filed, Board staff determines if the complaint is jurisdictional and, may refer nonjurisdictional complaints to another appropriate regulatory body, such as another state pharmacy board, another Texas health-care profession board, the Texas Office of the Attorney General, or the Medicaid Fraud and Abuse Unit of the Health and Human Services Commission.

For complaints that involve potential violations of the Texas Pharmacy Act or Board rules, the Board conducts investigations to determine if probable cause exists to believe that a violation has occurred. The Board employs 10 investigators, five of whom are peace officers commissioned by the Texas Commission on Law Enforcement Standards and Education. Five investigators work in the Austin office and five field investigators work out of their homes conducting investigations across the state. The chart, *Pharmacy Field Investigators*, shows the regions, as well as the number of complaints resolved by each investigator. As peace officers, Board investigators are able to access the Texas Law Enforcement Telecommunications System (TLETS) to perform criminal background checks on pharmacists or pharmacy owners. Recent legislative changes now permit Board investigators to examine criminal records across all states.

Pharmacy Field Investigators				
Location	Region	Completed Investigations		
		2001	2002	2003
<i>Karnes City</i>	San Antonio, South Texas	59	42	39
<i>Pearland</i>	Houston, Deep East Texas	22	39	14
<i>Sherman</i>	Dallas, Northeast Texas	21	35	36
<i>Austin</i>	Austin, Central Texas	23	29	28
<i>Fort Worth</i>	Fort Worth, West Texas	33	62	14

For complex complaints or complaints that through initial findings appear to warrant disciplinary action, Board staff conduct review meetings in which the Executive Director, General Counsel, and enforcement staff consider the allegations and preliminary findings and, based on Board guidance, determine whether to investigate further or to pursue enforcement action through an informal settlement conference. For simple violations, such as not completing the required continuing education credits, Board staff includes a proposed settlement with the notification, which if agreed to by the licensee and Board, obviates the need for a conference.

More serious cases go to an informal settlement conference in which a panel – consisting of the Executive Director, the Director of Enforcement,

and one Board member, who may be a public member. At the settlement conference, the licensee is offered the opportunity to show compliance with the law, and the panel considers the information provided before proposing a disciplinary action in accordance with the Texas Administrative Procedure Act.

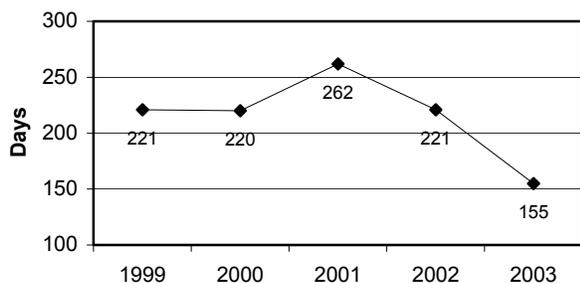
If the licensee agrees with the proposed sanction, the Board must approve the settlement agreement before entering a formal agreed order. If the licensee or the Board does not agree with the enforcement panel's proposed sanction, the case is referred to the State Office of Administrative Hearings. Ninety-seven percent of complaints that require sanctions are resolved through informal settlement conferences and both the licensee and Board

ultimately agree with the enforcement panel's recommendation. With the exception of substance abuse sanctions, Board disciplinary actions and sanctions are publicly available.

In fiscal year 2003, the Board resolved 1,850 complaints, with an average resolution time of 155 days. The chart, *Complaint Resolution Timeframes*, shows that the Board has consistently met its performance measure of resolving complaints within 300 days. The Board took enforcement

action on 213 licensees in fiscal year 2003, with 142 against pharmacists and 71 against pharmacies. Because the Board resolves most of its cases through agreed orders, in fiscal year 2003, only four cases were resolved through the State Office of Administrative Hearings. The chart, *Enforcement Actions*, shows the violations that were the basis of actions against a pharmacist or pharmacy and the sanctions taken by the Board. Most violations were from pharmacy practice deficiencies, which chiefly result from dispensing errors, such as dispensing the wrong drug or dose to failing to counsel patients about their medications. The Board estimates that 75 percent of errors that result in a disciplinary order might have been detected by counseling. The next most significant disciplinary category for pharmacists involves unprofessional conduct, which includes falsifying information on an application, failing to comply with a previously issued Board order, and controlled substance diversion.

Complaint Resolution Timeframes



Enforcement Actions FY 2003					
Type of Allegation/ Violation	Enforcement Action*				
	License Removed	Suspension/ Restriction	Fine	Reprimand	Other
Diversion	5	11	0	1	0
Conviction	4	15	0	2	0
Audit Discrepancy	0	8	16	5	0
Practice Deficiency	0	11	30	48	0
Unprofessional Conduct	9	20	15	4	0
Other	0	4	0	0	5
TOTAL	18	69	61	60	5

* As a result of a board order.
Diversion includes illegal delivery, illegal possession, theft of controlled substances and unauthorized dispensing.
Conviction includes deferred adjudication.
Audit Discrepancy includes drug audits and continuing education audits.
Practice Deficiency includes dispensing errors, no verbal counseling, no drug regimen reviews, and unauthorized substitution.
Unprofessional Conduct includes actions by other boards, non-compliance with previously entered orders, aiding and abetting.
Other includes orders reinstating a pharmacist license and orders to modify previously entered orders.

Pharmacy Peer Assistance Program

For pharmacists who develop substance abuse problems, the Board contracts with the Texas Pharmacy Association to administer the Pharmacist Recovery Network (PRN), Texas' pharmacist peer assistance program. Started in 1983, PRN is funded through a \$12 surcharge on pharmacy and pharmacist license renewals, and the agency expended \$159,014 in fiscal year 2003. The PRN operates a 24-hour toll-free hotline to accept reports of suspected impairment or requests for assistance. PRN staff then determines through formal evaluation by a mental health professional whether a substance abuse problem exists (with pharmaceuticals, illegal substances, or alcohol). If the pharmacist has a substance abuse problem, PRN works to develop a treatment plan for the pharmacist to get appropriate care, and works with the Board to establish expectations.

¹ Licensing renewal fees for pharmacists and pharmacies include a \$12 per license renewal surcharge for peer assistance and \$10 for Texas Online. Fees for pharmacy technicians include a \$3 Texas Online fee.

² Texas State Board of Pharmacy (TSBP), *Self-Evaluation Report*, submitted to the Sunset Advisory Commission (August 2003), p. 38.

³ Texas State Board of Pharmacy, *Annual Report, FY 2002* (Austin, Texas, 2002), p. 51.

⁴ California will begin using NAPLEX in January 2004.

⁵ TSBP, *Annual Report, FY 2002*, p. 50.

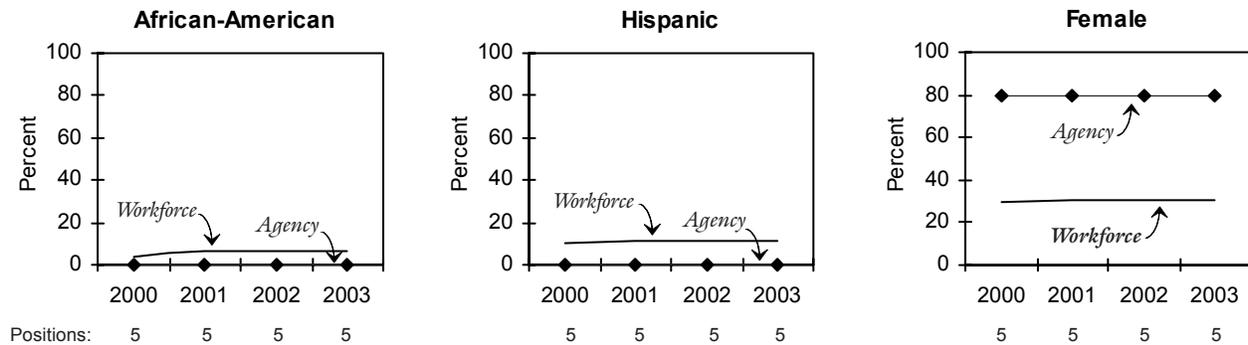
⁶ Texas Administrative Code, Title 22, part 15, rule 295.8.

APPENDICES

Equal Employment Opportunity Statistics 2000 to 2003

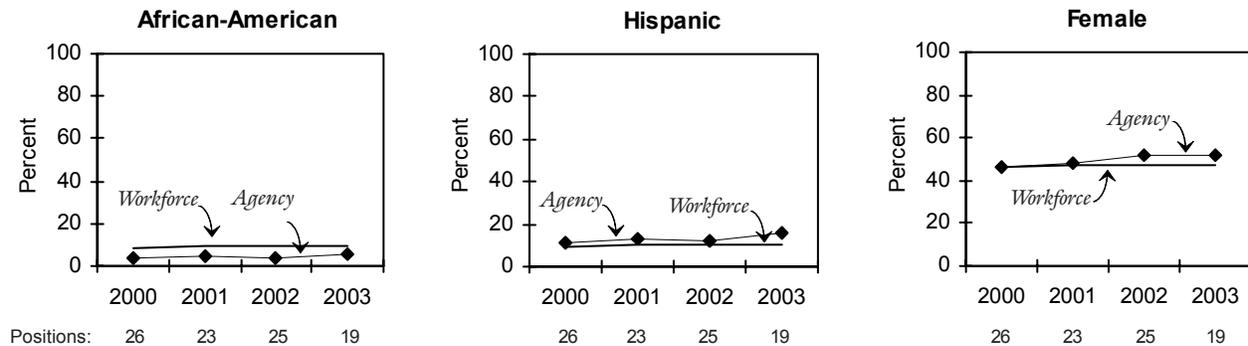
In accordance with the requirements of the Sunset Act, the following material shows trend information for the Texas State Board of Pharmacy employment of minorities and females in all applicable categories.¹ The agency maintains and reports this information under guidelines established by the Texas Commission on Human Rights.² In the charts, the solid lines represent the percentages of the statewide civilian workforce for African-Americans, Hispanics, and females in each job category. These percentages provide a yardstick for measuring agencies' performance in employing persons in each of these groups. The diamond-dashed lines represent the agency's actual employment percentages in each job category from 2000 to 2003.

Administration



The Board fell short of the State goal for African-American and Hispanics every year, but exceeded the goal for females each year.

Professional

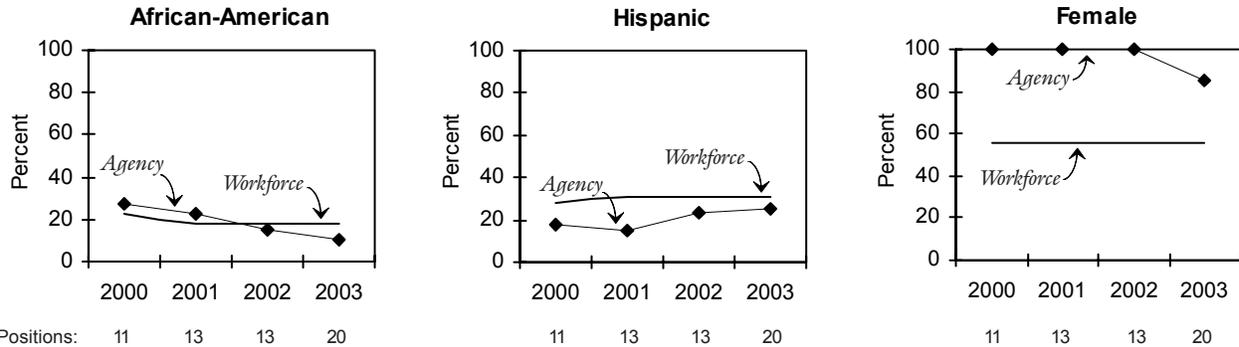


While the Board fell short of African-American employment each year, it met or exceeded for Hispanics and females each year.

Appendix A

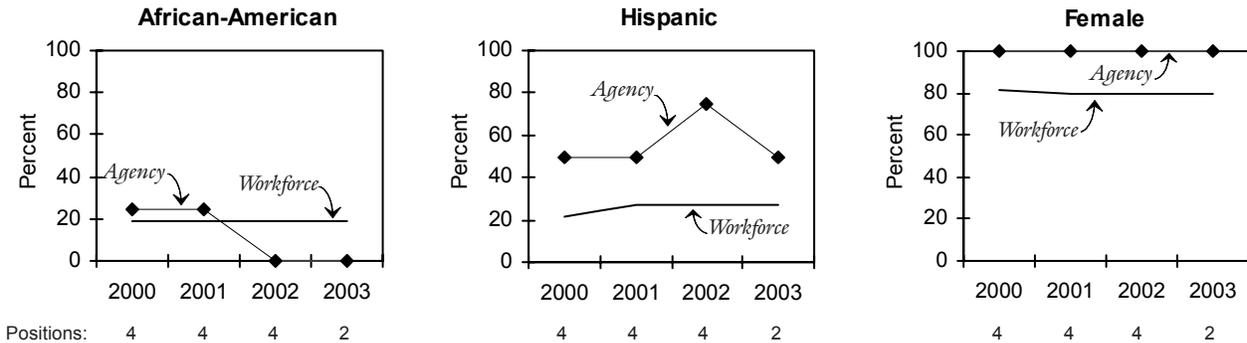
Equal Employment Opportunity Statistics

Para-Professionals



The Board exceeded State goals for African-American employees in fiscal years 2000 and 2001, but fell short in 2002 and 2003. The Board fell short of Hispanic employment State goals each year, but exceeded goals for female employment each year.

Administrative Support



The Board has generally exceeded State employment goals each year for African-American, Hispanic, and females, with the exception of fiscal years 2002 and 2003, in which it fell short of the goals for African-American employment.

¹ Texas Government Code, sec. 325.011(9)(A).

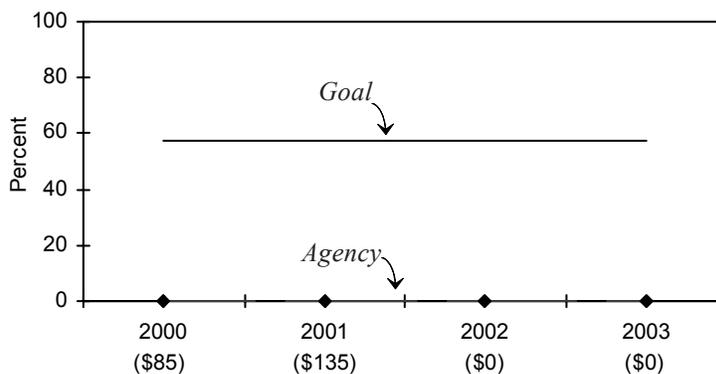
² Texas Labor Code, sec. 21.501. The Texas Human Rights Commission (HRC) has been the agency responsible for collecting and distributing EEO data. During the 2003 Session, the Legislature passed HB 2933 transferring the functions of HRC to a new civil rights division within the Texas Workforce Commission (TWC). The legislation is to take effect upon certification of the TWC civil rights division by the appropriate federal agency; no specific date has yet been established.

Historically Underutilized Businesses Statistics 2000 to 2003

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 the Texas Building and Procurement Commission's statute.² In the charts, the flat lines represent the goal for HUB purchasing in each category, as established by the Texas Building and Procurement Commission. The diamond-dashed lines represent the percentage of agency spending with HUBs in each purchasing category from 2000 to 2003. Finally, the number in parentheses under each year shows the total amount the agency spent in each purchasing category.

Special Trade

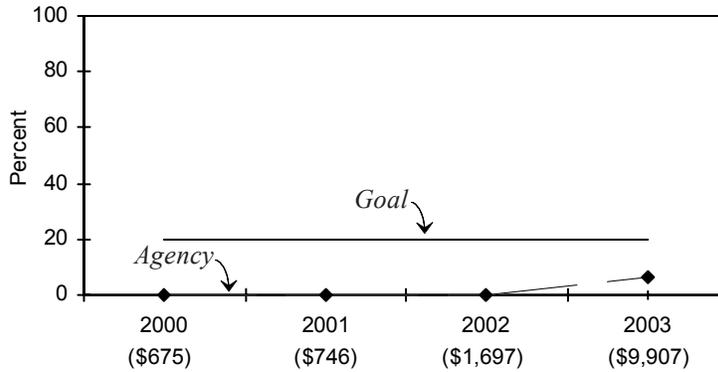


The Board fell short of the State goal, but has not spent much in this category.

Appendix B

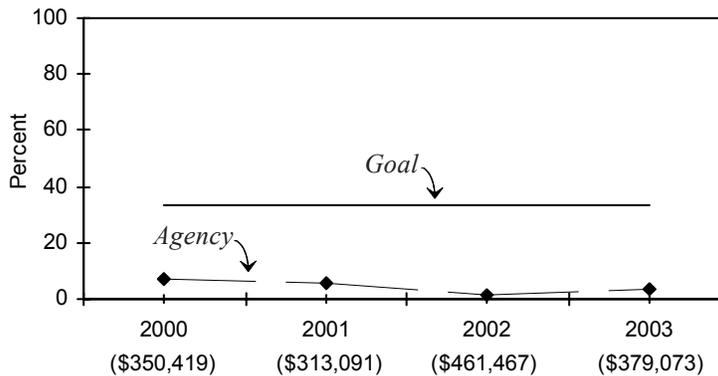
Historically Underutilized Businesses Statistics

Professional Services



The Board has fallen short of the State's goal for HUB, but has had little spending on professional services.

Other Services

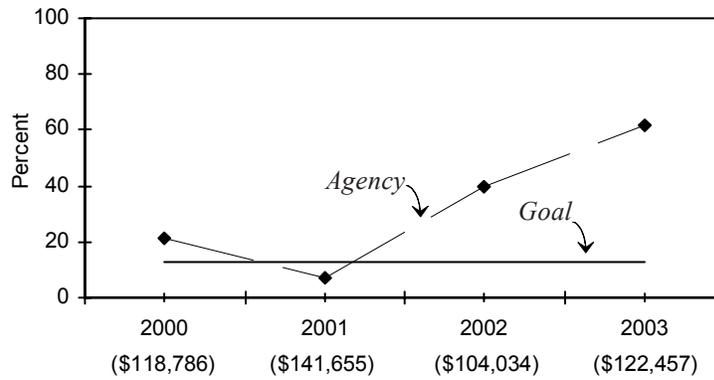


The Board has fallen short of the State's goal for HUB spending for other services because most of the Board's spending in this category is for its sole source contract for information services through the Department of Information Resources.

Appendix B

Historically Underutilized Businesses Statistics

Commodities



The Board has exceeded the State's goal for HUB spending on commodities for every year except 2001.

¹ Texas Government Code, sec. 325.011(9)(B).

² Texas Government Code, ch. 2161.

The Practice of Pharmacy

The practice of pharmacy involves more than simply counting pills and labeling bottles as prescribed by a physician. As a member of a larger health-care team, a pharmacist is responsible for providing patients with safe pharmaceutical therapy. To accomplish this, pharmacists must possess knowledge of pharmaceutical therapy and drug interactions, in addition to the numerous bodies of law governing pharmaceuticals, and must exercise good judgment to ensure patient safety in dispensing drugs. Laws governing the practice of pharmacy and pharmaceuticals in Texas include:

- Texas Pharmacy Act and Board rules;
- Texas Controlled Substance Act and rules;
- Texas Dangerous Drug Act;
- Texas Food, Drug, and Cosmetic Act;
- Federal Food, Drug, and Cosmetic Act;
- Federal Controlled Substances Act and rules;
- Poison Prevention Packaging Act; and
- Health Insurance Portability and Accountability Act.

These laws define the practice of pharmacy, set up minimum standards for pharmacy operations, and regulate numerous pharmaceuticals. The practice of pharmacy is primarily governed by Texas state laws, while drug regulation is primarily handled by federal law. The Texas Pharmacy Act defines the practice of pharmacy to include:

- providing pharmaceutical care;
- interpreting or evaluating a prescription drug order or medication order;
- participating in drug or device selection, administration, regimen review, and research;
- providing patient counseling;
- assuming responsibility for dispensing drug orders, compounding drugs, safely storing drugs, maintaining records, and overseeing delegated technician tasks;
- carrying out drug management therapy as delegated by a physician; and
- administering immunizations under protocol.

Pharmaceuticals, largely regulated by the U.S. Food and Drug Administration, are divided into two categories: nonprescription drugs, or over-the-counter (OTC) drugs; and prescription drugs, sometimes called legend drugs. Federal regulations focus on prescription drugs, which are considered potentially harmful if not used under the supervision of a licensed health-care practitioner. Some prescription drugs have additional restrictions because of their potential for abuse and are called controlled or scheduled drugs.

Appendix C

The Practice of Pharmacy

Scheduled drugs are further classified, I to V, by the U.S. Drug Enforcement Administration according to their potential for abuse. Schedule I includes drugs with an extremely high abuse risk and no accepted medicinal value in the United States, such as heroin, marijuana, LSD, and crack cocaine. Schedule II includes drugs with a high abuse risk, but also safe and accepted medical uses, such as morphine, Percodan, and Ritalin. Schedules III and V have a lower abuse risk, as well as an accepted medical use, and includes Tylenol 3, paregoric, Vicodin, Valium, and Xanax.

To further regulate addictive drugs, in 1981, Texas began requiring that physicians write Schedule II prescriptions on a triplicate form, with one copy maintained by the physician, one retained by the pharmacist, and one sent to the Texas Department of Public Safety (DPS) by the pharmacist. Schedule II triplicate prescriptions, permitted to be written only by physician, expire after seven days. Recent changes to the Schedule II laws still require a special prescription form, but permit pharmacies to submit information to DPS electronically. This extensive documentation permits the state to track potential abuse of these risky drugs.

Staff Review Activities

Sunset staff engaged in the following activities during the review of the Texas State Board of Pharmacy.

- Worked extensively with agency staff.
- Attended Board meetings and interviewed Board members.
- Reviewed Board documents and reports, state statutes, legislative reports, previous legislation, and literature on pharmacy issues.
- Met with in person or interviewed over the phone staff from the Texas Department of Health, Texas Health and Human Services Commission, Texas State Board of Medical Examiners, Texas Board of Nurse Examiners, Texas State Board of Dental Examiners, Texas Board of Chiropractic Examiners, Texas Optometry Board, and Texas State Board of Veterinary Medical Examiners.
- Conducted telephone interviews with staff from the U.S. Drug Enforcement Administration, the U.S. Food and Drug Administration, the National Association of Boards of Pharmacy, and the National Pharmacy Technician Certification Board.
- Conducted interviews and solicited written comments from state and national interest groups.
- Worked with the Governor's Office, Lieutenant Governor's Office, Speakers's Office, Legislative Budget Board, legislative committees, and legislator's staffs.
- Reviewed reports by the Legislative Budget Board, State Auditor's Office, National Association of Boards of Pharmacy, U.S. General Accounting Office, U.S. Food and Drug Administration, U.S. Substance Abuse and Mental Health Services Administration, and National Institute on Drug Abuse.
- Attended informal settlement conference hearings conducted by Board staff.
- Attended a complaint/case review conducted by Board staff.
- Accompanied Board staff on compliance inspections and complaint investigations.
- Researched the functions of pharmacy boards in other states, including conducting telephone interviews with staff from other state boards of pharmacy.
- Attended national conference on pharmacy issues.

**SUNSET REVIEW OF THE
TEXAS STATE BOARD OF PHARMACY**

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