

Summary

The Texas State Board of Pharmacy (the Board) was created in 1907 to regulate the practice of pharmacy, the operation of pharmacies, and the distribution of prescription drugs. The Board has the following primary functions: 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; and enforcing the Texas Pharmacy Act by investigating and resolving complaints against pharmacists, pharmacies, and pharmacy technicians. The Board operates with an annual budget of \$3.2 million, and has 48 staff positions.

Senate Bill 410 continues the Board for 12 years, and contains the Sunset Commission recommendations to strengthen the Board's regulation of pharmacists and pharmacies in Texas and licensed out-of-state pharmacies, such as Internet pharmacies. The bill also strengthens the Board's regulation of pharmacy technicians and establishes the regulation of pharmacy technician trainees to provide better control over persons having access to prescription drugs and controlled substances. Finally, the Legislature added a provision for the Board to authorize at least one, but not more than 10, Canadian pharmacies to ship prescription drugs to Texas residents. The list below summarizes the major provisions of S.B. 410, and a more detailed discussion follows.

Sunset Provisions

1. Strengthen the Board's Ability to Regulate Out-of-State Pharmacies.
2. Update the Board's Enforcement Authority to Address Needs Created by Changes in the Pharmacy Industry.
3. Conform Key Elements of the Board's Licensing and Regulatory Functions to Commonly Applied Licensing Practices.
4. Expand the Board's Enforcement Authority Over Pharmacy Technicians.
5. Authorize the Board to Register and Discipline Pharmacy Technician Trainees.
6. Make Confidential Personal Information About Persons Licensed and Registered by the Board.
7. Continue the Texas State Board of Pharmacy for 12 Years.

Provisions Added by the Legislature

8. Require the Pharmacy Board to Authorize Canadian Pharmacies to Dispense Prescription Drugs to Texas Residents on a Limited Basis.

9. Simplify the Process Between a Physician and a Pharmacist for Prescribing Certain Controlled Substances.
10. Allow the Board to Recognize Other Health-Care Professionals Besides Pharmacists as Preceptors to Supervise Pharmacist-Interns.
11. Clarify the Board's Jurisdiction Over Pharmacists With Expired Licenses for Enforcement Purposes.

Sunset Provisions

1. Strengthen the Board's Ability to Regulate Out-of-State Pharmacies.

Senate Bill 410 contains several provisions to hold out-of-state pharmacies to the same standards as in-state pharmacies. To be licensed by the Board, these pharmacies must meet comparable standards such as providing proof of credit worthiness and having a suitable inspection report. Out-of-state pharmacies also will be subject to the same grounds for disciplinary action as in-state pharmacies.

The bill also clarifies the Board's ability to take disciplinary action against out-of-state pharmacies. The bill removes 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 may initiate disciplinary action against one of these pharmacies without having to wait to allow the pharmacy board in the state where the pharmacy is located to take action first.

Senate Bill 410 requires out-of-state pharmacies to post on their Internet home page general information on filing a complaint with the Board. More detailed information on how to file a complaint with the Board must be no more than two links away from the pharmacy's initial home page. In addition, the Board must provide on its Web site information about Internet pharmacies licensed by the Board, including the pharmacy's name, license number, and state of physical location.

The bill also requires a pharmacist or pharmacy to determine that a prescription is valid before dispensing it, and prohibits the dispensing of a prescription drug if the pharmacist or pharmacy knows or should know that the prescription was issued on the basis of an Internet-based or telephonic consultation without a valid practitioner-patient relationship, except in emergencies.

2. Update the Board's Enforcement Authority to Address Needs Created by Changes in the Pharmacy Industry.

Senate Bill 410 expands the grounds for the Board to take enforcement action against Texas pharmacists and pharmacies. Specifically, pharmacists will be subject to disciplinary action for inadequate supervision of a pharmacy technician. Pharmacists and pharmacies will be subject to the Board's full range of disciplinary action for failure to comply with Board rules or orders, including confidential orders or contracts for pharmacists entered into through the Pharmacy Recovery Network peer assistance program. The bill also adds deferred adjudication to convictions for felonies or misdemeanors involving moral turpitude or that relate to statutes affecting the practice of pharmacy to the grounds for the Board to discipline pharmacists and pharmacy owners.

The bill allows the Board to discipline pharmacists and pharmacies – including out-of-state pharmacies – based on disciplinary action taken by another state pharmacy board, if the conduct is also a violation

of Texas law. This authority also applies to an out-of-state pharmacy that is disciplined by another state's board. The bill also holds pharmacists and pharmacy owners responsible for drug audit shortages, allowing the Board to pursue a more significant offense than the finding of inadequate record keeping, which is the only offense currently available to the Board.

3. Conform Key Elements of the Board's Licensing and Regulatory Functions to Commonly Applied Licensing Practices.

To bring the Board in line with standard licensing agency practices, Senate Bill 410 includes the following provisions.

- Requires the Board to adopt procedures to ensure that its exams are accessible to persons with disabilities in accordance with the Americans with Disabilities Act.
- Authorizes the Board to establish policies regarding nonrefundable testing fees.
- Simplifies the process for a pharmacist who holds an active license in another state to be licensed in Texas.
- Bases delinquent license renewal fees on the Board's normally required renewal fee.
- Authorizes staff to dismiss baseless cases.
- Increases the amount of the Board's administrative penalty authority and requires the Board to adopt an administrative penalty matrix in rule.
- Removes the requirement that a majority of Board members must approve temporary suspension of a license and provide for the temporary suspension of pharmacies' licenses.
- Authorizes the Board to use cease-and-desist orders with regard to practicing pharmacy without a license.
- Allows pharmacy faculty members to be eligible to serve on the Board.
- Authorizes Board members to receive reimbursement for travel expenses.
- Requires the Board to establish guidelines for Board subcommittees.
- Eliminates the Pharmacy Board Operating Account allowing the Board's funds to be deposited into and received from the General Revenue Fund.

4. Expand the Board's Enforcement Authority Over Pharmacy Technicians.

The bill expands the range of sanctions available to the Board in disciplining pharmacy technicians. In addition to the Board's current authority to refuse to issue or renew, suspend, or revoke a pharmacy technician's license, the Board will have authority to reprimand a pharmacy technician, restrict, retire, or temporarily suspend a pharmacy technician's registration, place the pharmacy technician on probation with certain guidelines, or impose an administrative penalty against a pharmacy technician. These changes bring the range of disciplinary sanctions for pharmacy technicians in line with those for pharmacists.

The Legislature added language to make pharmacy technicians subject to discipline if they receive deferred adjudication for any felony or misdemeanors involving moral turpitude or that relate to statutes affecting the practice of pharmacy. This language reflects the same provisions in the bill related to pharmacists and pharmacy owners placed on deferred adjudication.

5. Authorize the Board to Register and Discipline Pharmacy Technician Trainees.

Senate Bill 410 authorizes the Board to register individuals while they are working in a pharmacy as pharmacy technician trainees subject to qualifications specified by Board rule. The Legislature added language to authorize the Board to hold trainees to the same disciplinary grounds and disciplinary actions that are applied to pharmacy technicians, pharmacists, and pharmacies. As a result, trainees will be subject to discipline if they receive deferred adjudication for felonies or certain misdemeanors, just like pharmacy technicians. Trainees also will now be subject to temporary suspension and the full range of other disciplinary sanctions, including being reprimanded, placed on probation, or assessed an administrative penalty, in addition to being suspended or revoked.

6. Make Confidential Personal Information About Persons Licensed and Registered by the Board.

The bill makes information regarding the home address and telephone number of licensees and registrants confidential and not subject to disclosure under the Texas Public Information Act, clarifying and expanding the original Sunset Commission provision that pharmacists have the option of making this information confidential. Each person licensed or registered by the Board must provide a business address or address that is subject to disclosure and that may be posted on the Board's Internet site or in the Board's licensure verification database.

7. Continue the Texas State Board of Pharmacy for 12 Years.

The Board will continue as a separate, stand-alone agency for the standard 12-year period.

Provisions Added by the Legislature

8. Require the Pharmacy Board to Authorize Canadian Pharmacies to Dispense Prescription Drugs to Texas Residents on a Limited Basis.

The Legislature added a provision to require the Board to designate at least one, but not more than 10, Canadian pharmacies to dispense prescriptions under a prescription drug order to residents of Texas. To be designated by the Pharmacy Board to dispense prescription drugs to Texas, Canadian pharmacies must comply with safety standards and other requirements of the Texas Pharmacy Act and Board rules, and must meet additional qualifications, such as holding a Canadian license in good standing and being able to adequately respond to Board requests for information. The bill also limits the types of drugs that Canadian pharmacies may dispense to Texas residents.

Before a Canadian pharmacy may be designated to dispense prescription drugs to Texas residents, it must pass an initial inspection by the Pharmacy Board. Thereafter, these pharmacies are subject to

random inspections, conducted at least annually, that the Board may provide through an agreement with another state. The Board must set fees to cover its costs of inspecting these pharmacies, and must establish a Web site to provide information to enable Texas residents to conveniently order prescription drugs from designated Canadian pharmacies.

9. Simplify the Process Between a Physician and a Pharmacist for Prescribing Certain Controlled Substances.

The Legislature added a provision to eliminate the requirement that a physician who prescribes a schedule II controlled substance and faxes it to a pharmacy must deliver in person or by mail the official written copy to the pharmacist. Instead, the physician, after faxing the prescription, must write “void” on the original prescription and file it in the patient’s records.

10. Allow the Board to Recognize Other Health-Care Professionals Besides Pharmacists as Preceptors to Supervise Pharmacist-Interns.

The Legislature added this provision to allow other health-care professionals to serve as preceptors in situations, such as clinical rotations, in which pharmacy interns may need to be under the supervision of practitioners other than pharmacists, such as physicians.

11. Clarify the Board’s Jurisdiction Over Pharmacists With Expired Licenses for Enforcement Purposes.

The Legislature added a provision to ensure that the Board retains jurisdiction over pharmacists whose licenses have expired if they are subject to pending investigation or disciplinary action.

Provision Removed by the Legislature _____

1. Authorize the Board to Access Sales and Pricing Data During Investigations That Resulted From a Complaint or Previously Failed Inspection.

The Legislature did not adopt the Sunset provision removing the limitation on the Board’s access to sales and pricing data during a Board investigation of 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.

Fiscal Implication Summary _____

Senate Bill 410 contains provisions that will have an overall gain to the General Revenue Fund of \$4,847,320 in fiscal year 2006 and \$33,320 in fiscal year 2007 and each year thereafter. These provisions are discussed below, followed by a five-year summary chart.

Eliminating the Pharmacy Board Operating Account will result in \$4,814,000, as estimated by the Comptroller of Public Accounts, being transferred to the General Revenue Fund on September 1, 2006. The provision changing the basis of the late renewal penalties for pharmacists and pharmacies will result in a loss of revenue to the State of \$8,680 per year.

Provisions in the bill expanding the Board's disciplinary authority over pharmacy technicians and establishing the regulation of pharmacy technician trainees will result in additional costs to the Board of \$240,093 in fiscal year 2006 and \$191,446 in fiscal year 2007 and each year thereafter. The Legislature included a contingency appropriation in the General Appropriations Act for these costs to pay for increased overall technology costs and for three additional employees required for the anticipated increased workload associated with the growth in enforcement cases against pharmacy technicians and trainees. This appropriation is contingent on the Board assessing fees sufficient to cover these costs.

The strengthened enforcement authority over pharmacy technicians and trainees will also result in a revenue gain of \$42,000 annually from added enforcement orders and probationary fees assessed against registrants who violate the law or Board rule.

Providing for the Board to designate up to 10 Canadian pharmacies to distribute drugs to Texas residents will have costs of \$25,040 annually for staff travel to inspect these pharmacies and to address complaints against these pharmacies. However, because the Board did not receive additional funding for this provision, it must cover these costs with its current resources, at no additional cost to the State.

<i>Fiscal Year</i>	<i>Gain to the General Revenue Fund</i>	<i>Cost to the General Revenue Fund</i>	<i>Loss to the General Revenue Fund</i>	<i>Net Effect on the General Revenue Fund</i>	<i>Change in Staff Positions From FY 2005</i>
2006	\$5,096,093	\$240,093	\$8,680	\$4,847,320	+3
2007	\$233,446	\$191,446	\$8,680	\$33,320	+3
2008	\$233,446	\$191,446	\$8,680	\$33,320	+3
2009	\$233,446	\$191,446	\$8,680	\$33,320	+3
2010	\$233,446	\$191,446	\$8,680	\$33,320	+3