

SELF-EVALUATION REPORT
TO THE

SUNSET ADVISORY
COMMISSION

Submitted by

Texas State Board of Pharmacy

August 2015

TABLE OF CONTENTS

I. Agency Contact Information.....	1
II. Key Functions and Performance.....	1
III. History and Major Events.....	10
IV. Policymaking Structure	30
V. Funding.....	37
VI. Organization.....	40
VII. Guide to Agency Programs	
Indirect Administration Program.....	41
Licensing Program.....	52
Enforcement Program.....	86
VIII. Statutory Authority and Recent Legislation.....	148
IX. Major Issues	
1. Self-Direct/Semi-Independent Status for the Texas State Board of Pharmacy.....	153
2. Diversion of Controlled Substances Through the Dispensing of Prescriptions Without a Valid Medical Need.....	156
3. Underutilization of the Clinical Knowledge and Skills of Pharmacists in the Current Health Care System.....	157
4. Increase Licensee Compliance with Laws and Rules Relating to the Practice of Pharmacy Through Education of Licensees.....	158
5. Retirement of the Current Executive Director.....	159
6. Physician Dispensing.....	160
7. Dual Standards for Pharmacy Practice in Small and Large Hospitals.....	161

8.	Program for Pharmacy Technicians Who are Impaired by Chemical Abuse or Mental or Physical Illness.....	161
9.	Appropriate Level of Training and Supervision for Pharmacy Technicians.....	162
10.	Maintaining Agency’s Leadership Position in Pharmacy Practice Regulation Through Adequate Staffing and Adequate Compensation of Highly Qualified Agency Personnel.....	163
X.	Other Contacts.....	164
XI.	Additional Information.....	166
	Reporting Requirements.....	167
	Complaint Data.....	167
	Historically Underutilized Business (HUB) Data.....	167
	Equal Employment Opportunity (EEO) Data.....	169
XII.	Agency Comments.....	171

Texas State Board of Pharmacy Self-Evaluation Report

I. Agency Contact Information

A. Please fill in the following chart.

Exhibit 1: Agency Contacts

	Name	Address	Telephone & Fax Numbers	Email Address
Agency Head	Gay Dodson, R.Ph.	333 Guadalupe St, Suite 3-600; Austin TX 78701	512-305-8025 p 512-305-8082 fax	gay.dodson@pharmacy.texas.gov
Agency's Sunset Liaison	Cathy Stella	333 Guadalupe St, Suite 3-600; Austin TX 78701	512-305-8013 p 512-305-8075fax	cathy.stella@pharmacy.texas.gov

II. Key Functions and Performance

A. Provide an overview of your agency's mission, objectives, and key functions.

Mission

The mission of the Texas State Board of Pharmacy (TSBP) is to promote, preserve, and protect the public health, safety, and welfare by fostering the provision of quality pharmaceutical care to the citizens of Texas, through the regulation of: the practice of pharmacy; the operation of pharmacies; and the distribution of prescription drugs in the public interest.

Objectives

The Agency Objectives are as follows:

- (1) To establish and implement reasonable standards for pharmacist, pharmacy technician and pharmacy technician trainee education and practice, and for the operations of pharmacies to assure that safe and effective pharmaceutical care is delivered to the citizens of Texas [Texas Pharmacy Act (Occupations Code, Sec. 555-566 and 568-569)];
- (2) To assertively and swiftly enforce all laws relating to the practice of pharmacy:
 - (A) ensure that the public health and safety are protected from the following to:
 - incompetent pharmacists, pharmacy technicians and pharmacy technician trainees;

- unprofessional conduct, fraud, and misrepresentation by licensees;
 - diversion of prescription drugs from pharmacies; and
- (B) promote positive patient outcomes through the following:
- reduction of medication errors by encouraging or requiring licensees to implement self-assessment programs and continuous-quality improvement programs, including peer review processes; and
 - enforcement of rules relating to patient counseling and drug regimen review, including prevention of misuse and abuse of prescription drugs. [Texas Pharmacy Act (Occupations Code, Sec. 551-569), and Health and Safety Code, Chapter 483, Dangerous Drugs]; and
- (3) To establish and implement policies governing purchasing and public works contracting that foster meaningful and substantive inclusion of historically underutilized businesses (HUBs).

Key Functions

The agency’s key functions are:

- (1) Formulating public policy with regard to the practice of pharmacy through rulemaking (e.g., setting standards) and regulation (e.g., disciplinary actions);
- (2) Licensing qualified individuals to practice pharmacy or operate a pharmacy, and renewing those licenses on a biennial basis;
- (3) Registering qualified individuals to serve as pharmacist-interns, pharmacist-intern trainees, preceptors, pharmacy technicians, pharmacy technician trainees, and renewing those registrations;
- (4) Enforcing the laws relating to the practice of pharmacy by conducting inspections, investigating complaints, prosecuting licensees found in violation of pharmacy laws/rules, and monitoring licensees who are subject to disciplinary action;
- (5) Providing information regarding public records and agency services; and
- (6) Promoting voluntary compliance by providing information and technical assistance with regard to interpretations of laws/rules governing the practice of pharmacy.

B. Do your key functions continue to serve a clear and ongoing objective? Explain why each of these functions is still needed. What harm would come from no longer performing these functions?

Yes, the agency functions absolutely continue to serve a clear and ongoing overall objective to promote, preserve, and protect the public health and safety. TSBP is needed to promote, preserve, and protect the public health and safety, by:

- (1) Preventing incompetent or unqualified individuals from obtaining a license to practice or operate a pharmacy, or a registration to serve as a pharmacist-intern, preceptor, or pharmacy technician;
- (2) Removing licenses or registrations, after due process, of unscrupulous or incompetent individuals who violate the pharmacy and drug laws;
- (3) Helping to ensure that patients do not receive incorrect, adulterated, or misbranded prescription drugs or devices from pharmacies;
- (4) Preventing diversion of prescription drugs from pharmacies, so that dangerous and/or addictive drugs are not dispensed, distributed, delivered, or supplied in any manner except upon the order of a valid doctor-patient relationship; and
- (5) Promoting pharmaceutical care to increase the probability of desired patient outcomes and decrease the probability of undesired outcomes from drug therapy.

C. What evidence can your agency provide to show your overall effectiveness and efficiency in meeting your objectives?

Evidence that the agency is effective and efficient in meeting the objective can be shown through:

- (1) Accomplishment of 99% of the internally established Goals and Objectives for the agency in FY2014;
- (2) Met or exceeded 100% of the agency 10 Performance Measurers established in the Appropriations Act in FY2014;
- (3) An exception-free financial audit by the State Comptroller of Public Accounts in FY2014 (No issues were identified for payroll, purchase and travel transactions. In addition, the Board's internal control structure was reviewed and no issues were identified); and
- (4) An exception-free compliance audit in FY2013 of the agency's personnel policies and procedures systems by the Texas Workforce Commission Civil Rights Division.

D. Does your agency's enabling law continue to correctly reflect your mission, objectives, and approach to performing your functions? Have you recommended changes to the Legislature in the past to improve your agency's operations? If so, explain. Were the changes adopted?

Yes, the agency's enabling law continues to correctly reflect our mission, objectives, and approach to performing our function.

The agency has suggested changes to the statutes to improve the agency's operations in almost every session for the last 10 years, see the Texas Timeline in Section III. For example, during the 2015 Legislative Session, the agency suggested several changes that were included in Senate Bill 460 that was passed during the session. This bill made the following changes the Texas Pharmacy Act.

Senate Bill 460 amended the Pharmacy Act to:

- (1) Allow a pharmacy to use an electronic messaging system (digital marquee) to notify consumers how to file a complaint.
- (2) Allow the Board to inspect financial records relating to the operation of a pharmacy only in the course of an investigation of a specific complaint;
- (3) Allow the Board to inspect the records of a pharmacist if the pharmacist practices outside a licensed pharmacy;
- (4) Specify that a person cannot own a Class E Pharmacy license if the person has held a pharmacist license in this or another state that has been restricted, suspended, revoked, or surrendered for any reason;
- (5) Specify that a pharmacy license may not be renewed if the license has expired for 91 days or more;
- (6) Requires a pharmacy to report to the Board in writing no later than 30-days before the date of a change of location;
- (7) Prohibit waiving, discounting, or reducing, or offering to waive, discount, or reduce a payment copayment or deductible for a compounded drug in the absence of a legitimate, documented patient financial hardship; or evidence of a good faith effort to collect; and
- (8) Eliminate the requirement to post the "Generic Sign."

Senate Bill 460 also amended the Texas Dangerous Drug Act to add a provision currently in the Pharmacy Act that, in the event of a natural or manmade disaster, allows pharmacists to dispense up to a 30-day supply of a dangerous drug on a refill, without authorization of the practitioner, if:

- (1) Failure to refill the prescription might result in interruption of a therapeutic regimen or create patient suffering;
- (2) The nature of the disaster prohibits the pharmacist from contacting the practitioner;
- (3) The Governor has declared a state of disaster; and
- (4) The Board, through the Executive Director, has notified pharmacies they may dispense up to a 30-day supply of a dangerous drug.

E. Do any of your agency's functions overlap or duplicate those of another state or federal agency? Explain if, and why, each of your key functions is most appropriately placed within your agency. How do you ensure against duplication with other related agencies?

Similar enforcement programs and functions are provided by state boards of pharmacy in other states. Pursuant to Texas laws/rules governing the practice of pharmacy, pharmacies that are located in other states (but dispense/deliver prescriptions to patients in Texas) are required to be licensed in the state where the pharmacy is located and must also obtain one of the following types of pharmacy licenses issued by TSBP:

- (1) Class E (Non-Resident) Pharmacy license – if the pharmacy is not compounding sterile preparations; or
- (2) Class E-S (Non-Resident Sterile Compounding) pharmacy license -- if the pharmacy is compounding sterile preparations.

In addition, as indicated below, other state or federal programs may have similar enforcement programs, however, none of these agencies mission or goal is specific to pharmacy or the practice of pharmacy. TSBP works closely with the following agencies and conducts joint inspections with these agencies when the focus of complaints or investigations deals specifically with the pharmacy and/or pharmacy practice in the facility.

- (1) The Texas Department of State Health Services (DSHS) licenses and regulates hospitals, ambulatory surgical centers (ASCs), and freestanding Emergency Medical Care Facilities (FEMCFs). Class C (Institutional) Pharmacies are located in hospitals and Class F Pharmacies are located in Freestanding Emergency Medical Care facilities. DSHS personnel may conduct inspections in hospitals, ASCs, and FEMCFs, including the pharmacy.

- (2) The Texas Health and Human Services Commission (HHSC) contracts with pharmacies to provide services to Medicaid patients therefore, HHSC may conduct on-site visits to vendor pharmacies to check compliance with contract provisions. The Medicaid Fraud Unit of the Attorney General's office (AGMFU) investigates complaints involving Medicaid Fraud by pharmacies and pharmacists.
- (3) Local, State, and Federal Agencies may perform inspections or investigations of licensees and registrations – e.g., Drug Enforcement Administration (DEA); Department of Public Safety (DPS); Food and Drug Administration (FDA).

The agency's key functions #1, 2, and 5 as listed below are appropriately placed within this agency. TSBP is the only agency that is directly responsible these functions.

- (1) Preventing incompetent or unqualified individuals from obtaining a license to practice or operate a pharmacy, or a registration to serve as a pharmacist-intern, preceptor, or pharmacy technician;
- (2) Removing licenses or registrations, after due process, of unscrupulous or incompetent individuals who violate the pharmacy and drug laws; and
- (5) Promoting pharmaceutical care to increase the probability of desired patient outcomes and decrease the probability of undesired outcomes from drug therapy.

The agency's key function #3 as listed below is appropriately placed within this agency; however, other agencies, such as the Texas Department of State Health Services and the federal Food and Drug Administration may also have some jurisdiction, especially with regard to adulterated or misbranded prescription drug.

- (3) Helping to ensure that patients do not receive incorrect, adulterated, or misbranded prescription drugs or devices from pharmacies;

Key function #4 as listed below is appropriately placed within this agency; however, other agencies such as the Texas Department of Public Safety and the federal Drug Enforcement Administration also have jurisdiction over the dispensing and distribution prescriptions of controlled substances. (Note: TSBP is the agency responsible for the regulation of the Texas Dangerous Drug Act. Dangerous Drugs are prescription drugs that are not controlled substances.)

- (4) Preventing diversion of prescription drugs from pharmacies, so that dangerous and/or addictive drugs are not dispensed, distributed, delivered, or supplied in any manner except upon the order of a valid doctor-patient relationship; and

F. In general, how do other states carry out similar functions?

Each of the other states has a board of pharmacy. (See Attachment A - National Association of Boards of Pharmacy's Survey of Pharmacy Law)

G. What key obstacles impair your agency's ability to achieve its objectives?

The major "obstacles" that impair the agency's ability to achieve its objectives are as follows:

- (1) The Legislature generally does not appropriate to the agency an amount of funding or personnel equal to the amount requested. As a result, the workload of the agency does not match the staffing pattern and delays in processing work occur;
- (2) Currently, the agency has staff located in three separate spaces within the William P. Hobby, Jr. State Office Building. The largest numbers of in-house staff (56) are located on the 6th Floor of Tower 3 of the Hobby Building, accounting personnel (6) are located on the 2nd Floor of Tower 3, and licensing personnel (12), (including the Director of Administrative Services and Licensing) are located on the 4th Floor of Tower 1. Although we believe we have procedures in place that make this separation work, the simple fact that we are separated causes some delays in the movement of documents between the locations; and
- (3) This agency, as other small agencies, is expected to comply with requirements for all agencies. Many of these requirements, such as the Business Continuity Plan require an expertise most small agencies do not possess. This forces the agency to contract with an outside entity to assist in the preparation of the plan.

H. Discuss any changes that could impact your agency's key functions in the near future (e.g., changes in federal law or outstanding court cases).

The 2015 Texas Legislature passed Senate Bill 195. This bill transfers the responsibility for the operation of the Texas controlled substance prescription monitoring program (PMP) from the Texas Department of Public Safety (DPS) to the Texas State Board of Pharmacy (TSBP) on September 1, 2016. This will be a major new function for TSBP and the agency will begin preparation for this transfer in the fall of 2015. During FY16, the agency will award a contract for operation of the program and interview and hire the five individuals that will be responsible for the day-to-day operation of the program.

One provision of the bill specifies that licensing agencies for licensees authorized to access the data in the PMP may access a surcharge that will be transferred to the TSBP to be used to operate the program. This section should have become effective on passage of the bill; however, because of a drafting error this provision does not become effective until September 1, 2016. The Comptroller of Public Accounts has ruled that since the funding section of the bill does not become effective until September 1, 2016, TSBP cannot access the FY2016 funds

contained in the contingency rider for Senate Bill 195. Therefore, in FY2016 the agency has not been appropriated funds to pay for the contract with a vendor to operate the program or to hire the personnel to operate the program.

We have prepared a trimmed down budget of approximately \$887,500 that will allow the agency to award the contract and hire the appropriate personnel by the end of FY2016. Since the agency's appropriation for FY2016 does not contain funds for this program, the agency has applied for a \$500,000 federal grant from the United States Department of Health and Human Services. We anticipate the grant will be awarded in October 2015. In addition, the agency is talking to the Governor's office regarding applying for an emergency deficiency grant for the remaining \$387,500 necessary.

Additionally, should the additional funding through the grant and the emergency deficiency grant from the Governor's office not be available, TSBP is talking with the DPS regarding assuming their current contract for operation of the program. This option is not ideal since it would not allow TSBP to enhance the program to make it more useful the physicians and pharmacists when they are making decisions regarding the prescribing/dispensing controlled substance prescriptions to Texas citizens as envisioned by the Legislature.

I. What are your agency's biggest opportunities for improvement in the future?

- (1) One opportunity for improvement in the future will be a successful relocation of the three separate spaces within the William P. Hobby, Jr. State Office Building (sixth Floor of Tower 3, second Floor of Tower 3, and the fourth Floor of Tower 1) to one contiguous space. The Texas Facilities Commission is working with the agency to obtain the fifth floor of Tower 3. This space would house all of the current staff.
- (2) A recent audit of the Compliance Inspection Program by the State Auditor's office pointed out that TSBP experienced a significant turnover (24.2%) in its inspector positions during FY14. That turnover rate was higher than the Board's overall turnover rate of 13.5%, and it was higher than the statewide turnover rate of 11.9% for inspectors at all state agencies during the same time period. The TSBP Inspector positions are crucial to the agency's ability to monitor the operation of pharmacies. The Inspectors receive very extensive training for these positions that takes approximately six months. Because of the required training period, when we lose an inspector, it can take us nine months to a year to get a new person hired and fully trained.
- (3) During 2013, the Texas Legislature passed S.B. 1100 partially in response to a multistate outbreak of fungal meningitis and other infections among patients who received contaminated preservative-free methylprednisone steroid injections from the New England Compounding Center in Framingham, Massachusetts. A total of 754 patients residing in 20 states were infected and 64 patients died because of the infection. Texas had two patients that were infected with fungal meningitis, but these patients were treated and recovered.

S.B. 1100 set some new requirements for pharmacies that compound sterile products including a requirement that the pharmacy license of sterile compounding pharmacies cannot be renewed if the pharmacy has not been inspected within the last two years.

With 12 inspectors (the current number of funded inspector positions), the agency has been challenged to conduct all of the inspections of sterile compounding pharmacies by the required due dates. In addition, the recent audit of the Compliance Inspection Program by the State Auditor’s office pointed out that 23% of Texas licensed pharmacies have not been inspected in 5 years. Both of these factors together indicate that the agency needs more inspectors and we will be seeking funding to hire additional inspectors in the next Legislative Session.

- (4) In June 2011, the agency went live with a new database system [Versa Regulatory (VR) System]. The purchase and implementation of the new system was a joint project with four other agencies during which all of our computer systems were migrated to the shared VR system. TSBP has been using the system for over four years and we have discovered that because of the poor design of the system, it takes our staff longer to complete work in this new system than it did in our previous system. We are currently negotiating with the vendor to upgrade the system, but this solution may be cost-prohibitive unless funding can be obtained from the legislature.
- (5) TSBP is working toward using technology to improve the workflow within the agency. The agency currently shares an imaging system with other Health Professions Council agencies. This system is due to be replaced in the near future and the system currently under review has a workflow solution incorporated into the imaging system.

J. In the following chart, provide information regarding your agency’s key performance measures included in your appropriations bill pattern, including outcome, input, efficiency, and explanatory measures.

Exhibit 2: Key Performance Measures — Fiscal Year 2014

Key Performance Measures	FY 2014 Target	FY 2014 Actual Performance	FY 2014 % of Annual Target
Number of New Licenses Issued to Individuals	1,450	1,849	127.52%
Number of Licenses Renewed (Individuals)	14,514	15,544	107.10%
Number of Complaints Resolved	5,420	5,582	102.99%
Number of Licensed Individuals Participating in a Peer Assistant Program	180	182	101.11%
Average Time for Jurisdictional Complaint Resolution	180	176	97.78%
Total Number of Business Facilities Licensed	7,200	7,656	106.33%
Number of Jurisdictional Complaints Received	5,620	5,536	98.51%
Percent of Licensees with No Recent Violations	96.00%	95.50%	99.48%
Percent of Licensees Who Renew Online	93.00%	97.17%	104.48%
Percent of Complaints Resulting in Disciplinary Action	15.00%	11.63%	77.53%

III. History and Major Events

TEXAS TIME LINE

1889 Texas Legislature established boards of pharmaceutical examiners (three-man committees in each senatorial district of the state). Pharmacists were examined and certified by the multiple boards.

1907 Texas Legislature passed first Texas Pharmacy Act and established the Texas State Board of Pharmacy (TSBP) as an independent state regulatory board. The first meeting of the TSBP was held on August 27, 1907. The first Board consisted of five men, all pharmacist appointed by Gov. Thomas M. Campbell. Board members ranged in age from 27 – 60 years. The first Executive Secretary was hired, Robert H. Walker, and the Board office was located in Gonzales.

First examination was given on September 17, 1907. Eleven men and 1 woman took the exam. The Board minutes state the following: “It was indeed regrettable that all applicants should have failed but the Board is anxious to maintain a reasonable high standard of proficiency, so that other states may know that we are desirous of elevating the profession to higher and more substantial ideals.”

1915 Board minutes in January 1915 indicated that the Board was disturbed by the lack of training of pharmacists. The Board adopted a requirement to require at least one year of training in a reputable school of pharmacy.

1921 Gov. Pat Neff appointed the first woman member of the Board, Miss Adelaide Richardson.

Walter Cousins, Sr. was named Secretary of the Board and the offices of the Board were moved to Dallas.

1924 The January 24, 1924 minutes recorded the first action of canceling or revoking licenses after hearings held for two violators.

1925 The Board took a broad step in law enforcement and employed its first investigator, R.A. Green in June 1925.

1929 Bills were passed to require graduation from a reputable College of Pharmacy (a three-year course at that time) and complete one-year experience as a prerequisite to taking the exams.

In addition, a bill passed that gave the Board the authority to issue permits for stores. There were three classes: Pharmacies Permits for prescription service stores, Package Store Permits for non-pharmacy outlets, and Physician Permits allowing physicians to fill prescriptions for their own patients.

1933 The paying of \$2.00 of the \$3.00 renewal fee to the Texas Pharmacy Association was found to be unconstitutional.

1934 Texas Pharmacy Act was amended to set the minimum education requirement as graduation from a recognized College of Pharmacy having four terms of eight months each.

1941 The Boards minutes reflected an increasing number of hearings for law violations, particularly federal narcotic regulation irregularities.

November 23, 1941 – Walter Cousins, Sr., resigned as Secretary of the Board, his son, Walter Cousins, Jr., was named temporary Secretary, and in June 1942, Walter Cousins, Jr., was elected as Secretary of the Board.

1943 Texas Pharmacy Act was amended to include the following: required one year of practical experience prior to registration as a pharmacist; clarified the reasons for revocation and suspension of licenses; and set forth in detail the penalties for violation of the law.

1950 Buster Brown replaced Walter Cousins, Jr. as Secretary and the office was moved to Austin.

1951 The 52nd Legislature passed a bill that required anyone wishing to practice pharmacy or receive a license to practice pharmacy in the State of Texas to sign an oath stating that the individual was not a communist.

Another Bill passed during the 52nd Legislative session that was referred to as the Barbiturate Bill and regulated the possession, handling, sale, and distribution of barbiturates, amphetamines, and desoxyephedrine, and provided penalties for violations. The bill became effective September 7, 1951 and it was the responsibility of the Board of Pharmacy to enforce the law.

In June 1951, the Board printed copies of the new pharmacy law and Barbiturate Law and mailed a copy to all pharmacies in Texas.

1953 On September 30, 1953, Buster Brown resigned as Secretary and Walter Cousins, Jr., is rehired to serve as Secretary of the Board. Offices of the Board were moved to Dallas.

Board received an opinion from the Attorney General in answer to a request concerning the display of the word “pharmacy.” The opinion stated that the law required the sign to be visible on the front of the store to people entering from the front.

1958 The Board passed a regulation regarding the return of medication to a pharmacy. The minutes reflect: “In the interest of the public health of the State of Texas, and the possible adverse effect which the resale of drugs from broken packages may have upon the health of the public, the Board declares the following. “It shall be unlawful, after the effective date of this rule, for any pharmacist licensed by the Board to accept the return of any prescription drugs, liquid or otherwise, from packages which have been broken by the person for whom the prescription was originally filled.”

In July 1958, the Board passed the following resolution with regard to the Secretary: “Joe Arnette shall be elected Secretary of the Texas Board of Pharmacy to be effective not later than June 1, 1959.” Mr. Arnette was hired for full-time work and the Board’s office would be moved to Austin.

1959 On May 15, 1959, the Board’s offices were transferred from Dallas to Austin and Joe Arnette assumed the position of Secretary of the Board.

In July 1959, a “Practical Experience Regulation” required “persons desiring to take an examination to practice pharmacy in the State of Texas shall furnish the Texas Board of Pharmacy proof that he has had at least 1,000 hours practical experience in a retail pharmacy . . . delivery service or fountain experience will not be included.”

1960 The American Council on Pharmaceutical Education revised its standards to require graduates of approved colleges of pharmacy to complete a five-year program.

In February 1960, Secretary Arnette brought to the attention of the Board that “Prescription Mail Order Houses” were in operation in several states and that one was starting operation in Seagoville, Texas. The Board directed staff to send a letter to the this pharmacy informing them on how to operate in order not to violate the Pharmacy Law and Texas Dangerous Drug Law.

On March 31, 1960, the following licensure statistics were presented to the Board:

Pharmacists	6,660
Pharmacists in retail and hospital pharmacies	4,685
Out-of-state pharmacists	911
Pharmacies	2,744
Hospital pharmacies	79
Female pharmacists	218
Female pharmacy owners	31
Pharmacists in other fields	755

1965 In January 25, 1965, the Board appointed a committee to study practical experience and make recommendations to the Board on formulating a Preceptor's Guide. After a preliminary guide was reviewed by the Board, the guide, *Preceptor's and Interns Guide on Practical Experience*, was adopted, printed, and distributed.

In July, the Board adopted a regulation requiring interns to become proficient in typing by being able to type approximately 35 words per minute.

1966 The Board approved "hospital pharmacy" to be included in the regulations. In addition, the Board appointed a committee to study the in-patient filling of prescriptions by licensed pharmacists in hospitals.

1970 Secretary Arnette discussed with the Board members the idea of sending a bulletin or letter to all pharmacists licensed with the Board at least two to three times a year. The Board approved the idea.

1973 The Legislature passed House Bill 750 that required pharmacies to post, in complete public view, the one hundred most frequently prescribed drugs and include the pharmacy's maximum charge for each drug. The pharmacy was to indicate whether the professional services or non-professional convenience services were available to the customer. Any indication on the poster that one of the listed services was available, when in fact such services were not available, was considered a violation of the Act.

1975 The Board approved "Interim Guidelines for Licensure of Nuclear Pharmacies."

1976 On June 28, the Board unanimously chose Fred S. Brinkley, Jr., to replace Joe Arnette as Secretary of the Board beginning September 1, 1976. Mr. Arnette retired October 31, 1976. In December 1976, the Board voted to change the title from Secretary to Executive Director/Secretary.

In September 1976, the Board began using the National Association of Boards of Pharmacy Licensing Examination (written exam) along with a two-hour laboratory exam.

1977 Board initiated a comprehensive reorganization of the agency's internal organization and functions, which resulted in upgrading and refining examination process, computerization of licensure records, initiation of a voluntary compliance program (including random, unannounced inspections of pharmacies, as well as publication of agency newsletter). The agency consisted of two divisions, Investigations and Operations.

1980 Rules are adopted addressing the requirements for pharmacies using "data processing systems."

1981 Texas Legislature repealed and replaced the Texas Pharmacy Act with a new practice Act and extended the agency's existence for another 12 years, following the agency's first review by the Sunset Advisory Commission. The new Texas Pharmacy Act changed the composition and number of Board members from six pharmacists to nine members (seven pharmacists and two public members), created four classes of pharmacy licenses; regulation of institutional pharmacies began, and allowed drug product selection (generic substitution) for the first time, under conditions. Texas Legislature created the Triplicate Prescription Program, requiring special forms for a patient to receive a Schedule II controlled substance.

1983 Texas Legislature, through amendments to the Texas Pharmacy Act, established a program to address the problem of pharmacists who are chemically, mentally, or physically impaired (eligible pharmacy students added to the program in 1985).

The Board voted to allow "supportive personnel" to prepare prescription labels.

1984 The Board implemented a system to stagger the renewal dates of pharmacists throughout the year to spread the workload of licensing staff.

1985 The Texas Pharmacy Act was amended to allow a \$1.00 surcharge to the license renewal fees to fund the Impaired Pharmacist Program.

The Texas Legislature passed the Ambulatory Surgical Center Licensing Act which, for the first time, required ambulatory surgical centers to have a license. Subsequently, in 1986, the Board adopted rules regarding pharmacies in ambulatory surgical centers.

On August 27, 1985, the Board signed the first contract with the Texas Pharmacy Association Pharmacists Recovery Network. The one-year contract required PRN to provide evaluations and referral services for impaired pharmacist and eligible pharmacy students.

1986 The Board:

- adopted its first strategic plan;
- adopted a new logo/seal; and
- published Pharmacy Laws and Regulations Manual that contained the laws and rules related to the practice of pharmacy (Texas Pharmacy Act and Rules, Texas Controlled Substances Act and Rules, Texas Dangerous Drug Act, DEA Pharmacist Manual), and a section containing the procedures and forms.

- 1987 The Board discussed pharmacies in other states dispensing drugs to Texas residents and reviewed an Attorney General’s opinion that said that the Board did have the authority to regulate out-of-state pharmacies. At the same meeting, the Board also discussed the “continuing health problem of the importation of unapproved drugs from Mexico into the US”.

The Board adopted rules to regulate out-of-state pharmacies and required registration of out-of-state pharmacies dispensing drugs to Texas residents.

- 1988 The Board received the National Council on Licensure, Enforcement, and Regulation (CLEAR) Program award (awarded in Washington D.C.) for outstanding and innovative service to the regulatory community.

The agency implemented a system to stagger pharmacy license expiration dates to spread the workload throughout the year.

- 1989 Texas Legislature, through amendments to the Texas Pharmacy Act, established continuing education requirements for pharmacists to help assure continuing competency. Agency promulgated rules to expand the duties of pharmacy technicians.

- 1991 Texas Legislature, through amendments to the Texas Pharmacy Act, established a new class of pharmacy license (Class E or Non-Resident Pharmacy) for mail service pharmacies located in other states.

- 1992 The Board sent a letter to the Texas Department of Health (TDH) recommending the rescheduling of Hydrocodone from Schedule III to Schedule II and Carisoprodol from a dangerous drug to Schedule IV. A public hearing was held by TDH. There was concern that physicians would no longer prescribe the drugs to patients in pain. After discussions at several meetings, the Board adopted rules that required Carsioprodol, Stadol® and Nubain® to be included on a pharmacies annual inventory and a change of pharmacist-in-charge inventory.

- 1993 Texas Legislature, through amendments to the Texas Pharmacy Act, included the concept of pharmaceutical care, which established the legal basis for pharmacists’ increased involvement in patient care. Subsequent rules promulgated by the Board required pharmacists to provide written and verbal counseling to patients and conduct drug regimen reviews. Agency’s existence was extended another 12 years, following a successful review by the Sunset Advisory Commission and a requirement that 1/3 Board membership must be public members; composition of the nine-member Board changed from seven pharmacists and two public members to six pharmacists and three public members.

1995 Texas Legislature, after creating the Health Professions Council in 1993, required all health regulatory boards to co-locate and to study mechanisms for agencies to work together to reduce costs and standardize processes.

The Board became responsible for the registration and inspection of pharmacy balances.

1996 Texas Tech School of Pharmacy opened, resulting in four pharmacy schools/colleges in Texas. This was the first new school/college of pharmacy in Texas in almost 50 years.

1997 Texas Legislature, through amendments to the Texas Pharmacy Act, included the following: allowed pharmacists to administer immunizations and perform drug therapy management under certain conditions; stipulation that a prescription for a narrow therapeutic index (NTI) drug be refilled only with the same drug product by the same manufacturer last dispensed, unless otherwise agreed to by the prescribing practitioner.

On June 27, 1997, Executive Director/Secretary Fred S. Brinkley, Jr. retired from the Board after 21 years of service. Gay Dodson was named as his replacement.

1998 TSBP was sued regarding rules to implement legislation relating to NTI drugs. Litigation resulted in TSBP changing its procedures with regard to the adoption of rules. The lawsuit was ultimately withdrawn.

1999 Texas Legislature, through amendments to the Texas Pharmacy Act, gave the Board the authority to:

- establish the concept of a “pharmacy peer review committee” (made Texas the first state in the nation to pass such legislation);
- determine and issue standards for recognition and approval of pharmacist certification programs; to register pharmacy technicians beginning in 2001;
- require all technicians to be certified; and
- require entities providing professional liability insurance to report malpractice claims to the Board.

The agency established a comprehensive and user-friendly website to improve services and accessibility to its customers.

2000 The American Council on Pharmaceutical Education revised its standards to require all graduates of approved colleges of pharmacy to complete a six-year doctoral program, which is titled Pharm.D.

The agency was reorganized into four divisions, Administrative Services and Licensing, Enforcement, Legal, and Professional Services. These changes resulted in better coordination of enforcement activities and improved operations.

- 2001 Texas Legislature, through amendments to the Texas Pharmacy Act, established remote pharmacy services, increased the number of continuing education hours required for pharmacist renewal from 20 to 30 hours every two years; and changed requirements for prescribers who wish to prohibit generic substitution. Since the Texas Legislature did not fund the agency to register pharmacy technicians, the agency delayed implementation of this provision.
- 2002 Agency implemented online pharmacist renewal system.
- 2003 Texas Legislature, through amendments to the Texas Pharmacy Act, authorized the agency to create new classes of pharmacy licenses, if existing classes did not cover the practice; required the agency to provide information to licensees regarding the prescribing and dispensing of pain medications; set forth procedures for the reuse of certain unused prescription drugs dispensed to nursing home patients; permitted compounding pharmacists to promote and advertise compounding services; required pharmacists to report to the Texas Department of Health any situation that poses a risk to homeland security; and authorized advanced practice nurses and physician assistants to issue prescriptions for controlled substances.
- 2004 The agency began the process of licensing pharmacy technicians with all technicians required to be licensed by June 1, 2004.
- 2005 The Texas Legislature amended the Texas Pharmacy Act to extend the agency's existence for another 12 years following the agency's review by the Sunset Advisory Commission. Other significant amendments to the Act:
- abolished the dedication of the Board of Pharmacy fund;.
 - made the changes to the regulation of pharmacy technicians including:
 - a requirement that TSBP register pharmacy technician trainees;
 - an increased range of disciplinary sanctions, such as probation and administrative penalties that the Board may impose on pharmacy technicians; and
 - expanded grounds for discipline of a pharmacist's, pharmacy's, and pharmacy technician's license/registration to include deferred adjudication for misdemeanor offenses involving moral turpitude and any felony offenses.
 - required that the Board maintain a list of all licensed pharmacies that maintain an Internet website, including the pharmacy name, license number, and state in which it is located. In addition, the bill requires all pharmacies that maintain a website to post information on that website on how a consumer may file a complaint with the Board.

- made Class E (Non-Resident Pharmacies) subject to the same grounds for discipline as in-state pharmacies and allow the Board to take action on complaints immediately, rather than after referral and action by the Board in the home state.
- allowed a panel of three Board members to hear temporary suspension cases rather than the whole Board when the public is in immediate danger.
- allowed:
 - Class A and Class C Pharmacies to compound prescription drugs for “Office Use” by a practitioner;
 - Class A Pharmacies to compound prescription drugs for a Class C Pharmacy; and
 - Class C Pharmacies to “prepackage” prescription drugs for use by other Class C pharmacies under common ownership. In addition, the amendments clarify that TSBP may inspect pharmacies relative to components used in compounding and sample these items.
- required the Texas State Board of Pharmacy to inspect and authorize Canadian pharmacies to sell prescription medications to patients in the state of Texas. (Note: On December 21, 2005, Attorney General Greg Abbott issued Opinion #GA-0384, which states that designating certain Canadian pharmacies, listing them on the Board's website, and permitting Texas consumers to import prescription drugs from Canada would violate federal law. Because of this opinion, the Board did not implement the Canadian pharmacy provisions of the Act).

The agency quickly responded to emergency conditions that resulted from Hurricanes Katrina and Rita through the following actions.

- Because of the evacuation of New Orleans citizens to Texas and their need to receive medication, the agency, in consultation with the Governor’s office, quickly notified pharmacies in Texas that they could dispense up to 30-days’ supply of medication to these patients without contacting the patients’ physicians. This authorization was extended for approximately four months.
- The agency quickly developed and implemented a web-based online application form to expedite the issuance of temporary licenses to pharmacists licensed in other states, so that these pharmacists could work in Texas pharmacies to aid in the hurricane relief effort.
- The agency developed a procedure for quickly issuing temporary pharmacy licenses to pharmacies that were established in the various shelters throughout Texas.

- Because of the heavy damage to the city of New Orleans by hurricane Katrina, fourth year pharmacy students at Xavier were not able to complete their pharmacy practice rotations. The Texas colleges of pharmacy worked to place these students in rotations in Texas. The agency developed an expedited intern certification process so that the majority of these student interns were certified within one day of receipt of their application.
- To notify pharmacists, pharmacies, and the public of the actions taken by the agency in response to the hurricanes, the agency immediately:
 - placed this information on the agency Web-site;
 - notified all of the professional organizations; and
 - assigned personnel to be available by telephone to answer questions from pharmacists during the times the agency was closed.

2006 The Texas A & M Health Science Center Irma Lerma Rangel College of Pharmacy and the University of the Incarnate Word Feik School of Pharmacy opened, resulting in six pharmacy schools/colleges in Texas.

The agency began registration of Pharmacy Technician Trainees on September 1, 2006.

2007 The Texas Legislature passed several significant pieces of legislation, including:

- Amendments to the Pharmacy Act that:
 - require a Joint Committee made up of three members of the Texas State Board of Pharmacy and three members of the Texas Medical Board to review to make recommendations to the Board of Pharmacy regarding the addition of five transplant immunosuppressant drugs to a list of Narrow Therapeutic Index drugs. Drugs on this list could be refilled only with the same drug product by the same manufacturer last dispensed, unless otherwise agreed to by the prescribing practitioner.
 - allow the Board of Pharmacy to adopt rules governing the flavoring of prescriptions as a part of compounding rules.
 - allow the return and re-dispensing of prescription drugs from penal institutions.
- Amendments to the Controlled Substances Act that:
 - add prescriptions for Schedule III – V drugs to the controlled substance prescription monitoring program;

- require pharmacies to submit information on Schedule III – V prescriptions to DPS within 15 days of dispensing the prescription;
- delete the requirement that a Schedule II prescription may not be filled after 7 days. The director of DPS in consultation with TSBP and the Texas Medical Board must adopt a rule establishing the period after the issue date that a prescription for a Schedule II controlled substance may be filled. Rules were adopted that allow prescriptions for Schedule II controlled substances to be dispensed for 21 days;
- allow the Texas Department of Public Safety (DPS) to charge a late fee of not more than \$50 for late renewal of registrations; and
- give DPS the authority to assess administrative penalties on registrants who violate the law. The amount of the penalty may not exceed \$1,000 for each violation/day nor exceed a total of \$20,000.

2008 The agency successfully implemented a project that enabled TSBP to replace paper notebooks containing background material for Board Meetings with electronic notebooks. Notebook documents were published and shared electronically with Board members and staff for use on laptop computers at the meetings. Electronic documents were also available to the public on the TSBP website and viewable by the public during a board meeting or public hearing.

2009 The Texas Legislature passed several significant pieces of legislation, including:

- a provision that requires all regulatory agencies to conduct a preliminary evaluation of a person's eligibility for licensing prior to their application for a license/registration.
- amendments to:
 - the Health and Safety Code that allows for the licensing and regulation of "Freestanding Emergency Medical Care Facilities" by the Department of State Health Services. This action ultimately required the TSBP to adopt rules for a new class of pharmacy in these centers.
 - the Texas Pharmacy Act:
 - that defines the term rural hospital and allows pharmacy technicians to perform certain duties without the direct supervision of a pharmacist;
 - to allow TSBP investigators who are commissioned peace officers to carry weapons and make arrests;

- that specify conditions under which the Board may discipline a pharmacy technician; and
- give the Board the authority to order a pharmacy technician to submit to a mental or physical evaluation.
- the Medical Practices Act that ultimately allowed the TSBP to adopt rules that allow a pharmacist under certain conditions to sign a prescription under a drug therapy management protocol from a physician.
- the Texas Controlled Substances Act that:
 - make Carisoprodol (Soma®) a Schedule IV controlled substance; and
 - allow a physician to issue multiple prescriptions to one patient authorizing the patient to receive a total of 90-days' supply of a Schedule II drug.

The joint agency/Health Professions Council project to replace the TSBP database system and the database system for five other agencies (Texas State Board of Dental Examiners, Texas Optometry Board, Texas Board of Land Surveying, Texas Board of Examiners of Psychiatrist; and the Texas Board of Plumbing Examiners) and migrate to a Shared Regulatory Database System was completed. Each agency's Legislative Appropriations for FY2010-2011 included prorated funds to complete the project.

TSBP established a presence on Facebook and Twitter to better communicate with licensees about agency happenings.

2011 The Texas Legislature passed several significant pieces of legislation, including the following:

- Amendments to the Texas Pharmacy Act to:
 - clarify the confidentiality provisions of records regarding impaired pharmacists and when the TSBP can release investigative files;
 - streamline the temporary suspension provisions of the Act and the procedures for ordering a licensee to submit to a mental or physical examination; and
 - allow pharmacists to accelerate refills up to a 90-day supply under certain conditions.

- Amendments to the Controlled Substances Act to:
 - eliminate the requirement that a physician's DPS number be on a prescription for a controlled substance;
 - require pharmacies to submit information on controlled substance prescriptions to DPS at least every 7-days; and
 - allow the electronic transmission of Schedule II prescriptions.
- Amendments to the Health and Safety code to establish a real-time electronic logging system for the sale of ephedrine, pseudoephedrine, and norpseudoephedrine.

After over a year of planning and work, the Versa Regulatory System began operation on May 30, 2011, with the Versa Online System beginning operation on June 3, 2011. The conversion of the majority of the data from the prior system was successful. All licensing and enforcement functions of the agency have been operational since the May 30, 2011 date.

TSBP established a YouTube presence to upload educational videos regarding laws and rules for use by licensees.

The University of North Texas System College of Pharmacy in Fort Worth was established, becoming the seventh college of pharmacy in Texas.

2012 The agency began presenting educational webinars on changes to the laws and rules to licensees.

2013 The Texas Legislature passed several significant pieces of legislation, including the following:

- Amendments to the Texas Pharmacy Act to:
 - prohibit the Board from considering or acting on a complaint if the violation occurred more than 7-years before the date of the complaint;
 - allow the Board to issue a remedial plan to resolve certain complaints and assess a fee against a license holder participating in a remedial plan in an amount necessary to recover the cost of administering the plan;
 - increases the size of the Board of Pharmacy to 11-members by adding 1-pharmacist and 1-pharmacy technician;
 - give the Board the authority to inspect an out-of-state sterile compounding pharmacy;

- require an inspection prior to opening a sterile compounding pharmacy and specify that a pharmacy that compounds sterile preparations may not renew a pharmacy license unless the pharmacy has been inspected as provided by Board rule;
 - require the out-of-state sterile compounding pharmacy to reimburse the Board for travel and other expenses associated with the inspection; and
 - require a pharmacy that compounds a sterile preparation to notify the Board immediately of any adverse effects reported to the pharmacy or that are known by the pharmacy to be potentially attributable to a sterile preparation compounded by the pharmacy not later than 24 hours after the pharmacy issues a recall for a sterile preparation compounded by the pharmacy.
- Amendments to the Controlled Substances Act to:
 - allow pharmacy technicians working under the supervision of a pharmacist to query the Prescription Access in Texas (PAT) Program for the recent Schedule II-V prescription history of a particular patient;
 - allow a person authorized to receive information from the PAT to access it through a health information exchange (HIE), subject to proper security measures to ensure against disclosure to unauthorized persons;
 - allow a person authorized to receive information from PAT to include that information in any form in the medical or pharmacy record of the patient who is the subject of the information. (e.g. a physician may print-out the report and place it in a patient's file);
 - increase the time DPS can maintain the information in PAT from 12-months to 36-months.

The University of Texas at Tyler, Ben and Maytee Fisch College of Pharmacy is established. This is the eighth college of Pharmacy in Texas.

2014 The agency was partially successful in its efforts to obtain much needed space for its agency employees. The Texas Legislature approved funding to remodel unused space within the William P. Hobby, Jr. State Office Building. The new space is not contiguous with the agency's existing space and in fact, is located in another tower of the building, presenting workflow and efficiency challenges.

2015 The Texas Legislature passed several significant pieces of legislation, including the following:

- Amendments to the Pharmacy Act:
 - that allow pharmacists to substitute “biological products” if:
 - The physician authorizes substitution;
 - The patient doesn’t refuse the substitution; and
 - The “biological product” is designated as “therapeutically equivalent” to another product by FDA.
- Amendment to the Pharmacy Act that:
 - Allow pharmacists, in an emergency, to administer epinephrine to a patient using an auto-injector device.
 - Allow a pharmacy to use an electronic messaging system (digital marquee) to notify consumers how to file a complaint.
 - Allow the Board to inspect financial records relating to the operation of a pharmacy only in the course of an investigation of a specific complaint;
 - Allow the Board to inspect the records of a pharmacist if the pharmacist practices outside a licensed pharmacy.
 - Specify that a person cannot own a Class E Pharmacy license if the person has held a pharmacist license in this or another state that has been restricted, suspended, revoked, or surrendered for any reason;
 - Specify that a pharmacy license may not be renewed if the license has expired for 91 days or more;
 - Require a pharmacy to report to the Board in writing, no later than 30-days before the date of a change of location;
 - Prohibit waiving, discounting, or reducing, or offering to waive, discount, or reduce a payment copayment or deductible for a compounded drug in the absence of listed exceptions.
 - Eliminate the requirement to post the “Generic Sign.”

- Amendments to the Pharmacy Act and the Controlled Substances Act that:
 - Allow the Board, on or after 6/20/2015:
 - to adopt rules to implement a Prescription Monitoring Program (PMP) and certain other provisions related to prescriptions in the Controlled Substances Act;
 - Sign a contract with a vendor to operate the PMP; and
 - Call a meeting of the Prescription Monitoring Work Group.
 - Effective 9/1/2016:
 - Transfer the PMP from the Department of Public Safety to the Texas State Board of Pharmacy;
 - Establish a program to fund the PMP through a surcharge on the license fees of persons authorized to access the PMP; and
 - The Controlled Substance Registration program is abolished.
 - Amendment to the Texas Dangerous Drug Act that adds a provision currently in the Pharmacy Act that specifies that in the event of a natural or manmade disaster allows pharmacists to dispense up to a 30-day supply of a dangerous drug on a refill, without authorization of the practitioner, if:
 - Failure to refill the prescription might result in interruption of a therapeutic regimen or create patient suffering;
 - The nature of the disaster prohibits the pharmacist from contacting the practitioner;
 - The Governor has declared a state of disaster; and
 - The Board, through the Executive Director, has notified pharmacies they may dispense up to a 30-day supply of a dangerous drug.
 - Add a new Subchapter E. Opioid Antagonist to the Dangerous Drug Act that:
 - Allow a physician to prescribe/issue a standing order for an opioid antagonist, without risk of discipline, to: a person at risk of an opioid-related drug overdose; a family member, friend, or other person in a position to assist a person at risk of experiencing an opioid-related drug overdose.

- Specifies a pharmacist who dispenses or does not dispense an opioid antagonist under a valid prescription is not subject to criminal/civil liability or disciplinary action for dispensing or failing to dispense the opioid antagonist; or if the pharmacist dispenses an opioid antagonist, any outcome resulting from the administration of the opioid antagonist.
- Amendments to Chapter 55 of the Occupations Code to specify that all occupational licensing agencies must:
 - Waive the license application and examination fees for an applicant who is a military service member or military veteran:
 - Whose military service, training, or education substantially meets all of the requirements for the license; or
 - Who holds a current license issued by another jurisdiction that has licensing requirements that are equivalent those in Texas.
 - Adopt rules to:
 - Give military service members an exemption from paying a penalty for failing to renew;
 - Allow military service members an additional two years to complete any CE requirements or any other requirement related to the renewal of the license.
 - Allow agencies to adopt rules that establish alternate methods for a military service member, veteran, or spouse to demonstrate competency to meet the requirements for obtaining the license; and
 - Require agencies to post a notice on the home page of the agency's website describing the licensing provisions available to military service members, veterans, and spouses.

FEDERAL TIME LINE

- 1906 Federal Food and Drug Act set standards for purity of medication only with no efficacy requirements.
- 1912 Food and Drug Act amended to include within the definition of misbranding false or fraudulent claims for the curative powers of drugs.

- 1914 Federal Narcotic Drug Act (popularly known as the Harrison Narcotic Act) regulated the sale of drug products containing opium, morphine, heroin and other narcotics; pharmacists were required to obtain a license to sell drug products containing narcotics.
- 1938 Food, Drug, and Cosmetic Act (FD&C) set safety standards only with no efficacy requirements.

Major Amendments to FD&C

- 1951 Durham-Humphrey Amendment created “prescription only” and “over-the-counter” (OTC) drug categories, established how prescription drugs would be dispensed, and established drug labeling requirements.
- 1962 Kefauver-Harris Amendment established requirements for safety and efficacy of drug products.
- 1965 Drug Abuse Control Amendments were the effective precursor of the Drug Abuse Control Act. These amendments provided the first guidelines for determining the classifications of drugs subject to abuse.
- 1976 Medical Device Act established safety and efficacy requirements for medical devices and lab products.
- 1980 The first publication of Approved Drug Products with Therapeutic Equivalence Evaluations or “Orange Book” by the FDA.
- 1983 Orphan Drug Act established incentives for research and manufacturing of drugs for rare conditions.
- 1984 Drug Price Competition and Patent Restoration Act stated that the FDA would accept Abbreviated New Drug Applications’ for drugs first approved after 1962 in an effort to keep drug prices low. The act also required that the FDA provide a list of approved drug products with monthly supplements. The Orange Book satisfies this requirement.
- 1988 Prescription Drug Marketing Act of 1987 required licensing of prescription drug wholesalers, banned re-importation of prescription drugs produced in the US, and banned sale, trade, or purchase of samples.
- 1990 Safe Medical Devices Act required “device user facility” to report any death or serious injury of patient probably due to device. The act also required adoption of a device tracking method and post-marketing surveillance of devices.
- 1997 FDA Modernization Act created exemption to ensure availability of compounded drugs prepared by pharmacists in forms not commercially available.

- 1999 OTC Labeling Requirements made for a new standardized format and supplying more detailed product information to the consumer to make over-the-counter medicines safer for consumers. The provisions will be fully enacted by 2005.
- 2013 On November 27, 2013, the U.S. Drug Quality and Security Act was signed into law. This law removes the advertising provisions of Section 503A of the Food, Drug, and Cosmetic Act (FD&C Act) that were declared unconstitutional in 2002. With these provisions removed, this portion of the FD&C Act passed in 1997 became effective.
- Section 503A exempts pharmacy compounding from compliance of three specific sections of the FD&C Act that manufacturers are required to meet (FDA approval of products prior to marketing; Compliance with Current Good Manufacturing Practices and labeling with adequate directions for use). This act makes compounding pursuant to a prescription by pharmacists legal under the FD&C Act.
 - Section 503B allows facilities that are compounding sterile pharmaceuticals not pursuant to individual prescriptions and “outsourcing” these products to other entities to be registered as “outsourcing facilities” rather than as manufacturers. An outsourcing facility will also qualify for exemptions from certain provisions of the FD&C Act including those requiring FDA approval of products and the requirement to label products with adequate directions for use. However, these entities will not be exempt from complying with Current Good Manufacturing Practices.
- 1966 Federal Hazardous Substances Act, administered by the Consumer Product Safety Commission, regulates all hazardous substances. Labeling must have a warning statement; pharmacists must either sell products in original containers or label containers properly.
- 1968 Bureau of Narcotics and Dangerous Drugs (BNDD) was formed by combining Bureau of Narcotics (in the Treasury Department) and Bureau of Drug Abuse Control (in the Department of Health, Education, and Welfare). BNDD was responsible for regulating the sale/distribution of narcotics, barbiturates, amphetamines, and hallucinogens. This agency was the precursor to what is now known as the Drug Enforcement Administration (DEA).
- 1970 Comprehensive Drug Abuse Prevention and Control Act (Federal Controlled Substances Act) was created to regulate the production and distribution of controlled substances. All persons in the chain of manufacturing, distributing, and dispensing controlled substances were required to obtain a registration from DEA. The act also classified federally regulated substances into one of five classes.

Poison Prevention Packaging Act required that prescription and nonprescription drugs be dispensed to consumers in child-resistant containers. Exemptions to this packaging requirement include patient requests, bulk containers from wholesalers, containers distributed to institutionalized patients, and packaging for elderly patients. Some drugs were exempted like sublingual nitroglycerin and isosorbide dinitrate.

- 1973 All agencies involved in the drug abuse control and the enforcement of drug laws were combined into one agency, the Drug Enforcement Administration (DEA).
- 1990 Omnibus Budget Reconciliation Act (OBRA-90) administered by U.S. Department of Health and Human Services, expanded Medicare and Medicaid programs. The act requires services to patients receiving pharmaceutical services to include prospective drug use review and patient counseling. The requirements were set forth only to apply to Medicare and Medicaid patients, but most states, including Texas, apply this to all patients.
- 1996 Health Insurance Portability and Accountability Act (HIPAA) set up privacy protections for individually identifiable health information as applied to health plans, health care clearinghouses, and health care providers who conduct certain transactions electronically. Rules to implement the privacy provisions of the Act went into effect on April 14, 2003. HIPAA also called for creation of the Healthcare Integrity and Protection Data Bank (HIPDB). HIPDB was constructed to combat fraud and abuse in health insurance and health care delivery.
- 2003 Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), recognized that appropriate drug therapy is cost-effective and necessary in the inclusion of medication therapy management programs (MTM). The passage of this legislation is the first time that Congress recognized in national legislation the importance of pharmacist-provided drug therapy management. In addition, it was the first time that pharmacists would be allowed to bill for Medicare-related patient care services.
- 2006 Medicare Part D, prescription drug coverage for all Medicare recipients began on January 1, 2006. Implementation of this program was expected to increase dramatically the number of prescriptions filled by pharmacies in the United States.
- 2008 On October 15, 2008, the US Congress passed the Ryan Haight Online Pharmacy Consumer Protection Act. This act amended the Controlled Substances Act and Controlled Substances Import and Export Act by adding several new provisions to prevent the illegal distribution and dispensing of controlled substances by means of the Internet.

- 2009 HR 3590, the Patient Protection and Affordable Care Act, was signed into law by President Obama in March 2009. The sweeping legislation has projected price tag of \$938 billion over 10 years and will extend insurance coverage to roughly 32 million more Americans. The bill contains a number of provisions that directly affect community pharmacy and prescription drug coverage and will significantly expand the number of Americans who can afford prescription medications and other pharmacy services. The millions of additional people with health insurance will mean billions more in sales for drug manufacturers and expanded demand for pharmacy services.
- 2010 DEA adopted rules to allow the electronic prescriptions for Controlled Substances. These rules became effective June 1, 2010.

IV. Policymaking Structure

- A. Complete the following chart providing information on your policymaking body members.

Exhibit 3: Policymaking Body

Member Name	Term / Appointment Dates / Appointed by	Qualification (e)	City
Buford T. Abeltd, Dr., R.Ph.	05/09/2008 – 08/31/2019 Governor Perry	Industry Representative Pharmacist	Lufkin
Christopher M. Dembny, R.Ph.	09/26/2013 – 08/31/2017 Governor Perry	Industry Representative Pharmacist	Richardson
W. Benjamin Fry, R.Ph., FIACP, FACS	04/14/2004 – 08/31/2015 Governor Perry	Industry Representative Pharmacist	San Benito
L. Suzan Kedron	05/09/2008 – 08/31/2019 Governor Perry	Public Member	Dallas
Alice G. Mendoza, R.Ph.	08/10/2006 – 08/31/2017 Governor Perry	Industry Representative Pharmacist	Kingsville
Bradley A. Miller, Ph.T.R.	09/26/2013 – 08/31/2019 Governor Perry	Industry Representative Pharmacy Technician	Austin
Phyllis A. Stine	08/31/2011 – 08/31/2017 Governor Perry	Public Member	Abilene
Joyce A. Tipton, R.Ph., MBA	01/06/2010 – 08/31/2015 Governor Perry	Industry Representative Pharmacist	Houston
Jeanne D. Waggener, R.Ph.	08/10/2006 – 08/31/2017 Governor Perry	Industry Representative Pharmacist	Waco
Charles F. Wetherbee	01/06/2010 – 08/31/2015 Governor Perry	Public Member	Boerne
Dennis F. Wiesner, R.Ph.	05/09/2008 – 08/31/2019 Governor Perry	Industry Representative Pharmacist	Austin

B. Describe the primary role and responsibilities of your policymaking body.

The primary role and responsibilities of the policymaking body are as follows:

- (1) employs an Executive Director and ensures that the Executive Director carries out the management and administrative functions of the agency;
- (2) addresses major issues facing the agency;
- (3) approves an operating budget to guide the agency's fiscal activities and approves the agency's Legislative Appropriations Request; and
- (4) sets policy through formal guidelines/policy statements, promulgation of administrative rules and approval of disciplinary sanctions. The Board is the final decision maker on the entry of all disciplinary orders and rules. (See Policy Statements and Guidelines at the following link on the TSBP website:

<http://www.pharmacy.texas.gov/about/policyguidelines.asp>

In executing its role, the Board reviews/updates the agency's strategic plan every other year and monitors progress on long-term goals, establishes annual goals and objectives to provide direction with regard to the day-to-day operation of agency, and annually evaluates the performance of the Executive Director. The Board has set guidelines for evaluating the Executive Director. *(See Attachment #B - Board/Executive Director Relationship Section of the Policy and Procedure Manual)*

The major responsibilities of the Texas State Board of Pharmacy fall into the three categories listed below:

- (1) Licensing and Registration
 - Pharmacists
 - Initial Licensing after Examination and Training
 - Renewal of License
 - Initial Registration of Preceptors
 - Pharmacies
 - Initial Licensing
 - Renewal of License to Operate a Pharmacy

- Pharmacist-Interns (Initial Registration)
 - Pharmacist-Intern Trainees
 - Student Pharmacist-Interns
 - Extended Pharmacist-Interns
- Pharmacy Technicians
 - Initial Registration
 - Renewal of Registration
- Pharmacy Technician Trainees
 - Initial Registration

(2) Setting Standards

- Standards for Qualifications for Initial Licensing
- Standards for Operation of Pharmacies
- Standards for Recognition and Approval of Degree Requirements of Colleges of Pharmacy whose Graduates are Eligible for a License In Texas
- Standards for Practical Training, Including Internship
- Standards for Recognition and Approval of Training Programs for Pharmacy Technicians
- Standards for Recognition and Approval of Pharmacy Residency Programs
- Standards for Recognition and Approval of Pharmacist Certification Programs

(3) Regulating and Enforcing The Standards

- Inspecting Pharmacies
- Investigating Complaints
- Disciplining Licensees who Violate the Laws and Rules Governing the Practice of Pharmacy

C. How is the chair selected?

The chair of the Texas State Board of Pharmacy is appointed from its members by the Governor to serve at the pleasure of the Governor. Authority: Section 552.007, Texas Pharmacy Act.

D. List any special circumstances or unique features about your policymaking body or its responsibilities.

- (1) TSBP is self-supporting, in that the operations of the agency are supported primarily from statutory fees related to licensing, reciprocity, and examinations. The general operating fund of the Board is a general revenue account within the State Treasury Authority: Texas Pharmacy Act, Section 554.007.
- (2) The policymaking body is an eleven-member Board, with seven members who are pharmacists, one member who is a pharmacy technician, and three members who represent the public. At the time of their appointments, the pharmacist-members must have been licensed as a pharmacist for the five years preceding appointment, be in good standing with the Board, and be practicing pharmacy in this state. At the time of appointment, the pharmacy technician member must have been registered as a pharmacy technician for the five years preceding appointment, be in good standing with the Board, and be acting as a pharmacy technician in this state. In addition, the Board must include representation from pharmacists who are primarily employed in community and institutional pharmacies. Authority: Texas Pharmacy Act, Section 552.002 – 552.003.
- (3) The Board has the responsibility of regulating three distinct entities – the persons who dispense prescription drugs to the public (pharmacists) and those who assist the pharmacist (pharmacy technicians); the place where prescription drugs are dispensed to the public (pharmacies); and the distribution of dangerous drugs (prescription drugs that are not classified as controlled substances).
- (4) The Board has the sole responsibility for the administration and the enforcement of the Texas Pharmacy Act and Texas Dangerous Drug Act.

E. In general, how often does your policymaking body meet? How many times did it meet in FY 2014? In FY 2015?

The Texas State Board of Pharmacy generally meets four times a year. The Board meetings were held on the following dates in FY2014 and FY2015:

FY2014	FY2015
November 4-5, 2013	November 4, 2014
February 11, 2014	February 3, 2015
May 6, 2014	May 5, 2015
August 5, 2014	August 4, 2015

F. What type of training do members of your agency’s policymaking body receive?

New Board Members attend an intensive two-day orientation session conducted by the Executive Director and applicable agency staff. The Executive Director provides an overview of the Board organization, information regarding issues facing the Board, and statutory responsibilities of the Board and its members. Division Directors review agency programs and operations, including state accounting procedures, insurance, and instructions on preparation of travel vouchers. The agency’s General Counsel reviews the following items with new Board Members: specific laws, rules and policies that affect Board Members, such as the Texas Open Meetings Act, Texas Public Information Act, Texas Administrative Procedures Act, and laws relating to Ethics and ethical conduct and professional responsibilities related to State of Texas purchasers and contract managers. New Board Members do not vote on issues before the Board until they have completed this initial orientation session. New Board Members also attend an orientation program conducted by the Governor’s office.

(See Attachment #C – Board Member Orientation Agenda).

All Board Members attend conferences and meetings held by major pharmacy organizations to learn of issues facing the profession. Members are regularly notified of and encouraged to attend various programs presented by the Office of the Attorney General (OAG), the LBJ School of Public Affairs, and other organizations that periodically sponsor seminars or conferences relevant to service on the Board. The OAG generally offers an annual training session that inform members of their responsibilities under various state statutes such as the Texas Open Meetings Act, Texas Public Information Act, and ethics laws. Ongoing training sessions also occur at Board Meetings; see examples below:

- (1) At the meeting on November 4, 2014, the Board members heard two presentations as follows:
 - Electronic Viewing and Computerized Workflow Supervision Systems for Sterile Compounding Pharmacies; and
 - An Iowa Pilot Program regarding the use of one pharmacy technician to check the work of another pharmacy technician (Tech-Check-Tech).
- (2) At the meeting on February 3, 2015, the Board members watched a training program provided by the Office of the Comptroller titled *Governing Bodies Webinar Training on S. B. No. 1681*. This training covered the ethical and professional responsibilities related to State of Texas purchasers and contract managers.

In addition, the TSBP Executive Director provides information about new legislation and other pertinent matters to Board Members on an ongoing basis.

G. Does your agency have policies that describe the respective roles of the policymaking body and agency staff in running the agency? If so, describe these policies.

Yes. TSBP Board Members formulate public policy and are responsible for final decisions regarding rulemaking and entry of disciplinary orders, consistent with the administration and enforcement of the Texas Pharmacy Act. The agency staff carries out the policy and is responsible for the day-to-day operations of the agency. *See Policies and Procedures Relating to Board Members.* (See Attachment #E - Policies and Procedures Relating to Board Members)

H. What information is regularly presented to your policymaking body to keep them informed of your agency's performance?

At every meeting, the Board is updated on the status of the agency budget and on the agency's progress on complaint resolution. The agendas for the Board meetings contain numerous reports of activities of the agency. In addition, the executive director notifies the Board of any audit, performance review, or other reviews of the agency.

I. How does your policymaking body obtain input from the public regarding issues under the jurisdiction of the agency? How is this input incorporated into the operations of your agency?

TSBP obtains input regarding issues under the jurisdiction of the agency through a myriad of sources, including the following:

(1) Task Forces – The Board President appoints task forces to study issues and make recommendations to the Board (i.e., pre-rulemaking activity). The task forces provide an excellent mechanism to gather expertise and “grass-roots” advice from practicing pharmacists and other interested stakeholders on matters affecting the practice of pharmacy. If the task force is assisting the Board to develop rules to implement a new law passed by the Texas Legislature, TSBP invites the bill sponsor(s) to send representative(s) to the task force meetings. The three major professional organizations in Texas (Texas Pharmacy Association, Texas Society of Health-System Pharmacists, and Texas Federation of Chain Drug Stores) are also requested to nominate persons from each organization to serve on task forces. Examples of task forces appointed in the past five years are listed below:

(A) FY2013 – Task Force on Pharmacy Compounding;

(B) FY2014 – Task Force on Pharmacy Technicians;

(C) FY2015 – Task Force on C Pharmacies Located in Freestanding Ambulatory Surgical Centers and Class F Pharmacies Located in Freestanding Emergency Medical Care Centers;

- (2) Public Testimony at Public Hearings/Board Meetings – Any person can offer written comments on proposed rules that TSBP has published in the Texas Register. A person can request a public hearing on any proposed rule. If a public hearing is conducted, any person can offer verbal comments about the proposed rule. Persons who attend Board meetings may comment on any agenda item, when recognized by the Board President. If a person wishes to speak to the Board at a public meeting about an issue not already scheduled for discussion, the person must submit a request in writing six weeks prior to the date of the Board meeting.
- (3) Texas Pharmacy Congress – This group is composed of representatives of the eight colleges of pharmacy in Texas, the three major professional associations in Texas, and TSBP. The Congress meets quarterly to discuss issues of mutual concern. Each entity reports on activities and programs, and together the group addresses problems and recommends solutions.
- (4) Pharmacy Organizations – TSBP receives input from these groups on a regular basis; any suggested issues are scheduled for discussion at Board meetings.
- (5) Customer Service Survey – TSBP conducts a continuous survey of agency customers regarding the quality of service delivered by the agency as specified in Chapter 2113 of the Government Code. A biannual report is made to the Board and to the Governor’s Office of Budget, Planning and Policy Legislative Budget Board, regarding comments and recommendations that had been made on a myriad of issues. Some of the customers’ suggestions result in changes to agency operations.
(See Attachment #20 - Customer Service Survey Report)
- (6) Individuals – Board Members are individually contacted about issues; the agency receives visits, letters and telephone calls regarding issues. These issues may be addressed at Board meetings, which may result in rule changes.

J. If your policymaking body uses subcommittees or advisory committees to carry out its duties, fill in the following chart.

Exhibit 4: Subcommittees and Advisory Committees

Name of Subcommittee or Advisory Committee	Size / Composition / How are members appointed?	Purpose / Duties	Legal Basis for Committee
Executive Committee	Board President and elected officers (Vice President, and Treasurer are elected by the Board members)	Review and make recommendations regarding agency proposed operating budget prior to the full Board’s review and approval. In addition, the Executive Committee may review other issues as directed by the full board.	Texas Pharmacy Act, Section 554.001(b)(2)

V. Funding

A. Provide a brief description of your agency’s funding.

The agency's operating budget for fiscal year 2014 was approximately \$7.7 million, which includes all Legislative appropriations. In addition, other direct and indirect costs are charged to the agency such as the agency's payroll-related costs, bond debt service payments, and indirect costs relating to the Statewide Cost Allocation Plan.

The agency is totally self-supporting, in that the operations of the agency are supported primarily from statutory fees related to licensing, reciprocity, and examinations. Until 2005, the general operating fund of the Board was a general revenue dedicated account within the State Treasury. The 2005 Texas Legislature, passed legislation that abolished the Board of Pharmacy fund dedication and placed the agency funds into the General Revenue Fund.

B. List all riders that significantly impact your agency’s budget.

Rider Appropriation

- Article VIII-44 Controlled Substance Forfeiture Program (2014-2015 GAA).
- Article VIII-70 Section 3 Funding for Health Professions Council (2014-2015 GAA)
- Article VIII-71 Section 4 Texas.gov Appropriations (2014-2015 GAA)
- Article VIII-71 Section 5 Peer Assistance Program Funding Requirements (2014- 2015 GAA)
- Article IX-66 Section 17.06 Appropriation for a Salary Increase for General State Employees
- Article IX-71 Section 17.13 Additional Payroll Contribution for Retirement Contribution
- Article IX-81 Section 18.41 Contingency for SB 500.
- Article IX-82 Section 18.43 Contingency for SB 1100

C. Show your agency’s expenditures by strategy. See Exhibit 5 Example.

**Texas State Board of Pharmacy
Exhibit 5: Expenditures by Strategy — 2014 (Actual)**

Goal / Strategy	Amount Spent	Percent of Total	Contract Expenditures Included in Total Amount
1. Maintains Standards			
1.1. Licensing	\$850,095.21	13.5%	\$206,675.28
1.2. Texas.gov	\$226,986.00	3.6%	\$226,986.00
2. Enforcement Regulations			
2.1. Enforcement	\$4,160,797.32	66.3%	\$208,634.78
2.2. Peer Assistance	\$228,740.00	3.6%	\$186,260.00
3. Indirect Administration			
3.1. Indirect Administration-Licensing	\$121,354.26	1.9%	\$1,331.72
3.2. Indirect Administration-Enforcement	\$697,133.55	11.1%	\$7,546.42

Goal / Strategy	Amount Spent	Percent of Total	Contract Expenditures Included in Total Amount
GRAND TOTAL:	\$6,285,106.34	100.0%	\$837,434.20

- D. Show your agency's sources of revenue. Include all local, state, and federal appropriations, all professional and operating fees, and all other sources of revenue collected by the agency, including taxes and fines.**

Exhibit 6: Sources of Revenue — Fiscal Year 2014 (Actual)

Source	Amount
General Revenue Fund	\$9,917,821.00
Appropriated Receipts	8,056.00
TOTAL	\$9,925,877.00

- E. If you receive funds from multiple federal programs, show the types of federal funding sources.**

Not Applicable

- F. If applicable, provide detailed information on fees collected by your agency.**

**Texas State Board of Pharmacy
Exhibit 8: Fee Revenue — Fiscal Year 2014**

Fee Description/ Program/ Statutory Citation	Current Fee/ Statutory Maximum	Number of Persons or Entities Paying Fee	Fee Revenue	Where Fee Revenue is Deposited (e.g., General Revenue Fund)
Delinquent Penalty (Pharmacy, Pharmacist & Technician Occupations Code § 561.003, 568.005, 559.003	Varies	Unknown	\$144,922	General Revenue Fund
Examination Fee Occupations Code § 558.051	\$50	1,573	\$78,675	General Revenue Fund
Administrative Penalties (Fines) Occupations Code § 566.001, 562.002	Varies	219	\$283,500	General Revenue Fund
Office of Patient Protection Surcharge Occupations Code § 101.307	\$2 - \$5	50,687	\$162,642	General Revenue Fund
Other Fees & Permits Occupations Code § 554.006	\$10 - \$35	Unknown	\$39,622	General Revenue Fund

Self-Evaluation Report

Fee Description/ Program/ Statutory Citation	Current Fee/ Statutory Maximum	Number of Persons or Entities Paying Fee	Fee Revenue	Where Fee Revenue is Deposited (e.g., General Revenue Fund)
Pharmacist Licensure Fee (initial & biennial renewal) Occupations Code § 559.003	\$281	15,544	\$3,962,001	General Revenue Fund
Pharmacy Licensure Fee (initial & biennial renewal) Occupations Code § 560.052, 561.003	\$500	4,275	\$2,025,683	General Revenue Fund
Pharmacy Scales (biennial) Occupations Code § 554.005, 554.006	\$25	3,488	\$87,200	General Revenue Fund
Pharmacy Technician Registration Fee Occupations Code § 568.005	\$91	21,996	\$1,802,172	General Revenue Fund
Pharmacy Technician Trainee Occupations Code § 568.007	\$55	8,872	\$548,955	General Revenue Fund
Probation Penalty Occupations Code § 566.001, 566.002	Varies	133	\$96,400	General Revenue Fund
Reciprocity Fee Occupations Code § 558.101	\$250	803	\$200,788	General Revenue Fund
Texas Online Subscription Fees General Appropriations Act Govt Code & 2054.252	\$2 - \$15	52,536	\$226,929	General Revenue Fund
Peer Recovery Network Fees - Pharmacies & Pharmacist Occupations Code § 564.051	\$13 - \$15	19,819	\$251,344	General Revenue Fund
Controlled Substance Act Forfeiture Money Code of Criminal Procedure. GAA, 83 rd Legislature, Article VIII, Rider 3	Varies	Not Applicable	\$6,988	General Revenue Fund
Copies Occupations Code § 554.006	Varies	Not Applicable	\$596	General Revenue Fund

Fee Description/ Program/ Statutory Citation	Current Fee/ Statutory Maximum	Number of Persons or Entities Paying Fee	Fee Revenue	Where Fee Revenue is Deposited (e.g., General Revenue Fund)
Reimbursement – 3 rd Party General Appropriations Act, 82 nd Legislature, Article IX	Varies	Not Applicable	\$2,105	General Revenue Fund
Sale of Vehicles Occupations Code § 2175	Varies	Not Applicable	\$5,340	General Revenue Fund
Interest on Local Deposits – State Agencies Government Code §§ 103.011, 403.012	.00	Not Applicable	\$15	General Revenue Fund

VI. Organization

- A. Provide an organizational chart that includes major programs and divisions, and shows the number of FTEs in each program or division. Detail should include, if possible, Department Heads with subordinates, and actual FTEs with budgeted FTEs in parenthesis.

(See Attachment # E - Texas State Board of Pharmacy Organizational Chart FY2015)

- B. If applicable, fill in the chart below listing field or regional offices.

Exhibit 9: FTEs by Location — Fiscal Year 2014

Headquarters, Region, or Field Office	Location	Co-Location? Yes / No	Number of Budgeted FTEs FY 2014	Number of Actual FTEs as of June 1, 2014
Headquarters	333 Guadalupe St, Suite 3-600; Austin TX 78701	No	92	85
			TOTAL: 92	TOTAL: 85

C. What are your agency’s FTE caps for fiscal years 2014–2017?

Year	FTE Cap
2014	92
2015	92
2016	92
2017	99

D. How many temporary or contract employees did your agency have as of August 31, 2014?

Two

E. List each of your agency’s key programs or functions, along with expenditures and FTEs by program.

Exhibit 10: List of Program FTEs and Expenditures — Fiscal Year 2014

Program	Number of Budgeted FTEs FY 2014	Actual FTEs as of August 31, 2014	Actual Expenditures
Licensing	11.83	10.83	1,077,081.21
Enforcement	68.33	65.33	4,389,537.32
Indirect Administration	11.84	10.84	818,487.81
TOTAL	92.00	87.00	6,285,106.34

VII. Guide to Agency Programs – Indirect Administration

A. Provide the following information at the beginning of each program description.

Indirect Administration

Name of Program or Function: Indirect Administration

Location/Division: Headquarters – Office of the Executive Director and Division of Administrative Services

Contact Name: Cathy Stella
Director of Administrative Services & Licensing

Actual Expenditures, FY 2014: \$818,487.81

Number of Actual FTEs as of June 1, 2015: 11.84

Statutory Citation for Program: Occupations Code, Chapter 553,
Executive Director and Other Board
Personnel

B. What is the objective of this program or function? Describe the major activities performed under this program.

The Goals and Objectives of Indirect Administration include the Office of the Executive Director and the Administrative Services Division.

The Goal and Objectives of the Office of the Executive Director are as follows:

GOAL

To provide policy advice to the Board, implement Board policies, and manage the organization in a manner that will accomplish the stated mission, goals, and objectives of the agency.

Objectives (New for FY2015)

1. To provide testimony, attend public hearings, and provide any fiscal or technical information, and to review all legislation that has an impact on the practice of pharmacy and agency operations, and monitor the process of this legislation, throughout the 84th Texas Legislative Session.
2. To direct the submission of, provide testimony for, and monitor the progress of the agency's *Legislative Appropriation Request* and corresponding performance measures for FY2016-2017.

Objectives (Ongoing for FY2015)

1. To manage and monitor the agency's performance and operational efficiency throughout FY2015.
2. To coordinate the development of proposed goals and objectives and budget for FY2016 based on the *Strategic Plan* and projected budget for submission to the Board two weeks prior to the August 2015 meeting.
3. To direct TSBP's "*lead agency approach*" to help assure coordination of TSBP activities with those of other state and federal agencies involved in the regulation of the practice of pharmacy throughout FY2015.

4. To manage the information resource needs (data processing, telecommunication, and website) of the agency throughout FY2015 by:
 - A. evaluating and implementing solutions for the evolving computing needs of the agency;
 - B. providing a stable infrastructure for existing systems;
 - C. increasing the efficiency and productivity of Board operations; and
 - D. securing the agencies system against internal and external threats.
5. To review all federal statutes, regulations, and policies that may impact the regulation of the practice of pharmacy and make timely recommendations to the Board for implementation of any required Board actions throughout FY2015.
6. As the Executive Director of the Board, throughout FY2015, to:
 - A. represent Board policies and programs to local, state, and national pharmacy, health-related, and consumer organizations;
 - B. act as the Board's liaison to the pharmacy professional associations;
 - C. continue to take a proactive role in the operation of the Health Professions Council; and
 - D. continue to support and participate in the Texas Pharmacy Congress.
7. To recommend changes to the Texas Pharmacy Act and rules and to recommend policies and procedures that will enhance the agency's ability to protect the public health, safety, and welfare, or will improve the efficiency and effectiveness of the agency's operations throughout FY2015.
8. To maintain a staff development program by encouraging Executive Office staff to participate in professional and interpersonal development seminars, cross training, and on-the-job training and to conduct periodic reviews and annual evaluations of Division Directors and Executive Office staff and to monitor evaluations of employees in all Board Divisions throughout FY2015.
9. To provide the Board information necessary to conduct performance evaluation of the Executive Director by August 31, 2015.
10. To prepare a report on the accomplishments of the Office of the Executive Director and direct the preparation and submission of the agency's *FY2014 Annual Report* to be presented to the Board at the August 2015 meeting.

The Goal and Objectives of the Administrative Services Division are as follows:

To administer agency operations including personnel, finance, purchasing and risk management.

Objectives (New for FY2015)

To assist the Executive Director, in cooperation with other Divisions, in the following new objectives throughout FY2015:

1. Preparing testimony, attending public hearings, providing any fiscal or technical information, reviewing all legislation that has an impact on the practice of pharmacy and agency operations, and monitoring the process of this legislation, throughout the 84th Texas Legislative Session.
2. Monitoring the progress of the agency's Legislative Appropriations Request and corresponding performance measures for FY2016-2017.

Objectives (Ongoing) – Administrative Services

1. To prepare a proposed budget for FY2016 for submission to the Board two weeks prior to the 2015 Annual Policy Meeting.
2. To prepare and submit all required accounting and fiscal reports/reconciliations in compliance with all applicable state statutes throughout FY2015.
3. To review and recommend to the Executive Director additional sources of spendable revenue and to assess fees charged for Board services throughout FY2015.
4. To assess the material needs of the agency and supervise the purchasing and supply activities in accordance with all Texas Procurement and Support Services rules and procedures throughout FY2015.
5. To increase the efficiency and productivity of Board office operations by managing and coordinating space needs and on-site maintenance of the Board's office facilities throughout FY2015.
6. To serve as the agency's Human Resource Coordinator in ensuring agency compliance with all applicable state and federal personnel statutes throughout FY2015.
7. To serve as the Agency Records Retention Manager to the Texas State Library, in maintaining a Records Retention Program for the economical and efficient management of agency records throughout FY2015.
8. To serve as the Agency Risk Manager by annually assessing areas of agency risk exposures and recommending procedures to control these exposures throughout FY2015.

9. To provide verbal and written information to Board staff and customers throughout FY2015 including, by the assigned due dates, the preparation of the LBB Performance and Funds Management Report and other special reports as requested by LBB, legislative committees, legislators, and others, in conjunction with other Divisions as necessary.
 10. To assist the Executive Director in developing and implementing the objectives of the Health Professions Council (HPC) pertinent to Division activities throughout FY2015.
 11. To manage employees under the supervision of the Division throughout FY2015, in compliance with all applicable state and federal personnel statutes, including the following: to hire qualified applicants for new or vacant positions; to update or develop job descriptions in compliance with the State Classification System; to participate in State Classification audits of positions; to conduct periodic reviews and annual evaluations of Division employees; and to promote self-development through such activities as on-the-job training, cross-training, and attendance at professional seminars.
 12. To update the Agency Personnel Handbook and the Division's *Policies and Procedures Manual* as needed and submit any substantive revisions to the Executive Director for approval throughout FY2015.
 13. To recommend changes to the Texas Pharmacy Act and rules and to recommend policies and procedures that will enhance the agency's ability to protect the public health, safety, and welfare, or will improve the efficiency and effectiveness of the agency's operations, and forward the recommendations to the Executive Director throughout FY2015.
 14. To prepare a report on the accomplishment of Division objectives for incorporation into the agency's *FY2014 Annual Report* and submit to the Executive Director by the due date.
- C. What evidence can you provide that shows the effectiveness and efficiency of this program or function? Provide a summary of key statistics and outcome performance measures that best convey the effectiveness and efficiency of this function or program.**
- Exceeded all (100%) of its 10 key performance measures listed in the Appropriations Act and reported on an annual basis to the Legislative Budget Board for FY2013 - FY2015.
 - Monetary exception-free financial audit by the State Comptroller of Public Accounts in FY2014. No issues were identified for payroll, purchase and travel transactions. In addition, the Board's internal control structure was reviewed and no issues were identified.
 - Exception-free compliance audit in FY2013 of the agency's personnel policies and procedures systems by the Texas Workforce Commission Civil Rights Division.

- Web services are key to maintaining a high level of productivity and efficiency in dealings with the public. TSBP's site registers over 3 million hits per year providing services and information to the public twenty four hours a day and without direct staff interaction.
- To keep the agency running efficiently, computer equipment is replaced regularly and in conjunction with DIR recommendations
- The use of the imaging system has enhanced the access of documents, modernized the retention of documents and reduced the footprint necessary to store documents. In the past year alone, over 400,000 pages were loaded into the system.
- To help keep the agency secure, staff has worked with DIR since 2009, participating in annual penetration tests against agency systems with zero recorded breaches to our systems. Also, in 2015 the agency successfully participated in the DIR sponsored internal security review provided by Gartner Consulting Services.
- The implementation of new solutions such as the electronic board notebook project in conjunction with our imaging system has been a key factor in reducing our board meeting time to a single day.
- In January 2014, 80% of TSBP employees responded to the Survey of Employee Engagement (formerly known as Survey of Organizational Excellence). TSBP employees rated TSBP better than counterparts in other agencies on 14 of 19 constructs, including such constructs as Diversity, Internal Communication, External Communication, Job Satisfaction, Supervision, Agency Quality, Climate Atmosphere, Climate Ethics, Climate Fairness, Climate Feedback, and Climate Management.
- Customer Service Survey results for FY2015, indicate consistently high satisfaction ratings from agency customers on a monthly basis. Survey results indicate that customers are receiving the information they need; their inquiries are routed to the proper person and responses are received in a reasonable amount of time; the TSBP website is easy to use, well organized, and contains clear and accurate information.

D. Describe any important history regarding this program not included in the general agency history section, including how the services or functions have changed from the original intent.

Indirect administrative services functions are an essential part of the Texas State Board of Pharmacy and have not changed from the original intent.

E. Describe who or what this program or function affects. List any qualifications or eligibility requirements for persons or entities affected. Provide a statistical breakdown of persons or entities affected.

This function serves all of the TSBP employees and Board Members. The primary function is to manage the organization in a manner that will accomplish the stated mission, goals, and objectives of the agency. This affects the daily operations of the agency, that is, human resources, purchasing, finance, records management, property management, risk management, and information technologies.

F. Describe how your program or function is administered. Include flowcharts, timelines, or other illustrations as necessary to describe agency policies and procedures. Indicate how field/regional services are used, if applicable.

The Office of the Executive Director is administered by the Executive Director/Secretary, and consists of five FTE's:

- (1) Executive Assistant – reports directly to the Executive Director
- (2) Receptionist
- (3) Director of Information Resources – reports directly to the Executive Director
- (4) Network Specialists (2)

The Administrative Services section is administered by the Director of Administrative Services & Licensing, who reports directly to the Executive Director/Secretary. The Division Director is supervisor of six FTE's in this section:

- (1) Chief Accountant (Team Leader)
- (2) Staff Services Officer
- (3) Accountants (3)
- (4) Purchaser

The general activities of these programs are as follows:

EXECUTIVE OFFICE OPERATIONS

The Executive Assistant is responsible for:

- providing administrative support for the Executive Director and Board members;
- providing administrative support for all Board business meetings, including drafting board meeting minutes;
- managing calendars, meetings, and other activities on behalf of the Executive Director;
- screening and evaluating telephone calls to Executive Director;
- composing correspondence for Executive Director;
- making travel arrangements for Executive Director and Board Members;
- assisting in preparation of agency reports, including Report on Customer Service to Texas Legislature;
- coordinating agency participation in the Survey of Employee Engagement (formerly known as Survey of Organizational Excellence) and directing evaluation of survey results; and
- overseeing agency's customer service program, including supervision of customer reception (receptionist).

INFORMATION RESOURCE TECHNOLOGIES

The Director of Information Resources is responsible for:

- providing direction and guidance in strategic operations and planning of the agency's information resources (Work involves the management of the agency legacy system, internal LAN system, agency website and all external interfaces (Versa Online, DPS, PTCB, NABP, TGSL, OAG));
- performing advanced project management of the daily operations and of the following agency business activities:
- risk management (including risk assessment, business continuity, imaging of records, the retention of electronic records; and emergency preparedness);
 - developing policies;
 - reviewing guidelines, procedures, rules, and regulations;

- establishing priorities, standards, and measurement tools for determining progress in meeting goals; and
- coordinating and evaluating program activities; and reviewing and approving the information resources budget.

FISCAL ACTIVITIES

Chief Accountant and the accountants are responsible for:

- performing advanced professional accounting and administrative work in directing the accounting, budgeting, payroll, and fiscal activities of the state agency.
- preparing or supervising the preparation of financial analyses and reports; agency budgets; vouchers, and payrolls submitted by the agency; and
- supervising security and integrity of the Uniform Statewide Accounting System and other electronic accounting, fiscal, purchasing and cash systems.

PURCHASING ACTIVITIES

The Purchaser purchases commodities and services through open market or by contract requiring knowledge of the State of Texas purchasing policies and procedures, particularly legislative mandates addressing the use of Set Asides (TIBH and TCI) and HUBs.

HUMAN RESOURCES & SAFETY

The Staff Services Officer is responsible for:

- conducting several staff functions such as new hire processing, terminations, payroll, timekeeping, reconciliations, employee training, benefits, risk management, worker's compensation and safety.
- providing advice and service to agency personnel;
- maintaining liaison with federal, state and local agencies with regard to human resource and payroll requirements; and
- maintaining the overall quality control of the cash system.

Specific policies and procedures are dictated through a number of sources, primarily the Office of the State Auditor, State Comptroller of Public Accounts, Department of Information Resources, Legislative Budget Board, Governor's Budget Office, the General Appropriations Act, and Texas Government Code.

- G. Identify all funding sources and amounts for the program or function, including federal grants and pass-through monies. Describe any funding formulas or funding conventions. For state funding sources, please specify (e.g., general revenue, appropriations rider, budget strategy, fees/dues).**

The Indirect Administration Program receives no federal funds. The agency is totally self-supporting, in that the operations of the agency are supported primarily from statutory fees related to licensing, reciprocity, and examinations that support the agency's operations. See Section V of this report for details regarding funding.

- H. Identify any programs, internal or external to your agency, that provide identical or similar services or functions to the target population. Describe the similarities and differences.**

In the area of administration, there are programs across other state agencies that perform identical functions; however, a thorough analysis of these functions must be conducted before an assumption can be made that similar services can be provided to agency customers and employees, or that any cost efficiencies can be achieved through outsourcing or combining these functions.

- I. Discuss how the program or function is coordinating its activities to avoid duplication or conflict with the other programs listed in Question H and with the agency's customers. If applicable, briefly discuss any memorandums of understanding (MOUs), interagency agreements, or interagency contracts.**

The agency has an interagency agreement with the Health Professions Council to provide a prorated funding amount to assist the Council in carrying out its legislative mandate. The Council's administrative sharing efforts include the following activities:

- Information Technology Sharing
- Shared Database System
- Human Resources Program
- Training Opportunities
- Courier Services
- Legislative Tracking
- Regulatory Best Practices
- Toll Free Complaint Line

(See Attachment #F - Texas Health Profession Council Report for Fiscal Year 2014 - An Efficient Model for Licensing and Regulation)

- J. If the program or function works with local, regional, or federal units of government, include a brief description of these entities and their relationship to the agency.**

Not applicable

K. If contracted expenditures are made through this program please provide:

- a short summary of the general purpose of those contracts overall;
- the amount of those expenditures in fiscal year 2014;
- the number of contracts accounting for those expenditures;
- top contracts by dollar amount, including contractor and purpose;
- the methods used to ensure accountability for funding and performance; and
- a short description of any current contracting problems.

Indirect Administration issues no contracts over \$50,000.00.

L. Provide information on any grants awarded by the program.

No grants are awarded by the Indirect Administration Program.

M. What statutory changes could be made to assist this program in performing its functions? Explain.

The GAA, Article IX currently allows unexpended balances remaining in appropriations for the 1st fiscal year of a biennium, to be appropriated to the 2nd year of the biennium. A statutory change is also needed to allow the unexpended balances remaining in appropriations for the 2nd year of a biennium, to be appropriated to the next biennium.

N. Provide any additional information needed to gain a preliminary understanding of the program or function.

Not Applicable

O. Regulatory programs relate to the licensing, registration, certification, or permitting of a person, business, or other entity. For each regulatory program, if applicable, describe:

- why the regulation is needed;
- the scope of, and procedures for, inspections or audits of regulated entities;
- follow-up activities conducted when non-compliance is identified;
- sanctions available to the agency to ensure compliance; and
- procedures for handling consumer/public complaints against regulated entities.

Not Applicable

P. For each regulatory program, if applicable, provide the following complaint information. The chart headings may be changed if needed to better reflect your agency's practices.

This is not applicable for the Office of the Executive Director or Division of Administrative Services.

Licensing Program

Name of Program or Function: Licensing

Location/Division: Headquarters – Division of Administrative Services and Licensing

Contact Name: Cathy Stella
Director of Administrative Services and Licensing

Actual Expenditures, FY 2014: \$1,077,081.21

Number of Actual FTEs as of June 1, 2015: 11.833

Statutory Citation for Program: Occupations Code, Title 3, Subtitle J. The relevant statutory provisions are listed below.

Citation	Description
Section 551.002	Declares the purpose of the act is to promote, preserve and protect the public health and safety through effectively controlling and regulating the practice of pharmacy. This section also states that the act shall be liberally construed to regulate in the public interest the practice of pharmacy.
Section 554.002	Sets forth the general powers and duties of the Board and includes the following provisions: <ul style="list-style-type: none"> • issuing a license after examination or by reciprocity to qualified applicants and issuing licenses to pharmacies • renewing a license to practice or operate a pharmacy • determining and issuing standards for recognizing and approving degree requirements of colleges of pharmacy whose graduates are eligible for a license in this state • specifying requirements for practical training, including an internship • regulating the training, qualifications, and employment of a pharmacist-intern, and pharmacy technician and pharmacy technician trainee
Section 554.003	States that the Board shall specify the licensing procedures to be followed, including specification of forms to be used, in applying for a pharmacy license; and fees for filing an application for a pharmacy license
Section 554.053	Provides for the establishment of rules for the use and duties of a pharmacy technician and pharmacy technician trainee Provides that the board determine and issue standards for recognition and approval of a training program for pharmacy technicians
Chapter 557	Addresses registration of pharmacist-interns
Chapter 558	Addresses licensure of pharmacists
Chapter 559	Addresses renewal of pharmacist licenses, including Mandatory Continuing Education and Inactive Status

<i>Citation</i>	<i>Description</i>
Chapter 560	Addresses licensure of pharmacies; specifies the classification of pharmacy licenses and gives the Board the authority to determine the classification under which a pharmacy may be licensed <i>*Note: Sec. 560.0525 requires the Texas State Board of Pharmacy to inspect and authorize Canadian pharmacies to sell prescription medications to patients in the state of Texas. On December 21, 2005, Attorney General Greg Abbott issued Opinion #GA-0384, which states that designating certain Canadian pharmacies, listing them on the Board's website, and permitting Texas consumers to import prescription drugs from Canada would violate federal law. As a result, of this opinion, the Board did not implement the Canadian pharmacy provisions of the Act. This statutory provision should be removed.</i>
Chapter 561	Addresses the renewal of pharmacy licenses.
Section 562.108 – 110	Addresses Emergency Medication Kits, Automated Pharmacy Systems, and Telepharmacy.
Chapter 568	Addresses the qualifications, registration, renewal, fees procedures for pharmacy technicians and pharmacy technician trainees.

B. What is the objective of this program or function? Describe the major activities performed under this program.

The key services of the Licensing Program are listed below:

- (1) issuing licenses to qualified applicants for initial pharmacist licensure by examination, score transfer, or reciprocity;
- (2) issuing licenses to qualified applicants for pharmacist re-licensure or re-activating licenses of pharmacists who want to return to active status;
- (3) issuing registrations to qualified applicants for initial pharmacy technician trainee and initial pharmacy technician;
- (4) issuing licenses to qualified applicants for initial licensure of pharmacies, including pharmacies that are new business operations or existing pharmacies that undergo a change of ownership;
- (5) issuing registrations to qualified applicants to provide remote pharmacy services;
- (6) issuing registrations to qualified pharmacist-interns;
- (7) issuing certifications to qualified pharmacist-preceptors;
- (8) renewing licenses of pharmacists on active and inactive basis;
- (9) renewing registrations of pharmacy technicians on active basis;

- (10) renewing licenses of pharmacies that do not have a registration to provide remote pharmacy services;
- (11) renewing licenses of pharmacies that have a registration to provide remote pharmacy services;
- (12) renewing certifications of qualified pharmacist-preceptors;
- (13) updating pharmacists' licensing records with respect to change of name, change of employment, change of address, certifications;
- (14) processing applications from pharmacies for a change of name and/or change of location; processing notifications from pharmacies regarding permanent closings; and processing applications from pharmacies for a change of pharmacy class;
- (15) updating pharmacy licensing records with respect to changes of managing officers; pharmacy scales/balances; pharmacy services; employment changes;
- (16) updating *pharmacy* technician registration records with respect to change of name, change of employment and change of address;
- (17) providing information to the public, including requests for verification of licensure and/or intern status and requests for information regarding the laws/rules or policies/procedures relating to the pharmacy and pharmacist licensure system, pharmacist-intern registration system, and pharmacy technician registration system.

The major activities of each key service are described below:

INITIAL LICENSURE OR RE-LICENSURE OF PHARMACISTS

- (1) providing on-line and paper application forms to potential applicants for pharmacist licensure; may include determining the applicable form to distribute (i.e., different application forms are used, depending upon whether the applicant is applying for licensure by examination, score transfer, or reciprocity, or re-licensure);
- (2) after receiving any document relating to an application for initial pharmacist licensure, reviewing application to determine if the application is complete or incomplete and creating/maintaining pharmacist-applicant files, and if applicable, obtaining information regarding license status in other states;
- (3) determining eligibility of all pharmacist applicants to take the national examinations for pharmacist licensure;
- (4) communicating with the National Association of Boards of Pharmacy, who administers the national examinations;

- (5) determining if an applicant has completed a criminal history background check through the Texas Department of Public Safety and coordinating with the TSBP Enforcement/Legal Divisions if applicant has an enforcement record;
- (6) determining if applicant has met all requirements for licensure (e.g., completed 1,500 internship hours, passed licensure examinations with a minimum score of 75, completed appropriate application and submitted all required attachments, paid applicable fees, and when necessary, has received clearance from the Enforcement/Legal Divisions);
- (7) serving as liaison to the Examination Retake Committee who makes recommendations to applicants who have thrice failed a licensure examination;
- (8) serving as liaison with the coordinators of the eight Texas colleges of pharmacy regarding the registration of their students as pharmacist applicants;
- (9) communicating with and providing information to applicants regarding the status of their applications, including correspondence regarding “missing items” on the application; and
- (10) issuing license number and mailing congratulatory letter from Executive Director, this is later followed with the mailing of a hand-inscribed license suitable for framing (wall-certificate).

PHARMACY TECHNICIAN & TECHNICIAN TRAINEE REGISTRATION

- (1) providing online and paper application forms to potential applicants;
- (2) receiving and reviewing applications;
- (3) determining if an applicant has completed a criminal history background check through the Texas Department of Public Safety and coordinating with the TSBP Enforcement/Legal Divisions if applicant has an enforcement record;
- (4) determining if a pharmacy technician trainee applicant has met all requirements for registration (e.g., completed application, paid fees, and when necessary, has received clearance from the Enforcement/Legal Divisions);
- (5) determining if a pharmacy technician applicant has met all requirements for registration (e.g., completed application, verification that pharmacy technician carries a current certification from the Pharmacy Technician Certification Board, paid fees, and when necessary, has received clearance from the Enforcement/Legal Divisions);
- (6) issuing registration number and registration certificate; and
- (7) communicating with applicants regarding the status of their applications.

INITIAL LICENSURE OF PHARMACIES

- (1) distributing application forms to potential applicants for pharmacy licensure (located on TSBP website)
- (2) upon receipt of the application, determine if correct application form has been submitted (i.e., different application forms are used, depending upon the class of pharmacy license);
- (3) reviewing application and supporting documents to determine if the application is complete or incomplete and creating/maintaining pharmacy-applicant file;
- (4) conducting criminal history background checks on all persons who are listed as owners and/or managing officers on pharmacy applications and coordinating with the TSBP Enforcement/Legal Divisions on any enforcement record;
- (5) determining if applicant must undergo pre-inspection before pharmacy license can be issued and coordinate with Enforcement Division as required;
- (6) if the application is for a Class E (Non-Resident) or Class E-S (Non-Resident Pharmacy Engaged in Compounding Sterile Preparations) license, communicating with the state board of pharmacy in state where applicant is located with respect to the standing of the pharmacy license in that state;
- (7) if the application is for a Class E-S (Non-Resident Pharmacy Engaged in Compounding Sterile Preparations) license, coordinate with the Enforcement Division to determine if a proper, inspection has been submitted;
- (8) determining if applicant has met all requirements to obtain pharmacy license (e.g., completed appropriate application and submitted all required supplemental documents, paid applicable fees, and when necessary, has received clearance from the Enforcement/Legal Divisions);
- (9) verifying with applicable entities (i.e., Secretary of State, Department of State Health Services, etc.) if information submitted is true and correct (i.e., ownership information, other state required licenses, etc.);
- (10) communicating with and providing information to applicants regarding the status of their applications, including correspondence regarding “missing items” on the application and/or incomplete supporting documentation; and

- (11) if the pharmacy has undergone a change of ownership, issuing the license number and mailing the license to the pharmacy; or if the pharmacy is a new pharmacy, issuing the license number, and by letter, notifying the pharmacy owner(s) of the license number, which is later followed with the mailing of the actual license when the agency receives a statement from the pharmacy's pharmacist-in-charge advising TSBP that the pharmacy is open and operating.

REGISTRATION OF PHARMACIST-INTERNS

- (1) providing online application forms to applicants who are currently enrolled in an ACPE approved college of pharmacy;
- (2) reviewing supplemental document from the ACPE approved college of pharmacy to determine correct intern rank (i.e., intern trainee or student intern);
- (3) distributing application forms to eligible pharmacy graduates or applicants who are certified as a foreign pharmacy graduate, who may need to complete additional internship hours for licensure; these individuals must complete an application for Extended Pharmacist-Intern and receive an internship registration letter before the individuals can serve as pharmacist-interns in Texas pharmacies;
- (4) determining if an applicant has completed a criminal history background check through the Texas Department of Public Safety and coordinating with the TSBP Enforcement/Legal Divisions if applicant has an enforcement record;
- (5) after receiving any document relating to a pharmacist-intern application, reviewing application to determine if the application is complete or incomplete and creating/maintaining pharmacist-intern files;
- (6) determining if applicant has met all the requirements to obtain a pharmacist-intern registration, and when necessary, has received clearance from the Enforcement/Legal Divisions;
- (7) communicating with and providing information to applicants regarding the status of their application, including "missing items" on the application;
- (8) issuing internship registrations with an assigned expiration date;
- (9) monitoring the intern hours completed and verifying those hours to other state boards; and
- (10) serving as liaison with the internship coordinators of the eight Texas colleges of pharmacy regarding the registration of their students as pharmacist-interns.

INITIAL AND RENEWAL CERTIFICATION OF PRECEPTORS

- (1) distributing application forms to pharmacists who wish to become certified as preceptors (forms on TSBP website);
- (2) reviewing application to determine if the application is complete or incomplete;
- (3) determining eligibility of applicant, including whether the applicant has prior disciplinary history;
- (4) coordinating with the TSBP Enforcement Division if applicant has enforcement record;
- (5) issuing a preceptor certificate to pharmacist if applicant is eligible to be certified; and
- (6) repeating the process every two years in conjunction with the pharmacist license renewal (preceptors must be re-certified on a biennial basis).

RENEWAL OF A PHARMACIST LICENSE

- (1) licensure renewal notices mailed to licensees;
- (2) approximately 93% of renewal applications are completed online – the licensee’s computerized record is updated with new expiration date and status;
- (3) license is automatically generated, reviewed for accuracy and a renewal card is mailed to the licensee.
- (4) approximately 7% of paper renewal applications are received and reviewed to determine if the applications are complete or incomplete; if an application is incomplete, the application is returned to the licensee with a letter explaining that the license will not be renewed unless the application is completed and returned to TSBP;
- (5) if the application is complete, the licensee’s computerized record is updated with a new expiration date and mailing the renewal card to the licensee;
- (6) hard-copy and imaged licensing files are maintained;
- (7) communication is sent to licensees regarding the status of the renewal of their licenses, including correspondence to remind licensees of their expiration dates if the licensees have not renewed their licenses in a timely manner; and
- (8) the process is repeated every two years (licenses are renewed on a biennial basis).

RENEWAL OF A PHARMACY TECHNICIAN REGISTRATION

- (1) registration renewal notices are mailed to registrants;
- (2) approximately 99% of renewal applications are completed online – the registrant’s computerized record is updated with new expiration date and status;
- (3) the registration is automatically generated, reviewed for accuracy and a renewal card is mailed to the licensee;
- (4) hard-copy and imaged of registration files are maintained;
- (5) process is repeated every two years (registrations are renewed on a biennial basis).

RENEWAL OF A PHARMACY LICENSE

- (1) licensure renewal notices mailed to licensees;
- (2) reviewing application to determine if the application is complete or incomplete;
- (3) for all sterile compounding pharmacies (Class A-S, C-S, E-S), reviewing the inspection to determine if a completed inspection has been conducted within the past 2 years;
- (4) for all Non-Resident (Class E) pharmacies, reviewing the inspection to determine if a completed inspection has been conducted within the past 3 years;
- (5) if the application is incomplete or the inspection cannot be verified for the applicable class of pharmacy, a missing item letter is mailed to the licensee explaining that the license will not be renewed unless the deficient items are addressed;
- (6) if the application is complete and the inspection is verified for the applicable class of pharmacy, the licensee’s computerized record is updated with a new expiration date and the renewal card is mailed to the licensee;
- (7) hard-copy and imaged licensing files are maintained;
- (8) communication is sent to individuals regarding the status of the renewal of their registrations, including correspondence to remind individuals of their expiration dates if the registrants have not renewed their registrations in a timely manner; and
- (9) process is repeated every two years (registrations are renewed on a biennial basis).

PHARMACIST, PHARMACY TECHNICIAN AND PHARMACY CHANGES

- (1) updating a pharmacist's license record with respect to a change of employment, address, or certification, upon receipt of notification of the change;
- (2) updating a pharmacist's license record with respect to a change of name, upon receipt of required documentation;
- (3) updating a pharmacy's license record with respect to change of name and/or address, or change in pharmacy class, upon receipt of completed application and required documentation;
- (4) updating a pharmacy's license record with respect to changes of managing officers, change in services provided, or change in the number of pharmacy scales/balances, upon receipt of application and required documentation;
- (5) updating a pharmacy technician registration record with respect to a change of employment or address, upon receipt of notification of the change;
- (6) updating a pharmacy technician registration record with respect to a change of name, upon receipt of required documentation.

PROVIDING INFORMATION

- (1) Licensing Program staff communicate with licensees and the public regarding the laws/rules and policies/procedures relating to the Licensing Program. Licensing Program staff make every effort to provide the requested information in the format or method requested (e.g., telephone, email, U.S. mail). In FY2015, Licensing Program staff responded to approximately 27,000 email inquiries; and handled 28,000 telephone calls.
- (2) Licensing Program staff provide information regarding the status of a license (e.g., active, inactive, expired) and instructions for licensure or registration. In addition, the public can determine the status of a license via the TSBP website. In FY2014, TSBP received 3,307,581 website inquiries with approximately 58% of the inquiries using the license verification link to verify a pharmacist or pharmacy license or intern registration.

C. What evidence can you provide that shows the effectiveness and efficiency of this program or function? Provide a summary of key statistics and outcome performance measures that best convey the effectiveness and efficiency of this function or program.

The following information is contained in the FY2014 Annual Report regarding the Licensing Program – prior Annual Reports (FY2001 – FY2014) containing this information can be found on the Board of Pharmacy website under Public Reports, *Annual Reports*.

- (1) The following chart reflects all year-end data for Licensing Measures required to be reported on an annual basis to the Legislative Budget Board. The statistical data was submitted to the Legislative Budget Board and Governor’s Office of Budget, Planning, and Policy by the prescribed due dates, in conjunction with the enforcement performance measures. Within a 5% variance, the division met or exceeded 100% of the Key Performance measures.

PERFORMANCE MEASURES	TARGET FY2014	ACCOMPLISHED FY2014	KEY OR NON KEY (K-NK)	EXPECTATIONS
Percent of Licensees with No Recent Violations	96%	95.50%	K	Met
Percent of Licenses Who Renew Online	93%	97.17%	K	Exceeded
Percent of New Individual Licenses Issued Online	98%	96.52%	NK	Met
Number of New Licenses issued to Individuals (Pharmacists)	1,450	1,849	K	Exceeded
Number of Licenses Renewed (Individuals – Pharmacists)	14,514	15,544	K	Exceeded
Number of New Registrations Issued to Individuals (Technician and Trainee)	10,000	14,385	NK	Exceeded
Number of Registrations Renewed (Technicians)	14,384	16,483	NK	Exceeded
Percent of New Licenses Issued within 10 days	95%	100%	NK	Exceeded
Percent of Individual Licenses Issued within 7 days	99%	100%	NK	Exceeded
Total Number of Pharmacists Licensed	29,645	30,707	NK	Exceeded
Total Number of Facilities Licensed	7,200	7,656	K	Exceeded
Total Number of Individuals (Technicians & Trainees) Registered	50,000	57,451	NK	Exceeded
Percent of Licensees with No Recent Violations	96%	95.50%	K	Met
Percent of Licenses Who Renew Online	93%	97.17%	K	Exceeded
Percent of New Individual Licenses Issued Online	98%	96.52%	NK	Met
Number of New Licenses issued to Individuals (Pharmacists)	1,450	1,849	K	Exceeded
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Percent of New Licenses Issued within 10 days	95%	100%	NK	Exceeded
Percent of Individual Licenses Issued within 7 days	99%	100%	NK	Exceeded
Total Number of Pharmacists Licensed	29,645	30,707	NK	Exceeded
Total Number of Facilities Licensed	7,200	7,656	K	Exceeded
Total Number of Individuals (Technicians & Trainees) Registered	50,000	57,451	NK	Exceeded

- (2) At year-end a total of 2,949 qualified pharmacist-interns (student interns and intern trainees) were certified within one to four days of receipt of required documents.
- (3) Staff presented intern overviews and a NAPLEX and MPJE Orientation to upcoming graduates of Texas Southern University, University of Houston, Texas Tech University, University of Texas, Texas A&M Health Science Center, Irma Lerma Rangel Colleges of Pharmacy and the University of the Incarnate Word Feik School of Pharmacy.

The following statistics relate to all applicants who were determined eligible and received a score for the NAPLEX and MPJE.

JURISPRUDENCE (MPJE)	TOTALS
Candidates Passing	1601 (94.79%)
Candidates Failing	88 (5.21%)
TOTAL ADMINISTERED	1689

NAPLEX	TOTALS
Candidates Passing	899 (92.40%)
Candidates Failing	74 (7.60%)
TOTAL ADMINISTERED	973

The total number of new licenses issued to individuals is as follows:

NEW PHARMACISTS LICENSED – FY2014	
Graduates of Texas Colleges of Pharmacy	686 (37.10%)
Graduates of Out-of-State Colleges of Pharmacy	998 (53.98%)
Credentialed by the Foreign Pharmacist Equivalency Committee	150 (8.11%)
Relicensures	15 (0.81%)
TOTAL	849

Regarding reciprocity (license transfer) in and out of Texas, 605 candidates were licensed by reciprocity in FY2014. The National Association of Boards of Pharmacy reports that in calendar year 2014, Texas had the largest number of requests to transfer licensure into the state with 1,027 requests. Further, this is an 8.1% increase compared to the 950 requests to transfer a license to Texas made in 2013.

- (4) The agency issued 1,849 new pharmacist licenses with an average turnaround time of seven business days from the download of the examination results. Of note in calendar year 2014, Texas reports having 30,167 licensed pharmacists, making it one of the states with the highest number of licensed pharmacists, according to census data in the NABP 2015 Survey of Pharmacy Law.
- (5) The agency renewed 15,544 biennial pharmacist licenses during FY2014. Approximately 93% of eligible pharmacists renewed their licenses online. The average processing time to issue a renewal license from receipt of a completed application was two business days and 100% percent of licenses were issued within five business days.
- (6) The agency issued 8,872 new pharmacy technician trainee registrations bringing the total population of active registered technician trainees for this fiscal year to 15,751. Approximately 98% of trainees applied for their registrations online. The average processing time to issue a pharmacy technician trainee registration from receipt of a completed application was one business day and 100% of certificates were mailed within five working days or less.
- (7) The agency issued 5,513 new pharmacy technician registrations, and renewed 16,483 registrations on a biennial basis, bringing the total population of active registered technicians for this fiscal year to 41,700. Approximately 98% of eligible applicants and pharmacy technicians applied for or renewed their registrations online.

The average processing time to issue a renewal registration from receipt of a completed application was 1 business day and 100% of certificates were mailed within 10 working days or less. The average processing time to issue an initial registration from receipt of a completed application was 2 business days and 100% of certificates were mailed within 10 working days or less.

- (8) The agency issued 563 new pharmacy licenses and 137 changes of ownership, which resulted in a record 700 new licenses issued. 3,575 licenses were renewed on a biennial basis, bringing the total population of active registered pharmacies for this fiscal year to 7,656. Approximately 27% of eligible pharmacies renewed their licenses online.

The average processing time to issue a renewal license from receipt of a completed application was two business days and 95% of licenses were mailed within five working days or less.

The average processing time to issue an initial license from receipt of a completed application, inspection, and enforcement review was 4 business days, and 100% of applications were licensed within 21 working days or less.

The following chart represents the total number of pharmacy licenses (business or facilities) issued by the agency, and includes 11 classes of pharmacy licenses.

ACTIVE PHARMACIES FY2014	
Class Of Pharmacy	Number
Class A (Community)	4830
Class A-S (Community Pharmacy Engaged Compounding Sterile Preparations)	302
Class B (Nuclear)	35
Class C (Institutional)	736
Class C-S (Hospital Pharmacy Engaged In Compounding Sterile Preparations)	436
Class D (Clinic)	364
Class E (Non Resident)	642
Class E-S (Non-Resident Pharmacy Engaged In Compounding Sterile Preparations)	150
Class F (Freestanding Emergency Medical Centers)	147
Class G (Central Processing)	13
Class H	01
TOTAL	7,656

A total of 3,982 change documents were processed as follows:

PHARMACY APPLICATIONS PROCESSED	
Pharmacy Renewals	3,575
New Licenses Issued [new opens (563) and changes of ownership (137)]	700
Closings	246
Remote Pharmacies	200
TOTAL	4,721

- (9) Fingerprint-based criminal background checks continued on all applicants for pharmacist-intern, pharmacy technician, and pharmacy technician trainee registrations and pharmacist licensure. In addition, quarterly DPS background checks were run on all individuals, once they are licensed or registered.
- (10) Customer Service Survey results for FY2015; indicate consistently high satisfaction ratings from agency customers on a monthly basis. Survey results indicate that customers believe that the online registration and/or licensure application was clear and easy to use, and the online renewal process for registration and/or licensure is efficient.

D. Describe any important history regarding this program not included in the general agency history section, including how the services or functions have changed from the original intent.

Over the years, the services/functions of the Licensing Program have expanded, but the original intent of the Licensing Program has remained the same: to license only competent and qualified applicants to practice and operate a pharmacy, and to register qualified pharmacy technicians to assist pharmacists with non-judgmental duties relating to the dispensing of prescriptions.

The “Texas Time Line” (in Section III), notes the major changes to the Texas Pharmacy Act with regard to the Licensure Program. However, specific “important history” regarding the Licensure Program is set forth below:

1981 Prior to 1981 one type of pharmacist and pharmacy license; annual renewal.

- one type of pharmacist license; four types of pharmacy licenses; licensing of institutional pharmacies and clinic pharmacies began; and
- TSBP promulgated rules increasing the number of internship hours required for licensure to 1,500 hours.

1984 TSBP promulgated rules that:

- provided for the staggered renewal of pharmacist licenses (annual renewals); and
- prohibited a pharmacist from serving as a preceptor if the pharmacist had been the subject of disciplinary sanctions within the previous three years.

1987 TSBP promulgated rules that:

- allowed Class D Pharmacies to petition the Board to have expanded formularies of dangerous drugs, under certain conditions; and
- allowed persons who had graduated from a foreign pharmacy school to apply for pharmacist license in Texas under certain conditions.

1988 Staggered annual renewal of pharmacy licenses began.

1989 Mandatory continuing education for pharmacists (12 hours per year) began.

1991 Texas Legislature passed laws that:

- created a fifth type of pharmacy license (Class E);
- created a system whereby a pharmacist was allowed to place their license on Inactive Status if the pharmacist complied with all the licensing requirements for the renewal of the license other than completing the continuing education requirements;
- prohibited agencies from renewing or issuing a license to any person who was in default on his/her student loan; and
- gave the Texas Attorney General the authority to issue an order to a state licensing agency to suspend any license of a person who was in arrears on child support payments.

1997 TSBP implemented new procedures relating to the Licensing Program:

- computerized adaptive testing of NAPLEX began for initial licensing of pharmacists; and
- an expanded student pharmacist-intern registration program (allowed pharmacy students in and out of Texas to become interns in Texas; application form was expanded to include attest questions regarding criminal history).

1999 Texas Legislature required TSBP to register pharmacy technicians, but did not appropriate funding to implement the program.

2000 Staggered biennial renewal of pharmacist and pharmacy licenses began, as well as batch renewals of pharmacy licenses.

2001 Texas Legislature took the following actions:

- increased the mandatory continuing education requirements to 30 hours per biennial renewal period; and
- established conditions through which pharmacy services could be provided through remote pharmacy sites.

2002 TSBP promulgated rules that required pre-inspections of pharmacy applicants, under certain conditions. In addition, the Board approved the implementation of an expanded application process in order for the agency to obtain sufficient background information to help ensure that the applicant intended to operate a bona fide pharmacy.

2003 Texas Legislature took the following actions:

- gave the agency the authority to create new classes of pharmacy licenses;
- appropriated funding for the agency to register pharmacy technicians; and
- gave the agency the authority to require applicants to run federal criminal history background checks for applicants for licensing and licensees.

2004 Implementation of the Pharmacy Technician initial and renewal program was completed.

2005 The Texas Legislature amended the Texas Pharmacy Act to require that TSBP register pharmacy technician trainees.

2006 In response to the emergency conditions that resulted from Hurricanes Katrina and Rita, the Licensing Division played an integral role in the coordination and development of the agency's response to these disasters. This resulted in the immediate development and implementation of a web-based online application form to expedite the issuance of temporary pharmacist licenses & temporary remote pharmacy services, and an accelerated, successful certification of student interns who transferred from Louisiana to Texas following the devastation caused by Hurricane Katrina.

2006 The Texas A & M Health Science Center Irma Lerma Rangel College of Pharmacy and the University of the Incarnate Word Feik School of Pharmacy open, resulting in six pharmacy schools/colleges in Texas.

2007 Successful implementation of the program to register a new category of registration type – the Pharmacy Technician Trainee, occurred in October 2006.

2009 Fingerprint-based criminal background checks were implemented on all new pharmacist applicants in October 2008, and all new pharmacy technician and technician trainee applicants in March 2009.

2013 The Texas Legislature:

- authorized the University of Texas at Tyler to establish a school of pharmacy, resulting in seven pharmacy schools/colleges in Texas;
- required an inspection prior to opening a sterile compounding pharmacy and specify that a pharmacy that compounds sterile preparations may not renew a pharmacy license unless the pharmacy has been inspected as provided by Board rule.

The key services of the Licensing Program are reflected in the agency's mission statement, which is to regulate the practice of pharmacy, the operation of pharmacies, and the distribution of prescription drugs in the public interest. As long as the agency's statutory mission exists, and candidates seek licensure and registration, there will be a need for the program.

E. Describe who or what this program or function affects. List any qualifications or eligibility requirements for persons or entities affected. Provide a statistical breakdown of persons or entities affected.

The Licensure Program directly affects the following entities:

ENTITY	YEAR END FY2014
Pharmacists	30,707
Preceptors	8,850
Pharmacist-Interns	2,949
Pharmacy Technicians	41,700
Pharmacy Technician Trainees	15,751
Pharmacies	7,656

Additional statistics can be found in response to Question C above.

QUALIFICATIONS OR ELIGIBILITY REQUIREMENTS

(1) PHARMACISTS FOR LICENSURE BY EXAMINATION – To be eligible to be licensed as a pharmacist in Texas by examination, an applicant must meet the following requirements:

(A) Age – must be at least 18 years of age.

(B) Education –

- must have earned a B.S. in Pharmacy or a Pharm.D. degree from a college of pharmacy program accredited by the American Council on Pharmaceutical Education (ACPE); or
- must have graduated from a college of pharmacy program outside the U.S. and have obtained full certification from the Foreign Pharmacy Graduate Equivalency Committee.

(C) Examinations – must have passed NAPLEX and Multi-State Pharmacy Jurisprudence Examination (MPJE) with a minimum final score of 75.

(D) Experience – must have completed 1,500 hours of internship.

(2) PHARMACISTS FOR LICENSURE BY RECIPROCITY – To be eligible to be licensed as a pharmacist in Texas by reciprocity, an applicant must meet the following requirements:

(A) Age – must be at least 18 years of age.

(B) Education –

- must have earned a B.S. in Pharmacy or a Pharm.D. degree from a college of pharmacy program accredited by ACPE; or
- must have graduated from a college of pharmacy program outside the U.S. and have obtained full certification from the Foreign Pharmacy Graduate Equivalency Committee.

(C) Examinations – must have taken and passed licensure exam which meets the same standards required of those who take such exam in Texas; must also take and pass the MPJE (for Texas applicants), which covers the laws and rules governing the practice of pharmacy in Texas.

(D) Experience/Background – must be licensed and current in a state with which Texas has a reciprocal agreement. Texas does not reciprocate with foreign boards of pharmacy.

(3) PRECEPTORS – To be eligible to be certified as a preceptor in Texas, an applicant must meet the following requirements:

(A) License – must hold an active license issued by TSBP.

(B) Training – must have completed three hours of approved preceptor training.

(C) Experience – must have one year of experience as a pharmacist; or have completed six months of residence training in a program accredited by the American Society of Health-System Pharmacists.

(D) Background – must not have been the subject of an order of the Board imposing any penalty set out in the Texas Pharmacy Act, unless approved following a petition to the Board who may grant such petition.

(4) PHARMACIST-INTERNS – There are three types of interns, as described below:

(A) Pharmacist Intern Trainee – To be eligible to be registered as an Intern Trainee in Texas, an applicant must meet the following requirements:

- be enrolled in the professional sequence of a college/school of pharmacy; and
- have met all requirements necessary for the board to access the criminal history records information, including submitting fingerprint information. Such internship shall remain in effect during the time the intern-trainee is enrolled in the first year of the professional sequence and shall expire upon completion of the first year of the professional sequence or upon separation from the professional sequence.

(B) Student Pharmacist-Interns – To be eligible to be registered as a Student Pharmacist-Intern in Texas, an applicant must meet the following requirements:

- must be enrolled in the professional sequence of a college of pharmacy whose professional degree program has been accredited by ACPE and approved by the Board;
- has successfully completed the first professional year and a minimum of 30 credit hours of work towards a professional degree in pharmacy; and
- has met all requirements necessary for the board to access the criminal history records information, including submitting fingerprint information.

In Texas, the colleges of pharmacy have as a part of their curriculum a structured internship program, where the pharmacy student goes through a series of rotations, gaining internship experience in retail pharmacy, hospital pharmacy, and clinical pharmacy. The Texas student, upon graduation, satisfies and even exceeds the 1,500 hours of internship required for pharmacist licensure in Texas.

(C) Extended Pharmacist-Interns – To be eligible to be registered as an Extended Pharmacist-Intern in Texas, an applicant must complete the required application, have met all requirements necessary for the board to access the criminal history records information, including submitting fingerprint information, and meet one of the following requirements:

- passed NAPLEX and the MPJE but lacks the required number of internship hours for licensure; or
- applied to the Board to take the NAPLEX and the MPJE within six calendar months after graduation and has graduated and received a professional degree from an ACPE-accredited degree program approved by the Board; or

- applied to the Board to take the NAPLEX and MPJE within six calendar months after obtaining full certification from the Foreign Pharmacy Graduate Equivalency Commission; or
- applied to the Board for re-issuance of a pharmacist license which has expired for more than two years but less than ten years and has successfully passed the MPJE, but lacks the required number of hours of internship or CE required for licensure; or
- been ordered by the Board to complete an internship.

(5) PHARMACIES – TSBP issues licenses to eleven different classes of pharmacies, which are described below:

- Class A (Community) Pharmacy – is a pharmacy that dispenses a drug or device to the public under a prescription drug order. This pharmacy may not compound sterile preparations.
- Class A-S (Community Pharmacy Engaged in Compounding Sterile Preparations) – is a pharmacy located in Texas that is authorized to dispense a drug or device to the public under a prescription drug order and engage in compounding sterile preparations.
- Class B (Nuclear) Pharmacy – is a pharmacy that dispenses a radioactive drug or device for administration to the ultimate user.
- Class C (Institutional/Hospital/Ambulatory Surgery Center) Pharmacy – is a pharmacy located in Texas in an inpatient facility including a hospital, licensed under Chapter 241 or 577, Health and Safety Code; a hospital maintained or operated by the state; a hospice inpatient facility licensed under Chapter 142, Health and Safety Code; or an ambulatory surgical center licensed under Chapter 243, Health and Safety Code. This pharmacy may not compound sterile preparations.
- Class C-S (Institutional/Hospital/Ambulatory Surgery Center Pharmacy Engaged in Compounding Sterile Preparations) - is a pharmacy located in Texas in an inpatient facility including a hospital, licensed under Chapter 241 or 577, Health and Safety Code; a hospital maintained or operated by the state; a hospice inpatient facility licensed under Chapter 142, Health and Safety Code; or an ambulatory surgical center licensed under Chapter 243, Health and Safety Code; and engage in compounding sterile preparations.

- Class D (Clinic) Pharmacy - is a pharmacy that provides a limited type of drug or device under a prescription drug order. (e.g. Health Clinic or Planned Parenthood).
- Class E [Non-Resident (Out of State) Pharmacy] – is a pharmacy located in a state other than Texas whose primary business is to dispense a prescription drug or device under a prescription drug order; and deliver the drug or device to a patient, including a patient in this state, by United States mail, common carrier, or delivery service. This license may not compound sterile preparations.
- Class E-S [Non-Resident (Out of State) Pharmacy Engaged in Compounding Sterile Preparations] – is a pharmacy located in a state other than Texas whose primary business is to dispense a prescription drug or device under a prescription drug order; and deliver the drug or device to a patient, including a patient in this state, by United States mail, common carrier, or delivery service. This license allows the pharmacy to compound sterile preparations to be shipped to the state of Texas.
- Class F (Freestanding Emergency Medical Care Center Pharmacy) – is a pharmacy that is licensed by the Texas Department of State Health Services pursuant to Chapter 254, Health and Safety Code, to provide emergency care to patients.
- Class G (Central Prescription Drug or Medication Order Processing Pharmacy) – is a pharmacy established for the primary purpose of processing prescription drug or medication drug orders. A Class G pharmacy may not store bulk drugs, or dispense a prescription drug order.
- Class H (Limited Prescription Delivery Pharmacy) – is a pharmacy established for the primary purpose of limited prescription delivery by a Class A pharmacy. A Class H pharmacy may not store bulk drugs or dispense a prescription drug order.

The statistical breakdown of the numbers of pharmacies licensed by TSBP is shown below.

ACTIVE PHARMACIES FY2014	
Class of Pharmacy	Number
Class A (Community)	4,830
Class A-S (Community Pharmacy Engaged Compounding Sterile Preparations)	302
Class B (Nuclear)	35
Class C (Institutional)	736
Class C-S (Hospital Pharmacy Engaged In Compounding Sterile Preparations)	436
Class D (Clinic)	364
Class E (Non Resident)	642
Class E-S (Non-Resident Pharmacy Engaged In Compounding Sterile Preparations)	150
Class F (Freestanding Emergency Medical Centers)	147
Class G (Central Processing)	13
Class H	01
TOTALS	7,656

To qualify for a pharmacy license, the applicant must submit a completed application that has been signed and notarized by the pharmacist-in-charge (PIC) and the pharmacy owner. The PIC must attest that he/she has read and understands the laws and rules relating to the class of pharmacy for which the applicant is applying. There are no restrictions as to who may own a pharmacy, but if the owner is not a pharmacist and not eligible to serve as the pharmacy's PIC, the owner must employ a PIC to be responsible for the legal operation of the pharmacy. Each class of pharmacy requires extensive supplemental documents to be submitted. In addition, a pre-inspection is required where applicable. The instructions and application forms for the eleven different classes of pharmacy licenses are available on the TSBP website at <http://www.pharmacy.texas.gov/infocies/newcies.asp>

F. Describe how your program or function is administered. Include flowcharts, timelines, or other illustrations as necessary to describe agency policies and procedures. Indicate how field/regional services are used, if applicable.

The Licensing Program is administered by 10 Licensing Specialists, and one Licensing Manager, supervised by the Director of Administrative Services and Licensing (who is also the supervisor for most of the personnel administering the Indirect Administration Program). The Licensing Specialists work as a team, but each FTE has designated areas of responsibility, as described below:

- One FTE – has general responsibility for the registration of pharmacy interns;
- One FTE – has general responsibility for the initial licensure of pharmacists;
- One FTE – has general responsibility for pharmacist renewals;
- One FTE – has general responsibility for the initial licensure of pharmacies located in Texas (new pharmacies and changes of ownership);

- One FTE – have general responsibility for the initial licensure of pharmacies located outside the state of Texas (new pharmacies and changes of ownership);
- One FTE – has general responsibility for the renewal of pharmacy licenses, initial registration for remote pharmacy services, and licensee changes (pharmacy change of name/location, rank changes);
- One FTE – has the general responsibility for pharmacy closings, change of managing officers, managing delinquent pharmacies, other licensee changes, imaging of licensing records;
- One FTE – has general responsibility for the initial registration of pharmacy technicians and pharmacy technician trainees;
- One FTE – has general responsibility for the renewal of pharmacy technicians; and
- One FTE – has general responsibility for the registration of pharmacist-preceptors, assisting in the initial licensure of pharmacists, providing primary telephone support to other licensing specialists.

There are no field or regional offices.

POLICIES AND PROCEDURES

INITIAL LICENSURE OF PHARMACISTS

(1) Application Procedures

(A) Applicants for Licensure by Examination – Forms, instructions, and information for those seeking to obtain a new pharmacist license in Texas are available online at the TSBP website <http://www.pharmacy.texas.gov/infocist/Licenselink.asp>. The applicant must also file an online application with the National Association of Boards of Pharmacy (NABP) to take the NAPLEX and MPJE. The applicant must complete the online application, pay the applicable fee and submit the required supplemental information to TSBP. Graduation affidavits are completed and mailed directly to TSBP by each college of pharmacy. Graduation affidavits confirm that the applicant has graduated from a college of pharmacy program accredited by ACPE and also confirm the number of accredited internship hours.

(B) Applicants for Licensure by Examination via Score Transfer - method by which a NAPLEX candidate can take NAPLEX in one state and have the passing score transmitted by NABP to another state. To participate in this program, the applicant must register with NABP and have a valid NAPLEX score that does not to exceed two years from the date of exam administration. Forms, instructions, and information for those seeking to obtain a new pharmacist license in Texas are available online at the TSBP website <http://www.pharmacy.texas.gov/infocist/Licenselink.asp>

The applicant must also file an online application with the National Association of Boards of Pharmacy (NABP) to take the MPJE. The applicant must complete the online application, pay the applicable fee and submit the required supplemental information to TSBP. Graduation affidavits are completed and mailed directly to TSBP by each college of pharmacy. Graduation affidavits confirm that the applicant has graduated from a college of pharmacy program accredited by ACPE and also confirm the number of accredited internship hours. If the applicant is licensed in another state, a letter from the licensing board of pharmacy will substitute for the internship requirement.

- (C) Applicants for Licensure by License Transfer (Reciprocity) – Forms, instructions, and information for those seeking to obtain a new pharmacist license in Texas by reciprocity are available online at the TSBP website <http://www.pharmacy.texas.gov/infocist/Licenselink.asp>. Online instructions and applications consist of a Texas Application for Licensure by Reciprocity, instruction sheet, Preliminary NABP application, Candidate’s Guide to the MPJE, and registration bulletin for NAPLEX and MPJE exams. Applicant files online, the Preliminary NABP application to NABP with the appropriate fee. NABP processes the application and returns the official NABP application to the applicant. The applicant must return the supplemental documents as noted on the TSBP website. The applicant must also file an online application with the National Association of Boards of Pharmacy (NABP) to take the MPJE.
- (2) Receipt of Application Forms/Fees and Review of Application - when TSBP receives the online payment and application, the application and supplemental documents are reviewed by the designated Licensing Specialist to determine if the application is complete and if the applicant is eligible to take the examinations for licensure. The agency’s computerized data base is updated and a “missing item” letter is generated, if necessary.
- (3) Criminal History Background Check – In order for TSBP to conduct a background check, all applicants are required to complete a fingerprint session through Fingerprint Applicant Services of Texas. After an application is submitted, the applicant will receive an email with fingerprint instructions attached. This form is referred to as the "Fast Pass Fingerprint" form. Out of state applicants will also receive a packet with a fingerprint form and instructions sheet because the approved state vendor does not always allow a digital scan. The fingerprint packet is automatically mailed to the address provided on an application within 2 to 3 weeks of the date an application is submitted. Upon electronic receipt of the background check, the application is processed per procedure.

- (4) Coordination with Enforcement/Legal Divisions – The application is referred to the Enforcement/Legal Divisions for review if one or more of the following conditions apply:

(A) if the applicant checks “yes” to one or more of the attest questions;

(B) if the DPS or FBI background check is not clear; and/or

(C) if the applicant checks “no” to an attest question and the DPS or FBI background check indicates that the applicant should have checked “yes” to the attest question. When referring an applicant to the Enforcement/Legal Divisions, the designated Licensing Specialist completes a complaint form and places the applicant on Administrative Hold until released by the Enforcement/Legal Divisions.

TSBP does not allow an applicant to take the licensure examination if the agency is instituting disciplinary action to deny the issuance of the license.

- (5) Examination Results – Applicants may review individual examination results that post electronically on the NABP website. Examination results are downloaded to the TSBP database on a weekly basis and applicants are notified if the applicant is licensed or if the applicant must retake an examination.
- (6) Examination Retakes – If an applicant must retake the NAPLEX and/or MPJE, the applicant is notified of the retake procedures, including fees. In accordance with Section 558.055 of the Texas Pharmacy Act, applicants may not retake an examination if they have failed the examination three times, unless documentation is provided from a college of pharmacy stating that the applicant has successfully completed additional course work in the examination subject area the applicant failed. Note: the 84th Texas Legislature amended this section to allow an applicant to take an examination four additional times.
- (7) Issuance of Pharmacist License – If all requirements for pharmacist licensure have been met and the applicant has been cleared by the Enforcement/Legal Divisions, a license is issued and the applicant is notified of his/her license number. Included with this notification are instructions to initially renew the pharmacist license within 30 days of the date of licensure. If the license renewal is not completed and submitted with the appropriate fee within 30 days, the license expires and cannot be renewed after one year. The fee is prorated to coordinate with TSBP’s staggered biennial renewal of licenses, based on a licensee’s birth month. Within six weeks of the issuance of the license number, TSBP mails a hand-inscribed license (wall certificate) to the licensee.

RE-LICENSURE OF PHARMACISTS, REINSTATEMENTS AND DISCIPLINARY EXAMINEES

- (1) Re-licensure of Pharmacists – Texas pharmacists whose licenses have lapsed for more than one year must follow the re-licensure process as outlined in TSBP Rule 283.10. The procedures are outlined on the TSBP website: <http://www.pharmacy.texas.gov/infocist/relicensure.asp>. In addition, these applicants must take and pass the MPJE, complete additional hours of CE and may be required to complete internship hours. In the latter event, the applicant would be required to complete an application to become an Extended Pharmacist-Intern and follow the procedures to obtain the required number of hours. When all requirements have been met, and the Licensing Specialist has received clearance from the Enforcement/Legal Divisions, TSBP re-issues the license.
- (2) Reinstatement of Pharmacist License – If a Texas pharmacist had his/her license revoked or cancelled as a result of a disciplinary order, the pharmacist is eligible for reinstatement one year after the effective date of the revocation/cancellation. If the Board enters a subsequent order to reinstate the license, the applicant would be required to meet at least the minimum requirements set forth in TSBP Rule 283.10 with regard to completing additional CE, passing the MPJE, and completing internship hours. These applicants must pay a fee to take the MPJE and complete the required application form to take the exam. The designated Licensing Specialist would process the application form and coordinate the notification of the exam score with the Enforcement Division.
- (3) Disciplinary Examinees – The Board may enter a disciplinary order requiring a licensee to take the MPJE or NAPLEX. These applicants must pay the appropriate fees and complete the required application form. The designated Licensing Specialist would process the application form and coordinate the notification of the exam score with the Enforcement Division.

INITIAL LICENSURE OF PHARMACIES

- (1) Application Forms – Application forms for each of the eleven classes of pharmacy are available online at <http://www.pharmacy.texas.gov/infocies/newcies.asp>. The application form is unique to the class of pharmacy and requires extensive ownership information, including applications completed and signed by the managing officers; lease or property information, and if applicable, a copy of sales contract; credit worthiness documents and a new pharmacy checklist, which lists the minimum infrastructure requirements needed to apply for a new pharmacy license.
- (2) Receipt of Application Forms/Fees and Review of Application – When TSBP receives the application form and fee payment for a pharmacy license, the agency deposits the money and forwards the application documents to the designated Licensing Specialist who reviews the application to determine if the application is complete. The agency's computerized data base is updated and a "missing item" letter is generated, if necessary.

- (3) Criminal History Background Check – TSBP conducts a criminal history background check on each applicant from the Texas Department of Public Safety (DPS). If the background check is clear, the application is processed per procedure.
- (4) Coordination with Enforcement/Legal Divisions – Generally, all new pharmacy applications are reviewed by Enforcement prior to licensure. Depending on the class of pharmacy, reviews are conducted to determine if there is necessary enforcement action required as a result of a criminal history issue; a pre-inspection review; a nuclear floorplan and qualifications review; a Class D formulary and Policy and Procedure manual review; Class E inspection review. Class E-S pharmacy applicants require extensive review of the supplemental material listed at:
http://www.pharmacy.texas.gov/files_pdf/INSTRUCTIONS_CLASS_E_STERILE_PHCY.pdf
- (5) Pre-Inspection of Pharmacy Location – Prior to the issuance of a pharmacy license located in Texas, the Board conducts an on-site inspection of the pharmacy in the presence of the pharmacist-in-charge (PIC) and owner or representative of the owner, to ensure that the PIC and owner can meet the requirements of the Texas Pharmacy Act and TSBP rules.

Prior to the issuance of a Non-Resident (Out of State) Pharmacy (Class E), a current inspection conducted by the regulatory or licensing agency of the resident state no more than three years prior to the date of the application must be submitted. Prior to the issuance of a Non-Resident (Out of State) Pharmacy Engaged in Compounding Sterile Preparations (Class E-S), an inspection conducted within the previous two years by one of the TSBP's approved vendors as shown on the following link <http://www.pharmacy.texas.gov/Class-E-Non-Resident-Pharmacy-Inspectors.asp> must be submitted.

- (6) Remote Pharmacy Services – If the pharmacy is a provider of remote pharmacy services, a separate application is required for each remote location. No additional fee is required, but a separate registration card is generated for each remote location. Remote pharmacy services can include an automated pharmacy, emergency medication kit, or telepharmacy system.
- (7) Issuance of Pharmacy Licenses – If all requirements for licensure have been met and the applicant has been cleared by the Enforcement/Legal Divisions, the owner is notified of the pharmacy's license number (if a new pharmacy) and the pharmacist-in-charge is required to notify TSBP in writing of the opening date of business, whereupon TSBP will mail the actual pharmacy license to the pharmacy. If the pharmacy is already in operation (e.g., change of ownership), the pharmacy license is mailed to the pharmacy.

REGISTRATION OF PHARMACIST-INTERNS/INTERNSHIP

- (1) Application Process – Intern application forms are available online at the TSBP website, at http://www.pharmacy.texas.gov/infocist/intern_intro.asp. Application forms for extended internship are also available for download at this same site. TSBP does not charge a fee to process an application for a pharmacist-intern registration. Upon receipt of the supplemental documents, the designated Licensing Specialist determines correct intern rank (i.e., intern trainee or student intern). In the case of Extended Intern, a paper application is submitted and the rank is immediately determined.
- (2) Criminal History Background Check – same procedures as described previously with respect to initial licensure of pharmacists.
- (3) Coordination with Enforcement/Legal Divisions – same procedures as described previously with respect to initial licensure of pharmacists.
- (4) Issuance of Registration – If all requirements have been met and the applicant has been cleared by the Enforcement/Legal Divisions, the applicant is notified and sent an intern registration bearing an expiration date, as described below:
 - (A) Pharmacist Intern Trainee – In this case, the Texas college of pharmacy internship coordinator is notified of the pharmacist intern trainee approval. Such internship shall remain in effect during the time the intern-trainee is enrolled in the first year of the professional sequence and shall expire upon completion of the first year of the professional sequence or upon separation from the professional sequence.
 - (B) Each Student Pharmacist-Intern card has an expiration date that is set six months beyond the applicant’s anticipated date of graduation from pharmacy school/college. Internship authorization ceases immediately on the date of a letter informing the intern that he/she has failed an examination or if the allotted six month intern window has passed.
 - (C) Each Extended Pharmacist-Intern card has an assigned expiration date; the assigned expiration date is based on the length of time that the individual is eligible to be an intern (see eligibility requirements for Extended Pharmacist- Interns described above). All internship hours reported must be worked within the effective dates of that internship and during a period of time that the signing preceptor was certified.

INITIAL AND RENEWAL CERTIFICATION OF PRECEPTORS

- (1) Distribution of Application Forms (form is entitled “Agreement for Certification as a Preceptor”) – To become certified as a preceptor, a pharmacist must complete an application and attest that he/she has meet the eligibility requirements and will comply

with Board Rules. Application forms are available online on the TSBP website. If requested, TSBP will mail an application form to a pharmacist who wishes to become certified as a preceptor.

- (2) Receipt/Review of Application Form – TSBP does not charge a fee to process an application for a preceptor certification. Upon receipt of the application, the designated Licensing Specialist determines if the application is signed and complete, and also checks the following items:
 - (A) Status of Pharmacist License – to be eligible to become a preceptor, a pharmacist must have an “Active” pharmacist license issued by TSBP. The Licensing Specialist checks TSBP records to determine if license is current.
 - (B) Training – to be eligible to become a preceptor, a pharmacist must have completed the applicable three hour training course. The pharmacist is not required to submit proof of completion of the training course. Instead, the pharmacist attests on the application form that he/she has completed the three hour course.
 - (C) Experience – must have one year of experience as a pharmacist; or have completed six months of residence training in a program accredited by the American Society of Health-System Pharmacists.
 - (D) Background – must not have been the subject of an order of the Board imposing any penalty set out in the Texas Pharmacy Act, unless approved following a petition to the Board who may grant such petition. The Licensing Specialist will check the pharmacist’s enforcement history with TSBP. If the pharmacist has an enforcement record, the Licensing Specialist will forward the application to the Director of Enforcement (DOE) or designee for review.
- (3) Approving or Denying Application – If the DOE determines that the pharmacist is eligible to serve as a preceptor, the DOE will return the preceptor’s application to the Licensing Specialist with a note to process the application per procedure; if the DOE determines that the pharmacist is not eligible to serve as a preceptor, the DOE or designee notifies the licensee by telephone or letter.
- (4) Issuance of Initial Certificate – If the initial application is approved, the Licensing Specialist mails a certificate with an expiration date that is the same date as the expiration date of the pharmacist’s license.
- (5) Renewal of Certificate – A preceptor may renew his/her certification concurrently with his/her pharmacist license renewal, provided the pharmacist still meets the eligibility requirements to be a preceptor.

RENEWAL OF PHARMACIST LICENSES

- (1) Distribution of Renewal Application Forms – TSBP automatically mails renewal notices and/or applications to licensees 60 days prior to their license expiration date. If the licensee does not renew the license in a timely manner, TSBP will mail a reminder letter to the licensee 15 days before the license expires.
- (2) Receipt of Application Forms/Fees – The licensee renews the license by mailing the renewal application form and fee to TSBP, or submitting an online payment and application.
- (3) Review of Application Forms – After the payment and application are received/reviewed, the database is updated with the renewal information. The designated Licensing Specialist reviews the paper application to determine if the application is complete. Online applications and payment are automatically considered complete and updated immediately.
- (4) Complete Applications – If the paper application is complete, a license renewal certificate is mailed to the pharmacist. Online applications and payment are automatically considered complete and updated immediately. Approximately 93% of pharmacists participate in the online renewal system. The average turnaround time for processing a pharmacist renewal is one to two days.
- (5) Communication with Enforcement/Legal Divisions – A copy of the paper renewal application with attachment(s) is forwarded to Enforcement if the applicant checks “yes” to one or more of the attest questions. For online renewal application attestations, an electronic report is forwarded to Enforcement, indicating the “yes” responses.

Pharmacists are required to renew their licenses biennially. Accordingly, the process described above is repeated every two years.

RENEWAL OF PHARMACY LICENSES

- (1) Distribution of Renewal Application Forms – TSBP automatically mails renewal notices to licensees 60 days prior to their license expiration date. If the licensee does not renew the license in a timely manner, TSBP will mail a reminder letter to the licensee 15 days before the license expires.
- (2) Receipt of Application Forms/Fees – The licensee renews the pharmacy license by downloading the application form from the website: <http://www.pharmacy.texas.gov/infocies/renewals/lic/index.asp> and either mailing the renewal application form and fee to TSBP, or submitting an online payment.

- (3) Review of Application Forms – After the payment and application are received/reviewed, the database is updated with the renewal information. The designated Licensing Specialist reviews the paper application to determine if the application is complete. In addition, all sterile compounding pharmacies (both in state and out-of-state) may not renew their pharmacy license unless the pharmacy has been inspected by the Board or its designee within the last two years. Verification of inspection is required for renewal of sterile compounding pharmacies.
- (4) Complete Applications – If the application is complete, a license renewal certificate is mailed to the pharmacy. The average turnaround time for processing a completed pharmacy renewal is two days.
- (5) Communication with Enforcement/Legal Divisions – A copy of the paper renewal application with attachment(s) is forwarded to Enforcement if the applicant checks “yes” to one or more of the attest questions.

Pharmacies are required to renew their licenses biennially. Accordingly, the process described above is repeated every two years.

RENEWAL OF PHARMACY TECHNICIAN REGISTRATIONS

- (1) Distribution of Renewal Application Forms – TSBP automatically mails renewal notices to registrants 60 days prior to their registration expiration date.
- (2) Receipt of Application Forms/Fees – The pharmacy technician renews the registration by submitting an online payment and application. In some cases, a paper application is requested and mailed to the pharmacy technician.
- (3) Review of Application Forms – After the payment and application are received/reviewed, the database is updated with the renewal information. The designated Licensing Specialist reviews the paper application to determine if the application is complete. Online applications and payment are automatically considered complete and updated immediately.
- (4) Complete Applications – If the paper application is complete, a license renewal certificate is mailed to the pharmacy technician. Online applications and payment are automatically considered complete and updated immediately. Approximately 99% of pharmacy technicians participate in the online renewal system. The average turnaround time for processing a pharmacy technician registration is one day.

- (5) Communication with Enforcement/Legal Divisions – A copy of the paper renewal application with attachment(s) is forwarded to Enforcement if the applicant checks “yes” to one or more of the attest questions. For online renewal application attestations, an electronic report is forwarded to Enforcement, indicating the “yes” responses.

Pharmacy technicians are required to renew their registrations biennially. Accordingly, the process described above is repeated every two years.

PHARMACIST AND PHARMACY TECHNICIAN CHANGES

- (1) Change of Name – If an individual changes his/her name, the individual must submit supporting documentation (e.g., marriage certificate, divorce decree) and pay a fee of \$20. Refer to TSBP Rule 295.1. Once this information is obtained, the designated Licensing Specialist updates the agency’s computerized data base.
- (2) Change of Address/Employment – If an individual changes address or employment, he/she is required to notify TSBP within 10 days of the change. Refer to Section 562.053 of the Texas Pharmacy Act. Once this information is obtained, the designated Licensing Specialist updates the agency’s computerized data base.

PHARMACY CHANGES

- (1) Pharmacy Change of Name/Location – If a pharmacy changes name and/or location, a separate application and fee are required. Supporting documentation is also required for a change of location (i.e., a lease agreement or property ownership must be submitted with the application). Although the license number does not change, a new license under the correct name and/or location is issued and the agency’s computerized data based is updated. Refer to TSBP Rule 291.2. All application forms and instructions can be found on the TSBP website. In FY2014, TSBP processed 366 applications with respect to change of name/location.
- (2) Pharmacy Closings – If a pharmacy ceases operation, the pharmacy is required to comply with TSBP Rule 291.5. Upon receiving the written notification regarding the closing of a pharmacy, the designated Licensing Specialist determines if the written notification advises TSBP of the disposition of the drugs and records belonging to the pharmacy. If this information is not provided, the Licensing Specialist will contact the licensee by telephone or letter in order to obtain this information. Once this information is obtained, the data base is updated and the pharmacy is closed in TSBP records. In FY2014, TSBP processed 246 pharmacy closings.
- (3) Pharmacy Change of Classification – If a pharmacy changes its class of pharmacy, an application and fee are required. Although the license number does not change, a new license under the correct class is issued and the agency’s computerized data based is updated. Although any class change may be requested, the majority of class changes

occur between pharmacies that change to/from a pharmacy that compounds sterile preparations. Due to a law change and rule change in 2014, the agency processed approximately 1,026 Class Changes involving sterile compounding pharmacies, since February 2014 to date (August 2015). These types of class changes required not only a review of the application, but a review by Enforcement, of the most current inspection conducted.

- G. Identify all funding sources and amounts for the program or function, including federal grants and pass-through monies. Describe any funding formulas or funding conventions. For state funding sources, please specify (e.g., general revenue, appropriations rider, budget strategy, fees/dues).**

The Licensing Program receives no federal funds. The agency is totally self-supporting, in that the operations of the agency are supported primarily from statutory fees related to licensing, reciprocity, and examinations from licensure fees to support the agency's operations. See Section V of this report for details regarding funding.

- H. Identify any programs, internal or external to your agency, that provide identical or similar services or functions to the target population. Describe the similarities and differences.**

There are no programs, internal or external, that provide the level of service or functions of the Licensure Program.

- I. Discuss how the program or function is coordinating its activities to avoid duplication or conflict with the other programs listed in Question H and with the agency's customers. If applicable, briefly discuss any memorandums of understanding (MOUs), interagency agreements, or interagency contracts.**

Not applicable

- J. If the program or function works with local, regional, or federal units of government, include a brief description of these entities and their relationship to the agency.**

Not applicable

K. If contracted expenditures are made through this program please provide:

- a short summary of the general purpose of those contracts overall;
- the amount of those expenditures in fiscal year 2014;
- the number of contracts accounting for those expenditures;
- top two contracts by dollar amount, including contractor and purpose;

Expenditure	Contract Number	Vendor	Purpose
\$226,986.00	51500000088	TX NICUSA	DIR contract for collection of online fees.
\$196,963.20	515-4-0175	Texas Facilities Commission	Construction of office space for the Licensing Division in Tower 1 of the Hobby Building.

- the methods used to ensure accountability for funding and performance; and

TSBP staff complies with all appropriate statutes, rules, and policies. Major contracts are either issued under a DIR term contract, or are exempt by statute.

- a short description of any current contracting problems.

TSBP is always looking for ways to improve processes to ensure contracts meet the needs of internal customers while being in compliance with appropriate statutes, rules, and policies.

L. Provide information on any grants awarded by the program.

No grants are awarded by the Licensing Program.

M. What statutory changes could be made to assist this program in performing its functions? Explain.

The 2005 Texas Legislature amended the Pharmacy Act to require the Texas State Board of Pharmacy to inspect and authorize Canadian pharmacies to sell prescription medications to patients in the state of Texas. On December 21, 2005, Attorney General Greg Abbott issued Opinion #GA-0384, which states that designating certain Canadian pharmacies, listing them on the Board's website, and permitting Texas consumers to import prescription drugs from Canada would violate federal law. As a result of this opinion, the Board did not implement the Canadian pharmacy provisions of the Act. This statutory provision should be removed.

N. Provide any additional information needed to gain a preliminary understanding of the program or function.

Because of the complexity of the program, coordination between the Enforcement and Licensing Programs is essential.

O. Regulatory programs relate to the licensing, registration, certification, or permitting of a person, business, or other entity. For each regulatory program, if applicable, describe:

- why the regulation is needed;
- the scope of, and procedures for, inspections or audits of regulated entities;
- follow-up activities conducted when non-compliance is identified;
- sanctions available to the agency to ensure compliance; and
- procedures for handling consumer/public complaints against regulated entities.

Enforcement Program

<i>Name of Program or Function:</i>	Enforcement
<i>Location/Division:</i>	TSBP Headquarters – Hobby Building, 333 Guadalupe, Suite 3-600, Austin, Texas 78701
<i>Contact Name:</i>	(1) Carol Fisher, R.Ph., M.P.A. Director of Enforcement
	(2) Kerstin Arnold, J.D. General Counsel
	(3) Allison Benz, R.Ph., M.S. Director of Professional Services
<i>Actual Expenditures, FY 2014:</i>	4,389,537.32
<i>Number of Actual FTEs as of June 1, 2015:</i>	65.33

Statutory Citation for Program: Occupations Code, Title 3, Subtitle 1.

The relevant statutory provisions are listed below.

Citation	Description
Texas Pharmacy Act, Section 551.002	Declares the purpose of the Texas Pharmacy Act is to promote, preserve and protect the public health and safety through effectively controlling and regulating the practice of pharmacy. Also states that the Act shall be liberally construed to regulate in the public interest the practice of pharmacy.
Texas Pharmacy Act, Chapter 554.001 Subchapter A Includes: Section 554.001(a)(1) Section 554.001(a)(2) Section 554.002 Section 554.005 Section 554.010	Powers and Duties of the Board “Administer and enforce” the Texas Pharmacy Act and rules adopted under the Act and “enforce other laws relating to the practice of pharmacy.” Cooperate with other state and federal agencies in the enforcement of any law relating to the practice of pharmacy or any drug or drug-related law. Methods through which the Board shall regulate the practice of pharmacy, including enforcement and disciplinary sanctions. Methods through which the Board may and may not regulate prescription drugs and devices. The Board may commission a peace officer which carries with it the powers, privileges, and immunities of a peace officer.
Texas Pharmacy Act, Chapter 554.001 Subchapter B – Rulemaking Specifically, Section 554.051(a)	The Board shall adopt rules consistent with the Act for the administration and enforcement of the Act.
Texas Pharmacy Act, Chapter 555	Complaint Procedures.
Texas Pharmacy Act, Chapter 556	Administrative Inspections and Warrants.
Texas Pharmacy Act, Chapter 557.004	Disciplinary actions on a Pharmacist-Intern.
Texas Pharmacy Act, Chapter 559 Subchapter B Mandatory Continuing Education	Specifically, Section 559.056 relating to Demonstration of Compliance – Continuing Education Audits.
Texas Pharmacy Act, Chapter 564 Subchapter A and B	Program to Aid Impaired Pharmacists and Pharmacy Students.
Texas Pharmacy Act, Section 564.105	Authorizes the Board to issue subpoena for peer review committee proceedings.
Texas Pharmacy Act, Chapter 565 Includes: Section 565.051 Section 565.055 Section 565.056 Section 565.057 Section 565.058 Section 565.059	Disciplinary Actions and Procedures, including Grounds for Discipline for a pharmacist and pharmacy license Types of disciplinary sanctions that Board may impose on a pharmacist or pharmacy license. Provides that Investigative Files are confidential. Provides for informal proceedings to settle disciplinary cases. Requires the Board to monitor licensees who have been subject to disciplinary action. Authorizes the Board to issue subpoenas. Authorizes the Board to temporarily suspend or restrict a license, if continuing threat.

Section 565.060 Subchapter C	Establishes alternative resolution through Remedial Plan. Reinstatement of License.
Texas Pharmacy Act, Chapter 566	Procedures related to administrative penalties (fines), injunctive relief, civil penalties, and criminal penalties.
Texas Pharmacy Act, Chapter 568.003 Texas Pharmacy Act, Chapter 568.0035 Texas Pharmacy Act, Chapter 568.0036	Grounds for Disciplinary Action for a Pharmacy Technician and Pharmacy Technician Trainee. Disciplinary Sanctions that may be imposed for violations of 568.003; discipline on a Trainee remains in effect if Trainee becomes a Tech. Procedures for requiring mental or physician examination for Technician, Trainee or Applicant for Registration.
Texas Pharmacy Act, Chapter 568.0037	Procedures relating to Temporary Suspensions or Restriction of a Registration.
Texas Pharmacy Act, Chapter 569	Procedures relating to professional liability claims (malpractice reports).

B. What is the objective of this program or function? Describe the major activities performed under this program.

The key function of the Enforcement Program is to promote, preserve and protect the public health, safety, and welfare of the citizens of Texas through the regulation of the practice of pharmacy, the operation of pharmacies, and the distribution of prescription drugs in the public interest. The key services performed under this program are listed below:

- (1) resolving complaints through various means, including disciplinary actions;
- (2) conducting inspections of pharmacies, which includes the following activities:
 - conducting inspections of multiple classes of Texas pharmacies, including pharmacies that compound sterile and non-sterile preparations;
 - outsourcing inspections of Class E-S Pharmacies located in other states that compound sterile preparations; includes the monitoring of outside vendors who are contracted to conduct these inspections and reviewing the reports of the inspections conducted by inspectors employed by authorized vendors and following-up on unsatisfactory conditions detected by these inspectors;
 - conducting pre-inspections of facilities that have applied for a pharmacy license; and
 - includes collecting samples of compounded preparations during inspections, including compounded sterile preparations and compounded non-sterile preparations.
- (3) conducting audits to determine a licensee's or registrant's compliance with mandatory continuing education requirements;

- (4) monitoring compliance of licensees who have been the subject of a disciplinary order;
- (5) proposing and adopting rules relating to the practice of pharmacy;
- (6) providing information regarding laws/rules governing the practice of pharmacy, agency operations and agency records; information services are provided through a variety of mechanisms, such as verbal and written communications (e.g., telephone, letter and e-mail), newsletter, and education outreach programs;
- (7) assisting with the on-going development of the Multi-State Pharmacy Jurisprudence examination; and
- (8) providing legal services and monitoring vendor contracts.

The key services are provided through the following organizational divisions: Enforcement Division, Legal Division, and Professional Services Division. The major activities of each key service are described below:

- (1) **Complaints** – The Enforcement and Legal Divisions are responsible for resolving complaints.
 - (A) Enforcement Division staff performs the following major activities:
 - Investigates complaints received or opened by the agency, including criminal background investigations, and refers complaints to the Legal Division, when applicable;
 - Reviews professional liability claim forms (malpractice reports) and investigate reports, when applicable;
 - Communicates with the public regarding the complaint process, including verbal and written communication with complainants (persons who file complaints) about the receipt and disposition of their complaints;
 - Maintains evidence locker to ensure evidence security and chain of custody;
 - Cooperates with other regulatory and law enforcement agencies, and maintains liaison with local, state, and federal investigators, to enforce drug laws;
 - Prepares reports regarding complaints for various entities, including certification of enforcement-related performance measures; and
 - Maintains complaint files in accordance with agency's record retention schedule, including the imaging of files that have extended retention periods.

(B) Legal Division staff performs the following major activities:

- Reviews complaints, during all phases of the complaint process, including providing legal advice to investigators regarding appropriate course of action and evidentiary matters;
- Monitors receipt, assignment, and resolution of all cases referred to the Legal Division;
- Institutes disciplinary proceedings against licensees, registrants, and applicants, who have violated pharmacy and/or drug laws and rules;
- Plans/conducts informal settlement conferences and settles disciplinary cases through informal proceedings;
- Drafts proposed Agreed Board Orders for consideration and review by the Board;
- Files complaints with the State Office of Administrative Hearings (SOAH) if a case cannot be settled through informal proceedings;
- Prosecutes cases against licensees, registrants, and applicants through formal hearings before an Administrative Law Judge (ALJ) at SOAH;
- Reviews proposals for decision (PFD) drafted by ALJs and draft proposed Board Orders based upon ALJ's PFD to present to the Board for review and consideration;
- Communications with complainants verbally and in writing regarding the prosecution of the subject of their complaints; and
- Provides technical assistance to local, state, and federal prosecutors, legal divisions, and enforcement agencies involved in the investigation or prosecution of entities licensed by the Board.

(2) **Inspections** – The Enforcement Division has 12 employees (four pharmacists and eight pharmacy technicians) to perform the following major activities relating to inspections:

- Conducts pre-licensure inspections to help ensure the pharmacy is located in a legitimate location (e.g., not located in a personal residence) and the facility is in compliance with environmental requirements (e.g., ensure pharmacies who intend to compound sterile preparations have the required equipment and facilities);
- Conducts routine inspections of pharmacies licensed by TSBP;

- Conducts inspections of pharmacies that compound sterile preparations every two years, within the pharmacy's renewal period; otherwise, TSBP is prohibited from renewing the pharmacy license;
- Issues written warning notices regarding non-satisfactory conditions that exist in a pharmacy which requires the pharmacy to submit a response as to how the conditions are corrected, and monitors the receipt of the written response;
- Conducts non-routine inspections of pharmacies licensed by TSBP, including inspections (investigations) conducted as a result of a complaint and follow-up inspections to determine if the pharmacy has complied with previously-issued warning notices;
- Collects samples of compounded sterile preparations and non-sterile preparations; the state of Texas is only one of two states that have a program to collect samples of compounded preparations; and
- Initiates complaints (and collects evidence) for referral to the Legal Division, when applicable.

(3) Continuing Education (CE) Audits – The Professional Services Division staff performs the following major activities relating to CE audits:

- Orders a computer-generated list of pharmacists and technicians who are randomly selected for a CE audit (the agency's computer program selects the random sample);
- Reviews list of CE completed (by each pharmacist or technician selected in the random sample) that is on file with the CPE Monitor. If the CPE Monitor reflects that the selected pharmacist or technician has completed the required number of hours during the audit period, TSBP closes the audit and takes no further action. See response to Question C for additional details regarding the CPE Monitor;
- Downloads form letters addressed to a random sample of pharmacists and technicians, advising them that they are the subject of a CE audit, unless TSBP confirms (by reviewing the CPE Monitor) that the licensee/registrant has completed the required CE for the audit period;
- Mails a letter to each pharmacist or technician selected in the random sample, informing them that they must submit copies of the required number of CE certificates to TSBP by the due date provided in the letter;

- Monitors the return of the CE certificates;
- Determines, upon receipt of CE certificates, whether the pharmacist or technician has obtained the required number of hours;
- Initiates a complaint, if the pharmacist or technician has not responded to the CE audit letter or has not submitted the required number of CE hours; and either refers the complaint to the Legal Division or resolves the complaint by other means; and
- Communicates with pharmacists and technicians about CE audits and the laws/rules relating to CE, including letters to advise pharmacists and technicians of the outcome of the CE audits.

(5) **Monitoring Compliance with Terms/Conditions of Disciplinary Orders** – The staff of the Enforcement Division enters information regarding disciplinary orders into the agency’s computer system, and then notifies licensees and registrants of the entry of disciplinary orders by mailing a copy of the disciplinary order with a detailed cover letter that explains terms and conditions of the Order. The staff of the Enforcement Division then monitors licensees who have been the subject of a disciplinary order through the following major activities:

(A) In-House Monitoring

- Determines if licensee or registrant complies with the terms of the Order by the required due dates, such as payment of administrative penalties (fines) and probation fees, submission of required CE, and submission of policy/procedure manuals;
- Determines compliance with drug screening program, including whether the licensee or registrant has submitted to the required drug screen on the required day and determining if results of drug screens are positive for drugs for which the licensee/registrant does not have a prescription;
- Reviews required reports to determine if the reports are in compliance with the terms of the disciplinary orders;
- Updates agency’s computer system regarding status of license to “surrender” or “suspended” when pharmacist or technician has not complied with certain terms/conditions of the order, such as when the pharmacist or technician tests positive for an illicit drug; and notifies employers in writing of the licensee/registrant’s status; and
- Initiates complaints on pharmacists and technicians who are not in compliance with the terms of their disciplinary orders and refers complaints to the Legal Division, when applicable.

(B) Field Monitoring – Inspectors conduct inspections of pharmacies to ensure that pharmacists or technicians are not working with a revoked or suspended license or registration. Investigators may assist with on-site reviews of pharmacies that have been the subject of temporary (emergency) suspensions.

(5) **Rulemaking** – The Director of Professional Services and Legal Counsel are the individuals who primarily share the responsibility for the major activities relating to the drafting of new rules and rule amendments for consideration by the Board.

(A) The staff of the Professional Services Division accomplishes the following major activities with regard to Rulemaking:

- Drafts rules relating to professional issues and present these rules to the Board for consideration;
- Assists other Divisions with development of rules pertaining to Board operations;
- Establishes a schedule for ensuring that all agency rules are reviewed every four years;
- Coordinates and monitors all submissions to the *Texas Register*; and act as agency liaison to the *Texas Register*; and
- Provides professional staff support to members of any Board-appointed Task Force charged with reviewing and making recommendations with regard to rules or rule amendments pertaining to professional issues on specific topics.

(B) The General Counsel accomplishes the following major activities with regard to Rulemaking:

- Develops rules relating to disciplinary proceedings;
- Assists other Divisions and members of TSBP Task Forces with development of rules; and
- Reviews rule submissions to the *Texas Register* and certify that the agency has authority to propose the rule.

(6) **Information Services** – The responsibility for providing information is shared by the Enforcement Division, Legal Division, and the Professional Services Division; the following major activities are accomplished:

(A) Verbal and Written inquiries for Information

- Compliance Queue Line (512-305-8070) – a team of Enforcement staff are available during normal work days (from 8 a.m. through 5 p.m. Monday through Friday, except for major holidays) to answer telephone inquiries from TSBP customers. This key service is equivalent to the agency’s “call center” in that the designated staff answers all types of calls, primarily calls about laws/rules governing the practice of pharmacy and calls from applicants asking about the status of their application.
- Rx Law Portal – Enforcement staff respond to questions that are received by e-mail from TSBP customers who want information regarding laws/rules governing the practice of pharmacy.
- Open Records Requests – the staff of the Professional Services Division respond to requests for information in accordance with the procedures set forth in the Texas Public Information Act.

(B) *TSBP Newsletter* – the staff of the Professional Services Division publish a newsletter that contains such information as updates on pharmacy laws/rules and disciplinary orders entered by the Board.

(C) Educational Outreach – applicable staff of the Professional Services and Enforcement Divisions make presentations to agency customers regarding laws/rules governing the practice of pharmacy. They also display an exhibit at professional meetings regarding agency operations and new laws/rules. In 2012, the Director of Professional Services began providing education to agency customers regarding the laws and rules governing the practice of pharmacy by providing web-based learning opportunities through webinars and other social media. Numerous YouTube video tutorials have been developed regarding pharmacy practice issues and agency licensing procedures. In FY15, TSBP partnered with e-Strategies to assist in providing web-based programs to pharmacists and pharmacy technicians. Registration activities are coordinated by e-Strategies who also provides continuing education certificates to the licensee/registrant on behalf of TSBP. In addition, staff of all three Divisions make suggestions regarding updating the content of the TSBP website.

(7) **Pharmacy Law Exam Development** – The Director of Professional Services Division works with the National Association of Boards of Pharmacy (NABP) in the ongoing development of the Multi-State Pharmacy Jurisprudence Examination (MPJE). The Director and other agency staff review MPJE item pools to determine appropriate questions for Texas and provides new questions for MPJE as appropriate or requested by NABP.

(8) **Legal Services and Vendor Contracts**

(A) The Legal Division (in addition to its activities relating to complaints, rules, and information, as described above) perform the following major activities:

- Researches legal issues and when necessary, draft requests for Attorney General Opinions and Open Records Decisions;
- Provides technical assistance and advise the Board and Board Staff on a range of issues, including open meetings, open records, ethics, and agency procedures;
- Reviews agency contract and service agreements with outside vendors;
- Provides legal advice and consultation regarding employment matters in the agency; and
- Reviews new opinions of the Office of Attorney General and the Texas Ethics Commission.

(B) The staff of the Enforcement Division, in consultation with Legal Counsel, monitors compliance with the terms of contracts with the following Vendors, and serves as liaison with these Vendors:

- Professional Recovery Network (PRN), a voluntary peer assistance program; this program is authorized by the Texas Pharmacy Act, Chapter 564;
- Vendor to administer the agency's drug screening program (First Lab);
- Vendors to conduct inspections of Class E-S Pharmacies [National Association of Boards of Pharmacy (NABP), Accreditation Commission for Health Care (ACHC), and Superior Labs)]; and
- Vendor to conduct analysis of compounded samples that are collected during inspections of Texas pharmacies (Analytical Research Lab).

C. What evidence can you provide that shows the effectiveness and efficiency of this program or function? Provide a summary of key statistics and outcome performance measures that best convey the effectiveness and efficiency of this function or program.

The key statistics with regard to the efficiency and effectiveness of the Enforcement Program are described below.

(1) Complaints and Disciplinary Process – The chart below shows that TSBP met or exceeded (within a 5% variance) all six KEY performance measures in FY14. Of particular note is the Efficiency Performance Measure relating to Average Complaint Resolution Time.

Enforcement-Related Performance Measure	FY14 Projected Performance	FY14 Performance Attained	Key or Non-Key (K/NK)	Projected Target Met?*
Outputs:				
Inspections	2,400	1,698	NK	Not Met
Jurisdictional Complaints Resolved	5,420	5,582	K	Exceeded
Number of Licensed Individuals Participating in a Peer Assistance Program	180	182	K	Exceeded
Efficiency:				
Average Time for Jurisdictional Complaint Resolution	180	176	K	Exceeded
Outcomes:				
Percent of Jurisdictional Complaints Resolved Resulting in Disciplinary Action	15.0%	11.63%	K	Met
Percent of Licensees (Pharmacists and Pharmacies) with No Recent Violations (Disciplinary Orders)	96.0%	95.5 %	K	Met
Recidivism Rate of Those Receiving Disciplinary Action	4.0%	4.6%	NK	Met
Percent of Jurisdictional Complaints Resolved within Six Months	65.0%	70.32%	NK	Exceeded
Recidivism Rate for Participants in Peer Assistance Program	20.0%	34.09%	NK	Not Met
One-Year Completion Rate for Participants in Peer Assistance Program	85.0%	74.0%	NK	Not Met
Explanatory:				
Jurisdictional Complaints Received	5,620	5,536	K	Met

* Within a 5% variance, TSBP's actual performance was either: equivalent to projected performance ("Met") or better than projected performance ("Exceeded").

Other indicators of efficiency and effectiveness, with respect to the complaint and disciplinary process, are described below:

- (A) The scores that TSBP receives from agency customers who complete a Customer Service Survey show that customers are satisfied. This survey is conducted on an ongoing basis by an outside vendor (University of Texas) to ensure impartiality. TSBP Directors receive survey results on a monthly basis. One of the questions in this survey is: "If I filed a complaint, my complaint was addressed in a reasonable manner." The customer can answer 1 (Strongly Disagree), 2 (Disagree), 3 (Neutral), 4 (Agree) and 5 (Strongly Agree).

In FY14, the annual average score for this question was 3.76. These scores improved during FY15; as of publication date of this report, the 11-month average score for this question was 3.86. See chart below for details regarding the score for the “complaint question.” In addition, it should be noted that for numerous years, the agency has consistently received a score of better than 4.0 for “overall satisfaction” from persons completing the survey.

MONTH	SCORE (FY14)	# RESPONDENTS (FY14)	SCORE (FY15)	# RESPONDENTS (FY15)
September	3.07	106	3.53	89
October	3.85	58	3.93	64
November	4.12	92	3.47	85
December	3.69	58	3.88	64
January	3.75	60	3.82	55
February	3.31	78	3.93	75
March	4.29	53	4.23	81
April	3.77	56	4.07	67
May	3.92	89	3.28	82
June	3.07	58	4.25	66
July	3.93	71	4.05	87
August	4.31	73	*	*
TOTAL		852 (12 months) avg/mo = 71		805 (11 months) avg/mo = 73 **

* Data not available as of the publication date of report.

** Represents a 3% increase in the number of respondents in FY15 as compared to FY14.

(B) Indicators of efficiency and/or effectiveness, with respect to the disciplinary process, are described below:

(B-1) One indicator of effectiveness is the number of disciplinary orders that TSBP enters each year. Many of these Orders result in the revocation or suspension of a license or registration. The chart below shows the number of disciplinary orders entered by the Board during FY13-14 and the number of orders that imposed a revocation or suspension. In summary, during the past two years, TSBP entered 1,291 disciplinary orders, which resulted in the revocation of 207 licenses/registrations and the suspension of 131 licenses/registrations.

Entity	# of Orders (FY13)	# Revoke (FY13)	# Suspend (FY13)	# of Orders (FY14)	# Revoke (FY14)	# Suspend (FY14)
Licensee *	363	27	27	289	28	28
Registrant **	320	78	32	319	74	44
Total	683	105 (15%)	59 (9%)	608	102 (17%)	72 (12%)

* Disciplinary Orders entered on Interns, Pharmacists, Pharmacies and Applicants for Licensure for a Pharmacist or Pharmacy License or Intern Registration.

** Disciplinary Orders entered on Technicians, Technician Trainees and Applicants for Technician or Technician Trainee Registration.

- (B-2) During both FY2013 and FY2014, approximately 99% of the disciplinary cases against pharmacists and pharmacies and 100% of the cases against technicians were settled through the entry of Agreed Board Orders or Default Board Orders.

These types of Orders do not require a formal contested case hearing to be scheduled at the State Office of Administrative Hearings (SOAH). SOAH hearings consume an enormous amount of staff resources and lengthen the time to close a complaint. Accordingly, by resolving almost 100% of the disciplinary cases through Default Board Orders or informal proceedings, the agency achieves significant efficiencies, both in terms of complaint resolution time and agency expenditures.

- (B-3) In FY2005, due to the volume of disciplinary orders entered by TSBP, the Board voted to delegate the approval of certain types of disciplinary orders to the Executive Director (e.g., orders entered on applicants for a license or registration if the alleged violations were limited to misdemeanor offenses). Accordingly, with these types of limited cases, the notice of intent to take disciplinary action ("Preliminary Notice Letter") may enclose a proposed Agreed Board Order (ABO) which, if signed by the licensee/registrant, would settle the case. If the licensee or registrant signs this proposed ABO (strictly optional on the part of the licensee/registrant), the Order is signed and entered by the Executive Director. By signing this proposed ABO, the licensee/registrant waives the right to attend an informal settlement conference, which expedites the disciplinary process and saves the respondent's time and resources, as well as the agency's time and resources. For an applicant for licensure, this procedure is particularly efficient and effective because the license or registration process can begin immediately, rather than the applicant having to wait as long as three months for the Board to review the proposed disciplinary order (at the Board's next regularly scheduled quarterly meeting).

- (2) **Inspections** – Two indicators of the effectiveness of the inspection program are described below:

- (A) The number of pharmacies who receive a written warning notice during a compliance inspection is reflective of the agency's effectiveness of enforcement. A warning notice is issued when the Compliance Officer or Inspector detect a substantive deficiency during an inspection. In FY2013, Compliance Field Staff inspected 1,698 pharmacies and 597 of those pharmacies (35%) received a written warning notice. In FY2014, Compliance Field Staff inspected 1,698 pharmacies and 879 of those pharmacies (52%) received a written warning notice. Through written warning notices, TSBP allows a pharmacy to correct the

conditions and submit a written report explaining how the conditions have been corrected. Accordingly, issuing written warning notices is a cost-effective way for TSBP to help ensure that pharmacies come into compliance and the process is not punitive to pharmacies (no disciplinary action is taken against the pharmacy for non-compliance issues, unless upon re-inspection, TSBP determines that the pharmacy did not correct the conditions).

- (B) TSBP is authorized to collect samples of compounded preparations to determine if these preparations are being properly prepared. Analysis of samples includes testing for potency and contamination (sterility, endotoxins and fungus). This type of testing is critical to ensure the public's health, safety, and welfare, particularly for compounded sterile preparations. If a compounded sterile injectable drug is contaminated, the patient is at risk for serious consequences, including death. TSBP has been sampling compounded preparations for over five years and no injectable sterile preparation has failed contamination testing. During FY2014, Compliance Field Staff collected 124 samples of compounded preparations and 11 of those preparations failed potency testing (9% failure rate). Specifically, two of the seven non-sterile samples collected and nine of 117 sterile samples collected did not pass the potency test.
- (3) **Continuing Education (CE) Audits** – TSBP uses a computer-generated random sample to determine which entities to audit, which is an efficient and effective selection method. In addition, the staff of the Professional Services Division reviews a national data bank of CE listings to assist in confirming the CE that has been completed by a pharmacist or technician. This data bank is provided through the CPE Monitor, a collaborative service established by the Accreditation Council for Pharmacy Education (ACPE) and the National Association of Boards of Pharmacy (NABP). ACPE accredits CE providers. Accredited ACPE providers submit the names of pharmacists and technicians (who have completed the CE offered by the provider) to ACPE. ACPE subsequently provides the name of individuals completing the approved CE to NABP who makes this information available to respective state boards of pharmacy through the CPE Monitor. If the CPE Monitor reflects that the pharmacist or technician (who was selected in the random sample) has completed the required number of hours during the renewal period, TSBP will close the audit and take no further action. This process is an efficient and effective way to determine if a licensee/registrant has met the CE requirements, and saves staff time and mailing costs by not auditing individuals who are in compliance. Moreover, this process also saves the licensee/registrant's time and money by not having to respond to a CE audit.

- (4) **Monitoring Compliance** – The Board contracts with a vendor (First Lab) to administer the agency’s drug screening program. This vendor provides efficient and effective technology for probationers to comply with the terms of their orders, which saves the probationers’ time. For example, the probationers can determine if they have been selected to undergo a random drug screen on any particular day, either through on-line (Internet-based) systems or calling an 800 number and entering a unique PIN number. In addition, this vendor provides swift on-line reporting (through a Web-based system) of a probationer’s compliance or non-compliance. TSBP is able to protect the public health by rapidly learning if a probationer failed a drug test (e.g., tested positive for an illicit drug).
- (5) **Rulemaking Services** – The Board maintains an active role in updating rules relating to pharmacy practice, which is an indication of Board’s effectiveness in meeting changing practice and operational standards. During FY2013, the Professional Services Division made 34 submissions to the *Texas Register* regarding proposed and adopted rules. During FY2014, the Professional Services made 35 submissions to the *Texas Register*.
- (6) **Information Services** – Indicators of the efficiency and effectiveness regarding this key service are described below:

- (A) Number of Presentations -- During FY2013 and FY2014, the Director of Professional Services and the staff of the Enforcement Division made 78 presentations to approximately 6,000 agency customers, as reflected in the chart below:

Division	# Presentations (FY2013)	Attendance (FY2013)	# Presentations (FY2014)	Attendance (FY2014)
Professional Services	23	1700	23	2000
Enforcement	12	668	20	1620
Total	35	2368	43	3620

Accordingly, TSBP was able to educate a large number of licensees/registrants which in turn, helps ensure that licensees will comply with the laws/rules governing the practice of pharmacy. TSBP believes that 95% of the pharmacists will comply with pharmacy laws/rules if they understand what the laws/rules require. This type of “preventative enforcement” is cost-effective by reducing the number of investigations and disciplinary actions.

- (B) Web-based Presentations and Outsourcing of Registration Process – Many of these presentations listed above were provided through webinars and other web-based applications. Beginning in FY2015, TSBP partnered with e-Strategies who coordinated registration activities and provided proof of completion of the CE program (CE certificates) on behalf of TSBP. This partnership reduced agency costs by saving staff time, in that TSBP staff were able to outsource the registration process and production of CE certificates to e-Strategies.

- (C) “One-on-One” Education/Technical Assistance – The staff of the Enforcement Division provided technical assistance and answered questions regarding laws and rules governing the practice of pharmacy to over 111,000 callers over the past five fiscal years (FY2010 – FY2014) as reflected in the chart below:

Number of Telephone Calls via Compliance Queue Line	
Year	Number
FY2010	18,794
FY2011	23,095
FY2012	25,822
FY2013	21,323
FY2014	22,333
Total # of Calls	111,367
# of calls per year (5-year average)	22,273

The same comments made in (6)(A) above also apply to the large number of “one-on-one” verbal interactions (as indicated above) – i.e., informed licensees are more apt to comply with the laws/rules governing the practice of pharmacy.

- (D) Requests for Agency Records (e.g., licensing, complaints, disciplinary actions) – The staff of the Professional Services Division have a goal of producing the requested requests within ten business days, and they generally meet or exceed that expectation by delivering the requested records in less than ten business days. In Customer Service Surveys, the Professional Services Division staff receives compliments regarding their efficiency and effectiveness, which is admirable given the number of requests that they handle. As reflected in the chart below, the Professional Services Division has responded to a total of approximately 3,100 requests for information in FY2013 and FY2014, regarding 4,646 entities. Most requests for information involve more than one licensee/registrant.

Fiscal Year	Verbal Requests		Written Requests		Total # of Requests	
	# of Requests	# of Licensees	# of Requests	# of Licensees	# of Requests	# of Licensees
FY13	199	239	1,173	2,301	1,372	2,540
FY14	230	243	1,490	1,863	1,720	2,106
TOTAL	429	482	2,663	4,164	3,092	4,646

For more than 10 years, TSBP's webpage included a field regarding whether a licensee or registrant had been the subject of a prior disciplinary Order. Approximately 10 years ago, if the Order was a public Order, the TSBP webpage also included a summary of the Order [i.e., name of licensee/registrant, license/registration number, short description of violations or alleged violations, and sanction(s)]. More recently, to further assist agency customers, TSBP began posting an actual copy of a licensee's or registrant's public disciplinary Order on the TSBP website (on the respective entity's verification page). In so doing, agency customers have immediate access to a licensee's or registrant's disciplinary information.

(E) Satisfied Customers – Another indicator of effectiveness, with respect to information services, are the scores that TSBP receives from agency customers who complete a Customer Service Survey. See (1) above for details regarding the scoring system and administration of the survey. There are several questions on the survey that relate to Information Services. These questions are set forth below, along with the average score for FY2014 and FY2015 (as of 7/31/15), and indicate the average score on all five questions was higher in FY15 as compared to FY14:

- “The staff members were knowledgeable (able to answer my questions.” Overall score of 4.16 (FY14) and 4.39 (FY15).
- “The staff members were helpful (demonstrated a willingness to assist me).” Overall score of 4.20 (FY14) and 4.37 (FY15).
- “I received the information or service I needed.” Overall score of 4.22 (FY14) and 4.43 (FY15).
- “Material available online or in printed form provided thorough and accurate information.” Overall score of 4.15 (FY14) and 4.33 (FY15).
- “My inquiry was answered in a reasonable amount of time.” Overall score of 4.04 (FY14) and 4.23 (FY15).

D. Describe any important history regarding this program not included in the general agency history section, including how the services or functions have changed from the original intent.

The original purpose or intent of the Enforcement Program was to protect the health, safety, and welfare of the public. Although laws, rules, policies/procedures, and society's increasing use of licit and illicit drugs have changed over time, the original intent of the Enforcement Program has remained the same – to protect the public health. In 1981, the purpose/intent of the Board's mission was expanded to include "promoting" and "preserving" (as well as "protecting") the public health, safety and welfare, and these additional concepts have been incorporated into the TSBP Enforcement Program. In the interest of public health, the TSBP Enforcement Program will always be needed.

The following general government laws must be considered as "important history" to TSBP and its Enforcement Program (and to all other state agencies):

- (1) Open Meetings Act initially adopted in 1967;
- (2) Open Records Act initially adopted in 1973 (and replaced by the Texas Public Information Act in 1999);
- (3) Administrative Procedures Act (APA), previously called Administrative Procedures and Texas Register Act adopted on January 1, 1976; and
- (4) the law governing the management of state records; this law became effective in 1989 and required TSBP (and all state agencies) to develop a record retention schedule and destroy records only in accordance with an approved schedule.

Specific events that must be considered as "important history" to TSBP's Enforcement Program are listed and described below:

- 1977 TSBP initiated comprehensive compliance program, to include publication of agency newsletter and routine compliance inspections of pharmacies.
- 1978 TSBP formed its first task force to assist with the development of proposed rules.
- 1979 In accordance with the minimum standards of uniform practice and procedure established under the provisions of the Administrative Procedures Act for the hearing and resolution of contested cases, TSBP began to conduct informal settlement conferences and settle disciplinary cases through informal proceedings. Prior to 1979, disciplinary cases were considered by the full Board at a formal hearing (referred to as "violation hearings"). This procedure resulted in dramatic efficiencies with respect to reducing costs and complaint resolution time.

1981 The Texas Pharmacy Act was amended and modernized, creating four classes of pharmacy licenses, including Class C (Institutional) Pharmacies and Class D (Clinic) Pharmacies. As a result, inpatient pharmacy services and certain types of clinics (e.g., planned parenthood, public health departments) came under the regulatory authority of TSBP for the first time, which in turn, increased the number of licensees to regulate. Additionally, the Act was amended to clarify that the Board had the authority to inspect pharmacies with the consent of the owner, pharmacist or agent in charge of the pharmacy. Absent the pharmacy's agent consent, TSBP may inspect only after obtaining an Administrative Warrant from a court.

The Texas Legislature amended the Texas Controlled Substances Act to require triplicate prescription forms for the issuance of a prescription for a Schedule II controlled substance. This procedure reduced drug diversion of Schedule II controlled substances (but not drug diversion of Schedule III-V controlled substances).

1983 Through amendments to the Texas Pharmacy Act, the Texas Legislature authorized the establishment of a peer assistance program to aid pharmacists impaired by chemical abuse or mental or physical illness. These amendments stipulated that records relating to impaired pharmacists are confidential and may be disclosed only under very limited conditions.

1985 The Texas Legislature amended the Texas Pharmacy Act to expand the peer assistance program to cover pharmacy students who are enrolled in the professional sequence of an accredited pharmacy degree program approved by the Board.

1986 TSBP employed its first in-house General Counsel, which increased the efficiency and effectiveness of the agency's disciplinary process.

1989 The Texas Legislature amended the Texas Pharmacy Act, requiring pharmacists to obtain 12 hours of continuing education (CE) for license renewal. This change subsequently increased the disciplinary caseload due to audited pharmacists not being able to show proof of completion of the required number of CE hours.

1991 The Texas Legislature passed S.B. 884, creating the State Office of Administrative Hearings (SOAH) as an independent agency to conduct hearings to resolve disputes between Texas agencies and public citizens. SOAH conducted TSBP's first formal hearing in 1992. Prior to the creation of SOAH, the Board conducted its own disciplinary hearings. This procedure lengthened the amount of time to close a complaint and increased hearing costs.

- 1993 The Texas Pharmacy Act was amended to grant TSBP the authority to temporarily suspend a pharmacist's license under certain conditions and imposed numerous requirements relating to complaint procedures.

The Texas Legislature created the Health Professions Council (HPC) which subsequently funded a toll free telephone number for complainants to use for filing complaints against health professionals, including pharmacists. This process resulted in TSBP receiving an increased number of complaints.

- 1995 The Texas Legislature transferred the authority for inspection prescription balances from the Texas Department of Agriculture to TSBP. As a result of this change, more time was required to conduct inspections.

- 1999 The Texas Legislature passed S.B. 730, which amended the Texas Pharmacy Act to require insurers or other entities who provide professional liability insurance (to pharmacists, pharmacies and pharmacy technicians) to furnish information regarding malpractice reports (claims against the insured for failing to provide appropriate service within the scope of pharmaceutical services). TSBP must review the information (if three or more claims have been reported within a five-year period) in the same manner as if a complaint had been made against the individual.

- 2000 Texas State Board of Medical Examiners (TSBME) published guidelines regarding Internet prescribing. TSBP promulgated rules in concert with the TSBME guidelines. These rules state that a pharmacist may not dispense a prescription without a valid doctor-patient relationship, and that a valid doctor-patient relationship does not exist if the patient has merely had an "Internet or online consultation." TSBP began investigating complaints involving Internet pharmacy practice. These types of investigations are very complex and expensive to investigate.

- 2001 The Texas Legislature amended the Texas Pharmacy Act (H.B.99) to require TSBP to accept complaints through the Internet. After TSBP implemented an online complaint system, TSBP experienced a sizeable increase in the number of complaints being filed. In addition, the Texas Legislature increased the mandatory CE requirements for pharmacists to 30 hours per renewal period (every two years) and created several types of "remote" pharmacy sites.

- 2002 TSBP adopted rules that required pre-inspections of pharmacy applicants, under certain conditions. TSBP began to receive complaints regarding "pharmacy storefront operations" that were assisting patients to receive drugs from Canadian pharmacies. TSBP has serious concerns regarding the legality, safety and efficacy of drugs that are imported to Texas patients.

- 2003 The Texas Legislature appropriated funds for TSBP to register pharmacy technicians. The registration process began in 2004. TSBP registered approximately 30,000 technicians during a three-month period of time, which stretched the agency's human resources to the breaking point. The registration process included conducting a criminal background check on every applicant for a technician registration. A complaint was opened on any technician applicant who had committed one or more criminal offenses. Accordingly, complaints more than doubled from 1,936 (the number of complaints received in FY03) to 4,475 (the number of complaints received in FY04) – i.e., 131% increase from FY03 to FY04.
- 2005 The Texas Legislature amended the Texas Pharmacy Act to clarify that TSBP could obtain samples of products compounded by pharmacies during inspections, and approved the compounding of preparations for "Office Use." The Act was further amended in 2009 to stipulate that results of analysis of samples of compounded preparations were confidential and do not constitute public information under the Texas Public Information Act. Beginning in 2007, the Texas Legislature also appropriated funds for TSBP to pay for the analysis of these compounded preparations.

The Texas Legislature amended the Texas Pharmacy Act to allow the Board to institute disciplinary action on the grounds of a Deferred Adjudication for misdemeanor offenses involving moral turpitude and any felony offense; this amendment greatly increased the number of disciplinary orders entered by the Board. The Act was also amended to allow the Board to impose the same type of sanctions on a pharmacy technician as the Board could impose on a pharmacist or pharmacy license (i.e., prior to these amendments, TSBP had a limited range of sanctions that it could impose on a pharmacy technician). In addition, the Act was amended to provide a mechanism for three Board Members to hear temporary suspension cases rather than the entire Board, when there is a situation involving a "continuing threat to the public welfare."

- 2007 Following amendments to the Texas Pharmacy Act to require Pharmacy Technician Trainees to become registered, TSBP implemented this registration program. The same process (tsunami) occurred with the registration of trainees as occurred with the registration of technicians (as described above for the year 2003) – i.e., criminal background checks were conducted and a complaint was opened on any applicant with one or more criminal offenses. Accordingly, complaints once again increased – from 3,550 (the number of complaints received in FY06) to 5,849 (the number of complaints received in FY07) – i.e., 65% increase from FY06 to FY07 – and a 202% increase when comparing the number of complaints received in FY03 (1,935 complaints) to the number of complaints received in FY07 (5,849 complaints).
- 2007 The Texas Legislature amended the Texas Controlled Substances Act to require pharmacies to submit data regarding the dispensing of Schedule III-V prescriptions to the Texas Department of Public Safety (i.e., enlarged the prescription monitoring program from only Schedule II drugs to all schedules of controlled substances).

2009 The Texas Legislature amended the Texas Pharmacy Act to allow TSBP investigators who are commissioned peace officers to carry firearms and make arrests. The Act was also amended to expand the grounds for discipline of a pharmacy technician's or technician trainee's registration.

2013 The Texas Legislature amended the Texas Pharmacy Act which resulted in significant changes for the Enforcement Program, as described below:

- Section 565.060 established an alternative method to resolve certain types of complaints, other than through a disciplinary order. Specifically, TSBP may now issue a "Remedial Plan" (which is not a disciplinary order) and all records relating to the Remedial Plan must be removed from the Board's records within 5 years.
- Section 561.0032 prohibits TSBP from renewing the pharmacy license of a pharmacy that compounds sterile preparations, unless the pharmacy has been inspected as provided by Board Rule. The Board adopted rules to require sterile compounding pharmacies to be inspected every two years (to coincide with the biennial renewal of the pharmacy license).
- Section 556.054 allows TSBP to inspect a Non-Resident Pharmacy (located in another state) if the pharmacy compounds sterile preparations; and the Non-Resident Pharmacy is required to reimburse TSBP for all expenses, including travel, incurred by the Board in inspecting the pharmacy.
- Section 555.005 states that TSBP must maintain information about parties to the complaint, including the complainant's identity, for each complaint received by the Board, which in effect, prohibits TSBP from investigating anonymous complaints. In addition, Section 555.007(d) provides a "statute of limitations" of seven years on complaints filed by the Board. This section states: "The Board may not consider or act on a complaint involving a violation alleged to have occurred more than seven years before the date the complaint is received by the Board."

2015 The Texas Legislature amended the Texas Pharmacy Act to allow TSBP to inspect financial records under certain limited conditions. The Act was also amended to require a pharmacy to notify TSBP of a change of location 30 days prior to the address change and prohibits a pharmacy from waiving a co-pay for a compounded drug in the absence of limited exceptions.

E. Describe who or what this program or function affects. List any qualifications or eligibility requirements for persons or entities affected. Provide a statistical breakdown of persons or entities affected.

The Enforcement Program affects the following persons or entities:

- Pharmacists
- Applicants for a Pharmacist License
- Pharmacies
- Applicants for a Pharmacy License
- Pharmacist-Interns
- Applicants for a Pharmacist-Intern Registration
- Pharmacy Technicians
- Applicants for a Pharmacy Technician Registration
- Pharmacy Technician Trainee
- Applicants for a Pharmacy Technician Trainee Registration
- Texas Colleges or Schools of Pharmacy and Pharmacy Students

For a list of qualifications or eligibility requirements and statistical breakdown of the affected persons or entities listed in #1 through #10 above, see Agency Program relating to Licensing. With regard to the (11) above, there are eight (8) academic institutions in Texas that have a college or school of pharmacy to educate pharmacy students. These institutions are listed below:

- University of Texas College of Pharmacy
- Texas Southern University College of Pharmacy and Health Sciences
- University of Houston College of Pharmacy
- Texas Tech University School of Pharmacy
- University of the Incarnate Word Feik School of Pharmacy
- Texas A&M Health Sciences Center Irma Lerma Rangel College of Pharmacy
- University of North Texas Health Science Center (Candidate Status)
- University of Texas at Tyler (Pre-Candidate Status)

These academic entities have degree programs that are accredited by the Accreditation Council for Pharmacy Education (ACPE). These degree programs must be recognized and approved by the Board, in order for the respective graduates to be eligible for a license in this state. Refer to the Texas Pharmacy Act, Section 554.002(3). Based upon information that TSBP obtained from the aforementioned academic entities, TSBP estimates a total of approximately 3,200 pharmacy students are enrolled in pharmacy colleges/schools located in Texas.

In addition, the Enforcement Program affects all consumers of services provided by persons licensed or registered by TSBP. The number of persons or entities who receive pharmacy services is unknown, but the potential market is all Texas residents, as well as a substantial

number of residents of other states who obtain pharmacy services from pharmacies licensed by TSBP. Out-of-state patients receive prescriptions from TSBP-licensed pharmacies that dispense/deliver medications by mail (i.e., mail service pharmacies). Mail service pharmacies will be licensed as one of the following:

- (1) mail service pharmacies that are located in Texas – these pharmacies are licensed by TSBP as Class A (Community) Pharmacies; they dispense/ship prescription drugs to patients living in Texas and/or in other states; or
- (2) mail service pharmacies that are located in other states – these pharmacies are licensed by TSBP as either:
 - Class E (Non-Resident) Pharmacies, if the pharmacy is not compounding sterile preparations; or
 - Class E-S (Non-Resident Sterile Compounding) Pharmacies, if the pharmacy compounds sterile preparations.

F. Describe how your program or function is administered. Include flowcharts, timelines, or other illustrations as necessary to describe agency policies and procedures. Indicate how field/regional services are used, if applicable.

As described in Question B above, the Enforcement Program is administered through the three separate and distinct Divisions within the organizational structure. The goal and personnel of each Division are described below:

ENFORCEMENT DIVISION

- (1) Goal – To promote voluntary compliance with pharmacy laws and rules; to monitor compliance with pharmacy laws and rules; to enforce pharmacy laws and rules through inspections and investigations of pharmacists and pharmacies; to monitor the complaint process and transfer complaints involving substantive allegations to the TSBP Legal Division for review and potential prosecution; to monitor compliance with disciplinary orders; to provide information regarding pharmacy laws and rules to agency customers.
- (2) Personnel – The Enforcement Division is headed by a Director who directly or indirectly supervises 49 staff employed in the following capacities:
 - (A) Management/Professional Staff (5) – includes 4 pharmacists
 - (B) Field Investigators (9) (one vacancy as of 8/31/15)
 - (C) Field Compliance Staff (12) – includes 4 pharmacists
 - (D) In-House Investigators (9)
 - (E) Program Specialists (7)
 - (F) Technical/Administrative Staff (7)

The field staff office out of their homes. The nine field investigators (commissioned peace officers) are located in the Houston area (x 3), Dallas/Fort Worth area (x 3); and Central Texas area (x 3). The twelve compliance field staff (pharmacists and pharmacy technicians) are located in the Houston area (x 3), Dallas/Fort Worth area (x 3), Central Texas Area (x 2), San Antonio (x 1), Valley (x 1), East Texas (x 1) and West Texas (x 1).

LEGAL DIVISION

- (1) Goal – To prosecute violations of the laws and rules related to the practice of pharmacy; to provide adjudicative information to agency customers; to provide legal services and guidance to the Board and agency staff relating to the regulation of the practice of pharmacy and administration of the agency.
- (2) Personnel – The Legal Division is headed by the General Counsel who is supported by one Assistant General Counsel and three staff attorneys and nine legal assistants.

PROFESSIONAL SERVICES DIVISION

- (1) Goal – To facilitate agency operations by providing professional services, including rule development, law exam development, and task force support; by providing information services, including responding to requests for public information, making presentations (public speaking engagements) to agency customers, and publishing the TSBP *Newsletter*; and by serving as liaison to the *Texas Register*.
- (2) Personnel – The Professional Services Division is headed by a Director who is supported by two administrative assistants and one education coordinator.

POLICIES AND PROCEDURES

COMPLAINT PROCESS RELATING TO COMPLAINTS FILED BY THE PUBLIC

The Board Members set the policies regarding the resolution of complaints and agency staff carry out the policies. The Board periodically reviews and approves the policies and procedures for handling complaints. The primary steps of the complaint process for handling complaints filed by the public, are described below:

- (1) Submission of Complaint – Public complaints must be submitted in writing, except in unusual circumstances (e.g., complainant is disabled). Complainants may submit a complaint via a TSBP complaint form, a letter, or online complaint form. Written complaints may be submitted by fax, U.S. mail, or email. If a complainant telephones TSBP or the HPC Complaint Referral System (800-821-3205) and provides his/her name and address, the TSBP Enforcement Division staff will mail a TSBP complaint form to the complainant.

- (2) Receipt of Complaint – When a complaint is received, an Enforcement Specialist completes a complaint worksheet (determines data entry codes for source, form, subject of complaint, type of violation and drafts concise summary/description of complaint for data entry purposes). The complaint and coded worksheet is routed to the Director of Enforcement or designee (DOE) for review and determination of jurisdictional issues and how the complaint should be handled. The DOE may consult with others to determine appropriate course of action to take on the complaint (e.g., Executive Director or Legal Counsel).
- (3) Data Entry of Complaint – the DOE routes the complaint to an Enforcement Technician (ET) to enter the complaint into the agency’s computer system. After the entry of the complaint, the ET routes the complaint to an Administrative Assistant (AA) to prepare the applicable letter to the complainant.
- (4) Acknowledgment of Receipt of Complaint – The AA prepares applicable letter to complainant. If Waiver Form and/or Medical Release forms are needed, the AA holds the complaint in a suspense file until the forms are received. If the forms are not received by the due date, the complaint/file is routed to the DOE for closure of the complaint. If the complaint involves non-jurisdictional issues, the AA routes the complaint to the DOE for closure. If applicable, the DOE refers the complaint to another agency (e.g., entities that are not licensed by TSBP but are licensed by another agency). The complainant is notified of the closure or referral of the complaint.
- (5) Assignment of Complaint – The DOE assigns the complaint to either an In-House Investigator (less serious complaints), or an Inspector (more serious complaints), or a Field Investigator (most serious complaints). See also response to Question N (below) regarding the Board’s philosophy with respect to the approach the agency takes in handling complaints. In accordance with this approach, field investigations are conducted only when the complaint is likely to result in disciplinary action being instituted against the subject of the complaint. In-house investigations generally result in a less punitive action (such as a verbal or written warning).
- (6) Investigation of Complaint – In-house investigators interview complainants and subjects of complaints by telephone and collect records/evidence by mail. Field investigators conduct face-to-face interviews with complainants/subjects of complaints, and obtain affidavits and other evidence from complainants and subjects of complaints. Field investigators conduct both covert and overt investigations, including accountability audits and on-site, in-depth investigations of pharmacy operations.
- (7) Management Review – After the investigation has been completed and the report has been prepared, the complaint is routed to a supervisor (e.g., DOE and/or Compliance Program Officers for in-house investigations; DOE for complaints assigned to Field Staff).

- (A) The manager/supervisor may consult with others to determine appropriate course of action (e.g., to close the complaint with a verbal or written warning; to close the complaint with no further action due to insufficient evidence; or to return the complaint to the investigator to obtain more information/evidence).
- (B) If the manager/supervisor believes that the investigator has collected sufficient evidence of a substantive violation of the pharmacy and/or drug laws, the complaint may be routed to the Legal Division for a determination. If the Legal Division agrees that the case warrants the institution of disciplinary action, in accordance with Board rules and policies, the complaint is referred to the Legal Division (see Disciplinary Process).
- (8) Final Closure of Complaint – If the complaint is referred to the Legal Division and a final action has been taken, the case is returned to an Enforcement Specialist to close the complaint. If the complaint is not referred to the Legal Division, the manager/supervisor closes the complaint with the applicable disposition code. The complainant is notified of the decision. If the complaint is closed with a warning letter, the complainant receives a copy of the letter.

COMPLAINT PROCESS RELATING TO PHARMACIES WHO FILE A REPORT OF A THEFT/LOSS OF PRESCRIPTION DRUGS

- (1) Receipt of Theft/Loss Report – The laws/rules governing the practice of pharmacy require a pharmacy to report any theft or any significant loss of a prescription drug to TSBP. Such reports are routed to the Investigative Case Manager or designee (hereinafter, referred to as CM). These reports provide such information as type of theft/loss (e.g., night break-in; customer theft; armed robbery; or employee pilferage); date of discovery of theft/loss and list of the drugs that were stolen or lost. In order to track the number of theft/losses filed by a particular pharmacy, TSBP opens a complaint on the pharmacy after receiving any theft/loss report, regardless of the number of drugs that were stolen or lost.
- (2) Data Entry of Complaint Information – CM data enters the information regarding the theft/loss into the agency’s computer system, including the following information: source of complaint (generally a Pharmacy Manager, District Supervisor or Loss Prevention); form of complaint (generally a theft/loss report); subject of complaint (pharmacy); and a concise summary describing pertinent details [e.g., date of theft/loss, nature of theft/loss, name of suspect (if applicable), and number of dosage units reported stolen or lost].
- (3) Investigation of Complaint – CM contacts applicable pharmacy representatives, either by phone, letter, or e-mail, to obtain additional information. Representatives would include pharmacist-in-charge; regional or district pharmacy manager; and/or loss prevention manager. CM prepares a memo which summarizes the contacts made and the

information collected. If the theft/loss was due to employee pilferage, CM obtains pertinent documents, such as: copy of employee's Statement (if applicable) and copy of Loss Prevention Report (if available). If the suspect is a person licensed or registered by TSBP (e.g., pharmacist or technician), CM opens a complaint on the suspect.

(4) Management Review and Closure of Complaint or Further Action/Investigation

(A) In accordance with established policies/procedures, the CM may close a complaint after the CM has concluded the investigation of the complaint. However, in this event, the CM routes the complaint to a supervisor for final review and approval. These types of complaints would include theft/losses due to armed robberies or night break-ins involving a small quantity of drugs. These complaints would not include any type of theft/loss due to employee pilferage. Supervisor includes Director of Enforcement or designee (DOE) or a Compliance Program Officer.

(B) CM routes any complaint involving employee pilferage to DOE for review. If sufficient probable cause exists on a suspect pharmacist/technician, the DOE will assign the complaint on the suspect to a Field Investigator. Subsequent procedures would be same as procedures for complaints filed by the general public.

(C) If the theft/loss was due to employee pilferage or unknown reason, and the pharmacy was missing a large quantity of prescription drugs, CM routes complaint to DOE for review. Depending upon the quantity of drugs that were lost or stolen, the complaint would either be closed with no action (small losses) or warning letter (average losses). However, if the theft/loss report involved very large losses, the complaint would not be closed, but would be assigned to a Field Investigator to conduct an audit at the pharmacy. Following the field investigation, the subsequent processes would be same as for complaints filed by the general public (described above).

COMPLAINT PROCESS RELATING TO CRIMINAL BACKGROUND CHECKS

The Enforcement Division staff receives information regarding criminal offenses through the following four mechanisms:

- (1) Applications for Initial Licensure or Registration (i.e., applications for a pharmacist or pharmacy license, intern registration, or a pharmacy technician or technician registration) – these applications contain several attest questions regarding the applicant's criminal history and previous professional disciplinary history. If the applicant answered "yes" to one or more attest questions or should have answered "yes" to one or more attest questions, TSBP opens a complaint on the applicant.

- (2) Renewal Applications or Change of Managing Officer Applications – the same attest questions that are asked on initial applications for licensure or registration are also asked on applications to renew a license/registration and applications notifying TSBP of a change of managing officer. If the licensee or registrant answered “yes” to one or more attest questions and TSBP confirms that the offense is one that the agency was not previously aware, TSBP opens a complaint on the licensee/registrant. If a managing officer files a change of managing officer application and answers “yes” to one or more attest questions, or if the managing officer answered “no” to one or more attest questions, when the officer should have answered “yes,” TSBP opens a complaint on the pharmacy involved in the change of managing officer.
- (3) Rap Back Information – if a licensee or registrant violates Texas criminal statutes, and has a fingerprint report on file with TSBP and the Texas Department of Public Safety (DPS), TSBP receives an immediate electronic notification of the criminal offense, whereupon TSBP opens a complaint on the licensee/registrant.
- (4) DPS Quarterly Reports – for licensees and registrants who do not have a fingerprint on file with TSBP and DPS, TSBP coordinates collecting criminal history information from DPS every quarter, so that the agency can determine if a licensee or registrant has been the subject of a criminal offense within the past quarter. If TSBP determines the licensee or registrant has been the subject of a new offense that the agency was not previously aware, TSBP opens a complaint on the licensee/registrant.

The processing of this information is described below:

- (1) Receipt of Initial Application, Renewal Application, or DPS Report --
 - (A) When an Enforcement Division staff member (ES) receives a copy of an initial application and obtains applicable background information, the ES determines whether the documentation is sufficient to enter a complaint into the agency’s computer system.
 - (A-1) If the information is sufficient, the ES will complete a complaint worksheet and attach applicable documentation; or
 - (A-2) If the ES determines the information requires further review prior to entry of the complaint, the information is forwarded to the Enforcement Program Administrator (EPA) for review. If EPA determines that the application can be released (e.g., the applicant has already disclosed the offense on another application and the matter has been previously settled with no action or a warning letter), no further action is taken. If EPA determines a complaint must be opened, the documents are routed to the ES to complete the complaint worksheet.

- (B) Renewal Applications and Change of Managing Officer Applications – the Licensing Division forwards these documents to the Enforcement Division. If the ES determines that the application has been falsified or if the offense is one that the agency was not previously aware, the ES will complete a complaint worksheet, attach applicable documentation, and route this information to the Director of Enforcement or designee (DOE) for review.
 - (C) DPS Reports – After the agency receives a DPS Rap Back or determines that a licensee/registrant has been the subject of a new offense after reviewing a DPS Quarterly Report, the ES will complete a complaint worksheet, attach applicable documentation, and route this information to ES for data entry.
- (2) Data Entry of Complaint – The ES enters the complaint into the agency’s computer system with the appropriate codes and summary/description information. After the entry of the complaint, the complaint is routed to the EPA (or designee) for review. Designee is generally the Enforcement Program Officer (EPO).
 - (3) Assignment of Complaint – The EPO or EPA reviews the complaint information and either assigns the complaint to themselves or to an in-house investigator for further investigation.
 - (4) Investigation of Complaint – In-house investigators obtain the required documentation (court records and police reports) for each complaint. Some complaints require investigations by telephone in which the investigator conducts interviews with the applicant or licensee and prepares a confidential memorandum regarding the verbal interview.
 - (5) Management Review – After the in-house investigation has been completed, the complaint is routed to a manager/supervisor (EPA or designee or Senior Staff Investigator). The manager/supervisor may consult with others to determine appropriate course of action (e.g., close the complaint with a verbal or written warning; close a complaint with no further action due to insufficient evidence; return the file back to the investigator for further investigation or assign the information to another investigator to obtain additional information and/or contact the applicant or licensee to complete a Mental Health Professional substance abuse evaluation in accordance with TSBP policies and procedures);
 - (6) Legal Review – if the manager/supervisor believes sufficient evidence has been obtained to substantiate a violation of TSBP rules or statutes, the complaint is referred to the Legal Division (see Disciplinary Process). In some cases, the files may be routed to the Legal Division for a determination. If the Legal Division agrees the case warrants the institution of disciplinary action, the complaint is referred to the Legal Division (see Disciplinary Process).

- (7) Closure of Complaints that are Not Referred to the Legal Division – A manager/supervisor will close the complaint with a warning letter or no action, in accordance with established procedures, by entering the applicable disposition code and disposition date into the agency’s computer.
- (8) Closure of Complaints that Are Referred to the Legal Division -- if the complaint is referred to the Legal Division and a disciplinary Order is entered, the Legal Division routes the complaint to the Enforcement Program Specialist (or designee) to close. If the case is closed through some other action (e.g., disciplinary action was instituted but the applicant did not appear at an informal conference), the Legal Division routes the complaint to an ES to close.

COMPLAINT PROCESS RELATING TO CE AUDITS

- (1) Identification of Non-Compliance with CE Requirements – If the staff of the Professional Services Division determines that a licensee or registrant has failed to obtain the required number of CE hours, the staff complete a complaint worksheet and routes the worksheet to an Administrative Assistant (AA) to data enter the complaint.
- (2) Data Entry of Complaint – The AA enters the complaint information into the agency’s computer system, including the following information: license or registration number of the subject of the complaint; source of complaint (TSBP); form of complaint (Inter-Office Referral); subject of complaint (pharmacist or technician); and a concise summary describing pertinent details (e.g., date range for the audit and number of CE hours that the individual is short).
- (3) Management Review and Closure of Complaint or Referral of Complaint to Legal Division – Prior to final action being taken on the complaint, the Director of Professional Services confirms the complaint is being handled in accordance with established procedures.
 - (A) If the licensee or registrant is in substantial non-compliance, the complaint will be referred to the Legal Division to institute disciplinary action; or
 - (B) In the absence of substantial non-compliance (very small shortage of CE hours), the complaint is closed with a warning letter.

COMPLAINT PROCESS RELATING TO MONITORING PROCESS (Non-Compliance with Terms of Disciplinary Orders)

- (1) Data Entry of Disciplinary Order Information – After a Disciplinary Order or Remedial Plan has been entered by the Board; Enforcement Division staff enters information regarding these documents into the agency’s computer system. This information includes license or registration number of the entity who was the subject of the Order/Plan, date the Order/Plan was entered by the Board; disciplinary sanctions imposed by the Order, terms/conditions of the Order/Plan, and dates the various requirements are due (e.g., fines/fees, policy manuals, CE). This information is entered into the agency’s computer system as a complaint: under Case Type 03 (Disciplinary Order) or Case Type 07 (Remedial Plan).
- (2) Identification of Non-Compliance – Each month, the applicable Enforcement Specialist (ES) receives/reviews a computer-generated report that lists any item that has not been submitted to TSBP by the required due date, along with the name and license/registration number of the entity who is in non-compliance. This report is reviewed by the following four individuals
 - (A) the ES who monitors impaired/recovering pharmacists who have been the subject of confidential rehabilitation Disciplinary Orders;
 - (B) the ES who monitors technicians and technician trainees who have been the subject of a public Disciplinary Order;
 - (C) the ES who monitors compliance with Remedial Plans and public Disciplinary Orders that have been entered on pharmacists, interns, and pharmacies; and
 - (D) the Enforcement Program Specialist (PS) who supervises the three ES employees described in (A), (B), and (C) above.
- (3) Data Entry of Complaint – If the applicable ES confirms that a licensee or registrant is past due in submitting the required document or has some other type of non-compliance issue, the ES enters a Jurisdictional Complaint into the agency’s computer system (Case Type 01).
- (4) Investigation of Complaint – The applicable ES reviews the licensee or registrant’s Disciplinary Order or Remedial Plan to determine if the subsequent course of action is dictated by the Order/Plan [see (6) below]. If the Order/Plan does not specify the action to be taken in the event of non-compliance, the applicable ES reviews the licensee or registrant’s history to determine if the licensee/registrant has prior non-compliance issues, in that the action taken on the complaint may be different if the licensee/registrant is a “repeat offender” regarding non-compliance issues.

- (5) Management Review and Closure of Complaint or Referral of Complaint to Legal Division – The ES routes the complaint to the PS (supervisor of the ES) to confirm the complaint is being handled in accordance with established procedures. The action on the complaint depends upon the nature of the non-compliance complaint. The most common types of non-compliance complaints and the disposition that is taken on these types of complaints are described below:
- (A) Drug Screens (“No Shows”) – If a licensee/registrant was required to submit a drug screen on a specific day and failed to do so, the complaint is closed with a warning letter (first offense) or referral to the Legal Division (on each subsequent missed drug screen) for institution of disciplinary action.
 - (B) Positive Drug Screens – If a licensee/registrant tests positive for a substance for which the individual does not have a valid prescription, and the licensee/registrant is unable to provide a medically acceptable reason for the positive test result, the individual’s license or registration is surrendered – i.e., the licensee/registrant cannot practice pharmacy as a pharmacist or technician and may not have access to prescription drugs while the license/registration is surrendered. The ES updates the agency’s computer to show the individual’s “surrendered” status and the complaint is referred to the Legal Division for institution of disciplinary action. The license or registration will remain surrendered until a new Order is entered that lifts the surrender.
 - (C) Failure to Submit Quarterly Reports – If the ES determines that the licensee/registrant has not submitted a report that is due every three months (e.g., an on-going report due each quarter throughout the duration of the probation period), the ES prepares and mails a letter to the licensee/registrant to explain the non-compliance issue, and gives the licensee/registrant an opportunity to come into compliance by the new due date set forth in the letter. If the licensee/registrant submits the report, the complaint is closed upon receipt of the report. If the licensee/registrant does not submit the required report, a Warning Letter is prepared and mailed to the licensee/registrant, and the complaint is closed as of the date of the Warning Letter. If the same licensee/registrant subsequently continues to fail to submit a quarterly report, a new non-compliance complaint is entered into the agency’s computer system and this complaint is referred to the Legal Division for institution of disciplinary action.
 - (D) Failure to Submit a “One-Time” Report/Document or other Required Item (e.g., fine or probation fee) – If the ES determines that the licensee/registrant has not submitted the required document by the required due date, the ES prepares and mails a letter to the licensee/registrant to explain the non-compliance issue, and gives the licensee/registrant an opportunity to come into compliance (by the new due date set forth in the letter). The ES is allowed to call the licensee/registrant to expedite compliance, in lieu of preparing/mailling a letter. If the licensee submits the

document by the new due date, the complaint is closed upon the receipt of the document. If the licensee/registrant does not submit the required document by the new due date, the complaint is referred to the Legal Division for institution of disciplinary action.

- (6) Automatic Suspension or Revocation – Some disciplinary Orders stipulate that if the licensee/registrant does not comply with a certain requirement of the Order by the due date set forth in the Order, the license/registration is suspended or revoked. For those Orders which state that a license/registration will be suspended, the Orders may also state that continued non-compliance will result in the revocation of the license/registration by the due date set forth in the Order. With these types of Orders, the ES immediately suspends the license/registration in the agency's computer system (or revokes the license/registration, if applicable). The ES also prepares/-mails a letter to the licensee/registrant to notify the individual of the change in the individual's licensure/registration status. The letter explains that the licensee/registrant may not practice pharmacy or have access to prescription drugs during the time the license/registration is suspended. If the licensee/registrant is working in a pharmacy at the time the letter is prepared, a copy of the letter is also mailed to the individual's employer (pharmacist-in-charge and/or Owner) in order to provide notice to the pharmacy that an employee's license/registration has been suspended (or revoked) and the individual may not work in the pharmacy in any manner that would allow the individual to have access to prescription drugs. The complaint is closed as of the date that the license/registration is suspended or revoked, or comes into compliance with the terms of the Order.

DISCIPLINARY PROCESS RELATING TO PHARMACISTS, INTERNS, AND PHARMACIES

- (1) Assignment of Case – After investigation of a complaint on a pharmacist, intern, pharmacy (or applicant for a pharmacist or pharmacy license or intern registration) has been completed and the Legal Division has accepted the case, the case is assigned to a staff attorney who is responsible for prosecuting the case. The case assignment is logged into Abacus, a specialized software system that the Legal Division uses to track the status of a case as it goes through the disciplinary process.
- (2) Preliminary Notice Letter (PNL) – The prosecuting attorney prepares the PNL in accordance with established procedures. The PNL contains the following information: statement of charges that describe the violation(s) that the respondent has allegedly committed; the list of laws and/or rules that the respondent has allegedly violated; copies of applicable evidence that supports the charges being made against the respondent; a detailed explanation of the disciplinary process, including a description of the respondent's rights; and a cover letter that advises the respondent that the agency is considering the institution of disciplinary action against the respondent and offers the

respondent the opportunity to attend an informal settlement conference (ISC). The cover letter provides the date and time of the ISC. In accordance with Board policies and procedures, for certain types of cases, the PNL may enclose a proposed Agreed Board Order (ABO). If the licensee signs the ABO, the Order is either signed by the Executive Director (whereupon the Order is entered) or the Order is presented to the Board at its next regularly scheduled meeting for review and approval (or denial of the proposed Order). This procedure (of waiving the Informal Conference) expedites the disciplinary process and saves the respondent's time and resources, as well as the agency's time and resources.

- (3) Informal Settlement Conference (ISC) –The conferences are held at the TSBP office. One Board Member attends the ISC, and serves on the ISC panel, along with the Executive Director, and Director of Enforcement. The TSBP General Counsel conducts the ISC and the prosecuting attorney sets out the charges against the respondent. The respondent is given the opportunity to respond to the charges and show compliance with the law (i.e., present evidence to show why the respondent should not be charged with the allegations and why disciplinary action should not be taken against the respondent). If the respondent is unable to show compliance with the law, the respondent may present any other pertinent information (e.g., mitigating circumstances). After hearing the evidence, the ISC panel either recommends dismissal of the case or proposes a disciplinary sanction to settle the case. The respondent is not required to make a decision at the ISC regarding the panel's recommendation. The proposed disciplinary sanction is based upon TSBP Rules (such as Rule 281.64 relating to sanctions for criminal offenses and Rule 291.65 relating to administrative penalties) and sanctions imposed on licensees/registrants in similar cases in the past.
- (4) Proposed Agreed Board Order (ABO) – If the ISC panel recommends that disciplinary action be taken against a respondent, the TSBP prosecuting attorney drafts a proposed ABO. This proposed order is mailed to the respondent or respondent's attorney, if the respondent is being represented by counsel. If the respondent agrees to the terms of the proposed order, the respondent signs the proposed order and returns it to TSBP. The proposed order is presented to the Board at its next regularly scheduled Board Meeting. If the Board agrees to the terms of the proposed order, by vote of the majority, the order is entered. TSBP notifies the respondent of the entry of the Agreed Board Order within 30 days of the entry of the order. The respondent waives his/her right to judicial review (appeal to a court).
- (5) Default Board Order (DBO) - If the respondent fails to appear at the ISC, fails to respond in writing as required by Board rule, and adequate legal notice has been established, the prosecuting attorney drafts a DBO for the Board's review and consideration at the Board meeting. The default order is presented to the Board at its next regularly scheduled Board Meeting. If the Board agrees to the terms of the default order, by vote of the majority, the order is entered. The respondent's agreement is not required for entry of this type of order.

- (6) Remedial Plan – In certain types of cases, in accordance with established guidelines set by the Board, the agency mails the PNL to respondent together with a proposed Remedial Plan. In these cases, the respondent has the opportunity to attend an ISC or waive the ISC, by signing and returning the Remedial Plan. A Remedial Plan is not a disciplinary action.
- (7) When Informal Settlement Fails – A case cannot be settled through informal proceedings if one of the following events occurs: the respondent rejects the terms and conditions of the proposed ABO or does not sign/return the proposed ABO, or the Board rejects the terms of the proposed ABO. If one of these events occurs, TSBP (the prosecuting attorney) files a complaint with the State Office of Administrative Hearings (SOAH), who sets the case for a formal public hearing.
- (8) Mediated Settlement Conference – Prior to a formal hearing being conducted, either TSBP, the respondent or SOAH may request that the case be scheduled for a formal mediation process. SOAH conducts the mediation. If the mediation is successful, the case is settled with a proposed ABO that is presented to the Board at its next regularly scheduled Board meeting.
- (9) Formal Hearing – TSBP mails a Notice of Hearing to the respondent (notifies the respondent of the time, date and place of the hearing, along with the charges and laws/rules that have been allegedly violated). On the designated date, time and place, an Administrative Law Judge (ALJ) at SOAH conducts the hearing in the presence of a court reporter. Evidence is presented by TSBP and respondent.
- (10) Proposal for Decision (PFD) – The ALJ issues a PFD that sets forth Findings of Fact and Conclusions of Law and a recommended disciplinary sanction. The PFD is presented to the Board at its next regularly scheduled Board meeting. The Board votes whether to accept the ALJ’s Findings of Fact and Conclusions of Law, which are routinely accepted unless an error is made or compelling policy reasons dictate otherwise. The Board also votes on a sanction while taking into consideration the ALJ’s recommended disciplinary sanction.
- (11) Board Order – The TSBP prosecuting attorney drafts the proposed Board Order for the Board’s review and consideration at the Board meeting. The proposed Board Order contains the ALJ’s Findings of Fact and Conclusions of Law and a recommended sanction. If the Board accepts the Findings, Conclusions, and recommended sanction, by majority vote, the Board Order is entered. TSBP notifies the respondent of the entry of the Board Order within 30 days of the entry of the order. The respondent has the right to appeal the Board Order in accordance with the provisions of the Texas Administrative Procedures Act.

DISCIPLINARY PROCESS RELATING TO TECHNICIANS AND TECHNICIAN TRAINEES

- (1) Assignment of Case – After investigation of a complaint on a pharmacy technician or technician trainee has been completed and the Legal Division has accepted the case, the case is assigned to a Legal Assistant who is responsible for handling the case. The case assignment is logged into Abacus, a specialized software system that the Legal Division uses to track the status of a case as it goes through the disciplinary process.
- (2) Preliminary Notice Letter (PNL) – The Legal Assistant prepares the PNL in accordance with established procedures. The PNL contains the following information: statement of charges that describe the alleged violation(s) that the respondent has allegedly committed; the list of laws and/or rules that the respondent has allegedly violated; copies of applicable evidence that supports the charges being made against the respondent; a detailed explanation of the disciplinary process, including a description of the respondent’s rights; and a cover letter that advises the respondent that the agency is considering the institution of disciplinary action against the respondent and offers the respondent the opportunity to attend an informal settlement conference (ISC). The cover letter provides the date and time of the ISC. In accordance with Board policies and procedures, the PNL may enclose a proposed Agreed Board Order (ABO). If the technician signs the ABO, the Order is signed by the Executive Director, whereupon the Order is entered.
- (3) Informal Settlement Conference (ISC) –The conferences are held at the TSBP office. One Board Member attends the ISC, and serves on the ISC panel, along with the Executive Director, and Director of Enforcement. The TSBP General Counsel conducts the ISC and a Legal Assistant sets out the charges against the respondent. The respondent is given the opportunity to respond to the charges and show compliance with the law (i.e., present evidence to show why the respondent should not be charged with the allegations and why disciplinary action should not be taken against the respondent). If the respondent is unable to show compliance with the law, the respondent may present any other pertinent information (e.g., mitigating circumstances). After hearing the evidence, the ISC panel either recommends dismissal of the case or proposes a disciplinary sanction to settle the case. The respondent is given the opportunity to sign a proposed Agreed Board Order upon conclusion of the ISC. The proposed disciplinary sanction is based upon TSBP Rules (such as Rule 281.64 relating to sanctions for criminal offenses and Rule 291.65 relating to administrative penalties) and sanctions imposed on licensees/registrants in similar cases in the past.
- (4) Proposed Agreed Board Order (ABO) – If the registered technician or technician trainee (or applicant for a registration) signs the proposed ABO, this document is presented to the Board at its next regularly scheduled meeting for review and approval (or denial). If the Board agrees to the terms of the proposed order, by vote of the majority, the order is entered. TSBP notifies the respondent of the entry of the Agreed Board Order within 30 days of the entry of the order. The respondent waives his/her right to judicial review (appeal to a court).

- (5) Default Board Order (DBO) - same procedure as described above relating to the disciplinary process for pharmacists and pharmacies.
- (6) When Informal Settlement Fails – same procedure as described above relating to the disciplinary process for pharmacists and pharmacies.
- (7) Mediated Settlement Conference – same procedure as described above relating to the disciplinary process for pharmacists and pharmacies.
- (8) Formal Hearing and Proposal for Decision – same procedure as described above relating to the disciplinary process for pharmacists and pharmacies.
- (9) Board Order – same procedure as described above relating to the disciplinary process for pharmacists and pharmacies.

DISCIPLINARY PROCESS RELATING TO TEMPORARY SUSPENSION PROCESS

Section 565.059 of the Texas Pharmacy Act sets forth procedures that the Board may use to temporarily suspend or restrict a pharmacist or a pharmacy license under certain conditions. Section 568.0037 sets forth the same procedures and conditions for temporarily suspending or restricting a pharmacy technician or pharmacy technician trainee registration. The steps in this process include the following:

- (1) Identification of Continuing Threat – After TSBP staff identifies a situation that may constitute imminent peril to the public health, safety and welfare, TSBP immediately conducts an investigation. TSBP Investigator/Inspector works closely with the Legal Division to determine if sufficient evidence has been collected to prove a “continuing threat” to the public welfare. If sufficient evidence is collected, the Legal Counsel consults with the Executive Director and Board President who make the final determination regarding whether the Legal Division will proceed with a Temporary Suspension/Restriction hearing.
- (2) Scheduling the Hearing – The President of the Board appoints a disciplinary panel consisting of three Board Members. The Legal Division determines an immediate date when all three members are available to attend the Temporary Suspension/Restriction hearing.
- (3) Notice of Hearing – The prosecuting attorney determines whether the hearing will be conducted with or without notice of hearing.
 - (A) Without Notice of Hearing – The prosecuting attorney does not prepare and mail a Notice of Temporary Suspension or Restriction Hearing to the licensee/registrant. The hearing is conducted by the prosecuting attorney before the disciplinary panel in the absence of the licensee or registrant. A second hearing must be held with Proper Notice within 14 days of the initial hearing (as described below).

- (B) With Notice of Hearing -- The prosecuting attorney prepares a Notice of Temporary Suspension or Restriction Hearing and mails the Notice to the licensee or registrant with a minimum 10 days' notice of the hearing, advising the licensee/registrant of the date, time, and place of the hearing, along with the charges and laws/rules that have been allegedly violated.
- (4) Hearing Process – On the designated date, time and place, the TSBP Board President (or designee) conducts the hearing in the presence of a court reporter and as part of a disciplinary panel with two other Board Members. General Counsel advises the disciplinary panel on the process. Evidence is presented by the prosecuting attorney and, if applicable, the respondent and/or respondent's attorney. At the conclusion of the testimony, the disciplinary panel may go into Executive Session to consult with the General Counsel. The disciplinary panel does not deliberate or take a vote on the case during the Executive Session. Once out of Executive Session, the disciplinary panel discusses the issue and votes on whether the evidence or information presented to the panel during the hearing constitute a continuing threat to the public welfare. If the disciplinary panel, by majority vote, determines that the holder of a license or registration by continuation of the practice or operation of a pharmacy would constitute a continuing threat to the public welfare, the panel enters a Board Order to temporarily suspend or restrict the license or registration.
- (5) Subsequent Hearings
- (A) If a Temporary Suspension/Restriction Hearing was conducted “with no notice” and the disciplinary panel entered an Order to temporarily suspend or restrict the license or registration, a hearing with Proper Notice must be convened within 14 days of the “no notice” hearing. The same process described under “Hearing Process” above would apply. If the disciplinary panel, by majority vote, determines that the license or registration should continue to be temporarily suspended or restricted, the panel shall enter another Temporary Suspension or Restriction Order.
- (B) If a Temporary Suspension/Restriction Hearing was conducted “with notice” and the disciplinary panel entered an Order to temporarily suspend or restrict the license or registration, the Legal Division schedules an Informal Settlement Conference in an attempt to settle the case with an Agreed Board Order. If informal settlement fails, the prosecuting attorney schedules a contested case hearing to be held at the State Office of Administrative Hearings (SOAH) within 90 days. If (SOAH) does not hold the hearing within 90 days after the date of the temporary suspension or restriction, the suspended or restricted license/registration is automatically reinstated, pursuant to Section 565.059(c) and Section 568.0037(c) of the Texas Pharmacy Act.
- (6) Formal Hearing, Proposal for Decision (PFD), and Board Order – if a formal contested case hearing is conducted by SOAH, the same procedures would apply regarding the formal hearing, PFD and Board Order (as described above relating to the disciplinary process for pharmacists/pharmacies and technicians).

INSPECTION PROCESS

- (1) Regions – Each Compliance Officer/Inspector is responsible for inspecting pharmacies in an assigned region of Texas. For purposes of inspections, the state is divided into nine regions: Houston area (three field staff members divide this region); Dallas area (two field staff members divide this region); and one staff member in each of the following seven regions: Fort Worth area; San Antonio area; Austin/El Paso areas; Central Texas area; West Texas area; East Texas area; and South Texas/Valley area. Four of the Compliance Field Staff are pharmacists (their titles are Compliance Officers). Eight of the Compliance Field Staff are pharmacy technicians (their titles are Compliance Inspectors).

(See Attachment #13 – Pharmacy Regional Map)

- (2) Scheduling of Inspections – Compliance Officers/Inspectors determine their own weekly schedules, taking into consideration priorities for inspection [see next paragraph (3) below] and requests for inspection issued by the DOE [example, (B) below]. Compliance Officers/Inspectors are expected to maximize efficiencies by managing time and travel.

(A) Region Rosters – To assist in efficient routing, Austin headquarters provides a “region roster” to each Compliance Officer/Inspector. Region rosters are computerized printouts listing all pharmacies in the region, by zip code. The list includes the name and address of the pharmacy and additional information about the pharmacy (such as the name of the current pharmacist-in-charge, the date of the last inspection, and the deficiencies noted during the last inspection).

(B) Inspections of Class A-S, Class B, and Class C-S Pharmacies (pharmacies located in Texas that compound sterile preparations) – Effective September 1, 2014, Class A-S and Class C-S Pharmacies may not renew their pharmacy licenses unless TSBP has conducted an inspection of the pharmacy within the past two years (i.e., within the pharmacy’s biennial renewal period). Effective June 1, 2016, Class B Pharmacies will not be able to renew their pharmacy licenses unless TSBP has conducted an inspection of the pharmacy within the pharmacy’s biennial renewal period. To help ensure that Class A-S, Class B, and Class C-S Pharmacies are inspected prior to the pharmacy’s expiration date, the Director of Licensing (or designee) generates a computerized report of applicable pharmacies with upcoming renewal dates and provides that report to the DOE (Director of Enforcement or designee) on a monthly basis. This report (hereinafter, referred to as the “S” report) contains such information as the pharmacy’s license number and expiration date, the pharmacy’s name and address, and the date of the pharmacy’s last inspection. In the event the DOE reviews the “S” report and determines an “S” pharmacy has not been inspected within its renewal period, the DOE promptly notifies the applicable Compliance Officer or Inspector of this matter by e-mail (or some other means) and provides a deadline for the Compliance Officer/Inspector to accomplish this inspection. The DOE monitors “S” reports on a monthly basis to determine whether applicable deadlines have been met.

- (C) Class E-S (Non-Resident Sterile Compounding) Pharmacies – Effective September 1, 2014, Class E-S Pharmacies may not renew their pharmacy licenses unless TSBP has conducted an inspection of the pharmacy within the pharmacy’s biennial renewal period. TSBP outsources inspections of Class E-S Pharmacies to authorized Vendors. TSBP Licensing staff monitors the receipt of the renewal application. Before renewing the license of a Class E-S Pharmacy, Licensing staff works closely with the Enforcement staff to ensure that an inspection has been conducted. If a Class E-S Pharmacy’s license becomes delinquent and Enforcement staff determines the pharmacy shipped prescription drugs into Texas without an active license, applicable records are obtained. If sufficient evidence is collected to prove the violation occurred, a complaint is opened and referred to the Legal Division for the institution of disciplinary action.
- (3) Priorities for Inspections – Compliance Officers/Inspectors plan their itinerary based on established priorities. The Board sets the priorities for inspections each year, when it sets the agency’s annual goals and objectives.
- (4) Frequency of Inspections – As noted above, TSBP is required to inspect Class A-S, Class B, and Class C-S Pharmacies every two years. For Class A, Class C, and Class D Pharmacies, the agency has a general goal of inspecting these types of pharmacies at least every three to four years. The Board believes the more often inspections occur, the more likely it is that a pharmacy will be in compliance (fewer violations will be detected). However, if the agency experiences any turnover of Compliance Officers/Inspectors, the total number of inspections is decreased and the length of time between inspections is increased. Other factors that have an impact on the frequency of inspections include: number of Class A-S, Class B, and Class C-S Pharmacies in the region (because those inspections take a longer period of time to conduct); the geographical size of the territory (more time is spent traveling and less time is spent conducting inspections); and the number of priority inspections that need to be conducted in the region (e.g., pre-inspections of applicants for a pharmacy license and inspections that are conducted as a result of a complaint).
- (5) Unannounced Inspections – Inspections are conducted on an unannounced basis, except in very unusual circumstances (e.g., when the pharmacy is only open on a limited basis, the Compliance Officer or Inspector may need to schedule an appointment with the pharmacy’s representative).
- (6) Length of Inspections – The inspection generally takes a minimum of three hours to complete. If the Compliance Officer or Inspector discovers numerous or serious violations during the inspection, the inspection may take an entire day (eight hours) to complete. Inspections of pharmacies that compound sterile preparations may last one or more days.

- (7) Notice of Inspection – When Compliance Officers or Inspectors enter the pharmacy, they state their purpose, issue a Notice of Inspection, and identify themselves with credentials. The pharmacist on duty reads and signs the Notice, which grants TSBP the right to inspect the pharmacy. If the pharmacist on duty does not sign the Notice, TSBP must obtain an Administrative Warrant (from a court) before the inspection can be conducted. It is extremely rare for a pharmacy to refuse an inspection. Under the provisions of TSBP Rule 281.7(a)(7), it is grounds for discipline to refuse an inspection authorized by the Texas Pharmacy Act.
- (8) Inspection Report Form – After the Notice of Inspection is signed, the Compliance Officer/Inspector checks the pharmacy’s environment, equipment, drug stock, records, and practices/procedures. The Compliance Officer/Inspector determines the degree of compliance for each item on the Inspection Report Form and indicates “satisfactory” or “needs improvement” or “Warning Notice” (W/N) or “Refer to Legal” (R/L). The W/N and R/L are unsatisfactory conditions and are handled as follows:
- (A) Written Warning Notice – Compliance Officers/Inspectors may issue a written Warning Notice for certain unsatisfactory conditions, in accordance with established guidelines. The Warning Notice will give the pharmacy a due date to correct the conditions and submit a detailed report to TSBP outlining the changes that have been made. The due date is generally 30 days from the date of the inspection. Exceptions: a due date of 10 days is given if the condition is a potential risk to public health [e.g., animals (dogs, cats) in the pharmacy or the pharmacy is operating without a pharmacist-in-charge]; and a due date of 90 days is given if the pharmacy must make major changes requiring an extended period of time (e.g., the pharmacy must undergo construction or make major changes to its computerized record keeping system).
- (B) Refer Case to the Legal Division for Review – For certain types of violations, in accordance with established guidelines, Compliance Officers/Inspectors may become investigators and collect evidence. The Compliance Officer or Inspector advises the pharmacist on duty that the case will be referred to the Legal Division for review. The Compliance Officer/Inspector submits the evidence with a written report to the DOE. If the evidence is sufficient to institute disciplinary action, in consultation with the Legal Counsel, the DOE refers the case to the Legal Division.

- (9) Collection of Compounded Samples – Compliance Officers or Inspectors are authorized to collect samples of compounded preparations, which include compounded sterile preparations (e.g., injectable drugs) and compounded non-sterile preparations (e.g., capsules or topical preparations, such as creams or ointments). Samples of compounded preparations are collected upon “probable cause” (e.g., when the Compliance Officer or Inspector determines that the pharmacy is not in compliance with the laws and rules governing the operation of a pharmacy with respect to sanitation, equipment, records, training requirements, supervision of pharmacy personnel, or the rules governing the compounding of non-sterile or sterile preparations). In the presence of the pharmacy’s authorized agent, the Compliance Officer or Inspector does the following:
- (A) collects the compounded sample and applicable compounding records and places these items in an insulated shipping container, along with applicable TSBP forms (e.g., Chain of Custody and Sample Collection forms); and
 - (B) seals the shipping container.

The Compliance Officer or Inspector is required to take the shipping container to an authorized courier immediately after the inspection and ship the container to the agency’s contracted vendor to conduct the drug analysis of the sample. After the vendor notifies TSBP of the results of the drug analysis, TSBP notifies the pharmacy of the results of the drug analysis. If the sample does not pass the potency test or other tests run on the sample, TSBP opens a complaint, sends a written warning to the pharmacy and requires the pharmacy to file a written plan of correction.

- (10) Response to a Written Warning Notice – TSBP monitors the receipt of the pharmacy’s response to the Warning Notice.
- (A) Satisfactory Response – Austin headquarters acknowledges the receipt of the response and sends a copy of the response to the applicable Compliance Officer or Inspector.
 - (B) Unsatisfactory Response – If the pharmacy does not specifically state that the pharmacy has corrected the condition, TSBP contacts the pharmacist-in-charge (PIC) to explain why the response is unsatisfactory and gives the PIC the opportunity to re-submit an appropriate response. If the PIC is unresponsive, a letter is mailed to the pharmacy, by certified mail, to give the PIC a deadline to submit the appropriate response.
 - (C) No Response – If the pharmacy fails to respond to the Warning Notice by the specified due date, TSBP contacts the PIC to discuss this matter and gives the pharmacy an opportunity to correct the condition and notify TSBP that the condition has been corrected. If the PIC is unresponsive, TSBP notifies the pharmacy in writing

(by certified mail) that failure to submit a response may result in the institution of disciplinary action against the licensee. If the pharmacy does not respond to the certified letter from TSBP, the DOE consults with the Legal Counsel. If Legal Counsel confirms that there is sufficient evidence of non-compliance, a complaint is opened and referred to the Legal Division for institution of disciplinary action.

- (11) Follow-up Inspections – After the Compliance Officer/Inspector receives notice that the pharmacy has satisfactorily responded to the Warning Notice, the Compliance Officer or Inspector may conduct a follow-up inspection to ensure that the pharmacy has corrected the conditions as stated in the response to the Warning Notice. The follow-up inspection is an “abbreviated inspection” (i.e., Compliance Officer/Inspector only checks the conditions that “needed improvement” and the “unsatisfactory” conditions that resulted in the issuance of a written Warning Notice). If the pharmacy has not corrected the conditions as described in the pharmacy’s response to the Warning Notice, the Compliance Officer or Inspector contacts the DOE, Chief of Compliance and/or Legal Division to determine whether the case should be referred to the Legal Division. If applicable, the Compliance Officer or Inspector collects evidence and the case is referred to the Legal Division for institution of disciplinary action.
- (12) Pre-Licensure Inspections – These types of inspections are conducted prior to the issuance of a pharmacy license, to help ensure that the applicant for a pharmacy license is intending to operate a bona-fide pharmacy.

MONITORING PROCESS

- (1) Notification of Terms and Conditions of Disciplinary Orders – TSBP notifies respondents of the entry of Agreed Board Orders and Board Orders within 30 days of the entry of the order. TSBP mails a copy of the order to the respondent with a cover letter that details all the terms and conditions of the order, including specific due dates for all reports and other documents required to be submitted to TSBP. This process helps the respondent understand their responsibilities with respect to their compliance with the provisions of the order.
- (2) Inspections – If a pharmacist’s license or a technician’s registration has been revoked, retired or suspended (and TSBP records indicate this licensee/registrant is working in a pharmacy), the DOE routes a copy of the disciplinary Order to the applicable Compliance Officer or Inspector and requests that the Compliance Officer/Inspector conduct an inspection of the applicable pharmacy in order to determine if the licensee/registrant is working at the pharmacy (has access to prescription drugs) during the period of revocation, retirement, or suspension. The DOE may also request the applicable Compliance Officer or Inspector to conduct other types of “monitoring inspections” (e.g., pharmacies that are on probation; pharmacies that must implement a Continuous Quality Improvement Program; and pharmacies whose license has been revoked) to determine if the pharmacy is in compliance with the terms and conditions of its disciplinary order.

(3) Peer Assistance Program – TSBP has a contract with the Professional Recovery Network (PRN), a “voluntary” peer assistance program to aid impaired pharmacists. The Director of the PRN Program monitors individuals who self-report themselves to the program or who are referred to the program by a relative, colleague, or TSBP. After a licensee or an eligible pharmacy student is referred to the PRN Program, the PRN Director refers the individual to a mental health professional (MHP) for an evaluation. If the MHP determines the individual has an impairment, the individual must sign a rehabilitation contract with the PRN Program. The PRN Program monitors the individual’s treatment program, including attendance at AA or similar types of support meetings, and conducts unannounced, random drug screens. If this individual successfully completes the terms of this contract, TSBP will never become aware of this individual’s identity. However, the Director of the PRN Program will refer the individual to TSBP under the following circumstances:

- (A) if this individual does not cooperate with the PRN Program (i.e., does not agree to be evaluated or does not agree to sign the PRN contract); and/or
- (B) if this individual signs a PRN contract and experiences a relapse (e.g., positive drug screen for a substance that has not been dispensed pursuant to a valid prescription).

After receiving a referral from the PRN Program, TSBP initiates a complaint and if additional evidence is required, an investigation is conducted; and if sufficient evidence is collected, the case is referred to the Legal Division.

(4) Number and Types of Disciplinary Orders requiring Monitoring – In FY13, 86% of the 683 disciplinary orders entered by TSBP required some type of monitoring. In FY2014, 88% of the 608 disciplinary orders entered by TSBP required some type of monitoring. The typical terms and conditions imposed by disciplinary orders that require some type of monitoring include:

- (A) Rehabilitation orders – The standard rehabilitation order imposes a five-year probation on the impaired/recovering pharmacist and requires intense monitoring by TSBP due to the numerous terms and conditions set forth in the disciplinary order, including the following:
 - requiring the impaired/recovering pharmacist to submit quarterly self reports for the purpose of informing TSBP of the licensee’s status and conduct, including rehabilitation activities (e.g., signed attendance logs if licensee is required to attend 12-step meetings) and employment status (e.g., signed supervision logs if required to work under the supervision of another pharmacist);

- requiring the impaired/recovering pharmacist to work under the supervision of another pharmacist; in this event, the supervising pharmacist must submit quarterly reports regarding the impaired/recovering pharmacist's status and conduct (e.g., signed log showing required number of supervised hours per week; compliance with the laws/rules pertaining to the practice of pharmacy; conformance to work rules; relationship with other employees and customers; overall job performance; and any other relevant matter);
- requiring the impaired/recovering pharmacist's mental health professional (MHP) to submit quarterly reports regarding the status and conduct of the licensee, as long as the licensee is under the care of a MHP; and
- requiring the impaired/recovering pharmacist to submit to random drug screens (see below).

(B) Orders Imposing Drug Screens – TSBP has a contract with First Lab to administer a drug screening program for TSBP. First Lab provides the following services to TSBP:

- an online (Internet-based) system through which TSBP sets drug screening regimens for pharmacists who are required by a disciplinary order to submit to unannounced drug screens (hereinafter, referred to as “probationers”);
- an 800 number for probationers to telephone each weekday and an online system for probationers to access (the probationer enters his/her unique PIN number and the system will inform the probationer whether he/she has been selected to submit to a drug screen that day); and
- swift online reporting of the probationers' compliance or non-compliance (e.g., through the Web-based system, TSBP can determine what days the probationer called the 800 number and the time of the call; what days the probationer did not call the 800 number; whether the probationer submitted to a drug screen on the required day; and if the drug screen was negative, positive, dilute, or adulterated).

(C) Orders Requiring Submission of Policies and Procedures – Disciplinary orders against pharmacies may require the pharmacy to submit policies and procedures addressing how the pharmacy is going to prevent the alleged violation from recurring. For example, when a pharmacy has been the subject of a disciplinary order due to a dispensing error, the order generally requires the pharmacy to develop and implement a Continuous Quality Improvement Program (to include a peer review component) for the purposes of preventing and handling dispensing errors and submit a report describing the program.

- (D) Orders Imposing Additional Continuing Education (CE) – If a disciplinary order requires the licensee to obtain additional CE, the licensee is required to submit proof of attendance at the required CE programs (i.e., copies of CE certificates). TSBP tracks whether the licensee submits the required CE certificates.
- (E) Orders Imposing Administrative Penalties (Fines) or Probation Fees – the Enforcement Division staff works closely with the Accounting staff to monitor that an administrative penalty (fine) or probation fee is received. If the fine or fee is not received by the due date, a new complaint is opened and the license or registration may be suspended if so stipulated by the terms of the Order. If the suspension involves a pharmacist, intern, or technician who is working in a pharmacy, TSBP mails a letter to the employee to notify the employer of this matter. If the entity continues not to pay the fine or fee by a certain date, the license or registration may be revoked if so stipulated by the terms of the Order.
- (5) Tracking Due Dates – Information regarding disciplinary orders is data entered into the agency’s computerized complaint tracking system, including the entry of information regarding specific terms and conditions with applicable due dates. When required reports or other documents are received, the computerized “tickler system” is updated with the next due date. When the final report or document is submitted to TSBP, the computer is updated to show an ending date (i.e., no due date).
- (6) Non-Compliance with Terms of Disciplinary Order –
- (A) Drug Screens – TSBP opens a complaint if any one of the following three events occurred:
- if TSBP is notified that a probationer has tested positive for an illicit drug, TSBP opens a complaint, notifies the probationer to surrender his/her license pending a hearing, and the case is immediately referred to the TSBP Legal Division for the institution of disciplinary action against the license;
 - if TSBP is notified that a probationer has tested positive for a licit drug and TSBP has no prescription on file from the probationer for this drug, TSBP opens a complaint and notifies the licensee to surrender his/her license pending a hearing, or alternatively, produce a current prescription for the drug that caused the positive drug screen; this complaint would be referred to the TSBP Legal Division for the institution of disciplinary action if the probationer could not produce a valid prescription; and

- if TSBP is notified that a probationer has not submitted to a drug screen on the required day, TSBP opens a complaint. If this non-compliance is the probationer's first missed drug screen, the complaint is closed with a warning letter. However, if the probationer has received a prior warning letter for a missed drug screen, the case is immediately referred to the TSBP Legal Division for the institution of disciplinary action.

(B) Required Reports – Computerized reports listing “past due reports” are generated on a monthly basis. Enforcement Division staff use this report to identify a licensee's non-compliance. When Enforcement Division staff confirms that the licensee is in non-compliance with the terms of his/her disciplinary order, a complaint is opened and action is taken. The type of action that is taken depends upon the degree of non-compliance, the type of non-compliance, and the pattern of non-compliance. Complaints involving non-compliance may be closed through non-punitive methods (verbal warning, written warning, or inspection) or frequently, will be closed following an investigation and institution of disciplinary action.

RULEMAKING PROCESS

TSBP proposes and adopts rules in accordance with the Administrative Procedures Act. TSBP uses task forces for pre-rulemaking activities.

INFORMATION SERVICES

The Enforcement Program staff provides the following types of information services:

- (1) verbal and written information in response to requests for enforcement records (complaints and disciplinary orders) and licensure records;
- (2) verbal and written information in response to inquiries about agency or program operations, policies and procedures, and laws/rules governing the practice of pharmacy or interpretation of pharmacy laws/rules;
- (3) TSBP website – The staff of the Enforcement and Legal Divisions provide data regarding disciplinary actions which are posted to the applicable licensee's or registrant's record on the TSBP website. Enforcement Division staff prepare for posting a summary of each public disciplinary order within 30 to 60 days of the entry of the Order. The Legal Division staff prepare for posting an actual copy of the public disciplinary order which is posted within 30 days of the entry of the Order; and

- (4) publications (e.g., *TSBP Newsletter*). Beginning in 2012, TSBP began using an emailing service to send the TSBP Newsletter to subscribers.

The Enforcement Program staff makes every effort to provide the requested information in the format or method requested by the customer (e.g., telephone, TSBP website, fax, email, U.S. mail, TSBP Exhibit, and speaking engagements).

LEGAL SERVICES

TSBP Legal Division utilizes Westlaw online services to perform legal research regarding any issues of Texas law. TSBP has access to Texas statutes, administrative code, court rules and orders, and various advisory opinions and administrative decisions through Westlaw, which provides full search capability and annotations. In addition, TSBP Legal Division uses various agency websites, such as the Office of the Attorney General, the Texas Ethics Commission, and Secretary of State, for specific updates on opinions and law.

- G. Identify all funding sources and amounts for the program or function, including federal grants and pass-through monies. Describe any funding formulas or funding conventions. For state funding sources, please specify (e.g., general revenue, appropriations rider, budget strategy, fees/dues).**

The Enforcement Program's funding is appropriated by the Texas Legislature and is included under General Revenue funds. Although the Enforcement Program does not have another source of funding, the Enforcement Program has participated in the Department of Justice Forfeiture Program authorized by federal law – see 21 USC §881(e)(1)(A) and (e)(3); 565.001(a)(2); 18 USC §981(e)(2); and 19 USC §1616a. As a result of TSBP's joint investigative efforts with the Drug Enforcement Administration (DEA) on a particular case, TSBP has received a small percentage of assets seized and sold by DEA. In addition, TSBP has received money seized by state agencies who were conducting joint investigations with TSBP, pursuant to the Code of Criminal Procedure, Chapter 59. Rider 3 relating to the agency's budget under the General Appropriations Act, states that in addition to amounts appropriated, "all forfeited money collected under federal or state forfeiture programs, proceeds from the sale of forfeited property or similar monetary awards related to the Board of Pharmacy's participation in the seizure of controlled substances or other contraband, are hereby appropriated to the Board of Pharmacy to be used for Enforcement purposes."

H. Identify any programs, internal or external to your agency, that provide identical or similar services or functions to the target population. Describe the similarities and differences.

(1) Internal Programs – The Enforcement Program works closely with other programs within the agency, in the following ways:

(A) Enforcement Division works closely with the TSBP Accounting Section to ensure that administrative penalties (fines), probation fees, and charges for producing records are paid;

(B) Enforcement and Legal Divisions work closely with the Licensing Program to ensure that applicants with a criminal history record or record of disciplinary actions in other states are not licensed until the application has been thoroughly reviewed by the Enforcement and/or Legal Divisions – includes applicants for a Pharmacist License, a Pharmacy license, an Intern Registration, a Pharmacy Technician Registration, or a Pharmacy Technician Trainee Registration; and

(C) Both the Enforcement and Licensing Programs provide information about status of applications and public licensing records.

(2) External Programs

(A) Similar enforcement programs and functions are provided by state boards of pharmacy in other states. Pursuant to Texas laws/rules governing the practice of pharmacy, pharmacies that are located in other states (but dispense/deliver prescriptions to patients in Texas) are required to be licensed in the state where the pharmacy is located and must also obtain one of the following types of pharmacy licenses issued by TSBP:

(A-1) Class E (Non-Resident) Pharmacy license – if the pharmacy is not compounding sterile preparations; or

(A-2) Class E-S (Non-Resident Sterile Compounding) pharmacy license -- if the pharmacy is compounding sterile preparations.

(B) The Texas Department of State Health Services (DSHS) licenses and regulates hospitals, ambulatory surgical centers (ASCs), and freestanding Emergency Medical Care Facilities (FEMCFs). Class C (Institutional) Pharmacies are located in hospitals and Class F Pharmacies are located in Freestanding Emergency Medical Care facilities. DSHS personnel may conduct inspections in hospitals, ASCs, and FEMCFs, including the pharmacy.

(C) The Texas Health and Human Services Commission (HHSC) contracts with pharmacies to provide services to Medicaid patients. HHSC may conduct on-site visits to vendor pharmacies to check compliance with contract provisions. The Medicaid Fraud Unit of the Attorney General’s office (AGMFU) investigate complaints involving Medicaid Fraud by pharmacies and pharmacists.

(D) Private accrediting organizations perform on-site inspections of pharmacies to determine if the pharmacy meets the accrediting program’s standards – e.g., The Joint Commission [(TJC) formerly Joint Commission on Accreditation of Healthcare Organizations (JCAHO) and Joint Commission on Accreditation of Hospitals (JCAH)]; Accreditation Commission for Health Care (ACHC); Accreditation Association for Ambulatory Health Care (AAAHC); and DNV Healthcare.

(E) Local, State, and Federal Agencies may perform inspections or investigations of licensees and registrations – e.g., Drug Enforcement Administration (DEA); Department of Public Safety (DPS); Food and Drug Administration (FDA).

I. Discuss how the program or function is coordinating its activities to avoid duplication or conflict with the other programs listed in Question H and with the agency’s customers. If applicable, briefly discuss any memorandums of understanding (MOUs), interagency agreements, or interagency contracts.

- (1) Hospitals – If a hospital is accredited by The Joint Commission, TDH will not conduct an inspection of the hospital except in unusual circumstances (e.g., a complaint has been filed against the facility). TDH shares its investigative complaints with TSBP.
- (2) Pharmacies located in Texas – HHSC refers complaints on pharmacies and pharmacists to TSBP. Not all pharmacies serve Medicaid. In January 2015, HHSC discontinued its inspection program by regional pharmacists. FDA and other State Boards of Pharmacy may conduct inspections of Texas Pharmacies; in most instances, these entities notify TSBP in advance of the inspection and TSBP may accompany the entity to conduct a joint inspection.
- (3) Individuals and Facilities Licensed by TSBP – TSBP works closely with other regulatory and law enforcement agencies to investigate entities licensed or registered by TSBP. In 2012-2014, TSBP entered into a MOU with DEA/Houston to provide one field investigator to serve on a DEA Task Force whose primary purpose was to investigate “pill mill” pharmacies in the Houston area. In October 2014, TSBP did not renew the MOU with DEA/Houston beyond the initial two-year period. TSBP engages in active communication and liaison with all applicable local, state, and federal agencies to coordinate activities and investigations of pharmacies, pharmacists and other entities licensed and regulated by TSBP.

(4) Class E and Class E-S Pharmacies (pharmacies located in other states) – TSBP may refer complaints on Non-Resident Pharmacies to the state board of pharmacy where the pharmacy is located. TSBP contracts with vendors to conduct inspections of Class E-S Pharmacies (pharmacies that compound sterile preparations). These pharmacies may be inspected by the state board of pharmacy located in that state; however, some states either do not have an inspection program or do not have an adequate inspection program to inspect pharmacies that compound sterile preparations.

(5) MOUs – TSBP coordinates activities with the following two agencies:

(A) For several years, TSBP has entered into a MOU with the Texas Health and Human Services Commission – Office of Inspector General (HHSC-OIG) on an annual basis. This MOU required TSBP to provide to HHSC-OIG copies of disciplinary orders that have been entered by TSBP. As a result of recent amendments to the Texas Government Code which became effective on 9/1/15, HHSC-OIG is required to enter into a MOU with each licensing authority that requires the submission of fingerprints for the purpose of conducting a criminal history information check of a health care professional, such as entities licensed by TSBP. The purpose of this MOU is to ensure that only persons who are licensed and in good standing as health care professionals participate as providers in Medicaid. HHSC-OIG and TSBP are both “participating agencies” for purposes of exchanging information.

(B) The Poison Prevention Packaging Act (PPPA), which was enacted by Congress in 1970, authorizes the Consumer Product and Safety Commission (CPSC) to establish child-resistant packaging standards in order to restrict children’s access to prescription drugs. The applicable law/rules stipulate that pharmacies must dispense prescription drugs in child-resistant containers, with some exemptions (e.g., the consumer specifically requests a non-child-proof container). Due to the large number of pharmacies in the United States, CPSC requests the states to assist in enforcing and monitoring compliance of PPPA regulations. For many years, TSBP has entered into an annual MOU with CPSC to inspect a limited number of Texas pharmacies for the purpose of determining if these pharmacies were in compliance with PPPA regulations. The number of inspections that TSBP is expected to conduct is set forth in the MOU, along with the time period during which the inspections must be conducted. CPSC pays a nominal fee to TSBP for each pharmacy inspected on behalf of CPSC.

J. If the program or function works with local, regional, or federal units of government, include a brief description of these entities and their relationship to the agency.

See response to Question I.

K. If contracted expenditures are made through this program please provide:

- a short summary of the general purpose of those contracts overall;
- the amount of those expenditures in fiscal year 2014;
- the number of contracts accounting for those expenditures;
- top three contracts by dollar amount, including contractor and purpose;

Expenditure	Contract Number	Vendor	Purpose
\$186,260.00	515-4-0001	Texas Pharmacy Association	Agency-solicited contract with optional renewals. For the Peer Recovery Network, a substance abuse rehabilitation program for pharmacy professionals.
\$86,540.50	515-4-0002	Analytical Research Laboratories	Agency-solicited contract with optional renewals. For analysis of sterile compounded pharmaceuticals.
\$73,800.00	515-4-0014	Pitney-Bowes Reserve	Exempt purchase of postage. Payments to mail reserve for postage. Cost apportioned according to the full time employee count.
\$58,425.00	515-4-0074	Caldwell Country Chevrolet	TPASS automated contract purchase. Purchase of vehicles for use by field staff.

- the methods used to ensure accountability for funding and performance; and

TSBP staff complies with all appropriate statutes, rules, and policies. Major contracts are either awarded under solicitations delegated to TSBP after review by TPASS or issued under a TPASS term contract. Agency contract monitoring processes are in place for 515-4-0001 and 515-4-0002. Texas Pharmacy Association makes quarterly reports of the number of patients treated and expenditures for the program. Invoices from Analytical Research Laboratories are reviewed by a Compliance Program Officer for accuracy and adherence to contract terms.

- a short description of any current contracting problems.

TSBP is always looking for ways to improve processes to ensure contracts meet the needs of internal customers while being in compliance with appropriate statutes, rules, and policies.

L. Provide information on any grants awarded by the program.

No grants are awarded by the Enforcement Program.

M. What statutory changes could be made to assist this program in performing its functions? Explain.

- (1) Section 554.005(a)(b) of the Texas Pharmacy Act allows the Board to seize prescription drugs or devices that pose a hazard to the public health and welfare, but only after “notice and hearing.” Section 556.107 of the Texas Pharmacy Act stipulates the conditions under which “seized property” may be disposed. Many pharmacies cease operation and abandon the prescription drug inventory at the location. The Texas Pharmacy Act should be amended to allow TSBP to seize and destroy abandoned prescription drugs, including controlled substances, without having to comply with the cumbersome procedures imposed on TSBP by the aforementioned sections of the Texas Pharmacy Act.
- (2) The Texas Pharmacy Act should be amended to allow TSBP agents to quarantine drugs or devices that pose a hazard to the public health and welfare, similar to the authority granted to the Texas Department of State Health Services, pursuant to the Texas Food, Drug and Cosmetic Act, Chapter 431 Health and Safety Code, Subchapter C relating to the ability to “detain” or “embargo” an article.
- (3) In certain types of investigations, such as investigations of “pill mill” pharmacies, TSBP is hampered by the fact that the agency is unable to obtain medical records from the prescribers who may have issued prescriptions outside the course of professional practice. TSBP does not have the power to subpoena these types of medical records. Section 565.058 should be clarified and expanded to broaden the Board’s subpoena powers to cover medical records.
- (4) Many pharmacies cease operation and do not notify TSBP, which is a violation of the Texas Pharmacy Act. However, if a pharmacy is owned by a non-pharmacist, this person can rarely be located. In this event, TSBP may be unable to determine the whereabouts of the prescription records or prescription drug inventory belonging to the pharmacy. The Texas Pharmacy Act should be amended to require a pharmacy owner to post a bond of a significant amount, which will be forfeited to the state of Texas, in the event that the owner fails to comply with pharmacy closing procedures.
- (5) Section 565.059 of the Texas Pharmacy Act sets forth procedures that the Board may use to temporarily suspend or restrict a pharmacist or a pharmacy license under certain conditions. Section 568.0037 sets forth the same procedures and conditions for temporarily suspending or restricting a pharmacy technician or pharmacy technician trainee registration. Subsection (c) of both of these citations state that “Not later than the 90th day after the date of the temporary suspension or restriction, the board shall initiate a disciplinary action under this chapter, and a contested case hearing shall be held by the State Office of Administrative Hearings. If the State Office of Administrative

Hearings does not hold the hearing in the time required by this subsection, the suspended or restricted registration is automatically reinstated.” In TSBP experience, the State Office of Administrative Hearings has granted continuances at the request of the licensee/registrant, which requires TSBP, at expense to the state, to hold another temporary suspension hearing in order to continue the temporary suspension. Accordingly, these two Subsections should be replaced with the following language:

565.059(c) – “Following a temporary suspension or restriction of the registration by the disciplinary panel, the board shall initiate disciplinary action against the license holder as soon as practicable by filing a complaint for contested case hearing with the State Office of Administrative Hearings.”

568.0037(c) – “Following a temporary suspension or restriction of the registration by the disciplinary panel, the board shall initiate disciplinary action against the license holder as soon as practicable by filing a complaint for contested case hearing with the State Office of Administrative Hearings.”

- (6) The Texas Code of Criminal Procedure and Texas Government Code should be amended to prohibit the expungement of Disciplinary Orders. The reasons for this statutory change are listed below:
- (A) TSBP publishes disciplinary orders in Newsletters and Board Meeting minutes, which means TSBP cannot ensure that documents that have already been disseminated to others would be expunged and not available to the public. Therefore, an expunction order may not accomplish its purpose in regard to any records that are not internal records on file at the TSBP office.
 - (B) The interests of defendants in regard to the expunction of criminal records are to restore the civil and personal rights of the defendants, in contrast to the purpose of retaining the disciplinary actions taken by TSBP to inform the public of such actions. The public has a right to know about any disciplinary action on a licensee or registrant, and expunging the underlying criminal offense should not change that goal. For example, employers who hire pharmacists and technicians have a right to know about criminal offenses for theft for security purposes.
 - (C) The process to expunge records is onerous on TSBP staff due to the computerized records of the agency and the on-line presence that the agency has adopted. The time and expense of conducting the expunction are not outweighed by the public’s right to have the information contained in the disciplinary orders.

- (7) Currently, Texas has different requirements for pharmacy services in large hospitals (101 beds or more) and small hospitals (100 beds or less). One of the areas where these standards differ is in the requirements for review of medication orders by pharmacists. Larger hospitals are required to review medication orders and a patient's medical history prior to administration of the drug. Small hospitals are not required to meet this requirement. The Board believes that recent advancements in technology will allow this drug use review to be performed in a more cost effective manner.

In order to protect patients' health and to eliminate the dual standards between large and small hospitals, the Board should enter in discussions with stakeholders to amend the rules to require drug regimen review prior to administration of any medication in small hospitals.

In addition, Section 562.1011 of the Pharmacy Act (Operation of Class C Pharmacy in Certain Rural Hospitals) sets up a third standard for rural hospitals with 75 beds or fewer that is located in a county with a population of 50,000 or less or has been designated by the Centers for Medicare and Medicaid Services as a critical access hospital, rural referral center, or sole community hospital. This section allows pharmacy technicians in these hospitals to perform some duties without pharmacists reviewing their work. Since technology has now become less expensive and more reliable, the Board believes that this section of the law should be amended to require remote pharmacist supervision.

- (8) The Texas Pharmacy Act authorizes a representative of the Board to enter and inspect a pharmacy relating to drug storage, security, equipment, sanitary conditions, and records. This list is limiting. In an effort to protect public health, the Board's inspection authority should be clarified to allow the Board to observe and copy records related to the professional conduct of persons licensed or registered by TSBP, as the conduct relates to the practice of pharmacy in accordance with the laws/rules governing the practice of pharmacy.
- (9) The Texas Pharmacy Act does not specifically state that pharmacists have the discretion to refuse to fill a prescription for any professional reason, such as if the pharmacist believes the prescription may present a danger to the patient. In an effort to protect the public health, the Texas Pharmacy Act should be amended to clarify that pharmacists have professional discretion when deciding to dispense a Rx or medication order.
- (10) Pharmacy technicians are an integral part of the dispensing process and want to assume a more active role in pharmacy practice. Currently, technicians only need a high school diploma or be enrolled in a high school program. For technicians to assume more responsibilities in the dispensing process, technicians must be adequately trained. In an effort to protect public health, the Texas Pharmacy Act should be amended to stipulate that all pharmacy technicians, before becoming registered with TSBP, must complete a Board-approved training program, with a provision that would "grandfather" persons already registered as pharmacy technicians, as of the effective date of the amendment.

- (11) Currently, there is no regulation of Pharmacist/Technician Relief Services. In the past, TSBP has had problems obtaining information from these services, including if a pharmacist is working for this service and where a pharmacist is working on any given day. In an effort to protect public health, and enhance the agency's ability to investigate complaints on pharmacists who are employed by relief agencies, the Texas Pharmacy Act should be amended to give the Board regulatory authority over pharmacist-relief agencies/services.
- (12) It is imperative that pharmacists not practice pharmacy in an impaired condition. Many pharmacies, when investigating a pharmacist or technician for potential impairment or theft of controlled substances from the pharmacy, or during a pre-employment screening process, will conduct a drug screen. Currently, there is no requirement for the employer to report to TSBP if the employee or prospective employee (pharmacist or technician) tests positive for an illicit drug or a drug for which the employee has no valid prescription. To protect the public health, the Texas Pharmacy Act should be amended to require an employer to report a drug screen that is positive for an illicit drug or a non-prescribed drug, and additionally, provide civil immunity to the employee if the results of the drug screen were reported in good faith.
- (13) The Federal and Texas Controlled Substances Act and the Texas Dangerous Drug Act has provisions which require a pharmacy to maintain records for only two years. Most insurance companies and other vendors who contract with pharmacies require pharmacies to maintain records for five to seven years. A two-year time period is not sufficient, particularly in view that TSBP receives Malpractice Reports regarding errors that that may have occurred over two years from the date that the Malpractice Report was filed. If a pharmacy is only required to maintain records for two years, the records (required to properly investigate a complaint) may no longer exist. Accordingly, in an effort to protect public health, the Texas Pharmacy Act, Texas Controlled Substances Act, and Texas Dangerous Drug Act should be amended to require the pharmacy to keep records for a minimum of 3 years from the date of dispensing (for the original prescription) and 5 years for electronic records.
- (14) The 76th Texas Legislature, through the passage of S.B. 780, gave pharmacists and the Board a valuable tool (pharmacy peer review committees) to use in assessing medication errors and creating safer systems. This bill was the first in the nation to set up pharmacy peer review committees. After this bill became effective in September 1999, the Board began to order pharmacies who were the subject of disciplinary orders involving dispensing errors, to implement continuous quality improvement programs (CQIP) to detect errors, to rectify errors that have occurred, and to prevent future errors. The Texas Pharmacy Act should be amended to allowing the Board to adopt rules to require all pharmacies to establish CQIP programs as a method to help reduce dispensing errors.

- (15) Due to the volume of disciplinary orders entered by TSBP, the Board has delegated certain authority to the Executive Director. Both the Texas Medical Practices Act and the Nursing Practice Act contain specific language regarding the delegation of certain functions to the Executive Director. However, the Texas Pharmacy Act is silent on the Board's ability to delegate certain duties to its Executive Director. Accordingly, the Texas Pharmacy Act should be amended to clarify that the Board may delegate certain duties to the Executive Director. This clarification would promote efficiency and effectiveness to the agency's operation.

N. Provide any additional information needed to gain a preliminary understanding of the program or function.

- (1) TSBP takes a dual approach to enforcement, which includes "prevention" (through education) and "treatment" (disciplinary sanctions) for violators of pharmacy and drug laws. TSBP believes that 95% of the pharmacists will obey the laws/rules governing the practice of pharmacy if they are aware of the requirements of the laws/rules and understand the requirements. Accordingly, TSBP takes great efforts to educate pharmacists via inspections, the *TSBP Newsletter*, speaking engagements/presentations, and "online" technical assistance (i.e., Compliance Queue Line and Rx Law Portal).
- (2) TSBP handles complaints in the most efficient and cost-effective manner possible. After complaints are received, they are reviewed to determine the seriousness of the violation and the licensee's prior complaint history. If a licensee has no prior complaint history and the allegations are not egregious, the complaint will be closed with a written warning, in accordance with Board policies and procedures, unless the violation is minor, in which case, the complaint will be closed following a phone call (or verbal admonition). However, if a complaint involves an egregious violation (e.g., diversion of controlled substances), or a pattern of complaints/violations, the complaint will be assigned to a field investigator to conduct an in-depth investigation. If sufficient evidence is collected during the investigation, the case will result in the institution of disciplinary action against the licensees involved. Accordingly, not all complaints result in disciplinary action being taken against a licensee.
- (3) TSBP settles almost all of its disciplinary cases with an Agreed Board Order (consent order), which results in significant efficiencies, both in terms of complaint resolution time and costs. These orders do not contain Findings of Fact or Conclusions of Law (i.e., no finding of guilt). The licensee does not admit nor deny the allegations set out in the order, but the licensee agrees to the sanction.
- (4) Violations of Texas and Federal Drug Laws subject pharmacists and pharmacies to criminal penalties (as a result of prosecution in state or federal courts), as well as administrative sanctions against their licenses to practice and operate a pharmacy (by TSBP).

- (5) The regulation of the practice of pharmacy is highly specialized and complex. Enforcement Program staff are required to investigate, inspect, and prosecute complaints involving numerous pharmacy and drug laws (e.g., Texas and Federal Controlled Substances Act; Texas and Federal Food, Drug, and Cosmetic Act; Texas Dangerous Drug Act; Texas Pharmacy Act) and rules promulgated pursuant to these Acts. In order to carry out their duties, Enforcement Program staff are required to have a thorough knowledge of all the aforementioned laws/rules.
- (6) TSBP issues 11 different types of pharmacy licenses:
- Class A (Community) Pharmacies
 - Class A-S (Community Sterile Compounding) Pharmacies
 - Class B (Nuclear) Pharmacies
 - Class C (Institutional) Pharmacies
 - Class C-S (Institutional Sterile Compounding) Pharmacies
 - Class D (Clinic) Pharmacies
 - Class E (Non-Resident) Pharmacies
 - Class E-S (Non-Resident Sterile Compounding) Pharmacies
 - Class F (Freestanding Medical Care Centers) Pharmacies
 - Class G (Central Processing) Pharmacies
 - Class H (Limited Prescription Delivery) Pharmacies

Each class of pharmacy has a unique set of rules and operating standards. Compliance Officers/Inspectors are required to check for non-compliance in a particular class of pharmacy applying the operating standards for that class. Accordingly, inspection procedures are complex and challenging.

- (7) TSBP employs nine commissioned peace officers. Pursuant to Section 554.010 of the Texas Pharmacy Act, these employees have all the powers, privileges, and immunities of a peace officer, including carrying a firearm and making an arrest.
- (8) TSBP is authorized to maintain an in-house Texas Law Enforcement Telecommunications System that allows the agency to send and receive statewide and national messages of inquiry concerning criminal history records of those individuals under investigation by this division.

- (9) Pharmacies that compound sterile preparations may not renew a pharmacy license unless the pharmacy has been inspected within the past two years – i.e., within the pharmacy’s renewal period. This requirement is based upon Section 561.0032(a)(1) of the Texas Pharmacy Act, which became effective September 1, 2013. Accordingly, the Enforcement Division staff must work closely with the Licensing Program staff to determine which pharmacies have an upcoming renewal. If the pharmacy has not been inspected within the past two years, the applicable Inspector is notified to conduct the inspection prior to the pharmacy’s expiration date, in order to prevent a non-renewal situation. In addition, the Licensing Program staff must be diligent not to renew a license of a Class A-S, Class B, Class C-S, and Class E-S Pharmacy license if the pharmacy has not been inspected within the two years prior to the pharmacy’s expiration date. Section 556.0551 of the Texas Pharmacy Act states that TSBP may inspect a Non-Resident pharmacy that compounds sterile preparations and that this Non-Resident Pharmacy must reimburse TSBP for all expenses incurred by the Board in inspecting this pharmacy, including travel. Inspections of Class E-S Pharmacies are conducted by vendors who have been contracted by TSBP to conduct these inspections, on behalf of TSBP.
- (10) Section 556.053(a)(3) of the Texas Pharmacy Act authorizes TSBP to obtain samples of preparations compounded by pharmacies, which includes samples of compounded sterile preparations (e.g., injectable preparations) and samples of compounded non-sterile preparations (e.g., oral and topical formulations). TSBP contracts with a vendor (Analytical Research Laboratories in Oklahoma City, Oklahoma) to conduct drug analysis on the samples that are collected by TSBP inspectors. TSBP closely monitors the results for potency, sterility, and contamination issues (e.g., fungus). The reports, records, formulas and test results of samples of products compounded by pharmacies obtained by TSBP may be provided to the pharmacy that compounded the preparation, but otherwise are confidential [i.e., are not public information for purposes of the Texas Public Information Act, Chapter 552, Government Code, with limited exceptions as specified in Section 556.053(c)]. However, the Act does allow TSBP to disclose statistical information from the test results of samples of compounded preparations (e.g., number of samples collected and number of failures).
- O. Regulatory programs relate to the licensing, registration, certification, or permitting of a person, business, or other entity. For each regulatory program, if applicable, describe:**
- **why the regulation is needed;**
 - **the scope of, and procedures for, inspections or audits of regulated entities;**
 - **follow-up activities conducted when non-compliance is identified;**
 - **sanctions available to the agency to ensure compliance; and**
 - **procedures for handling consumer/public complaints against regulated entities.**

- (1) Why Regulation is needed – The Enforcement Program helps to ensure that the public’s health, safety and welfare is protected, through various means, including inspections and investigations of pharmacies and other entities licensed by the Board. If there were no Enforcement Program, the public may have their prescriptions dispensed by incompetent pharmacists and prescription drugs may be diverted to the streets.
- (2) Scope of, and procedures for, inspections – The inspections cover a check list of hundreds of items, including environmental standards (cleanliness); operational standards (whether currently licensed/registered persons are performing duties within their scope of practice, including checks for compliance with accurate dispensing and verbal counseling); and prescription records. See also response to Question F.
- (3) Follow-up activities conducted when non-compliance is identified during an Inspection – The Inspector takes one of the following actions:
 - Issues Needs Improvement for minor non-compliance. No follow-up activity is conducted;
 - Issues written Warning Notice and the pharmacist-in-charge of the pharmacy must respond in writing by the due date; this procedure gives the pharmacy an opportunity to correct the deficiencies, without being subject to disciplinary action, unless TSBP determines, upon the re-inspection of the pharmacy, that the pharmacist-in-charge failed to correct the conditions (i.e., falsified the response to the Warning Notice); or
 - Collects evidence and refers the matter to the agency’s Legal Division; the Legal Division will institute disciplinary action, if there is sufficient evidence to prove a substantive violation of the laws/rules governing the practice of pharmacy.

See also response to Question F.
- (4) Disciplinary Sanctions that are available to the agency – See Section 565.051 of the Texas Pharmacy Act, regarding “Discipline Authorized” – which includes one or more of the following sanctions (i.e., discipline may include a combination of the following sanctions): Revocation; Retire; Suspension; Probation; Administrative Penalty (fine); Restriction; Reprimand; and Refuse to Issue or Renew a license.
- (5) Procedures for handling consumer complaints – See Response to Question F.

- P. For each regulatory program, if applicable, provide the following complaint information. The chart headings may be changed if needed to better reflect your agency's practices.

(Enforcement Program)
Exhibit 11: Information on Complaints Against Regulated Persons or Entities
Fiscal Years 2013 and 2014

	Fiscal Year 2013	Fiscal Year 2014
Total number of regulated persons	86,182	88,158
Total number of regulated entities	7,350	7,656
Total number of entities inspected	1,698	1,698
Total number of complaints received from the public (regardless of the date of the receipt of the complaint) that were closed in FY	2,171	1,712
Total number of complaints opened by TSBP (regardless of the date of the receipt of the complaint) that were closed in FY	4,381	3,894
Number of complaints pending from prior years NOTE: data is obtained from the annual August Board meeting minutes which contains data as of the date of the meeting – i.e., this data does not reflect year-end data.	2,415	2,676
Number of non-jurisdictional complaints received	36	25
Number of jurisdictional complaints closed with disciplinary action	736	649
Number of jurisdictional complaints resolved	6,504	5,582
Average number of days for complaint resolution	187	176
Number of Disciplinary Orders imposing the following sanction (total)s:	683	608
administrative penalty (fine) – includes fine with reprimand and/or conditions	262	204
Reprimand – includes reprimand with conditions	108	107
Probation – includes probation with conditions and/or fine	126	113
Suspension – includes suspension with fine and/or conditions	59	72
Revocation/Retire	105	102
Other (e.g., restriction; modification; and denial of reinstatement)	23	10

VIII. Statutory Authority and Recent Legislation

- A. Fill in the following charts, listing citations for all state and federal statutes that grant authority to or otherwise significantly impact your agency. Do not include general state statutes that apply to all agencies, such as the Public Information Act, the Open Meetings Act, or the Administrative Procedure Act. Provide information on Attorney General opinions from FY 2011–2015, or earlier significant Attorney General opinions, that affect your agency’s operations.

Exhibit 12: Statutes / Attorney General Opinions

Statutes

Citation / Title	Authority / Impact on Agency <i>(e.g., “provides authority to license and regulate nursing home administrators”)</i>
Texas Occupations Code, Title 2, Chapter 53 Consequences of Criminal Conviction	Provides the Board with the authority to discipline the license of an individual convicted of a felony or misdemeanor that directly relates to the duties of the license.
Texas Occupations Code, Title 2, Chapter 54 Examination on a Religious Holiday	Requires the Board to permit an examinee who wishes to observe a religious holiday to take an examination scheduled on a religious holiday on alternate date.
Texas Occupations Code, Title 2, Chapter 55 Renewal of a License While on Military Duty	Provides that the Board may not require a licensee to pay a penalty for late renewal of a license if the licensee has been serving active duty in the United States Armed Forces outside of Texas.
Texas Occupations Code, Title 3, Subtitle J Chapters 551 through 569, other than Chapter 567 (relating to labeling requirements for certain prescription drugs or drug products) / Texas Pharmacy Act	Provides the statutory authority for the Texas State Board of Pharmacy to regulate the practice of pharmacy; provides for licensure/registration of pharmacists, pharmacies, and pharmacy technicians and pharmacy technician trainees; establishes authority to discipline licensees who violate the Act or the Board’s rules; establishes pharmacy peer review and a confidential program to aid impaired pharmacists and pharmacy students; and establishes the requirements of labeling certain prescription drugs. The Act also provides for the registration of certified pharmacy technicians.
Texas Health and Safety Code, Chapter 483 / Texas Dangerous Drug Act	Permits the Board to establish guidelines for pharmacies and pharmacists relating to the administration and dispensation of dangerous drugs including the requirement that pharmacies not dispense dangerous drugs unless pursuant to a valid prescription. Requires pharmacies to label all dangerous drugs dispensed and retain appropriate records including the original prescription for no less than two years.
Texas Health and Safety Code, Chapter 481 / Texas Controlled Substances Act	Permits the Board to establish guidelines for pharmacies and pharmacists relating to the dispensation of controlled substances and record-keeping requirements for the purchase, possession, and dispensation of controlled substances.

Self-Evaluation Report

Citation / Title	Authority / Impact on Agency <i>(e.g., "provides authority to license and regulate nursing home administrators")</i>
Texas Health and Safety Code, Chapter 431 / Texas Food Drug and Cosmetics Act	Enables the Board to regulate pharmacies and pharmacists according to the requirements of the Texas FDCA which sets out requirements regulating the storage, sale, possession, distribution, dispensation and labeling of drugs and drug products or devices.
Texas Occupations Code, Title 3, Chapter 101 / Health Professions Council	Specifies TSBP is a member of the Health Professions Council (HPC) and establishes a means for HPC agencies to coordinate administrative and regulatory efforts.
15 U.S.C. §§ 1471-1476 / Poison Prevention Marketing Act	Requires pharmacies covered by this act to follow the requirements related to "special packaging" (i.e. packaging that is designed or constructed to be significantly difficult for children under five years of age to open or obtain a toxic or harmful amount of the substance contained therein, and not difficult for normal adults to use properly).
21 U.S.C §§ 301, 331, 333, 353, 381 / Prescription Drug Marketing Act	Establishes a violation under the act to knowingly sell, purchase or trade a drug sample or knowingly offer to sell, purchase, or trade a drug sample.
21 USC § 353a / Food and Drug Modernization Act	Requires pharmacies that compound drugs or produce compounded drugs for consumers to meet requirements as set forth in the act : (1) compounded drugs be dispensed only pursuant to a valid prescription; (2) compounded drugs be comprised of FDA approved ingredients; (3) compounded drugs may not be copies of existing FDA approved drugs; and (4) the compounded drug must not present problems of safety or efficiency.
21 U.S.C §§ 301, 321, 331-337, 341-356, 358-363, 371-379, 381-384, 391-399 / Federal Food, Drug, and Cosmetics Act	Regulates the storage, sale, possession, distribution, dispensation and labeling of drugs and drug products or devices in U.S. pharmacies. Pharmacies and pharmacists are subject to relevant provisions of this act.
21 U.S.C §§ 801-802, 811-814, 821-830, 841-844, 846-848, 850-856, 858-864, 871-887, 899-904 / Federal Controlled Substances Act	Establishes schedules of controlled substances and makes it illegal to possess, prescribe, distribute, administer, or dispense certain drugs unless allowed under the exceptions set forth under the act.

Attorney General Opinions

Attorney General Opinion No.	Impact on Agency
Texas Attorney General Opinion No. GA-0384 (2005)	The requirement that the Board “designate” Canadian pharmacies, promote them on its website, and allow Texas consumers to import prescription drugs would require the Board to violate the federal Food, Drug, and Cosmetics Act.
Texas Attorney General Opinion No. JC-0341 (2001)	Tex. Occ. Code Ann. § 562.014 (Vernon 2001) does not require the Board to specify drugs to be included on a list of narrow therapeutic index drugs.
Texas Attorney General Opinion No. JC-0186 (2000)	An automated dispensing machine to dispense prescription drugs at a nursing home is only legal under the Texas Pharmacy Act if the facility at which it is located is licensed as a pharmacy. In addition, the machine must be under a pharmacist's continuous on-site supervision.
Texas Attorney General ORD- 614 (1993)	Information indicating a disciplinary action was taken under section 27(a) of the Texas Pharmacy Act is not made confidential by section 27(d) of the Pharmacy Act, and must be made available to the public. The terms of impairment orders issued prior to June 18, 1983, are excepted from required public disclosure under the Open Records Act.
Texas Attorney General ORD-493 (1988)	Agreed Board Orders that would adversely affect the Board’s strategy with a licensee in a double-licensee situation (pharmacy / pharmacist) may be withheld from disclosure subject to a case specific inquiry.
Texas Attorney General ORD-474 (1987)	Board investigative files are exempt from disclosure under the Open Records Act. Preliminary notice letters, notice of informal or formal hearings, and Agreed Board Orders are not exempt from disclosure.
Texas Attorney General Opinion No. JM-555 (1986)	The Texas State Board of Pharmacy may regulate out-of-state mail-order pharmacists only to the extent that they actually engage in the practice of pharmacy or dispense, deliver, or distribute prescription drugs within the state of Texas. Such regulation is not per se unconstitutional under the Commerce Clause of the United States Constitution.
Texas Attorney General Opinion No. MW 410 (1981)	A practitioner may not practice pharmacy unless he is also licensed as a pharmacist under this act. No licensed pharmacy may legally operate unless there is a pharmacist-in-charge who is a licensed pharmacist. A practitioner who undertakes to fill a prescription of another practitioner engages in the practice of pharmacy, which he may not do unless licensed as a pharmacist. A practitioner who dispenses drugs to his own patients from his office, and charges a separate fee therefor, is engaged in the practice of pharmacy, which he may not do unless licensed as a pharmacist.

- B. Provide a summary of recent legislation regarding your agency by filling in the charts below or attaching information already available in an agency-developed format. Briefly summarize the key provisions. For bills that did not pass, briefly explain the key provisions and issues that resulted in failure of the bill to pass (e.g., opposition to a new fee, or high cost of implementation). Place an asterisk next to bills that could have a major impact on the agency.**

Exhibit 13: 84th Legislative Session

Legislation Enacted

Bill Number	Author	Summary of Key Provisions / Reason Bill Did Not Pass
H.B. 751	Zerwas	Amends the Pharmacy Act (Subchapter J, Occupations Code) to allow pharmacists to substitute “biological products” if: The physician authorizes substitution; The patient does not refuse the substitution; and the “biological product” is designated as “therapeutically equivalent” to another product by FDA. Requires pharmacists to notify the physician of the substitution
H.B. 1550	Zerwas	Amends the Pharmacy Act (Subchapter J, Occupations Code) by adding a new Section 562.057 that: (1) Allows pharmacists, in an emergency, to administer epinephrine to a patient using an auto-injector device; (2) Requires the pharmacist to report the administration to the patient’s primary care physician; (3) Specifies that a pharmacist may not receive remuneration for the administration; and (4) Provides that the pharmacist is not liable for civil damages if the pharmacist acts in good faith and complies with Board rules.
*S.B. 195	Schwertner	S.B. 195 amends the Texas Controlled Substances Act (Chapter 481, Health and Safety Code) to: (1) Effective 9/1/2016: Transfer the prescription monitoring program (PMP) from the DPS to TSBP; Establish a program to fund the Prescription Monitoring Program (PMP) through a surcharge on the license fees of persons authorized to access the PMP; and The Controlled Substance Registration program is abolished. (2) Allow the Board, on or after 6/20/2015: PMP and certain other provisions related to prescriptions in the Controlled Substances Act; Sign a contract with a vendor to operate the PMP; and Call a meeting of the Prescription Monitoring Work Group.

Bill Number	Author	Summary of Key Provisions / Reason Bill Did Not Pass
S.B. 460	Schwertner	<p>Amends the Pharmacy Act (Subchapter J, Occupations Code) to:</p> <ol style="list-style-type: none"> (1) Allow a pharmacy to notify consumers how to file a complaint using an electronic messaging system; (2) Allow the Board to inspect financial records relating to the operation of a pharmacy only in the course of an investigation of a specific complaint; <p>Allow the Board to inspect the records of a pharmacist if the pharmacist practices outside a licensed pharmacy;</p> <ol style="list-style-type: none"> (3) Specify that a person cannot own a Class E Pharmacy license if the person has held a pharmacist license in this or another state that has been restricted, suspended, revoked, or surrendered for any reason; (4) Specify that a pharmacy license may not be renewed if the license has expired for 91 days or more; (5) Requires a pharmacy to report to the Board in writing, no later than 30-days before the date of a change of location; (6) Prohibit waiving, discounting, or reducing, or offering to waive, discount, or reduce a payment copayment or deductible for a compounded drug; and Eliminate the requirement to post the "Generic Sign." <p>Amends the Dangerous Drug Act (Chapter 483, Health and Safety Code) to add a provision currently in the Pharmacy Act that in the event of a natural or manmade disaster allows pharmacists to dispense up to a 30-day supply of a dangerous drug on a refill, without authorization of the practitioner, if:</p> <ol style="list-style-type: none"> (1) Failure to refill the prescription might result in interruption of a therapeutic regimen or create patient suffering; (2) The nature of the disaster prohibits the pharmacist from contacting the practitioner; (3) The Governor has declared a state of disaster; and The Board, through the Executive Director, has notified pharmacies they may dispense up to a 30-day supply of a dangerous drug.
S.B. 807	Campbell	<p>Amends Chapter 55, Occupations Code by adding Section 55.009 that specifies that the Board must waive the license application and examination fees for an applicant who is a military service member or military veteran:</p> <ol style="list-style-type: none"> (1) Whose military service, training, or education substantially meets all of the requirements for the license; or (2) Who holds a current license issued by another jurisdiction that has licensing requirements that are equivalent those in Texas.
S.B. 1243		<p>Amends the Texas Food, Drug, and Cosmetic Act (Chapter 431, Health and Safety Code) to establish a Prescription Drug Donation Pilot Program (Program) in the Department of State Health Services (DSHS). The Program must be established in one or more cities with a population of more than 500,000 but less than one million.</p> <ol style="list-style-type: none"> (1) A Charitable Drug Donor (pharmacy, nursing home, manufacturer, hospital, etc.) may donate non-controlled p drugs to DSHS for use in the Program. (2) The donated drugs may be accepted and provided or administered to patients only by a: Charitable medical clinic; Physician's office for patients who receive assistance from an indigent health care program; or Licensed health care professional in a penal institution. (3) DSHS must establish and maintain an electronic database which: Lists the name and quantity of each drug donated to DSHS under the program; and Allows a charitable medical clinic, physician, or other licensed health care professional to search for and request drugs. (4) The entity providing or administering the drug may charge a nominal handling fee in an amount prescribed by DSHS rule.

Bill Number	Author	Summary of Key Provisions / Reason Bill Did Not Pass
S.B. 1307	Mendez	Amends Chapter 55, Occupations Code to specify that all occupational licensing agencies must adopt rules to: (1) Give military service members, veterans, or spouses an exemption from paying a penalty for failing to renew; (2) Allow military service members, veterans, or spouses an additional two years to complete any CE requirements or any other requirement related to the renewal of the license. (3) Allow agencies to adopt rules that establish alternate methods for a military service member, veteran, or spouse to demonstrate competency to meet the requirements for obtaining the license; (4) Requires agencies to post a notice on the home page of the agency's website describing the licensing provisions available to military service members, veterans, and spouses.

Legislation Not Passed

Bill Number	Author	Summary of Key Provisions / Reason Bill Did Not Pass
H.B. 3146	Lozano	Would have amended the Pharmacy Act (Subchapter J, Occupations Code) to make a legislative finding that pharmacists are health care providers. / The bill did not pass because there was opposition to adding this provision to the Pharmacy Act.
H.B. 3246	Crownover	Would have amended the Pharmacy Act (Subchapter J, Occupations Code) by adding a new Section 554.058 to that would all the board, with the advice of the Texas Medical Board, to adopt rules governing the procedures and requirements for a pharmacist to dispense and deliver tobacco cessation drugs under protocol of a physician. /The bill did not pass because there was opposition to expanding the scope of practice of pharmacists.
S.B. 480	Perry	Would have amended the Section 554.052 of the Pharmacy Act (Subchapter J, Occupations Code) to allow pharmacists to administer immunizations and vaccines to patients under 7-years rather than the current 14-years; and makes several other “clean-up” amendments. The bill did not pass because there was opposition to expanding the scope of practice of pharmacists.

Leg IX. Major Issues

ISSUE #1: SELF-DIRECTED/SEMI-INDEPENDENT STATUS FOR THE TEXAS STATE BOARD OF PHARMACY

A. Brief Description of Issue

The rapid changes occurring in pharmacy practice and the changing demands and pressures on the Board’s resources has prompted concern by the Board that it may not have the financial resources and the flexibility to meet its responsibilities efficiently and effectively. If TSBP had self-directed/semi-independent status, the agency will have the flexibility to expand and contract resources as needed, thus being more responsive to constituents and the public. This should result in more timely resolution of licensing and disciplinary matters.

B. Discussion

The Texas State Board of Pharmacy (TSBP) should pursue authorization to function as a self-directed/semi-independent (SDSI) agency. The operations of TSBP are supported solely by examination, licensing, and other fees paid by the licensees/registrants. The legislature approves the Board's operating budget each biennium and the agency funds are deposited in the state treasury. Each biennium TSBP collects approximately \$2 million more than it is budgeted. These excess funds are returned to the state treasury. Additionally, the Board is required each biennium to fund any new program with new fees rather than the use of any of the current funds it deposits in the treasury.

SDSI status would allow the agency to respond to crises in a timelier manner. For example, in September 2012, a multistate outbreak of fungal meningitis and other infections occurred among patients who received contaminated preservative-free methyl prednisone steroid injections from the New England Compounding Center in Framingham, Massachusetts. A total 754 patients were infected in 20-states and 64 patients died because of the infection. Texas had two patients who were infected with fungal meningitis, but these patients were treated and recovered. In order to assure that Texas patients were receiving safe products from pharmacies licensed by TSBP, the agency put a priority for inspection on sterile compounding pharmacies. However, without additional staff, we could not do these inspections as quickly. During the 2013 Texas Legislative Session, the Legislature funded the agency for an additional five compliance inspectors. If the agency had SDSI status, we could respond to situations like this in a much more timely matter and without having to wait for a Legislative Session.

During the 76th (2005) Legislative Session, S.B. 1438 was passed to allow three state agencies to participate in a self-directed/semi-independent pilot program (Board of Public Accountancy, Board of Professional Engineers, and the Board of Architectural Examiners). The agencies were permitted to move their funds outside the state treasury, pay their own bills, and reimburse the State for services rendered. The enabling statutes are still under direct control of the legislature and each agency must report certain information to the state regarding accountability of funds, services, and goals. The agencies are also subject to audit by the Office of the State Auditor.

Again, during the 81st (2009) Legislative Session, four additional state agencies were granted self-directed/semi-independent status by House Bill 2774. These included the Texas Finance Commission, the Texas Department of Banking, the Department of Savings and Mortgage Lending, the Office of Consumer Credit Commissioner, and the Credit Union Department.

During the 82nd (2011) Legislative Session, the Real Estate Commission was granted self-directed/semi-independent status by Senate Bill 1000. In addition, during the 82nd Session, House Bill 2092 was introduced that would give the Texas State Board of Pharmacy and the Texas Board of Nursing self-directed/semi-independent status. House Bill 2092 was voted out of the House Public Health Committee during the last few weeks of the session, but it was not heard by the House.

During the 83rd (2013) Legislative session, a bill was introduced during the 2013 Texas Legislative Session that would have given TSBP, the Texas Medical Board, and the Texas Board of Nursing to have self-directed/ semi-independent status. This bill was not passed by the legislature but the Legislature directed the Texas Sunset Commission to conduct a study of Self-Directed Semi-independent Status for state agencies and to make recommendations to the legislature by December 31, 2014. In July 2015, the Sunset Advisory Commission issued a report titled "Self-Directed Semi-Independent Status of State Agencies." This report determined "that the State has an undefined and inconsistent approach to managing the SDSI process, which exposes the State to unnecessary risk. No single entity is responsible for administering and overseeing the SDSI process. Therefore, a comprehensive process with clearly-defined requirements for obtaining and retaining SDSI status does not exist."

C. Possible Solutions and Impact

If the legislature considers SDSI status for agencies and if TSBP is granted self-directed/semi-independent status, TSBP would be removed from the legislative budgeting process and the budget would be adopted and approved by the board members appointed by the Governor. On the first day of each regular legislative session, TSBP would be required to submit a report to the Legislature and the Governor describing all of the agency's activities in the previous biennium. In addition, TSBP would be required to report its two-year expenses and revenue collections by November 1 of each year to the Legislature, the Legislative Budget Board, and the Governor. The TSBP employees would remain members of the Employees Retirement System of Texas under Chapter 812 of the Government Code. The State Auditor would contract with TSBP to conduct financial and performance audits and the Attorney General would collect fees for their legal services. All agency supplies, materials, records, equipment, and facilities would be transferred to TSBP.

The advantages of moving TSBP to self-directed/semi-independent status to the State of Texas are as follows.

- The number of hearings and legislative time spent on agency budgets is reduced.
- The administrative burden of state government will be reduced by approximately:
 - 99 employees will be removed from the state payroll; and
 - More than a \$10,000,000 will be removed from the state budget, thus reducing the biennial state budget.
- State oversight agencies such as the State Auditor, Comptroller of Public Accounts, State Office of Administrative Hearings, and Office of the Attorney General will receive actual reimbursement costs for services.

- The agency will have the flexibility to expand and contract resources as needed, thus being more responsive to constituents and the public. This should result in more timely resolution of licensing and disciplinary matters.
- The number of reports to oversight agencies will be reduced with most reports required annually.
- The governing Board of the agency will be held to a higher level of accountability to their constituents.
- The agency budget will be held to a higher level of scrutiny by licensees and professional associations.

The move to self-directed/semi-independent is a major change to how the agency finances are managed. This shift from direct state oversight to an agency-driven process is a significant change but has been tested by a number of licensing agencies and has proven to be successful and effective. By virtue of past State Auditor, Comptroller, and State Office of Risk Management audits, the Texas State Board of Pharmacy has proven to be an effective, efficient, and well-managed state agency and an excellent candidate for self-directed/semi-independent status.

ISSUE #2: DIVERSION OF CONTROLLED SUBSTANCES THROUGH THE DISPENSING OF PRESCRIPTIONS WITHOUT A VALID MEDICAL NEED

A. Brief Description of Issue

A limited number of pharmacists and pharmacies are creating a situation that has a critical impact on the public health and safety through the dispensing of controlled substances to patients who do not have a valid medical reason to receive these prescriptions at “Pill Mill” pharmacies. These types of pharmacies dispense controlled substances outside the course of professional practice. The prescribers who issue the prescriptions are not prescribing the controlled substances for a legitimate medical need and the pharmacies are dispensing these invalid prescriptions.

B. Discussion

The presence of these “Pill-Mill” Pharmacies in Houston and other Texas cities is having a dramatic and deadly effect on the citizens of Texas. In 2013, the CDC called prescription drug abuse a “growing epidemic.” Nearly three of four prescription drug overdoses is caused by opioid pain medication, and more people have died in recent years from the abuse of prescription drugs than from heroin and cocaine combined. The Harris County Coroner’s Office reported in 2010 that prescription drugs have killed more than 1,200 people in Harris County since 2006.

While there has been a marked decrease in the use of some illegal drugs like cocaine, data from the National Survey on Drug Use and Health (show that nearly one-third of people aged 12 and over whom used drugs for the first time in 2009 began by using a prescription drug non-medically. Some individuals who misuse prescription drugs, particularly teens, believe these substances are safer than illicit drugs because they are prescribed by a healthcare professional and dispensed by a pharmacist.

Due to the huge number of prescribers and pharmacies involved in this type of activity, in the Houston area, TSBP signed a contract with the Drug Enforcement Administration in 2012 for one field investigator to work full-time with a Drug Enforcement Administration Task Force in the Houston area. This contract ended in October 2014. Unfortunately, at the end of this two-year period, DEA determined not to seek prosecution of any of the pharmacies investigated by the Task Force. The Board will continue to pursue cases against pharmacies and pharmacists for “pill mill” activity in the administrative/licensing system as well as assisting with criminal prosecution of those licensees involved.

C. Possible Solutions and Impact

Since these cases are very difficult to investigate, prepare the case for hearing and prosecute the case, the agency must have additional funds and personnel to pursue the prosecution of pharmacies and pharmacists who are willfully ignoring the law and dispensing prescriptions that are not issued for a valid medical use.

ISSUE #3: UNDERUTILIZATION OF THE CLINICAL KNOWLEDGE AND SKILLS OF PHARMACISTS IN THE CURRENT HEALTH CARE SYSTEM

A. Brief Description of Issue

Pharmacists have the knowledge and opportunity to help patients achieve better outcomes from drug therapy and, in turn, provide a significant cost savings to Texas' healthcare system. The cost of this pharmaceutical care can very likely be recovered from the savings it generates.

B. Discussion

The positive outcome for patients and cost savings to the healthcare system can be realized only if an environment is created by healthcare reform that recognizes that the savings are not likely to be generated at the pharmacist-patient level. The savings will be generated at the level of patients' therapeutic successes and the resulting reductions in hospitalizations, surgeries, repeated office visits, nursing home admissions, and prolonged illnesses that result from patients using their medications improperly.

C. Possible Solutions and Impact

Pharmacists must become participating members of the healthcare team and work collaboratively with physicians and other healthcare practitioners to provide total care to the patient. This process is currently occurring in Texas in that many pharmacists provide expanded patient care services such as drug therapy management, administration of immunizations, disease state management, disease screening, and health promotion and disease prevention.

Because the clinical knowledge and skills of pharmacists is underutilized in the current healthcare system pharmacists must work to expand the scope of collaborative practice agreements. The Board should monitor legislative efforts to expand the scope of collaborative practice agreements.

ISSUE #4: INCREASE LICENSEE COMPLIANCE WITH LAWS AND RULES RELATING TO THE PRACTICE OF PHARMACY THROUGH EDUCATION OF LICENSEES

A. Brief Description of Issue

Because the profession is changing rapidly, the laws and rules relating to the practice of pharmacy are also changing. The Board should re-dedicate its efforts to educate pharmacist about the laws and rules that relate to the practice of pharmacy including the importance of patient counseling.

B. Discussion

Since 1982, the Board has following a “*preventative*” approach to enforcement based upon the belief that 95% of its licensees/registrants will obey the laws and rules governing the practice of pharmacy, if the licensees are well informed as to the requirements of the pharmacy laws and rules. A review of prior reports of TSBP performance measure *Percent of Licensees with No Recent Violations* proves that preventive enforcement is working well. This successful educational program must expand and continue.

C. Possible Solutions and Impact

In developing this educational program, the Board should use all of the tools available to educate licensee including written information with the TSBP Newsletter, the TSBP website, social media such as Facebook, Twitter, YouTube, etc., presentations in person and on the Web, and compliance inspections.

ISSUE #5: RETIREMENT OF THE CURRENT EXECUTIVE DIRECTOR

A. Brief Description of Issue

The current executive director has indicated that she will retire in August 2017. The Board will establish a plan for hiring a new executive director. The Texas Pharmacy Act requires that the executive director of TSBP be a pharmacist. One item may make the process of finding a pharmacist to be the executive director of TSBP is the salary paid to this position. Currently the legislature has placed the salary of the executive director in exempt group 4, which has a minimum salary of approximately \$106,500 and a maximum salary of \$171,688 per year. However, the legislature has specified that the executive director's salary be set at \$127,280 for FY2016-2017.

B. Discussion

The current salary for the position results in the executive director position being very difficult to fill, since this salary is less than that paid to some beginning pharmacists and certainly less than that paid to pharmacy managers. A 2014 survey of pharmacist's salary conducted by "Drug Topics" reported the annual base salary for staff pharmacists is between \$116,000 and \$140,000 a year (Note: this salary is for staff pharmacist, not managers. Salary.Com reports that pharmacist managers make a median salary of \$137,836).

A survey of the salaries of the Executive Director of Oklahoma, Arkansas, and Louisiana show that the average salary for these individuals is \$140,000 or \$13,000 less than that of the Executive Director in Texas. It should be noted that Texas licenses 52% more pharmacies, 55% more pharmacists, and 136% more pharmacy technicians than OK, LA, and OK combined.

C. Possible Solutions and Impact

If the salary for the Executive Director position is not increased to be competitive, the agency will have a very difficult time hiring a person with the management, strategic thinking, and planning skills necessary to manage the agency.

For the last two legislative sessions, the Board has asked the legislature to give them the authority to set the salary within the Group 4 exempt salary range. With this authority, the Board will be able to pay the person who is the executive director a salary that is competitive to pharmacists' manager salaries and one that recognizes the qualifications necessary for the executive director.

ISSUE #6: PHYSICIAN DISPENSING**A. Brief Description of Issue**

In 1981, Attorney General Mark White issued A.G. Opinion 410 regarding the dispensing of prescriptions by a physician (practitioner). This opinion stated:

A practitioner may not practice pharmacy unless he is also licensed as a pharmacist under this act. No licensed pharmacy may legally operate unless there is a pharmacist-in-charge who is a licensed pharmacist. A practitioner who undertakes to fill a prescription of another practitioner engages in the practice of pharmacy, which he may not do unless licensed as a pharmacist. A practitioner who dispenses drugs to his own patients from his office, and charges a separate fee therefor, is engaged in the practice of pharmacy, which he may not do unless licensed as a pharmacist.

In each of the last three sessions, the Texas Legislature has considered bills that would change the law and allow physicians to dispense prescriptions from their office.

B. Discussion

The bills that have been introduced during the 2013, 2014, and 2015 sessions, have generally limited the dispensing in physician's offices to certain "aesthetic pharmaceuticals" such as Bimatoprost (Latisse), Hydroquinone (Lustra, Claripel), and Tretinoin (Retin A).

None of these bills has become law. However, during the 2013 session, a bill did pass the Legislature. Governor Perry vetoed this bill and recognized in his veto proclamation the important role of the pharmacist and the Board of Pharmacy by stating the following:

"SB 227 would circumvent existing safeguards for the dispensing of certain prescription cosmetic drugs by allowing physicians and optometrist to sell these medications directly. It is the role of the pharmacists – who are trained specifically in drug interactions, side effects and allergies – to dispense the medications. Additionally, the State Board of Pharmacy has the authority to inspect pharmacies to ensure drugs are stored securely and at safe temperatures."

It is expected another bill that would allow limited dispensing by physicians will be introduced during the 2017 session.

C. Possible Solutions and Impact

The Board and the profession may need to review the issue to see if there might be a way to allow some limited, dispensing in physician's office provided oversight of the dispensing by a pharmacist is provided. As Governor Perry indicated in his "Veto Proclamation" in 2013, *"It is the role of the pharmacists – who are trained specifically in drug interactions, side effects and allergies – to dispense the medications."* Any changes to this law need to recognize this important role of the physician in diagnosing and prescribing prescription drugs and the important role of the pharmacist in conducting a drug utilization review of all medications taken by a patient and dispensing the prescription.

ISSUE #7: DUAL STANDARDS FOR PHARMACY PRACTICE IN SMALL AND LARGE HOSPITALS

A. Brief Description of Issue

Currently, Texas has different requirements in the Pharmacy Act for pharmacy services in large hospitals (101 beds or more) and small hospitals (100 beds or less).

B. Discussion

The Pharmacy Act in Section 562.1011 (Operation of Class C Pharmacy in Certain Rural Hospitals) sets up a different standard of practice in rural hospitals with 75 beds or fewer, if the hospital is located in a county with a population of 50,000 or less or has been designated by the Centers for Medicare and Medicaid Services as a critical access hospital, rural referral center, or sole community hospital. This section allows pharmacy technicians to be supervised by nurses rather than pharmacists.

C. Possible Solutions and Impact

The Board believes that recent advancements in technology will allow pharmacist to supervise the work of pharmacy technician's in a more cost effective manner. In order to protect patients' health and to eliminate the dual standards between large and small hospitals, the Board should enter in discussions with stakeholders to amend the Act to eliminate the dual standard established in the Pharmacy Act and to require pharmacy technicians to be supervised by a pharmacist.

ISSUE #8: PROGRAM FOR PHARMACY TECHNICIANS WHO ARE IMPAIRED BY CHEMICAL ABUSE OR MENTAL OR PHYSICAL ILLNESS

A. Brief Description of Issue

The Texas Pharmacy Act contains provisions that authorize the agency to fund a Peer Assistance Program for pharmacists impaired by chemical abuse or mental or physical illness. However, there is not such program for pharmacy technicians.

B. Discussion

Since 1983, the Texas Pharmacy Act (Act) has authorized the agency to contract with an entity that operates a program established to aid pharmacists or eligible pharmacy students impaired by chemical abuse or mental or physical illness. In addition, the Act authorizes the agency to collect a surcharge on pharmacists' licenses to fund this program.

This program has been very successful in treating and rehabilitating pharmacists and pharmacy students and the success rate has been very high as can be seen by the agency performance measures. In FY2015, the one-year completion rate for pharmacists and students in the program was 74%. In addition, 66% of these individuals who completed one year of sobriety in FY2012, completed an additional 3 years of sobriety in FY2015 [i.e., the recidivism rate (relapse) was 34% in FY2015]. These numbers are much higher than those achieved in other recovery programs.

C. Possible Solutions and Impact

The Texas Pharmacy Act should be amended to allow pharmacy technicians to participate in the program.

ISSUE #9: APPROPRIATE LEVEL OF TRAINING AND SUPERVISION FOR PHARMACY TECHNICIANS

A. Brief Description of Issue

The practice of pharmacy is evolving and pharmacists are now required to perform more: cognitive services such as review of patient's prescriptions to assure that drugs do not interact with others taken by the patient; and professional services such as administration of immunizations and vaccines to patients. This evolution of the pharmacist's role is placing more time demands on the pharmacists and a corresponding desire to delegate more functions to pharmacy technicians.

B. Discussion

Currently, the Texas Pharmacy Act specifies that a pharmacy technician is individual employed by a pharmacy "whose responsibility is to provide technical services that do not require professional judgment regarding preparing and distributing drugs and who works under the direct supervision of and is responsible to a pharmacist." The Act also specifies that a pharmacy technician must have:

- a high school diploma or a high school equivalency certificate or be working to achieve an equivalent diploma or certificate; and
- passed a board-approved pharmacy technician certification examination.

Because pharmacists are spending more and more time conducting “cognitive services” such as drug use review and counseling patients on how to use their prescription drugs, the demand to expand the duties of pharmacy technicians is growing.

As the demand for expanding the duties of pharmacy technicians grows, the discussion regarding the appropriate level of training and education of pharmacy technicians also grows. Most believe that it is imperative to “raise” the level of practice of pharmacy technicians and to this, the pharmacy technician must be better educated.

In 2013, the Pharmacy Technician Certification Board (PTCB) announced changes to their certification program that will require individuals to have completed an American Society of Health-System Pharmacists (ASHP) accredited training program prior to taking the PTCB examination by 2020. This decision will affect the TSBP since pharmacy technicians must have taken and passed the PTCB examination in order to become a pharmacy technician in Texas.

C. Possible Solutions and Impact

In November 2013, the Board formed a Pharmacy Technician Task force to review pharmacy technician practice in the State of Texas including educational requirements, scope of practice and overall regulation of pharmacy technicians in all pharmacy settings, including hospital and community. The Task Force held two meetings and presented its report to the Board at its meeting on May 6, 2014. Included in this report were several suggestions for the expansion of duties that could be performed by pharmacy technicians in both community and hospital pharmacies. As of August 2015, the Board has not taking action on the suggestions from the Task Force.

The Board will continue to study the duties and education of pharmacy technicians in Texas and will make recommendations for changes to the Pharmacy Act when a consensus is reached.

ISSUE #10: MAINTAINING AGENCY’S LEADERSHIP POSITION IN PHARMACY PRACTICE REGULATION THROUGH ADEQUATE STAFFING AND ADEQUATE COMPENSATION OF HIGHLY QUALIFIED AGENCY PERSONNEL

A. Brief Description of Issue

The Board of Pharmacy needs to continue its partnership with the public and profession to aggressively promote the highest level of pharmacy services possible. In addition, opportunities exist for the Board to continue its national leadership role in progressive regulation. While being “out-front” is never comfortable, the pharmacy profession in Texas has come to expect the Board to act in a key leadership position while addressing public needs. However, given the growth in both size and complexity of pharmacy practice and healthcare, multiplied by the continued increase in demand for services, the agency’s ability to accomplish its mission is severely challenged. The agency must aggressively pursue activities to retain and increase the number of highly qualified personnel employed by the agency.

B. Discussion

The Board of Pharmacy must be visionary in order to stay on the cutting edge of regulation. The Board must continue to play a public advocacy role and stay focused on enhanced patient outcomes, with continued examination of those issues that are truly important, embracing current technology, and acting aggressively and fairly to hold pharmacists accountable for the patient care they provide. In order to protect the public health, safety and welfare, the agency must be adequately staffed. TSBP regulates a total population of 98,763 entities (as of year-end FY14) with a smaller number of FTEs than other regulatory agencies who are regulating the same or a smaller number of entities. Moreover, the agency's population is growing. In addition, the salaries of key positions are way below not only market, but other state agencies. Key positions that are currently underpaid contribute to turnover. If the agency experiences high turnover in these areas, it will certainly cripple the agency's ability to function efficiently and effectively. During the 2015 Legislative Session, the agency requested funding to reclassify key positions but this funding was not granted.

C. Possible Solutions and Impact

The Board should continue to work with stakeholders to strike the appropriate balance in achieving its public protection mandate, yet be flexible enough to develop regulations to facilitate pharmacy practice changes. The Board should continue to seek increased funding from the Texas Legislature to hire an adequate number of staff to meet the increasing demand for licensing and enforcement services. In addition, the Board should continue to seek increased funding from the Texas Legislature to adequately compensate key positions.

X. Other Contacts

A. Fill in the following charts with updated information on people with an interest in your agency, and be sure to include the most recent email address.

Texas State Board of Pharmacy Exhibit 14: Contacts

Interest Groups

(groups affected by agency actions or that represent others served by or affected by agency actions)

Group or Association Name/ Contact Person	Address	Telephone	Email Address
Texas Pharmacy Association Joe DaSilva, CAE Executive Director	6207 Bee Caves, Suite 120 Austin, Texas 78746	(512) 615-9170	jdasilva@texaspharmacy.org
Texas Society of Health-System Pharmacists Deanna Menesses, CAE Executive Director	3000 Joe DiMaggio #30-A Round Rock, TX 78665-3994	(512) 906-0546	Deanna.Menesses@tshp.org

Self-Evaluation Report

Group or Association Name/ Contact Person	Address	Telephone	Email Address
Texas Federation of Drug Stores Brad T. Shields, Executive Director	504 W. 12th St. Austin, TX 78701	(512) 413-2700	brad@bradshields.com
Alliance of Independent Pharmacists of Texas Audra L. Conwell, Executive Director/CEO	400 W. 15th Street, Ste. 950 Austin, TX 78701	(512) 487-4009	aconwell@aiptexas.org
Irma Lerma Rangel College of Pharmacy Texas A&M Health Science Center Indra K. Reddy, Professor and Dean	MSC 131, 1010 West Avenue B Kingsville, TX 78363-8202	(361) 221-0601	ireddy@pharmacy.tamhsc.edu
College of Pharmacy and Health Sciences Texas Southern University Edward Stemley, Jr., Dean	3100 Cleburne Street Houston, TX 77004	(713)313-7777	stemleyec@tsu.edu
School of Pharmacy Texas Tech University Health Sciences Center Quentin Smith Dean	1300 South Coulter Amarillo, TX 79106	(806) 414-9277	quentin.smith@ttuhsc.edu
The University of Texas at Austin College of Pharmacy M. Lynn Crismon, Dean	2409 University Ave., Mail Stop A1900 Austin, TX 78712-1113	(512) 471-3718	lynn.crismon@austin.utexas.edu
The University of Texas at Tyler Ben and Maytee Fisch College of Pharmacy Dr. Lane Brunner, Dean	3900 University Blvd. Tyler, TX 75799	(903) 565-5920	lbrunner@uttyler.edu
University of Houston College of Pharmacy Lamar Pritchard, Dean	4800 Calhoun, SR-2,141 Houston, TX 77204-5511	(713)743-1253	flpritchard@uh.edu
University of North Texas System College of Pharmacy Myron K. Jacobson, Dean	3500 Camp Bowie Boulevard Fort Worth, TX 76107	(817) 735-7616	myron.jacobson@unthsc.edu
Feik School of Pharmacy University of the Incarnate Word Arcelia Johnson-Fannin, Dean	703 E. Hildebrand San Antonio, TX 78209	(210) 883-1000	johnsonf@uiwtx.edu

Interagency, State, or National Associations*(that serve as an information clearinghouse or regularly interact with your agency)*

Group or Association Name/ Contact Person	Address	Telephone	Email Address
National Association of Boards of Pharmacy Carmen Catizone, Executive Director	1600 Feehanville Drive Mount Prospect, IL 60065- 6014	(847) 391-4406	exec-office@nabp.net
Pharmacy Technician Certification Board Everett B. McAllister, R.Ph., MPA, Executive Director/CEO	2215 Constitution Avenue NW, Suite 101 Washington, DC 20037	(800) 363-8012	contact@ptcb.org

Liaisons at Other State Agencies*(with which your agency maintains an ongoing relationship, e.g., the agency's assigned analyst at the Legislative Budget Board, or attorney at the Attorney General's office)*

Agency Name / Relationship / Contact Person	Address	Telephone	Email Address
Texas State Auditor's Office Kendra Campbell	1501 N Congress Ave Austin TX 78701	512-936-9769	kcampbell@sao.state.tx.us
Office of the Governor Budget & Policy Kara Crawford	1100 San Jacinto Austin TX 78701	512-463-1778	Kara.crawford@gov.texas.gov
Office of the Attorney General Contact: Joe Pitner	P.O. Box 12548 Austin, TX 78711-2548	512-475-4199	joseph.pitner@oag.state.tx.us
Legislative Budget Board Trevor Whitney	P.O. Box 12666 Capitol Station Austin, TX 78711	512-463-1169	Trevor.whitney@lbb.state.tx.us
Comptroller of Public Accounts Ben Strausser	111 E 17 th St Austin TX 78701	512-463-9019	Ben.strausser@cpa.texas.gov

XI. Additional Information

- A. Texas Government Code, Sec. 325.0075 requires agencies under review to submit a report about their reporting requirements to Sunset with the same due date as the SER. Include a list of each agency-specific report that the agency is required by statute to prepare and an evaluation of the need for each report based on whether factors or conditions have changed since the statutory requirement was put in place. Please do not include general reporting requirements applicable to all agencies, reports that have an expiration date, routine notifications or notices, posting requirements, federally mandated reports, or reports required by G.A.A. rider. If the list is longer than one page, please include it as an attachment.**

NOT APPLICABLE

- B. Has the agency implemented statutory requirements to ensure the use of "first person respectful language"? Please explain and include any statutory provisions that prohibits these changes.**

The agency uses the preferred language when referring to individuals with disabilities when appropriate.

- C. Fill in the following chart detailing information on complaints regarding your agency. Do not include complaints received against people or entities you regulate. The chart headings may be changed if needed to better reflect your agency's practices.**

**Texas State Board of Pharmacy
Exhibit 16: Complaints Against the Agency — Fiscal Years 2013 and 2014**

	Fiscal Year 2013	Fiscal Year 2014
Number of complaints received	0	0
Number of complaints resolved	0	0
Number of complaints dropped / found to be without merit	0	0
Number of complaints pending from prior years	0	0
Average time period for resolution of a complaint	0	0

- D. Fill in the following charts detailing your agency's Historically Underutilized Business (HUB) purchases.**

Exhibit 17: Purchases from HUBs

Fiscal Year 2013

Category	Total \$ Spent	Total HUB \$ Spent	Percent	Agency Specific Goal*	Statewide Goal
Heavy Construction	\$0.00	\$0.00	0.00%	None	11.2%
Building Construction	\$0.00	\$0.00	0.00%	None	21.1%
Special Trade	\$0.00	\$0.00	0.00%	None	32.7%
Professional Services	\$2,218.00	\$2,218.00	100.0%	23.6%	23.6%
Other Services	\$225,878.00	\$17,409.00	7.71%	24.6%	24.6%
Commodities	\$137,209.00	\$62,709.00	45.7%	21.0%	21.0%
TOTAL	\$365,305.00	\$82,336.00	22.54%		

* If your goals are agency specific-goals and not statewide goals, please provide the goal percentages and describe the method used to determine those goals. (TAC Title 34, Part 1, Chapter 20, Rule 20.13)

Fiscal Year 2014

Category	Total \$ Spent	Total HUB \$ Spent	Percent	Agency Specific Goal	Statewide Goal
Heavy Construction	\$0.00	\$0.00	0.00%	None	11.2%
Building Construction	\$0.00	\$0.00	0.00%	None	21.1%
Special Trade	\$0.00	\$0.00	0.00%	None	32.7%
Professional Services	\$2,175.00	\$2,175.00	100.0%	23.6%	23.6%
Other Services	\$442,560.00	\$48,896.30	11.05%	24.6%	24.6%
Commodities	\$162,730.00	\$61,537.00	37.82%	21.0%	21.0%
TOTAL	\$607,465.00	\$112,608.30	18.54%		

Fiscal Year 2015

Category	Total \$ Spent	Total HUB \$ Spent	Percent	Agency Specific Goal	Statewide Goal
Heavy Construction	\$0.00	\$0.00	0.00%	None	11.2%
Building Construction	\$0.00	\$0.00	0.00%	None	21.1%
Special Trade	\$0.00	\$0.00	0.00%	None	32.7%
Professional Services	\$1,349.50	\$1,349.50	100.0%	23.6%	23.6%
Other Services	\$310,941.97	\$4,001.72	1.29%	24.6%	24.6%
Commodities	\$196,099.70	\$33,864.81	17.27%	21.0%	21.0%
TOTAL	\$508,391.17	\$39,216.03	7.71%		

E. Does your agency have a HUB policy? How does your agency address performance shortfalls related to the policy? (Texas Government Code, Sec. 2161.003; TAC Title 34, Part 1, rule 20.15b)

Yes. The TSBP will make a good faith effort to utilize HUBs in contracts for services (including professional and consulting services), and commodities purchases. This effort includes assistance to HUBs in receiving a portion of the total contract value of all contracts that the TSBP expects to award in a fiscal year, including subcontracting opportunities, in accordance with the percentages set forth in Title 1, Part V, Chapter 111 of the Texas Administrative Code.

- F. For agencies with contracts valued at \$100,000 or more: Does your agency follow a HUB subcontracting plan to solicit bids, proposals, offers, or other applicable expressions of interest for subcontracting opportunities available for contracts of \$100,000 or more? (Texas Government Code, Sec. 2161.252; TAC Title 34, Part 1, rule 20.14)**

Yes. The agency requires completed HUB subcontracting plans for all solicitations valued at over \$100,000.00

- G. For agencies with biennial appropriations exceeding \$10 million, answer the following HUB questions.**

- 1. Do you have a HUB coordinator? If yes, provide name and contact information. (Texas Government Code, Sec. 2161.062; TAC Title 34, Part 1, rule 20.26)**

Yes. David Hardy, phone: 512-305-8023, e-mail: david.hardy@pharmacy.texas.gov

- 2. Has your agency designed a program of HUB forums in which businesses are invited to deliver presentations that demonstrate their capability to do business with your agency? (Texas Government Code, Sec. 2161.066; TAC Title 34, Part 1, rule 20.27)**

No.

- 3. Has your agency developed a mentor-protégé program to foster long-term relationships between prime contractors and HUBs and to increase the ability of HUBs to contract with the state or to receive subcontracts under a state contract? (Texas Government Code, Sec. 2161.065; TAC Title 34, Part 1, rule 20.28)**

No.

- H. Fill in the charts below detailing your agency's Equal Employment Opportunity (EEO) statistics.**

Exhibit 18: Equal Employment Opportunity Statistics

1. Officials / Administration

Year	Total Number of Positions	Percent African-American	Statewide Civilian Workforce Percent	Percent Hispanic	Statewide Civilian Workforce Percent	Percent Female	Statewide Civilian Workforce Percent
2013	5	0.00%	8.99%	0.00%	19.51%	100.00%	39.34%
2014	5	0.00%	8.99%	0.00%	19.51%	100.00%	39.34%
2015	5	0.00%	8.99%	0.00%	19.51%	0.00%	39.34%

2. Professional

Year	Total Number of Positions	Percent African-American	Statewide Civilian Workforce Percent	Percent Hispanic	Statewide Civilian Workforce Percent	Percent Female	Statewide Civilian Workforce Percent
2013	21	9.52%	11.33%	9.52%	17.4%	57.14%	59.14%
2014	26	7.69%	11.33%	11.54%	17.4%	61.54%	59.14%
2015	27	11.11%	11.33%	11.11%	17.4%	66.67%	59.14%

3. Technical **Not Applicable****4. Administrative Support**

Year	Total Number of Positions	Percent African-American	Statewide Civilian Workforce Percent	Percent Hispanic	Statewide Civilian Workforce Percent	Percent Female	Statewide Civilian Workforce Percent
2013	7	28.57%	13.57%	14.29%	30.53%	100.00%	65.62%
2014	16	12.5%	13.57%	25.00%	30.53%	100.00%	65.62%
2015	13	15.38%	13.57%	30.77%	30.53%	92.31%	65.62%

5. Service / Maintenance

Year	Total Number of Positions	Percent African-American	Statewide Civilian Workforce Percent	Percent Hispanic	Statewide Civilian Workforce Percent	Percent Female	Statewide Civilian Workforce Percent
2013	44	0.00%	14.68%	34.09%	48.18%	75.00%	40.79%
2014	44	2.27%	14.68%	31.82%	48.18%	65.91%	40.79%
2015	46	2.17%	14.68%	30.43%	48.18%	71.74%	40.79%

6. Skilled Craft **Not Applicable****I. Does your agency have an equal employment opportunity policy? YES How does your agency address performance shortfalls related to the policy?**

TSBP's policy is not to discriminate against any employee or applicant for employment because of race, color, religion, national origin, sex, age or disability status. Further, the TSBP takes all necessary affirmative steps to ensure the employment and promotion of otherwise qualified minorities, women and disabled persons who may be under represented in the agency's workforce.

TSBP is committed to the principles of equal employment opportunity law. Therefore, this written plan has been prepared to ensure that the TSBP's Recruitment Plan is properly implemented and no artificial barriers are intentionally or otherwise created to deny applicants for employment or employees of the TSBP equal employment opportunities.

The plan is available for review by TSBP employees, applicants for employment, and the general public upon request.

XII. Agency Comments

Provide any additional information needed to gain a preliminary understanding of your agency.

NO ADDITIONAL COMMENTS.