

SELF-EVALUATION REPORT

TO THE

SUNSET ADVISORY COMMISSION



Submitted by

Texas State Board of Pharmacy

August 2003

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Attachments Referred to in Self-Evaluation Report

- Attachment A. National Association of Boards of Pharmacy Survey of Pharmacy Law**
- Attachment B. Section 2 – Policies & Procedures Relating to Board Members (Texas State Board of Pharmacy Policy and Procedure Manual)**
- Attachment C. Agenda – Texas State Board of Pharmacy Board Member Orientation**
- Attachment D. Policies and Procedures for Handling Complaints**
- Attachment E. Texas State Board of Pharmacy Goals and Objectives Fiscal Year 2003**
- Attachment F. Informal Conference Procedures**
- Attachment G. Texas State Board of Pharmacy Compliance Regions**
- Attachment H. Notice of Inspection – Texas State Board of Pharmacy**
- Attachment I. Warning Notice – Texas State Board of Pharmacy**
- Attachment J. Texas Pharmacy Recovery Network (Brochure)**
- Attachment K. Texas State Board of Pharmacy Report on Customer Service (FY2002)**

Attachments Required by the Sunset Advisory Commission

Attachments Relating to Key Functions, Powers, and Duties

- Attachment 1. Texas Pharmacy Laws and Regulations**
- Attachment 2. Texas State Board of Pharmacy Annual Reports, FY1998-FY2002**
- Attachment 3. Texas State Board of Pharmacy Newsletters, FY2001 and FY2002**
- Attachment 4. FACTS about Prescription Medicines, Pharmacists, and Pharmacies – an Information Brochure for Consumers of Pharmacy Services**
- Attachment 5. N/A**

Attachments Relating to Policymaking Structure

- Attachment 6. Biographical Information on Members of the Texas State Board of Pharmacy**
- Attachment 7. Texas Pharmacy Laws and Regulations (Attachment 1)**

Attachments Relating to Funding

- Attachment 8. Texas State Board of Pharmacy Legislative Appropriations Request With Building Blocks for FY2004 and FY2005**
- Attachment 9. Texas State Board of Pharmacy Savings Plan for FY2003**
- Attachment 10. Texas State Board of Pharmacy Annual Financial Reports, FY2000-2002**
- Attachment 11. Texas State Board of Pharmacy Operating Budgets, FY2000-2002**

Attachments Relating to Organization

- Attachment 12. Organization Chart, Texas State Board of Pharmacy**
- Attachment 13. N/A**

Attachments Relating to Agency Performance Evaluation

- Attachment 14. Quarterly Performance Reports, FY2000-2002**
- Attachment 15. N/A**
- Attachment 16. Texas State Board of Pharmacy, Audit Programs for FY2003**
- Attachment 17. List of Internal Audits, FY1998-2002**
- Attachment 18. List of State Auditor Reports, FY1998-2002**
- Attachment 19. N/A**
- Attachment 20. N/A**

Texas State Board of Pharmacy Self-Evaluation Report

I. Key Functions, Powers, and Duties

A. Provide an overview of the agency's mission, key functions, powers, and duties. Specify which duties are statutory.

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.

The agency's key functions are:

- (1) formulating public policy with regard to the practice of pharmacy through rulemaking (i.e., setting standards) and regulation (i.e., 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, preceptors, and pharmacy technicians, 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.

The powers and duties of TSBP are outlined in Chapter 554 of the Texas Pharmacy Act, Texas Occupations Code Ann. §551.001 et seq. (Vernon 2003), and include the following:

- (1) enforcing the laws governing the practice of pharmacy;
- (2) cooperating 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;
- (3) regulating the practice of pharmacy through licensure examinations, renewal of licenses, setting standards for internship programs, and disciplining licenses;
- (4) determining and issuing standards for recognizing and approving degree requirements of colleges of pharmacy whose graduates are eligible for a license in this state;
- (5) regulating the training and qualifications of pharmacist-interns and pharmacy technicians;
- (6) recognizing and approving pharmacist certification programs;

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- (7) specifying procedures to apply for a pharmacy license and setting minimum standards for the operation of pharmacies;
- (8) specifying conditions under which a pharmacist can administer medications (i.e., immunizations or vaccinations);
- (9) regulating the delivery or distribution of prescription drugs or devices;
- (10) establishing fees to produce sufficient revenue to cover the cost of the agency's operation;
- (11) depositing revenues, other than administrative penalties, in a special pharmacy account in the general revenue fund;
- (12) commissioning peace officers to enforce the Texas Pharmacy Act;
- (13) approving pilot and demonstration research programs for innovative applications in the practice of pharmacy; and
- (14) adopting rules consistent with the administration and enforcement of the Texas Pharmacy Act.

All of the duties outlined above are statutory.

B. Does the agency's enabling law correctly reflect the agency's mission, key functions, powers, and duties?

Yes.

C. Please explain why these functions are needed. Are any of these functions required by federal law?

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;

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- (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.

None of these functions are required by federal law.

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

Each state has a state board of pharmacy. **See Attachment #A.**

E. Describe any major agency functions that are outsourced.

TSBP outsourced the following major agency functions in FY2003:

- (1) Licensing and Enforcement Database – TSBP contracts with Northrop Grumman Technical Services, Inc. (NGTSI), through a contract with the Department of Information Services for computer services. TSBP’s licensing and enforcement computerized database is supported by NGTSI and provides the following functions:
 - (A) online inquiry/updates of licensing records, with the exception of processing of license renewals, which occurs in nightly batch processing; and
 - (B) online inquiry and updates of complaint/disciplinary information.

Updated licensing information is downloaded once daily to the agency’s Web site, where the public can obtain information regarding pharmacies and pharmacists. TSBP staff work directly with NGTSI staff when changes need to be made to the system (e.g., when legislative changes establish new programs, such as continuing education requirements for pharmacists and registration of pharmacy technicians).
- (2) Peer Assistance Program – TSBP contracts with the Pharmacy Recovery Network that is administered by the Texas Pharmacy Association to aid pharmacists and eligible pharmacy students impaired by chemical abuse or mental or physical illness, and to monitor the success of individuals in the program.
- (3) Internal Auditor - TSBP contracts with Porterfield & Associates to perform the services required under the Internal Auditing Act.
- (4) Miscellaneous Services –
 - (A) Texas Building & Procurement Commission for mail services and printing/copy services;
 - (B) Calligraphy of pharmacist wall certificates;

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- (C) Iron Mountain for shredding services that are considered confidential;
- (D) Diane Fulmer, CPA, with preparation of the Annual Financial Report;
- (E) Ginny's Copy Service for larger copy jobs;
- (F) Greater Texas Moving & Storage for storage of files and furniture;
- (G) Texas Printing Company for mail out preparation of monthly license renewals;
- (H) Interagency contract with the Texas State Board of Medical Examiners for courier service for deposit and lockbox delivery;
- (I) Interagency contract for record storage services and microfilming of certain records with the Texas State Library; and
- (J) Comptroller of Public Accounts for lockbox services (no cost to the agency).

F. Discuss anticipated changes in federal law and outstanding court cases as they impact the agency's key functions.

TSBP does not anticipate any changes in federal law or court cases to impact the agency's key functions. However, there has been federal interest with regard to the following issues:

- (1) prescription drugs being dispensed/delivered to patients through Internet operations that are not in compliance with state and federal laws;
- (2) prescription drugs being dispensed/delivered to patients from Canadian pharmacies; and
- (3) prescription drug coverage for patients covered by Medicare.

G. Please fill in the following chart, listing citations for all state and federal statutes that grant authority to or otherwise significantly impact the agency.

Texas State Board of Pharmacy Exhibit 1: Statutes/Attorney General Opinions	
Statutes	
Citation/Title	Authority/Impact on Agency
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.

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<p>Texas Occupations Code, Title 2, Chapter 55 Renewal of a License While on Military Duty</p>	<p>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.</p>
<p>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</p>	<p>Provides the statutory authority for the Texas State Board of Pharmacy to regulate the practice of pharmacy; provides for licensure of pharmacists and pharmacies; 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.</p>
<p>Texas Health and Safety Code, Chapter 483 / Texas Dangerous Drug Act</p>	<p>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.</p>
<p>Texas Health and Safety Code, Chapter 481 / Texas Controlled Substances Act</p>	<p>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.</p>
<p>Texas Health and Safety Code, Chapter 431 / Texas Food Drug and Cosmetics Act</p>	<p>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.</p>
<p>Texas Occupations Code, Title 3, Chapter 101 / Health Professions Council</p>	<p>Provides the TSBP is a member of the Health Professions Council (HPC) and establishes a means for HPC agencies to coordinate administrative and regulatory efforts.</p>
<p>15 U.S.C. §§ 1471-1476 / Poison Prevention Marketing Act</p>	<p>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).</p>
<p>21 U.S.C §§ 301, 331, 333, 353, 381 (2003) / Prescription Drug Marketing Act</p>	<p>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.</p>

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21 USC § 353a (2003) / 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. The act no longer enjoins pharmacies from advertising compounding services to the public after a 2002 U.S. Supreme Court opinion invalidated as unconstitutional that portion of the act that prohibited advertising.
21 U.S.C §§ 301, 321, 331-337, 341-356, 358-363, 371-379, 381-384, 391-399 (2003) / 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 (2003) / 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
Tex. Att'y Gen. 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.
Tex. Att'y Gen. 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.
Tex. Att'y Gen. 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.
Tex. Att'y Gen. 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.
Tex. Att'y Gen. 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.

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Attorney General Opinion No.	Impact on Agency
Tex. Att'y Gen. 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.

A. Please fill in the following chart:

Texas State Board of Pharmacy Exhibit 2: Agency Contacts				
	Name	Address	Telephone & Fax Numbers	Email Address
Agency Head	Gay Dodson, R.Ph.	Wm. P. Hobby State Office Building, 333 Guadalupe, Suite 3-600, Austin, TX 78701	305-8026 FAX 305-8082	gay.dodson@tsbp.state.tx.us
Agency's Sunset Liaison	Cathy Stella Director of Administrative Services and Licensing	same as above	305-8013 FAX 305-8082	cathy.stella@tsbp.state.tx.us

II. History and Major Events

Provide a time line discussion of the agency's history, briefly describing the key events in the development of the agency, including:

- C the date the agency was established;
- C the original purpose and responsibilities of the agency;
- C major changes in responsibilities or statutory authority;
- C agency/policymaking body name and composition changes;
- C the impact of state/federal legislation, mandates, and funding;
- C the impact of significant state/federal litigation that specifically affects the agency's operations; and
- C key organizational events, and areas of change and impact on the agency's organization (e.g., a major reorganization of the agency's divisions or program areas).

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 as an independent state regulatory board.

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- 1929 Texas Pharmacy Act was amended to upgrade the eligibility requirements for pharmacists, requiring applicants to be graduates of a recognized college of pharmacy (a three-year course at that time).
- 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.
- 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.
- 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 an agency newsletter).
- 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; began regulation of institutional (hospital) pharmacies and clinic pharmacies; and allowed drug product selection (generic substitution) for the first time under conditions. Texas Legislature created 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 issue of pharmacists who are chemically, mentally, or physically impaired (eligible pharmacy students added to the program in 1985).
- 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.
- 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. A requirement that one-third Board Membership must be public members changed the composition of the nine-member Board from seven pharmacists and two public members to six pharmacists and three public members.

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- 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.
- 1996 Texas Tech School of Pharmacy opens, resulting in four pharmacy schools/colleges in Texas. 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.
- 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 following authority: to establish the concept of a "pharmacy peer review committee" (which made Texas the first state in the nation to pass such legislation); to determine and issue standards for recognition and approval of pharmacist certification programs; to register pharmacy technicians; to require all technicians to be certified; and to require entities providing professional liability insurance to report malpractice claims to the Board. In addition, the agency established a comprehensive and user-friendly Web site to improve services and accessibility to its customers.
- 2001 Texas Legislature, through amendments to the Texas Pharmacy Act, established remote pharmacy services; increased the number of continuing education hours required for pharmacist biennial renewal to 30 hours; and changed requirements for prescribers who wish to prohibit generic substitution.
- 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; 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. In addition, the Texas Legislature provided funding for TSBP to initiate the Pharmacy Technician Registration Program.

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FEDERAL TIME LINE

- 1906 Federal Food and Drug Act set standards for purity of medication only with no efficacy requirements.
- 1912 Federal 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.
- 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 will accept Amended 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 reimportation 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.

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- 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.
- 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 classifies federally regulated substances into one of five classes.
- 1970 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, like sublingual nitroglycerin and isosorbide dinitrate are exempted.
- 1973 All agencies involved in drug abuse control and the enforcement of drug laws were combined into one agency, the Drug Enforcement Administration (DEA).
- 1980 The first publication of Approved Drug Products with Therapeutic Equivalence Evaluations or "Orange Book" by the FDA.
- 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.

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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.

III. Policymaking Structure

A. Please complete the following chart:

Texas State Board of Pharmacy Exhibit 3: Policymaking Body					
Member Name	Term/ Appointment Dates/ Appointed by	Qualification (e.g., public member, industry representative)	Address	Telephone & Fax Numbers	Email Address
Roger W. Anderson, Dr. P.H., R.Ph.	11/10/1999 - 08/31/2005 Governor Bush	Pharmacist	M.D. Anderson Cancer Center 1515 Holcombe Blvd., Box 90 Houston, TX 77030	Telephone: 713/792-2753 FAX: 713/796-1910	randerson@tsbp.state.tx.us
Juliette F. Bartlett-Pack, Ph.D.	01/13/2003 - 08/31/2007 Governor Perry	Public Member	333 Guadalupe, Ste. 3-600 Austin, TX 78701	Telephone: 512/305-8026 FAX: 512/305-8082	jbartlett@tsbp.state.tx.us
W. Michael Brimberry, R.Ph., MBA	12/19/2001- 08/31/2007 Governor Perry	Pharmacist	Seton Healthcare Network 601 E. 15 th St. Austin, TX 78701	Telephone: 512/324-8206 FAX: 512/324-8297	mbrimberry@tsbp.state.tx.us
Kim A. Caldwell, R.Ph.	10/27/1997- 08/31/2003 Governor Bush	Pharmacist	333 Guadalupe, Ste. 3-600 Austin, TX 78701	Telephone: 512/305-8026 FAX: 512/305-8082	kcaldwell@tsbp.state.tx.us
Rosemary Forester Combs	11/10/1999- 08/31/2005 Governor Bush	Public Member	333 Guadalupe, Ste. 3-600 Austin, TX 78701	Telephone: 512/305-8026 FAX: 512/305-8082	rcombs@tsbp.state.tx.us
Wiki Erickson, M.A.	10/27/1997- 08/31/2003 Governor Bush	Public Member	1200 Knotty Oaks Dr., Waco, TX 76712	Telephone: 512/305-8026 FAX: 512/305-8082	werickson@tsbp.state.tx.us

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Member Name	Term/ Appointment Dates/ Appointed by	Qualification (e.g., public member, industry representative)	Address	Telephone & Fax Numbers	Email Address
Doyle E. High, R.Ph.	12/19/2001- 08/31/2007 Governor Perry	Pharmacist	333 Guadalupe, Ste. 3-600 Austin, TX 78701	Telephone: 512/305-8026 FAX: 512/305-8082	dhigh@ tsbp.state.tx.us
Oren M. Peacock, Jr., R.Ph.	11/10/1999- 08/31/2005 Governor Bush	Pharmacist	333 Guadalupe, Ste. 3-600 Austin, TX 78701	Telephone: 512/305-8026 FAX: 512/305-8082	opeacock@ tsbp.state.tx.us
Donna Burkett Rogers, M.S., R.Ph.	10/27/1997- 08/31/2003 Governor Bush	Pharmacist	Texan Heart Hospital 6655 First Park Ten, Suite 230 San Antonio, TX 78213	Telephone: 512/305-8026 FAX: 512/305-8082	drogers@ tsbp.state.tx.us

B. How is the chair of the policymaking body appointed?

The chair of the Texas State Board of Pharmacy is elected from its members for a one-year term. Authority: Section 552.007, Texas Pharmacy Act.

C. Describe the primary role and responsibilities of the 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. For examples of policy statements, see TSBP Web site (includes TSBP's policy on handling dispensing error complaints). The Board is the final decision maker on the entry of all disciplinary orders and rules.

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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.**

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

- (1) licensure and registration
 - (A) pharmacists
 - initial licensure after examination and training
 - renewal of license
 - initial registration of preceptors
 - (B) pharmacies
 - initial licensure
 - renewal of license to operate a pharmacy
 - (C) pharmacist-interns (initial registration)
 - student pharmacist-interns
 - extended pharmacist-interns
 - (D) pharmacy technicians
 - initial registration
 - renewal of registration
- (2) setting standards
 - (A) standards for qualifications for initial licensure
 - (B) standards for operation of pharmacies
 - (C) standards for recognition and approval of degree requirements of colleges of pharmacy whose graduates are eligible for a license in Texas
 - (D) standards for practical training, including internship
 - (E) standards for recognition and approval of training programs for pharmacy technicians

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- (F) standards for recognition and approval of pharmacy residency programs
- (G) standards for recognition and approval of pharmacist certification programs
- (3) regulating and enforcing the standards
 - (A) investigating complaints
 - (B) disciplining licensees who violate the laws and rules governing the practice of pharmacy

D. List any special circumstances or unique features about the 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 dedicated account within the State Treasury (Texas Pharmacy Act, Section 554.007).
- (2) The policymaking body is a nine-member Board, with six members who are pharmacists 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. In addition, the Board must include representation from pharmacists who are primarily employed in community and institutional pharmacies.
- (3) The Board has the responsibility of regulating three distinct entities – the persons who dispense prescription drugs to the public (pharmacists) and 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 the policymaking body meet? How many times did it meet in FY 2002? in FY 2003?

The Texas State Board of Pharmacy generally meets four times a year. The Board meetings were held on the following dates in FY2002 and FY2003:

FY2002	November 13-14, 2001
	February 5-6, 2002
	May 7-8, 2002
	July 21, 2002
	August 6-7, 2002

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FY2003 November 19-20, 2002
 February 4-5, 2003
 May 13-24, 2003
 July 19, 2003
 August 5-6, 2003

F. What type of training do the agency's policymaking body members 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. **See Attachment #C.** 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.

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 which informs 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) in FY2000, the Board participated in one training session regarding strategic planning that was conducted by a representative of the Governor's office, as well as two strategic planning workshops;
- (2) in FY2001, the Board received a four-hour lecture on drug and alcohol dependency and peer assistance issues presented by a professor of a Texas College of Pharmacy; and
- (3) in FY2003, the Board listened to a presentation on the Health Insurance Portability and Accountability Act (HIPAA) and federal rules promulgated pursuant to that Act relating to privacy issues and confidentiality of protected health information.

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

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G. Does the agency have policies that describe the respective roles of the policymaking body and agency staff in running the agency? If so, please 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 carry out the policy and are responsible for the day-to-day operations of the agency. **See Attachment #B .**

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

Texas State Board of Pharmacy Exhibit 4: Subcommittee and Advisory Committees			
Name of Subcommittee or Advisory Committee	Size/Composition/How are members appointed	Purpose/Duties	Legal Basis for Committee
Executive Committee	Elected officers (President, Vice President, and Treasurer)	Review, make recommendations regarding agency's proposed operating budget prior to the full Board's review/approval.	Texas Pharmacy Act, Section 554.001(b)(2)

I. How does the policymaking body obtain input from the public regarding issues under the jurisdiction of the agency? How is this input incorporated into the operations of the 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) FY1999 – Task Force on Pharmacists’ Working Conditions and Their Impact on Public Health; and Task Force on Non-Resident Pharmacies and Automation in Pharmacies;

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- (B) FY2000 – Task Force on Standards for Pharmacy Technician Training Programs; and Task Force on Standards for Pharmacist Certification Programs;
 - (C) FY2001 – Task Force on Remote Pharmacy Services (to implement S.B. 65, 98 and provisions of S.B. 768); and Task Force on Peer Review Guidelines (to implement provisions of S.B. 768);
 - (D) FY2002 – Task Force on Technician Registration; and Work Group on Dispensing Directive for Generic Substitution (to implement provisions of S.B. 768); and
 - (E) FY2003 – Task Force on Pharmacy Compounding.
- (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 intended 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 four 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 – In FY2000 and FY2002, TSBP conducted a survey of agency customers regarding the quality of service delivered by the agency as specified in Chapter 2113 of the Government Code. Following each survey, a report was made to the Board regarding comments and recommendations that had been made on a myriad of issues. Many of the customers' suggestions resulted in changes to agency operations. See response to Question F in Section VII regarding Agency Performance.
- (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.

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IV. Funding

A. Describe the agency's process for determining budgetary needs and priorities.

PREPARATION OF BUDGET REQUEST

The preparation of each year's annual operating budget, as well as the Agency's Legislative Appropriation Request, occurs after the following reviews are conducted:

- (1) The Executive Director presents a review to the Board, of the current year's progress towards objectives to determine not only the progress towards the Agency's goals and objectives, but any workload and/or fiscal restraints that have an impact on the accomplishment of those objectives.
- (2) The Board reviews the Agency's Strategic Plan to determine not only financial impact, but workload and human resource impact. This review also serves the purpose of "linking" the Strategic Plan to the Annual Goals and Objectives and the budgeting process.

Following these reviews, a financial budget is prepared, which is necessary to accomplish the adopted goals. In addition, a fee structure required to support the budget is determined. In this preparation, the Director of Administrative Services performs the following process:

- (1) reviews past budgetary expenditure trends to determine historical patterns of spending;
- (2) reviews any new legislation that may have an impact on financial affairs, (e.g., increase in mileage, across-the-board budget cuts, transfers to other state agencies);
- (3) consults with the Executive Director and Division Directors to determine needs in each program area, considering increases to workload as well as new programs/initiatives that may affect the budgetary process; and
- (4) reviews available data regarding key performance measures that may have an impact on revenues produced, (e.g., projected number of licensees, projected number of examinations, estimated sale of surplus property).

APPROVAL OF BUDGET REQUEST

- (1) The Board Executive Committee reviews and makes any recommendations regarding the draft of the Agency Strategic Plan and Legislative Appropriations Request.
- (2) At a public meeting of the Board, the Board Members review and approve the final Agency Strategic Plan, key performance measures (i.e., projected outcomes, outputs, workload measures) and upcoming Biennial Budget for submission to the Legislative Budget Board (LBB) and Governor's Budget Office (GBO). By approval of the Strategic Plan and Biennial Budget, the Board ensures that Board policy is reflected.

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- (3) The Executive Director takes actions to accomplish Board objectives within the adopted budget. Agency staff submits the Legislative Appropriation Request (LAR) according to specified instructions detailed by the LBB and GBO.
- (4) Agency staff conducts an informal orientation of the agency organization and budgetary process with LBB and GBO staff analysts, to familiarize these individuals with agency operations.
- (5) During the biennial legislative session, the Board President and the Executive Director present the budget to the House Appropriations Committee and the Senate Finance Committee. In addition, agency staff maintains constant communication with agency representatives of the LBB and GBO throughout the entire budget process to clarify any portion of the agency's LAR. Agency staff prepares and submits additional financial data as required to LBB and GBO staff analysts.
- (6) After the final Legislative Appropriations Act is approved by the Texas Legislature, the Executive Director reports this action to the Board and presents the upcoming Annual Goals and Objectives and the Biennial Budgets for review and approval.

MONITORING OF BUDGET PROCESS

- (1) Board Responsibilities
 - (A) Reviews quarterly internal operating budget to assure that the expenditures do not exceed appropriated funds; expenditures do not materially deviate from Board priorities without approval; and expenditures do not violate applicable laws and rules.
 - (B) Reviews and approve any unusual or one-time budgeting requests, such as consultant studies not already approved in the annual goals and objectives; travel waiver requests; contract relating to the Peer Assistance Program; and any emergency budget items.
- (2) Management Staff Responsibilities

These responsibilities are identified in the agency's Annual Goals and Objectives for each fiscal year. Management staff periodically, and at least quarterly, reviews fund availability within each strategy or appropriation/program cost account, to ensure that funds are available in the correct strategy, and takes budgetary action to ensure that appropriations are not overspent in any category. Management staff also periodically reviews the internal controls in place to ensure accountability of all agency spending (i.e., travel, high risk expenditures, contracts).

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B. Show the agency's sources of revenue. Please include all local, state, and federal appropriations, all professional and operating fees, and all other sources of revenue collected by the agency.

Texas State Board of Pharmacy Exhibit 5: Sources of Revenue — Fiscal Year 2002 (Actual)	
Source	Amount
General Revenue Fund - Dedicated Pharmacy Board Operating Account No. 523	\$ 3,820,501.00
General Revenue Fund No. 001 - Fines	\$ 67,500.00
Appropriated Receipts	\$ 137,110.00
TOTAL	\$ 4,025,111.00

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

Not Applicable.

D. If applicable, please provide detailed information on fees collected by the agency.

Texas State Board of Pharmacy Exhibit 7: Fee Revenue and Statutory Fee Levels — Fiscal Year 2002 (Actual)				
Description/ Program/ Statutory Citation	Current Fee/ Statutory maximum	Number of persons or entities paying fee	Fee Revenue	Where Fee Revenue is Deposited
Pharmacist Licensure	\$ 227 / None	11,362	\$ 2,218,787	Pharmacy Board Operating Fund - 523
Pharmacy Licensure	\$ 363 / None	3,495	\$ 1,160,101	Pharmacy Board Operating Fund - 523
Examination	\$ 50 / None	715	\$ 35,750	Pharmacy Board Operating Fund - 523
Reciprocity	\$ 250 / None	334	\$ 83,550	Pharmacy Board Operating Fund - 523
Probation Fees	\$1,200 / None	30	\$ 36,000	Pharmacy Board Operating Fund - 523
Administrative Penalties (Fines)	Varies Based on Violations / None	39	\$ 67,500	General Revenue Fund - 001

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E. Show the agency's expenditures by strategy.

Texas State Board of Pharmacy Exhibit 8: Expenditures by Strategy — Fiscal Year 2002 (Actual)	
Goal/Strategy	Amount
Goal A: Maintain Standards	Goal A Total: \$ 439,054.00
A.1.1 Licensing	\$ 439,054.00
Goal B: Enforce Regulations	Goal B Total: \$ 2,243,879.00
B.1.1 Enforcement	\$ 2,083,555.00
B.1.2 Peer Assistance	\$ 160,324.00
Goal C: Indirect Administration	Goal C Total: \$ 552,929.00
C.1.1 Indirect Administration	\$ 552,929.00
GRAND TOTAL:	\$ 3,235,862.00

F. Show the agency's expenditures and FTE's by Program – Fiscal Year 2002 (Actual)

Texas State Board of Pharmacy Exhibit 9: Expenditures and FTE's by Program – Fiscal Year 2002 (Actual)					
Program	Budgeted FTE's, FY 2002	Actual FTE's as of August 31, 2002	Federal Funds Expended	State Funds Expended	Total Actual Expenditures
Licensing	4.83	4.686	0	\$ 439,054.00	\$ 439,054.00
Enforcement	32.33	31.68	0	\$2,243,879.00	\$ 2,243,879.00
Indirect Administration	9.84	9.437	0	\$552,929.00	\$ 552,929.00
TOTAL	47.00	45.803	0	\$3,235,862.00	\$ 3,235,862.00

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G. Show the agency's objects of expense for each category of expense listed by your agency in the General Appropriations Act FY2004-2005.

Texas State Board of Pharmacy Exhibit 10: Objects of Expense by Program or Function – Fiscal Year 2004				
Object-of-Expense Informational Listing	Strategy Licensing	Strategy Enforcement	Strategy Peer Assistance	Strategy Indirect Administration
Salary & Wages	283,955	1,376,433	52,325	443,967
Other Personnel Costs	2,840	21,256		21,040
Professional Fees & Services	147,210	16,972	94,500	7,481
Fuels & Lubricants		9,882		29
Consumable Supplies	3,430	15,314		4,951
Utilities	4,275	2,030		1,303
Travel	1,112	74,443		20,539
Rent - Building	25	393		784
Rent - Machine & Other	1,306	8,759		2,659
Other Operating Expense	350,363	104,600		30,416
Capital Expenditures	2,700	31,950		12,450
Total, FY2004 Object-of-Expense Informational Listing	<u>797,216</u>	<u>1,662,032</u>	<u>146,825</u>	<u>545,619</u>

Texas State Board of Pharmacy Exhibit 10: Objects of Expense by Program or Function – Fiscal Year 2005				
Object-of-Expense Informational Listing	Strategy Licensing	Strategy Enforcement	Strategy Peer Assistance	Strategy Indirect Administration
Salary & Wages	283,955	1,544,669	52,325	443,967
Other Personnel Costs	2,840	21,256		21,040
Professional Fees & Services	107,411	42,203	94,500	8,549
Fuels & Lubricants		13,482		29
Consumable Supplies	3,070	16,874		4,951
Utilities	4,275	3,074		1,303
Travel	1,112	86,265		20,539

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Object-of-Expense Informational Listing	Strategy Licensing	Strategy Enforcement	Strategy Peer Assistance	Strategy Indirect Administration
Rent - Building	25	393		784
Rent - Machine & Other	1,306	8,759		2,659
Other Operating Expense	362,525	120,108		32,442
Capital Expenditures		67,801		
Total, FY2005 Object-of-Expense Informational Listing	<u>766,519</u>	<u>1,924,884</u>	<u>146,825</u>	<u>536,263</u>

H. Please fill in the following chart.

Texas State Board of Pharmacy Exhibit 11: Purchases from HUBs				
FISCAL YEAR 2000				
Category	Total \$ Spent	Total HUB \$ Spent	Percent	Statewide Goal
Heavy Construction	0	0	0	11.9%
Building Construction	0	0	0	26.1%
Special Trade	85	0	0	57.2%
Professional Services	675	0	0	20.0%
Other Services	350,419	25,241	7.2%	33.0%
Commodities	118,786	25,277	21.27%	12.6%
TOTAL	469,965	38,080		
FISCAL YEAR 2001				
Category	Total \$ Spent	Total HUB \$ Spent	Percent	Statewide Goal
Heavy Construction	0	0	0	11.9%
Building Construction	0	0	0	26.1%
Special Trade	135	0	0	57.2%
Professional Services	746	0	0	20.0%
Other Services	313,091	17,108	5.46%	33.0%
Commodities	141,655	10,290	7.26%	12.6%
TOTAL	455,627	27,398		

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FISCAL YEAR 2002				
Category	Total \$ Spent	Total HUB \$ Spent	Percent	Statewide Goal
Heavy Construction	0	0	0	11.9%
Building Construction	0	0	0	26.1%
Special Trade	0	0	0	57.2%
Professional Services	1,697	0	0	20.0%
Other Services	461,467	7,613	1.64%	33.0%
Commodities	104,034	41,413	39.8%	12.6%
TOTAL	567,198	49,026		

I. Does the agency have a HUB policy? How does the agency address performance shortfalls related to the policy?

The agency attempts to utilize HUB vendors for all delegated purchases and, in fact, has a HUB policy. In the event of performance shortfalls, the agency reviews the requirements listed in the overall bid process and notes any constraints that exist, specifically constraints relating to contracts that are proprietary in nature. Agency data regarding goals, actual performance and constraints are noted in the agency Strategic Plan and Annual Non-Financial Report.

J. For agencies with contracts valued at \$100,000 or more:

	Response/ Agency Contact
Does your agency follow a HUB subcontracting plan to solicit bids, proposals, offers, or other applicable expressions of interest for subcontracting opportunities available under contracts of \$100,000 or more? (Tex. Government Code. Sec. 2161.252; TAC 111.14)	The agency has two contracts valued at over \$100,000. One contract is with Northrup Grumman Technical Services, Inc. (NGTSI) for computer services. This contract complements the original statement of Work, Terms and Conditions between the Department of Information Resources and (NGTSI). The second contract is for the Pharmacists Peer Assistance Program and subcontracting opportunities are not applicable.

K. For agencies with biennial appropriations exceeding \$10 million:

Not Applicable

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V. Organization

A. Please fill in the chart below. If applicable, list field or regional offices.

Texas State Board of Pharmacy Exhibit 12: FTE's by Location — Fiscal Year 2002			
Headquarters, Region, or Field Office	Location	Number of Budgeted FTE's, FY2002	Number of Actual FTE's as of August 31, 2002
Headquarters	333 Guadalupe St, Ste 3-600; Austin TX 78701	46.9	46
TOTAL		46.9	46

B. What was the agency's FTE cap for fiscal years 2002-2005?

Fiscal Year	FTE's
2002-2003	46.9
2004	48
2005	54

C. How many temporary or contract employees did the agency have as of August 31, 2002?

None

D. Please fill in the chart below.

Texas State Board of Pharmacy Exhibit 13: Equal Employment Opportunity Statistics FISCAL YEAR 2000							
Job Category	Total Positions	Minority Workforce Percentages					
		Black		Hispanic		Female	
		Agency	Civilian Labor Force %	Agency	Civilian Labor Force %	Agency	Civilian Labor Force %
Officials/Administration	5	0%	5%	0%	8%	80.00%	26%
Professional	26	3.85%	7%	11.54%	7%	46.15%	44%
Technical	0	0%	13%	0%	14%	0%	41%
Protective Services	0	0%	13%	0%	18%	0%	15%
Para-Professionals	11	27.27%	25%	18.18%	30%	100.00%	55%
Administrative Support	4	25.00%	16%	50.00%	17%	100.00%	84%

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Skilled Craft	0	0%	11%	0%	20%	0%	8%
Service/Maintenance	0	0%	19%	0%	32%	0%	27%
FISCAL YEAR 2001							
Job Category	Total Positions	Minority Workforce Percentages					
		Black		Hispanic		Female	
		Agency	Civilian Labor Force %	Agency	Civilian Labor Force %	Agency	Civilian Labor Force %
Officials/Administration	5	0%	5%	0%	8%	80.00%	26%
Professional	23	4.35%	7%	13.04%	7%	47.83%	44%
Technical	0	0%	13%	0%	14%	0%	41%
Protective Services	0	0%	13%	0%	18%	0%	15%
Para-Professionals	13	23.08%	25%	15.38%	30%	100.00%	55%
Administrative Support	4	25.00%	16%	50.00%	17%	100.00%	84%
Skilled Craft	0	0%	11%	0%	20%	0%	8%
Service/Maintenance	0	0%	19%	0%	32%	0%	27%
FISCAL YEAR 2002							
Job Category	Total Positions	Minority Workforce Percentages					
		Black		Hispanic		Female	
		Agency	Civilian Labor Force %	Agency	Civilian Labor Force %	Agency	Civilian Labor Force %
Officials/Administration	5	0%	5%	0%	8%	80.00%	26%
Professional	25	4.00%	7%	12.00%	7%	52.00%	44%
Technical	0	0%	13%	0%	14%	0%	41%
Protective Services	0	0%	13%	0%	18%	0%	15%
Para-Professionals	13	15.38%	25%	23.08%	30%	100.00%	55%
Administrative Support	4	0%	16%	75.00%	17%	100.00%	84%
Skilled Craft	0	0%	11%	0%	20%	0%	8%
Service/Maintenance	0	0%	19%	0%	32%	0%	27%

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E. Does the agency have an equal employment opportunity policy? How does the agency address performance shortfalls related to the policy?

The agency Personnel Manual and Employee Handbook contains a Recruitment Plan/Affirmative Action Plan. This plan is designed to assure the implementation of human resource policies and practices to promote equal employment opportunities. TSBP recognizes that full and equal participation of minorities, women and disabled persons in all employment opportunities is a necessary component of an effective Recruitment Plan/Affirmative Action Plan. TSBP's plan is designed to conform in good faith with the Affirmative Action Guidelines adopted by the U.S. Equal Employment Opportunity Commission (EEOC) and developed with the assistance of the Texas Commission on Human Rights.

The plan is available for review by TSBP employees, applicants for employment, and the general public upon request. The Plan is also available on the TSBP Internet Web site: www.tsbp.state.tx.us.

To address any potential performance shortfalls, the TSBP has adopted an internal grievance procedure for the prompt and equitable resolution of complaints alleging any adverse action that results from discrimination based on race, color, religion, national origin, sex, age, or disability. In addition, an employee may also seek an administrative remedy through federal agencies such as the Equal Employment Opportunity Commission, the Department of Justice, Civil Rights Division, or state agencies such as the Texas Commission on Human Rights.

VI. Guide to Agency Programs – Licensing

A. Licensing Program

Texas State Board of Pharmacy Exhibit 14: Program or Function Information — Fiscal Year 2002	
Name of Program or Function	Licensing
Location/Division	Headquarters - Administrative Services & Licensing
Contact Name	Cathy Stella
Number of Budgeted FTE's, FY 2002	4.83
Number of Actual FTE's as of August 31, 2002	4.686

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B. What are the key services of this function or program? Describe the major activities involved in providing all services.

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 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;
- (4) issuing registrations to qualified applicants to provide remote pharmacy services;
- (5) issuing registrations to qualified pharmacist-interns;
- (6) issuing certifications to qualified pharmacist-preceptors;
- (7) renewing licenses of pharmacists on active and inactive basis;
- (8) renewing licenses of pharmacies that do not have a registration to provide remote pharmacy services;
- (9) renewing licenses of pharmacies that have a registration to provide remote pharmacy services;
- (10) renewing certifications of qualified pharmacist-preceptors;
- (11) monitoring pharmacists' compliance with continuing education requirements;
- (12) updating pharmacists' licensing records with respect to change of name, change of employment, and change of address;
- (13) processing applications from pharmacies for a change of name and/or change of location; processing notifications from pharmacies regarding permanent closings; and updating licensing records;
- (14) providing information to the public, including requests for verification of licensure 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; and
- (15) beginning FY2004, implementing a new program to register pharmacy technicians.

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The major activities of each key service are described below:

INITIAL LICENSURE OR RE-LICENSURE OF PHARMACISTS

- (1) distributing 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) conducting criminal history background checks of all applicants through the Texas Department of Public Safety and coordinating with the TSBP Enforcement/Legal Divisions if applicant has an enforcement record;
- (6) notifying applicant of examination scores;
- (7) determining if applicant has met all requirements for licensure (e.g., completed 1,500 internship hours, passed licensure examinations with a 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);
- (8) serving as liaison to the Examination Retake Committee who makes recommendations to applicants who have thrice failed a licensure examination;
- (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 signed by Executive Director, which is later followed with the mailing of a hand-inscribed license suitable for framing (wall-certificate).

INITIAL LICENSURE OF PHARMACIES

- (1) distributing application forms to potential applicants for pharmacy licensure; may include determining the applicable form to distribute (i.e., different application forms are used, depending upon the class of pharmacy license);
- (2) after receiving any document relating to a pharmacy application, reviewing application to determine if the application is complete or incomplete and creating/maintaining pharmacy-applicant file;

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- (3) conducting criminal history background checks on all persons who are listed as owners on pharmacy applications and coordinating with the TSBP Enforcement/Legal Divisions on any enforcement record;
- (4) determining if applicant must undergo pre-inspection before pharmacy license can be issued and coordinate with Enforcement Division as required;
- (5) if the application is for a Class E (Non-Resident) Pharmacy 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;
- (6) determining if applicant has met all requirements to obtain pharmacy license (e.g., completed appropriate application and submitted all required attachments, paid applicable fees, and when necessary, has received clearance from the Enforcement/Legal Divisions);
- (7) communicating with and providing information to applicants regarding the status of their applications, including correspondence regarding “missing items” on the application; and
- (8) 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) distributing application forms to Texas colleges of pharmacy for pharmacy students who are enrolled in the professional sequence (these students must complete an application for Student Pharmacist-Interns and receive an internship registration card before enrolling in certain course work);
- (2) distributing application forms to applicants from out-of-state colleges of pharmacy for pharmacy students who are enrolled in the professional sequence (these students must complete an application for Student Pharmacist-Interns and receive an internship registration card before serving as pharmacist-interns in Texas pharmacies);
- (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) 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;

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- (5) conducting criminal history background checks of all applicants through the Texas Department of Public Safety and coordinating with the Enforcement/Legal Divisions if applicant has an enforcement record;
- (6) determining if applicant has met all the requirements to obtain a pharmacist-intern registration card (e.g., completed appropriate application and submitted all required attachments, 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 registration card with an assigned expiration date; and
- (9) serving as liaison with the internship coordinators of the four Texas colleges of pharmacy regarding the registration of their students as pharmacist-interns.

INITIAL AND RENEWAL CERTIFICATION OF PRECEPTORS

- (1) distributing application forms to and receiving applications from pharmacists who wish to become certified as preceptors;
- (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 PHARMACIST AND PHARMACY LICENSES

- (1) mailing licensure renewal applications to licensees;
- (2) receiving and reviewing renewal applications to determine if the applications are complete or incomplete; if an application is incomplete, returning the application to the licensee with a letter explaining that the license will not be renewed unless the application is completed and returned to TSBP;
- (3) if the application is complete, updating the licensee’s computerized record with a new expiration date and mailing the renewal card to the licensee by U.S. mail;
- (4) maintaining hard-copy and imaged licensing files;

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- (5) communicating with 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
- (6) repeating the process every two years (licenses are renewed on a biennial basis).

CONTINUING EDUCATION (CE) AUDITS

- (1) downloading form letters addressed to a random sample of pharmacists (agency's computer program selects random sample) advising pharmacists that they are the subject of a CE audit;
- (2) mailing a letter to each pharmacist in random sample informing pharmacist that he/she must submit copies of certificates of the required number of CE hours to TSBP by the due date provided in the letter;
- (3) monitoring the return of the CE certificates;
- (4) upon receipt of the CE certificates, determining if the pharmacist has obtained the required number of CE hours;
- (5) initiating complaint and forwarding the complaint to the Enforcement Division if the pharmacist has not responded to the CE audit letter or has not submitted the required number of CE hours set forth in the CE audit letter; and
- (6) communicating with pharmacists about CE audits and the laws/rules relating to CE, including notification letters to advise the pharmacists of the outcome of the CE audits.

PHARMACIST AND PHARMACY CHANGES

- (1) updating a pharmacist's license record with respect to a change of employment or address, 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; and
- (3) updating a pharmacy's license record with respect to change of name and/or address, upon receipt of completed application and 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 FY2002, Licensing Program staff mailed 2,000 packets of information; responded to 5,100 email inquiries; and handled 16,000 telephone calls.

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- (2) Licensing Program staff provide information regarding the status of a license (e.g., active, inactive, expired) either by phone, email, fax, or U.S. mail. In addition, the public can determine the status of a license via the TSBP Web site. In FY2002, TSBP received 112,184 Web site inquiries with approximately 65% of the inquiries using the license verification link to verify a pharmacist or pharmacy license or intern registration.

PHARMACY TECHNICIAN REGISTRATION

Licensing Program staff is gearing up to implement new rules relating to the registration of pharmacy technicians. TSBP estimates that it will receive and process applications from an estimated 26,000 pharmacy technicians. Major activities will include the following:

- (1) distributing application forms to potential applicants (Online applications will be accepted on the TSBP Web site.);
- (2) receiving and reviewing applications;
- (3) conducting criminal history background checks of all applicants through the Texas Department of Public Safety;
- (4) determining if an 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);
- (5) issuing registration number, notification letter, and registration certificate; and
- (6) communicating with applicants regarding the status of their applications.

<p>C. When and for what purpose was the program or function created? Describe any statutory or other requirements for this program or function.</p>
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Legislation that first recognized the need for regulation of the practice of pharmacy in Texas was passed in 1889. That year the legislature established boards of "*pharmaceutical examiners*," which were three-man committees in each senatorial district of the state. Pharmacists were tested and certified by these committees, although there was much inconsistency as to standards. Few records were kept, and there was no central authority to coordinate the committees' activities.

To bring consistency and centralization to pharmacy practice regulation, the legislature passed the first Texas Pharmacy Act in 1907. This Act established the Texas State Board of Pharmacy as an independent state regulatory board.

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Statutory requirements relating to the Licensing Program are set forth in the Texas Pharmacy Act, Texas Occupations Code Ann. §551.001 et seq. (Vernon 2003). 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"> C issuing a license after examination or by reciprocity to qualified applicants and issuing licenses to pharmacies C renewing a license to practice or operate a pharmacy C determining and issuing standards for recognizing and approving degree requirements of colleges of pharmacy whose graduates are eligible for a license in this state C specifying requirements for practical training, including an internship C regulating the training, qualifications, and employment of a pharmacist-intern and pharmacy technician
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
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
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
Chapter 561	addresses the renewal of pharmacy licenses
Section 568.002	states that a pharmacy technician must register with the Board with certain exceptions
Section 562.108-110	addresses Emergency Medication Kits, Automated Pharmacy Systems, and Telepharmacy.

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D. Describe any important history not included in the general agency history section, including a discussion of how the services or functions have changed from the original intent. Will there be a time when the mission will be accomplished and the program or function will no longer be needed?

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 more recently, to register qualified pharmacy technicians to assist pharmacists with non-judgmental duties relating to the dispensing of prescriptions.

The "Texas Time Line" (in Section II), 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:

Prior
to

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

- 1981
- 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.

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- 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 (applicable rules were implemented in May 1993);
 - 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; 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

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- gave the agency the authority to require applicants to run federal criminal history background checks for applicants for licensing and licensees.

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 persons:

- (1) pharmacists – 21,334 (as of July 2003)
- (2) preceptors – 3,445 (as of July 2003)
- (3) pharmacist-interns – 1,831 (as of July 2003)
- (4) pharmacies – 5,793 (as of July 2003)
- (5) applicants for licensure and registration (varies*).

* as of year-end FY2002, there were 1,900 new licenses issued, as follows:

new pharmacist licenses –	855
new pharmacies –	443
new pharmacy licenses issued as a result of a change of ownership	602

In FY2004, the Licensure Program will also affect pharmacy technicians (estimated number is 26,500). The Licensure Program could also affect, indirectly, the consumers of services provided by licensees (number of persons who receive pharmacy services is unknown).

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.

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- (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. California is the only state that does not reciprocate licensure with Texas and other states. Florida reciprocates with other states under the condition that the applicant has taken and passed the NAPLEX within the last 12 years. Texas reciprocates with Florida under like conditions. 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 in the type of internship practice setting where the training will occur; 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.

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

(A) 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; and
- C has successfully completed the first professional year and a minimum of 30 credit hours of work towards a professional degree in pharmacy.

In Texas, the four 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.

(B) Extended Pharmacist-Interns – To be eligible to be registered as an Extended Pharmacist-Intern in Texas, an applicant must complete the required application 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 three 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 three 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 five different classes of pharmacies, which are described below:

(A) Class A (Community) Pharmacy – is a pharmacy that dispenses a drug or device to the public under a prescription drug order.

(B) Class B (Nuclear) Pharmacy – is a pharmacy that dispenses a radioactive drug or device for administration to the ultimate user.

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- (C) Class C (Institutional) Pharmacy – is a pharmacy that is located in one of the following facilities:
- 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.
- (D) Class D (Clinic) Pharmacy – is a pharmacy that provides a limited type of drug or device under a prescription drug order.
- (E) Class E (Non-Resident) Pharmacy – is a pharmacy that is located in another state 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 Texas, by U.S. mail, common carrier, or delivery service.

The statistical breakdown of the numbers of pharmacies licensed by TSBP, by class of pharmacy license, is reflected in the chart below. Data is as of July 2003.

PHARMACIES ACTIVE	
Class A (Community)	4,136
Class B (Nuclear)	38
Class C (Institutional)	867
Class D (Clinic)	446
Class E (Non Resident)	306
TOTAL	5,793

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. Following the amendments to TSBP Rule 291.1, which became effective in March 2003, the pharmacy application forms were updated and expanded to require numerous items of information. The instructions and application forms for the five different classes of pharmacy licenses are available on the TSBP Web site.

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F. Describe how the program or function is administered. Include flowcharts, time lines, or other illustrations as necessary to describe agency policies and procedures. List any field or regional services.

The Licensing Program is administered by four Licensing Specialists, 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:

- (1) One FTE – has general responsibility for the initial licensure of pharmacists;
- (2) One FTE – has general responsibility for pharmacist renewals and continuing education audit functions;
- (3) One FTE – has general responsibility for the initial licensure of pharmacies (new pharmacies and changes of ownership) and pharmacy closings; and
- (4) 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 and pharmacist change of employment/address).

There are no field or regional services.

POLICIES AND PROCEDURES

INITIAL LICENSURE OF PHARMACISTS

- (1) Distribution of Application Forms
 - (A) Applicants for Licensure by Examination – Application forms are available online at TSBP Web site. The applicant must also file an application with the National Association of Boards of Pharmacy (NABP) to take the NAPLEX and MPJE. The Texas colleges of pharmacy distribute applicable forms to their students. If requested, (e.g., out-of-state graduates), TSBP will mail an application packet containing the following information: Application for Licensure by Examination, instruction sheet, Candidate's Guide to the MPJE, and registration bulletin for NAPLEX and MPJE exams.

The applicant must return the completed application to TSBP with a \$50 fee, recent photograph, copy of birth certificate, and affidavit of graduation. For individuals graduating from Texas colleges of pharmacy, the colleges mail the graduation affidavits directly to TSBP. Applicant also submits the following information to NABP – registration forms to take the NAPLEX and MPJE, along with applicable fees found in the Registration Bulletin.

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- (B) Applicants for Licensure by Score Transfer – The NAPLEX Score Transfer Program, administered by the NABP, is a 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. Upon receipt of the candidate’s passing score, TSBP mails an Application for Licensure by Examination via Score Transfer to applicant.

The applicant must return the completed application to TSBP with a \$50 fee, photograph, graduation affidavit, birth certificate, and proof of 1,500 hours of internship (unless the applicant is already licensed and current in another state).

- (C) Applicants for Licensure by License Transfer (Reciprocity) – Upon request, TSBP will mail an application packet containing the following information: 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 sends 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 following items to TSBP: completed Texas Reciprocity Application, official NABP application, \$250 fee, recent photograph, and birth certificate.

- (2) Receipt of Application Forms/Fees and Review of Application – When TSBP receives the fee payments, 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 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 – The designated Licensing Specialist orders 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 – 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 background check is not clear; and/or
 - (C) if the applicant checks “no” to an attest question and the DPS 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.

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- (5) Examination – The designated Licensing Specialist will notify the applicant of the scores made on the NAPLEX and MPJE examinations, unless the applicant has an “Administrative Hold” in which case the Licensing Specialist notifies the Director of Enforcement (DOE) of the score. The DOE, in turn, notifies the Legal Division and one of the Divisions will notify the applicant of the score and potentially, the agency’s intent to institute disciplinary action to deny the issuance of the license. Generally, TSBP will not allow an applicant to take the licensure examination if the agency is instituting disciplinary action to deny the issuance of the license. TSBP notifies each person taking an examination of the results of the examination not later than the 30th day after the date TSBP receives the results from NABP.
- (6) Examination Retakes – If an applicant must retake the NAPLEX and/or MPJE, the applicant is required to:
- (A) submit a new completed Texas application and the retake fee of \$50; and
 - (B) complete the applicable registration form(s) to take the NAPLEX or MPJE or both and send the appropriate retake fees to NABP.

If the applicant is a reciprocity candidate and the NABP application is over one year old, the applicant must also submit a new application to NABP.

- (7) Examination Retake Procedures After Three Failures – 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. In this event, the following steps are required for an applicant to retake an exam.
- (A) The applicant must submit a written request for an analysis of his/her performance on the exam(s).
 - (B) The analysis is returned to the applicant after completion by the testing service. After receiving the analysis, the applicant sends a copy of this document to the Examination Retake Committee (ERC) with a letter requesting that the committee review it and recommend course work.
 - (C) The ERC reviews the analysis and recommends college course work that must successfully be completed in order to retake the examination. The ERC notifies the applicant of the resulting recommendation.
 - (D) After following the recommendations of the ERC and successfully completing the courses set forth in the recommendation, the applicant must submit this documentation to the ERC. If satisfied that the applicant has complied with its recommendations, the ERC may then submit documentation to TSBP reflecting that the applicant has successfully completed appropriate additional course work.
 - (E) When TSBP receives such documentation from the ERC, the applicant will receive a schedule of future examination dates, along with application deadlines. The applicant will then be able to apply for a retake of the examination.

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- (8) 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 score and license number. Included with this notification is a pharmacist license renewal application that the new licensee must complete and submit to TSBP within 30 days of the date of the letter. If the license renewal application 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) Relicensure of Pharmacists – Texas pharmacists whose licenses have lapsed for more than one year must follow the re-licensure process outlined in TSBP Rule 283.10. The same procedures are used (distributing appropriate application forms, receiving payment/application form, depositing payment, reviewing forms to see if application is complete, and conducting DPS background check). However, these applicants must also 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 (mails a renewal card to the licensee).
- (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 \$50 exam 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) Distributing Application Forms – Application forms are available online at TSBP Web site. Upon request, TSBP will mail the appropriate pharmacy license application form and instruction sheet. The application form is unique to the class of pharmacy and requires extensive ownership information, including such supporting documentation as lease or property information, and if applicable, a copy of sales contract, birth certificate or passport, current driver's license or state issued photo identification card, approved credit application from a primary wholesaler or other proof of credit worthiness (i.e.,

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contingent approval letter). If the pharmacy owner is a publicly held corporation, the application must include a copy of the corporation's 10K Filing with the Security and Exchange Commission.

- (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 background checks on all pharmacist owners, using the same procedures described above with respect to initial licensure of pharmacists.
- (4) Coordination with Enforcement/Legal Divisions – same procedures as those described above with respect to initial licensure of pharmacists.
- (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.
- (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) Distribution of Forms – Application forms are also available online at the TSBP Web site. The four Texas colleges of pharmacy distribute applications for pharmacist-intern registrations to their respective students. If requested (e.g., Extended Pharmacist-Interns), TSBP will mail an appropriate form to the applicant.
- (2) Receipt/Review of Application Form – TSBP does not charge a fee to process an application for a pharmacist-intern registration. Upon receipt of the application, the designated Licensing Specialist determines if the application is complete. A "missing item" letter is generated, if necessary. The computer assigns an identification number (serves as the intern's registration number).

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- (3) Criminal History Background Check – same procedures as described previously with respect to initial licensure of pharmacists.
- (4) Coordination with Enforcement/Legal Divisions – same procedures as described previously with respect to initial licensure of pharmacists.
- (5) 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 card bearing an expiration date, as described below:
 - (A) Each Student Pharmacist-Intern card has an expiration date that is set three 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 three month intern window has passed.
 - (B) Each Extended Pharmacist-Interns 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. Eligibility requirements for preceptors are set forth above. Application forms are available online on the TSBP Web site. 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.

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- (C) Enforcement History – to be eligible to become a preceptor, a pharmacist may not have been the subject of disciplinary action within the past three years. 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) 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. A form to renew the preceptor certification is enclosed with the pharmacist’s license renewal application and both forms are mailed to the pharmacist approximately 60 days before the expiration date of the pharmacist’s license.

RENEWAL OF PHARMACIST AND PHARMACY LICENSES

- (1) Distribution of Renewal Application Forms – TSBP automatically mails renewal 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 either the Treasury Lock Box or submitting the form/fee to TSBP.
- (3) Review of Application Forms – After the payment and application are received/reviewed, the data base is updated with the renewal information. The designated Licensing Specialist reviews the application to determine if the application is complete.
- (4) Non-Renewal of Applications – TSBP may experience a number of exceptions in the processing of license renewals, such as:
- (A) Exceptions in the processing of pharmacist renewal applications:
- incorrect payment;
 - name change without appropriate documentation;
 - late renewals; and
 - incomplete response with regard to CE requirements.

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- (B) Exceptions in the processing of pharmacy renewal applications:
- incomplete applications;
 - incorrect payment;
 - location change without appropriate documentation;
 - late renewals;
 - change of ownership of the pharmacy license; and
 - change of provider information or type of services for any remote pharmacy services.

These exceptions cause TSBP to contact the licensee by telephone or letter. In the case of incomplete applications, a “missing item” letter is mailed to the licensee requesting the necessary documentation. If the licensee does not return the completed application, the license will expire. When the licensee has not renewed the license within 45 days after the expiration date, a “delinquent” letter is mailed to the licensee, advising the licensee that practicing pharmacy or operating a pharmacy with an expired license is a violation and grounds for disciplinary action being taken against the license.

- (5) Complete Applications – If the application is complete, a license renewal certificate is mailed to the pharmacist. The average turnaround time for processing a pharmacist renewal is one to two days.
- (6) Communication with Enforcement/Legal Divisions – A copy of the renewal application with attachment(s) is forwarded to the Director of Enforcement (DOE) if the applicant checks “yes” to one or more of the attest questions.

Online Renewal (Pharmacist Licenses Only) – In late October 2002, TSBP implemented the pharmacist online renewal system through the Texas OnLine system. As of July 2003, approximately 20% of all pharmacists have renewed their licenses using the Texas OnLine method. To renew the license online, certain conditions must be met, such as:

- (1) TSBP records must indicate that the current license expires within 60 days;
- (2) the pharmacist license number provided must be correct;
- (3) the social security number must exist in TSBP records and be correct;
- (4) the address may not be a foreign country;
- (5) the license cannot qualify for “exempt” status;
- (6) TSBP records cannot indicate more than 10 places of employment; and

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- (7) the licensee cannot be requesting to change his/her name or requesting to go from Inactive to Active status, because additional documentation is required in both of those situations.

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

CONTINUING EDUCATION (CE) AUDITS

- (1) Random Sample and Preparation of CE Audit Letter – The designated Licensing Specialist submits a request to the TSBP computer to initiate the CE audit process. A random sample of pharmacists will be selected by the computer and form letters will be generated. The form letters have preprinted information regarding the audit period and the number of hours to be audited. The sample is drawn from pharmacists who have renewed their licenses during the month prior to the month that the audit is conducted.
- (2) Mailing of CE Audit Letter – The Licensing Specialist pulls the licensing file of each pharmacist selected and double checks the form letter for accuracy. If form letters are accurate, the Licensing Specialist mails the CE audit letter to the random sample of pharmacists.
- (3) Determination of Compliance – The Licensing Specialist has a suspense file to monitor the return of the CE certificates. If the CE certificates are returned, the Licensing Specialist determines if the pharmacist has obtained the required number of CE certificates for the CE audit period. If the pharmacist has complied with the CE requirements, the Licensing Specialist closes the audit and notifies the licensee.
- (4) Non-Compliance – If the pharmacist is not in compliance or fails to respond to the CE audit letter, the Licensing Specialist forwards the information to the Director of Enforcement (DOE) for review; if the DOE confirms that the pharmacist is not in compliance, the DOE will open a complaint and the case will be referred to the Legal Division for the possible institution of disciplinary action against the licensee.

PHARMACIST AND PHARMACY CHANGES

- (1) Pharmacist Changes
 - (A) Pharmacist Change of Name – If a pharmacist changes his/her name, the pharmacist must submit supporting documentation (e.g., marriage certificate, divorce decree) and pay a fee of \$20. Refer to TSBP Rule 295.1(b). Once this information is obtained, the designated Licensing Specialist updates the agency's computerized data base.
 - (B) Pharmacist Change of Address/Employment – If a pharmacist 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. In FY2002, TSBP processed 2,200 changes of address and 4,500 changes of employment.

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(2) Pharmacy Changes

- (A) 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 base is updated. Refer to TSBP Rule 291.2. All application forms and instructions can be found on the TSBP Web site. In FY2002, TSBP processed 160 applications with respect to change of name/location.

- (B) 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 FY2002, TSBP processed 350 pharmacy closings.

(3) Communication with Enforcement/Legal Divisions

Licensing Specialists notify the Enforcement and Legal Divisions regarding any change made to a licensing record, if the licensee or applicant is the subject of an active complaint or pending disciplinary action.

G. If the program or function works with local units of government, (e.g., Councils of Governments, Soil and Water Conservation Districts), please include a brief, general description of these entities and their relationship to the agency.

Not Applicable

H. Identify all funding sources and amounts for the 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. TSBP is self-supporting by generating sufficient revenues from licensure fees to support the agency's operations. See Section IV of this report for details regarding funding. TSBP is funded by the General Revenue Dedicated - Pharmacy Board Operating Account 523. The types of appropriation, appropriation authority and amounts for each are listed below:

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Licensing Program (Licensing Strategy) General Revenue Dedicated-Pharmacy Board Operating Account No. 523	FY2002 Budget
Regular Appropriation	334,227.00
Rider Appropriation Article IX-96, Section 10.52(c) Contingency Appropriation SB 65 (2002-03 GAA) Article IX-93, Section 10.40 Contingency Appropriations SB 187 (2002-03 GAA)	22,159.00 67,610.00
Transfer Article IX, Section 10.12(a) Salary Increase (2002-03 GAA) Article IX, Section 10.12(l) Longevity Increase (2002-03 GAA) Article IX, Section 6.08 Appropriation Transfers (2002-03 GAA)	5,973.00 940.00 12,000.00
Other Funds Regular Appropriations - Appropriated Receipts	8,533.00
Total Funding Sources - Licensing Program	451,442.00

I. Are current and future funding resources appropriate to achieve program mission, goals, objectives, and performance targets? Explain.

With the recent budget reductions (7% in FY2003 and 12.5% in FY2004-2005), the agency is struggling to maintain its level of service. Significant reductions occurred in the areas of travel, salaries, information resource technologies, vehicles, agency newsletter, registration and training, and merit pay. The budget reductions (\$789,696 for FY2004-05) occurred at the same time that new funding (\$726,269 for FY2004-2005) was approved to implement an existing agency statutory mandate. The mandate to register a new population of applicants, the pharmacy technician, requires the agency to double its population of licensees in FY2004 and will cause a dramatic increase in the public's demand for agency services in every area of its operation. The impact of this new population on the level of services provided by the agency, will significantly impact the agency's ability to provide quality customer service, information and protection to the citizens of Texas.

These areas must be addressed in the next legislative session and additional resources will certainly be requested.

J. Identify any programs internal or external to the agency that provide identical or similar services or functions. Describe the similarities and differences.

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

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

Not Applicable

L. Please provide any additional information needed to gain a preliminary understanding of the program or function.

- (1) Because of the complexity of the program, coordination between the Enforcement and Licensing Divisions is essential. See Regulatory Program.
- (2) The Texas Legislature appropriated funds to implement the technician registration program in FY2004 and FY2005. As a result of this additional funding, TSBP will be hiring a Licensing Program Manager and an Administrative Technician to assist with the registration of an estimated 26,500 individuals.

M. Regulatory programs relate to the licensing, registration, certification, or permitting of a person, business, or other entity. If this is a regulatory program, please describe:

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

See Regulatory Program

N. Please fill in the following chart for each regulatory program. The chart headings may be changed if needed to better reflect the agency's practices.

Not Applicable

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VI. Guide to Agency Programs – Indirect Administration

A. Indirect Administration

Texas State Board of Pharmacy Exhibit 14: Program or Function Information — Fiscal Year 2002	
Name of Program or Function	Indirect Administration
Location/Division	Headquarters - Administrative Services & Licensing
Contact Name	Cathy Stella
Number of Budgeted FTE's, FY 2002	9.840
Number of Actual FTE's as of August 31, 2002	9.437

B. What are the key services of this function? Describe the major activities involved in providing all services.

Key services include personnel, accounting, budgeting, purchasing, property management, and information technologies.

Key Objectives and Services of this program in FY2002/2003 include the following:

- (1) to assist the Executive Director in updating and preparing the TSBP *Strategic Plan* for the 2003-2007 period, and submitting the plan to the Governor's Office of Budget and Planning and the Legislative Budget Board;
- (2) to prepare, submit and monitor the agency's *Legislative Appropriation Request*, corresponding performance measures, and revenue estimates for FY2004-05; prepare and monitors resulting annual internal operating budgets;
- (3) to review all legislation that has an impact on the practice of pharmacy and agency operations, and monitor the progress of this legislation;
- (4) to assist the Executive Director, in cooperation with other Divisions, in the agency Sunset Review Process, including preparation of the agency Self-Evaluation Report;
- (5) to comply with all Comptroller Accounting Policies, Notices to State Agencies, and Attorney General Opinions relating to fiscal matters by specified due dates;
- (6) to prepare and submit all required accounting and fiscal reports and reconciliations to the appropriate oversight agencies;
- (7) to assess the material needs of the agency and supervise the purchasing and supply activities in accordance with all General Services Commission rules and procedures;

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- (8) 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;
- (9) to serve as the agency's Human Resources, Staff Development, Payroll, Employee Benefits, Risk & Safety Office in ensuring agency compliance with all applicable state and federal personnel statutes;
- (10) to manage the information resource needs (data processing, telecommunication and web site) of the agency;
- (11) 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.
- (12) to assist the Executive Director, in conducting a survey of agency customers regarding the quality of service delivered by the agency as specified in Chapter 2113 of the Government Code;
- (13) to provide verbal and written information to Board staff and customers in the preparation of:
 - (A) 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;
 - (B) responses to surveys and questionnaires; and
 - (C) a report of the types and numbers of surveys/questionnaires/reports completed by all Divisions; and
- (14) to assist the Executive Director in developing and implementing the objectives of the Health Professions Council pertinent to Division activities.

C. When and for what purpose was the function created? Describe any statutory or other requirements for this program or function.

To handle such key services as human resources, accounting, budgeting, risk management, purchasing, property management, and information technologies.

D. Describe any important history not included in the general agency history section, including a discussion of how the services or function has changed from the original intent. Will there be a time when the mission will be accomplished and the program or function will no longer be needed?

The administrative functions are an essential part of the Texas State Board of Pharmacy. As such, it will always be needed.

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E. Describe who or what this 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. Functions are: daily operations of the agency, human resources, purchasing, budgeting, accounting, cash receipts, payroll, record management, property management, risk management, and information technologies.

F. Describe how the function is administered. Include flowcharts, time lines, or other illustrations as necessary to describe agency policies and procedures. List any field or regional services.

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

- (1) Chief Accountant
- (2) Accountant IV
- (3) Accountant II
- (4) Purchaser II
- (5) Staff Services Officer
- (6) Information Resources Manager
- (7) Web Technician

The Executive Director's Office supervises two FTE's as follows:

- (1) Executive Assistant
- (2) Receptionist

The general duties and functions of these staff are described as follows:

Accounting, Budget and Fiscal Activities – The three (3) Accounting staff perform these general activities:

- (1) prepares financial analyses and reports; revenue estimates and cash flow; and financial transactions involving agency budgets, vouchers, and payrolls submitted by the agency;
- (2) supervises security and integrity of the Uniform Statewide Accounting System and other electronic accounting, fiscal, purchasing and cash systems;

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- (3) records, classifies, examines, and analyzes financial records, cash documents, or reports;
- (4) maintains inventory of office equipment and accounting records;
- (5) responsible for maintaining an effective accounting control system by reconciliation and auditing of various accounts; and
- (6) maintains timekeeping records.

PURCHASING ACTIVITIES – The Purchaser II performs these general activities:

Purchases commodities, services, equipment, etc., that require knowledge of the state of Texas purchasing policies and procedures, particularly legislative mandates addressing the use of Historically Underutilized Businesses.

HUMAN RESOURCES & SAFETY – The Staff Services Officer performs these general activities:

- (1) conducts several functions such as new hire processing, terminations, benefits, training, reconciliations, safety, risk management, worker's compensation and record keeping;
- (2) provides advice and information to agency personnel; and
- (3) maintains liaison with federal, state and local agencies with regard to human resources and payroll requirements.

INFORMATION RESOURCE TECHNOLOGIES – The Information Resources Manager and Web Technician perform these general activities:

- (1) coordinates the development, implementation and maintenance of a local area network (LAN) and agency web site;
- (2) responsible for network installation, testing, maintenance, enhancement, and documentation;
- (3) coordinates the agency's training activities relating to technology;
- (4) performs research towards the definition of software and hardware requirements for agency;
- (5) coordinates any required software or hardware evaluations/recommendations;
- (6) provides technical assistance in the implementation and use of USPS/USAS and VAX;
- (7) prepares all reports required by the Department of Information Resources, including the Biennial Operating Plan and Strategic Plan for Information Resources;
- (8) maintains systems security by developing policies and procedures designed to ensure the integrity of the agency LAN/WAN environment and determine standards on network security.

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EXECUTIVE OFFICE OPERATIONS

- (1) The Executive Assistant performs these general activities:
 - (A) administrative support for the Executive Director/Secretary and Board Members;
 - (B) serves as agency's customer service representative in conjunction with the agency's Compact with Texans and supervises customer reception (receptionist);
 - (C) coordinates, plans, and implements the agency's participation in the Survey of Organizational Excellence; directs evaluation of survey results; and coordinates planning of changes to agency policy and/or procedures in response to survey results;
 - (D) plans and coordinates on-site staff training programs; and
 - (E) coordinates employee wellness program; and
 - (F) serves as the agency's facilitator to the Texas State Employee Incentive Commission.

- (2) The Receptionist performs these general activities:
 - (A) operates multi-line telephone system; routing calls and/or taking messages;
 - (B) receives/greets visitors, monitors sign-in/sign-out register, and routes visitors to appropriate party;
 - (C) processes and distributes daily incoming mail, including special delivery items and cash;
 - (D) coordinates maintenance of the telephone system and processes orders for changes or moves of telephone equipment;
 - (E) coordinates office maintenance and serves as liaison between the agency and building management personnel; and
 - (F) administrative support work to include data entry.

Specific policies and procedures are dictated through a number of sources, primarily the Office of the State Auditor, State Comptroller of Public Accounts, Texas Building & Procurement Commission, Legislative Budget Board, Governor's Budget Office, the General Appropriations Act, Texas Government Code, and other state and federal oversight agencies.

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G. If the function works with local units of government, (e.g., Councils of Governments, Soil and Water Conservation Districts), please include a brief, general description of these entities and their relationship to the agency.

Not Applicable

H. Identify all funding sources and amounts for the 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. TSBP is self-supporting by generating sufficient revenues from licensure fees to support the agency's operations. See Section IV of this report for details regarding funding. TSBP is funded by the General Revenue Dedicated - Pharmacy Board Operating Account 523. The types of appropriation, appropriation authority and amounts for each are listed below:

Indirect Administration Program (Indirect Administration Strategy) General Revenue Dedicated Pharmacy Board Operating Account No. 523	FY2002 Budget
Regular Appropriation	489,441.00
Rider Appropriation Article IX-112, Section 10.102 Contingency HB 609 (2002-03 GAA)	9,375.00
Transfer Article IX, Section 10.12(a) Salary Increase (2002-03 GAA) Article IX, Section 10.12(l) Longevity Increase (2002-03 GAA) Article IX, Section 10.23 Contingency Appropriation HB 2976 Article IX, Section 6.08 Appropriation Transfers (2002-03 GAA) Article IX, Section 6.17 UB - Capital Budget Transfer to Fiscal Year 2003 (2002-03 GAA)	17,125.00 5,000.00 47,772.47 -4,800.00
Total Funding Sources - Indirect Administration Program	564,633.47

I. Are current and future funding resources appropriate to achieve program mission, goals, objectives, and performance targets? Explain.

With the recent budget reductions (7% in FY2003 and 12.5% in FY2004-2005), the agency is struggling to maintain its level of service. Significant reductions occurred in the areas of travel, salaries, information resource technologies, vehicles, agency newsletter, registration and training, and merit pay. The budget reductions (\$789,696 for FY2004-05) occurred at the same time that new funding (\$726,269 for FY2004-2005) was approved to implement an existing agency statutory mandate. The mandate to register a new population of applicants, pharmacy technicians, requires the agency to double its population of licensees in FY2004 and will cause

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a dramatic increase in the public's demand for agency services in every area of its operation. The impact of this new population on the level of services provided by the agency will significantly impact the agency's ability to provide quality customer service, information and protection to the citizens of Texas.

These areas must be addressed in the next legislative session and additional resources will certainly be requested.

J. Identify any programs internal or external to the agency that provide identical or similar services or functions. 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.

K. Discuss how the program or function is coordinating its activities to avoid duplication or conflict with the other programs listed in Question J 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:

- (1) Purchasing: Maximize cooperative purchasing arrangement between member boards.
- (2) Payroll: Maximize ongoing cooperative arrangements between member agencies in payroll processing and reporting; provide training to new employees and back up staff as needed.
- (3) Risk Management: Agencies continue to use the Council's joint Risk Management Manual and Disaster Recovery Plan.
- (4) Benefits Seminars: The HPC sponsors periodic information sessions for HPC member agency employees and other small agencies located in the Hobby Building.
- (5) Toll Free Complaint Line: Initiated in November 1995, the Council's toll-free complaint hotline continues to work to provide 24-hour referral services for persons seeking information about a health profession regulated by the state.
- (6) Employee Assistance Program: HPC agencies negotiated a group arrangement for an employee assistance program for member agency employees. Member agencies contract individually with the provider, but receive a standard contract at a lower rate.

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- (7) Space: Work with member agencies to maximize the shared space in the Hobby Building (storage rooms, conference rooms, mail room, imaging room, etc).
- (8) Document Management Center, shared courier service, board member training manual and a consolidated library of training videos.

L. Please provide any additional information needed to gain a preliminary understanding of the program or function.

Not Applicable

M. Regulatory programs relate to the licensing, registration, certification, or permitting of a person, business, or other entity. If this is a regulatory program, please describe:

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

Not Applicable

VI. Guide to Agency Programs – Regulatory Program

A. Regulatory Program

Texas State Board of Pharmacy Exhibit 14: Program or Function Information — Fiscal Year 2002	
Name of Program or Function	Regulatory Program
Location/Division	Headquarters - Enforcement Division; Legal Division; and Professional Services Division – office at Hobby Building, 333 Guadalupe, Suite 3-600, Austin, TX. Enforcement Division has 10 field personnel who office out of their homes (see response to Question F below for details regarding locations of field personnel).
Contact Name	Carol Fisher, R.Ph., Director of Enforcement Kerstin Arnold, J.D., General Counsel
Number of Budgeted FTE's, FY 2002	32.3*
Number of Actual FTE's as of August 31, 2002	32.09*

* Based on actual number of hours worked for all staff in Regulatory Program.

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B. What are the key services of this function or program? Describe the major activities involved in providing all services.

The key function of the Regulatory Program is to promote, preserve and protect the public health, safety, and welfare 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 of the Regulatory Program are listed below:

- (1) resolving complaints through various means, including disciplinary actions;
- (2) conducting inspections of pharmacies, non-licensed facilities and internship programs;
- (3) monitoring compliance of licensees who have been the subject of a disciplinary order;
- (4) proposing and adopting rules relating to the practice of pharmacy;
- (5) providing information, including responses to requests for records relating to complaints and disciplinary orders; publication of *TSBP Newsletter*; and speaking engagements;
- (6) developing pharmacy jurisprudence examination; and
- (7) providing legal services.

The key services are provided through the following three organizational divisions: Enforcement Division, Legal Division and Professional Services Division. Refer to response to Question F for further information regarding these divisions. The major activities of each key service are described below:

COMPLAINTS

The Enforcement and Legal Divisions are responsible for resolving complaints, in accordance with the policies established by the Board Members.

- (1) With respect to this particular key service, the staff of the Enforcement Division accomplish the following major activities:
 - (A) investigate complaints, including background investigations of applicants for licensure;
 - (B) review professional liability claims (malpractice reports) and open complaints on such reports, when applicable;
 - (C) notify complainants of the receipt, status, and disposition of their complaints;
 - (D) review cases with Executive Director and/or General Counsel to determine if sufficient evidence exists to warrant the institution of disciplinary action;
 - (E) maintain evidence locker to ensure the security and chain of custody of evidence;

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- (F) refer complaints to the Legal Division and assist with the prosecution of complaints;
 - (G) liaison with federal, local, or other state investigators to enforce drug laws, to include exchanging investigative information and conducting joint investigations;
 - (H) coordinate and monitor the resolution of all complaints received by the agency; prepare/certify performance measures relating to complaints; and prepare reports to the Board regarding the number and age of active/pending complaints;
 - (I) maintain complaint files and destroy evidence/files in accordance with agency's approved record retention schedule; and
 - (J) provide information to the public about the complaint process, including brochures and a sign for pharmacies to post that tells consumers how to file complaints with TSBP.
- (2) With respect to this particular key service, the staff of the Legal Division accomplish the following major activities:
- (A) coordinate/monitor receipt, assignment, and resolution of all cases referred to the Legal Division;
 - (B) review all cases referred to the Legal Division for potential disciplinary action;
 - (C) assist the Enforcement Division in reviewing and resolving complaints, including the review of applications of individuals who have a criminal history record;
 - (D) assist the Enforcement Division in its investigation of complaints by drafting subpoenas and providing training/assistance regarding evidentiary standards;
 - (E) institute disciplinary proceedings against licensees/applicants who have violated laws/rules;
 - (F) plan and conduct informal settlement conferences;
 - (G) settle disciplinary proceedings through informal proceedings;
 - (H) draft proposed Agreed Board Orders (consent disciplinary orders) for consideration and review by the Board;
 - (I) file complaints with the State Office of Administrative Hearings (SOAH) if a complaint cannot be settled through informal proceedings;
 - (J) prosecute cases against licensees/applicants through formal hearings before an Administrative Law Judge (ALJ) at SOAH;
 - (K) review proposals for decision (PFD) drafted by ALJs and draft proposed Board Orders based upon ALJ's PFD to present to the Board for considerations and review by the Board;

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- (J) interact with complainants regarding the status of the disciplinary proceedings and the prosecution of the subject of their complaints; and
- (K) provide technical assistance to local, state, and federal prosecutors, legal divisions, and enforcement agencies involved in the investigation or prosecution of Board licensees.

INSPECTIONS

- (1) With respect to this particular key service, the staff of the Enforcement Division accomplish the following major activities:
 - (A) conduct pre-licensure inspections;
 - (B) conduct routine inspections of pharmacies licensed by TSBP;
 - (C) conduct non-routine inspections of pharmacies licensed by TSBP and on occasion, non-licensed facilities (e.g., inspections that are necessitated as a result of a complaint);
 - (D) conduct joint inspections with other agencies;
 - (E) issue written warning notices regarding non-satisfactory conditions that exist in a pharmacy and give a due date for the pharmacy to correct the conditions and file a report detailing the corrections that have been made;
 - (F) monitor the responses to warning notices to ensure that the required report is submitted, and conduct follow-up inspections to ensure that the pharmacy has corrected the conditions; and
 - (J) initiate complaints for referral to the Legal Division when licensees have not corrected conditions (i.e., falsified response to warning notice) or when Compliance Officers/Inspectors discover serious or excessive non-satisfactory conditions in a pharmacy.
- (2) The Director of Professional Services conducts on-site campus visits at Texas colleges of pharmacy to inspect records and determine if the internship programs are adequate to prepare a student for pharmacy practice and if the Colleges are maintaining complete and accurate records with regard to internship hours.

MONITORING COMPLIANCE

The staff of the Enforcement Division notify licensees/applicants 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 activities:

- (1) In-House Monitoring
 - (A) conduct random drug screens;

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- (B) determine if licensees do not submit to required drug screens on the required days;
 - (C) determine if results of drug screens are positive for licit or illicit drugs;
 - (D) if licensee has a positive drug screen for an illicit drug: notify licensee to surrender pharmacist license; update TSBP computerized records/Web site to show the status of license as "surrendered"; and if applicable, notify pharmacy-employer(s) of status of license;
 - (E) if licensee has a positive drug screen for a licit drug, determine if licensee has a valid prescription for this drug; if licensee does not have valid prescription: notify licensee to surrender pharmacist license; update TSBP computerized records/Web site to show the status of license as "surrendered"; and if applicable, notify employer(s) of status of license;
 - (F) determine if required reports are submitted to TSBP by due date;
 - (G) review required reports and determine if reports are in compliance with terms of disciplinary orders;
 - (H) determine if examinations, additional continuing education requirements, or other requirements have been completed by due date (audits of CE records are conducted by TSBP Licensing Division at request of Director of Enforcement);
 - (I) determine if administrative penalties (fines) and probation fees are paid by due date (receipt of payment is accepted and processed by TSBP Accounting Division);
 - (J) if the individual's pharmacist license has been revoked, suspended, cancelled or retired, determine if individuals have returned licensure documents (e.g., wall certificate) to TSBP;
 - (K) return wall certificate and licensure documents to individual if license is reinstated or if licensee has successfully completed suspension period; and
 - (L) initiate complaints on licensees who are not in compliance with the terms of their disciplinary orders and refer complaints to the agency's Legal Division for possible disciplinary action on the non-compliance, as applicable.
- (2) Field Monitoring of Licensees
- (A) conduct inspections of pharmacies that had their licenses revoked or suspended to ensure that the pharmacies are not operating with a suspended or revoked license;
 - (B) conduct inspections of pharmacies that employed a pharmacist whose license to practice was revoked, suspended, or retired, to ensure that these individuals are not practicing pharmacy;

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- (C) conduct inspections of pharmacies where disciplined pharmacists are working to ensure that the pharmacists are in compliance with the terms of their orders; and
 - (D) conduct inspections of pharmacies who have been the subject of disciplinary orders to ensure that the pharmacies are in compliance with the terms of their orders.
- (3) Monitoring Contracts (persons who have a contract with TSBP to provide monitoring services)
- (A) Monitors contract with Pharmacy Recovery Network (PRN), a voluntary peer assistance program administered by the Texas Pharmacy Association (TPA); such a peer assistance program is authorized by the Texas Pharmacy Act (see Chapter 564); this monitoring function includes:
 - ensuring that PRN Director submits required reports to TSBP on a monthly and quarterly basis;
 - working with PRN Director to submit reports to the Board regarding peer assistance performance measures; and
 - exchanging information with PRN regarding licensees who have relapsed while under a voluntary PRN contract or a TSBP disciplinary order.
 - (B) Monitors contract with National Confederation with Professional Services (NCPS), the organization who administers a drug screening program for TSBP; this monitoring function includes monitoring contract provisions and serving as liaison to NCPS.

RULEMAKING SERVICES

The staff of the Professional Services Division and Legal Division are the individuals who primarily share the responsibility for the major activities relating to the preparation and revision of rules for adoption by the Board.

- (1) With respect to this particular key service, the staff of the Professional Services Division accomplish the following major activities:
 - (A) coordinate rule reviews;
 - (B) develop rules relating to professional issues and present rules to the Board for consideration;
 - (C) assist other Divisions with development of rules pertaining to Board operations;
 - (D) coordinate and monitor all submissions to the *Texas Register*; act as agency liaison to the *Texas Register*; and

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- (E) provide 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.
- (2) With respect to this particular key service, the staff of the Legal Division accomplish the following major activities:
- (A) develop rules relating to disciplinary proceedings;
 - (B) assist other Divisions and members of TSBP task forces with development of rules; and
 - (C) review rule submissions to the Texas Register and certify that the agency has authority to propose the rules.

INFORMATION SERVICES

The responsibility for providing information is shared by the Enforcement Division, Legal Division and Professional Services Division; the following major activities are accomplished:

- (1) Verbal and Written Inquiries
- (A) respond to verbal and written requests for information regarding complaints and disciplinary actions, in accordance with the procedures set forth in the Texas Public Information Act, Tex. Gov't Code §552.001 et seq. (Vernon Supp. 2003);
 - (B) respond to verbal and written inquiries from agency customers regarding the laws/rules governing the practice of pharmacy, including interpretation of laws/rules; and
 - (C) provide technical assistance to other agency staff and other agencies regarding the Texas Pharmacy Act and other laws/rules governing the practice of pharmacy.
- (2) Publications
- (A) publish TSBP Newsletter containing such information as text of new laws and rules; interpretation of laws/rules; details regarding public disciplinary orders entered by the Board (including the name of licensee, license number, and description of violation and sanction);
 - (B) coordinate updating of law reference manual which contains all laws and rules governing the practice of pharmacy in Texas; and
 - (C) publish a consumer brochure containing information about TSBP and other helpful information to consumers of pharmacy services.

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- (3) Presentations/Speaking Engagements
 - (A) make presentations to agency customers regarding agency operations, as well as information regarding laws and rules governing the practice of pharmacy; and
 - (B) prior to January 2003, agency staff attended professional meetings and displayed an exhibit regarding updates on new laws and/or rules governing pharmacy practice; this function was eliminated as a result of budgetary cutbacks mandated by the 78th Texas Legislature.
- (4) TSBP Web site – Enforcement Program staff participate in an in-house committee that makes recommendations with regard to the format and content of the agency's Web site.

PHARMACY LAW EXAM DEVELOPMENT

The Director of the 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 of the Professional Services Division and the staff of the Enforcement Division (Compliance Officers) review MPJE item pools on an agreed time table with NABP to determine appropriate questions for Texas and provides new questions for MPJE as appropriate or requested by NABP.

LEGAL SERVICES

Legal Division – in addition to its activities relating to complaints, rules, and information (see above), the Legal Division accomplishes the following activities:

- (1) research legal issues, and when necessary, draft requests for Attorney General Opinions and Open Records Decisions;
- (2) provide technical assistance and advise the Board and Board staff on a range of issues, including open meetings, open records, ethics, and agency procedures;
- (3) review agency contract and service agreements with outside vendors;
- (4) provide legal advice and consultation regarding employment matters in the agency; and
- (5) review new opinions of the Office of Attorney General and the Texas Ethics Commission.

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C. When and for what purpose was the program or function created? Describe any statutory or other requirements for this program or function.

The purpose of the Regulatory Program is an integral part of the agency’s mission. Refer to the agency’s response to the first question in the first section of this report (Section 1).

- (1) **Disciplinary Actions** – As early as 1923, the Board was disciplining pharmacists. The minutes of the Board meeting held on September 18, 1923, indicate that the Board voted to notify two different pharmacists to appear before the Board to show cause why their certificates should not be revoked. The Board also decided, by unanimous vote, to “go on record as proposing to revoke the certificate to practice pharmacy in Texas of any person, clerk, or proprietor who is convicted or enters a plea of guilty to violating the Harrison Narcotic Act or the violation of the Volstead Prohibition Act or the Dean law.”
- (2) **Investigations** – In June 1925, the Board employed its first investigator.
- (3) **Inspections** – TSBP began its comprehensive compliance program in 1977. This program was created to promote voluntary compliance with the laws and rules governing the practice of pharmacy. This program included regular, unannounced inspections of pharmacies, publication of TSBP Newsletter, and “online” technical assistance. The program began with one Compliance Officer and by 1982, had expanded to a field staff of six Compliance Officers.
- (4) **Legal Services** – TSBP employed its first in-house General Counsel in 1986 to handle the increasing caseload of disciplinary actions. In 2000, the Legal Division, with a General Counsel and two staff attorneys, was created as a separate Division, to handle all legal services as described in the response to Question B (above).

Statutory requirements relating to the Regulatory Program are set forth in the Texas Pharmacy Act (“Act”), Texas Occupations Code Ann. §551.001 et seq. (Vernon 2003). 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 554.001	sets forth the general powers and duties of the Board and includes the following provisions: C “administer and enforce” the act and rules adopted under the Act and “enforce other laws relating to the practice of pharmacy”; C “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”; and C “may be represented by counsel, including the Attorney General, District Attorney, or County Attorney, if necessary in a legal action” taken under the act.
Section 554.002	lists the methods through which the Board shall regulate the practice of pharmacy, including enforcement and disciplinary sanctions.
Section 554.005	lists the methods through which the Board may and may not regulate prescription drugs and devices.

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Citation	Description
Section 554.010	states that the Board may commission a peace officer which carries with it the powers, privileges, and immunities of a peace officer, except that the employee may not carry a firearm or make an arrest.
Subchapter B C 554.051 C 554.052 C 554.053 C 554.054 C 554.055 Section 559.052 Section 559.101 Section 561.003 Section 562.014 Section 562.015 Section 562.108(b) Section 562.109(e) Section 562.110(e) Section 568.001(b) Section 569.002	Subchapter B addresses “rulemaking” and Section 554.051 provides the Board with its general rulemaking authority. The other sections pertain to rulemaking in certain areas of practice that the Board shall and shall not adopt.
Chapter 555	addresses complaint procedures.
Chapter 556	addresses inspection powers, procedures, and limitations/restrictions; also requires Board to adopt a code of professional responsibility for persons who conduct inspections of pharmacies.
Section 557.004	authorizes the Board to deny, restrict, suspend, or revoke a pharmacist-intern’s registration.
Chapter 564, Subchapter A and B	addresses the peer assistance program (program to aid impaired pharmacists and eligible pharmacy students).
Section 564.105	authorizes the Board to issue subpoena for peer review committee proceedings.
Chapter 565 C 565.001 C 565.002 C 565.003;.053-.054 C 565.051; 565.060 C 565.055 C 565.056 C 565.057 C 565.058 C 565.059 C Subchapter C	addresses disciplinary actions and procedures; authorizes the Board to deny licensure and to discipline licensees: C lists grounds for discipline for pharmacists/applicants; C lists grounds for discipline for pharmacies/applicants; C lists grounds for discipline for Class E Pharmacies; C lists types of disciplinary sanctions that the Board may impose; C provides that investigative files are confidential; C provides for informal proceedings to settle disciplinary cases; C requires the Board to monitor licensees who have been subject to disciplinary action; C authorizes the Board to issue subpoenas; C authorizes the Board to temporarily suspend a pharmacist’s license under certain conditions; and C addresses procedures relating to reinstatement of a license.
Chapter 566	addresses procedures relating to administrative penalties (fines), injunctive relief, civil penalties, and criminal offenses.
Section 567.003	authorizes criminal penalties relating to licensees or non-licensees who mislabel prescription drugs.
Section 568.003	authorizes the Board to deny, suspend, or revoke a pharmacy technician registration.
Chapter 569	addresses procedures related to professional liability claims (malpractice reports).

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D. Describe any important history not included in the general agency history section, including a discussion of how the services or functions have changed from the original intent. Will there be a time when the mission will be accomplished and the program or function will no longer be needed?

The following general government laws must be considered as “important history” to TSBP and its Regulatory 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 Regulatory 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 has resulted in dramatic efficiencies with respect to reducing costs and complaint resolution time.
- 1981 • TSBP underwent its first review by the Sunset Advisory Commission. An updated and modernized Texas Pharmacy Act was enacted, 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.

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- 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
- The Texas Legislature created the Health Professions Council 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 (increased workload).
 - 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
- TSBP underwent its second review by the Sunset Advisory Commission. The Texas Pharmacy Act was amended as a result of several recommendations made by the Sunset Advisory Commission, to include: granting TSBP the authority to temporarily suspend a pharmacist's license under certain conditions and imposing numerous requirements relating to complaint procedures, such as:
- maintaining complaint files;

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- establishing policies and procedures concerning the investigation of a complaint filed with the Board, to include: determining the seriousness of the complaint, ensuring that complaints are not closed without appropriate consideration, ensuring that a letter is sent to the person who filed the complaint explaining the action taken on the complaint; and ensuring that the person who filed the complaint has an opportunity to explain the allegations made in the complaint;
 - notifying complainants of the receipt of the complaint no later than 30 days after the date of the receipt of the complaint and every four months until the complaint is closed; providing reasonable assistance to the complainant; and giving the complainant the opportunity to attend an informal settlement conference;
 - distributing information to the general public describing the functions of the Board and the procedures by which complaints are filed with and resolved by the Board; and
 - notifying complainants of the Board's name, address, and telephone number through such methods as a complaint sign prominently displayed in a pharmacy.
- 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. This amendment has substantially increased the Regulatory Program's workload.
- 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 Internet pharmacy practice. These types of cases 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.
 - The Texas Legislature passed S.B. 768 which transferred the authority of the regulation of emergency kits in nursing homes from Texas Department of Human Services (TDHS) to TSBP. Although the rider to the bill provided funding for 1 FTE, the Appropriations Act did not increase the FTE cap for TSBP. TSBP met with TDHS staff on April 5, 2002, and sent a follow-up letter, requesting that

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TDHS enter into an interagency contract with TSBP, in which TSBP would agree to pay a reasonable fee to TDHS to inspect emergency kits in nursing homes. TSBP did not receive a written response from TDHS.

2002 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. This new program will result in approximately 26,500 additional individuals for TSBP to regulate.

The original purpose or intent of the Regulatory 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 Regulatory Program has remained to protect the public health. When the Pharmacy Act was amended (“modernize/updated”) 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 Regulatory Program. In the interest of public health, the TSBP Regulatory Program will always be needed.

<p>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.</p>
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The Regulatory Program affects the following persons or entities:

- (1) Pharmacists
- (2) Pharmacies
- (3) Applicants for Pharmacist License
- (4) Applicants for Pharmacy License
- (5) Pharmacist-Interns
- (6) Pharmacy Technicians
- (7) Texas Colleges 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 #6 above, see Agency Program relating to Licensing. With regard to the 7th entity listed above, there are four academic institutions in Texas that train/graduate pharmacy students. Specifically, there are three colleges of pharmacy (University of Texas, Texas Southern University, and University of Houston) and one school of pharmacy (Texas Tech University Health Sciences at Amarillo). All four academic entities have degree programs that are accredited by the American Council on Pharmaceutical Education.

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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). In addition, TSBP must annually review and approve the internship programs of the Texas colleges of pharmacy: refer to TSBP Rule 283.4(c)(1)(A). There are approximately 1,700 pharmacy students in Texas (i.e., students who are enrolled in the professional sequence in one of the four above-mentioned academic programs).

In addition, the Regulatory 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.
- (2) mail service pharmacies that are located in other states – these pharmacies are licensed by TSBP as Class E (Non-Resident) Pharmacies; they dispense/ship prescription drugs to patients living in Texas and/or in other states.

F. Describe how the program or function is administered. Include flowcharts, timelines, or other illustrations as necessary to describe agency policies and procedures. List any field or regional services.

As described in Question B above, the Regulatory 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; and to respond to requests for records.

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(2) Personnel – The Enforcement Division is headed by a Director who directly or indirectly supervises 24 staff employed in the following capacities (before budget cutbacks):

(A) Investigators (10) – 1 Chief, 5 field investigators, and 4 in-house investigators. The 5 field investigators conduct field investigations throughout the state of Texas. These employees office out of their homes in the following cities:

- Karnes City (this investigator is primarily responsible for conducting investigations in San Antonio and the South Texas area);
- Pearland (this investigator is primarily responsible for conducting investigations in Houston and the Deep East Texas area);
- Sherman (this investigator is primarily responsible for conducting investigations in Dallas and the Northeast Texas area);
- Austin (this investigator is responsible for conducting investigations in Austin and the Central Texas area); and
- Fort Worth area (this investigator is responsible for conducting investigations in Fort Worth and the West Texas area).

(B) Pharmacist Staff (8) – 1 Assistant Division Director, 1.75 in-house Compliance Officers, and 5.25 field personnel (1 Chief Compliance Officer and 4.25 field Compliance Officers who conduct inspections). The 5.25 field personnel conduct on-site inspections of pharmacies in assigned regions within the state.

NOTE: In FY2004, due to budget cut-backs, one of the in-house pharmacist positions will be eliminated, and two of the 5.25 pharmacist-field personnel will be replaced with non-pharmacists.

One pharmacist position inspects pharmacies in Austin/Travis County and surrounding counties on a 0.25 basis and has in-house duties on a 0.75 basis. This position offices in the Austin headquarters office. The remaining five field personnel office out of their homes in the following cities:

- San Antonio (this Compliance Officer conducts inspections of pharmacies located in San Antonio and South Texas);
- Houston (there are two Compliance Officers located in Houston; one Compliance Officer conducts inspections of pharmacies located in West Houston and areas west of Houston, extending into North Central and Central Texas; the other Houston Compliance Officer conducts inspections of pharmacies located in East Houston, East Texas, and Southeast Texas);

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- Dallas (this Compliance Officer conducts inspections of pharmacies located in the Dallas-Forth Worth and Northeast Texas areas); and
 - Breckenridge (this Compliance Officer conducts inspections of pharmacies located in West Texas, Panhandle, and El Paso areas).
- (C) Program Specialists – 2
- (D) Administrative Staff – 4

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 a General Counsel who is supported by two staff attorneys and two legal assistants.

PROFESSIONAL SERVICES DIVISION

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

POLICIES AND PROCEDURES

COMPLAINT PROCESS

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. **See Attachment #D** for a description of the policies and procedures for handling complaints, as reviewed and approved by the Board on May 8, 2002. Attachment D also includes a flow chart of the complaint process. The primary steps of the complaint process are described below:

- (1) Submission of Complaint – Complaints must be submitted in writing, except in unusual circumstances. 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 Hotline (800-821-3205) and provides his/her name and address, the TSBP Enforcement Division staff will mail a TSBP complaint form to the complainant. In FY2002, TSBP mailed 1,524 complaint forms to complainants.

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- (2) Receipt of Complaint – When a complaint is received, agency staff complete a complaint worksheet (determine data entry codes for source, form, subject of complaint, type of violation and draft concise summary/description of complaint for data entry purposes). The coded worksheet is routed to the responsible administrative assistant (“AA”) who data enters the complaint into the agency’s complaint tracking system and prepares the complaint file.
- (3) Determination of Jurisdictional Issues – The AA routes the complaint/file (and files relating to the subject’s prior history) to the Enforcement Specialist (“ES”), who double checks the AA’s data entry information for errors and determines if the complaint is a jurisdictional complaint. If the complaint is not within the agency’s jurisdiction to handle, the complaint is routed to the Assistant Director of Enforcement (“ADE”) for review. If the ADE confirms that the complaint is non-jurisdictional, the ADE closes the complaint with no action and the complainant is notified of the agency’s decision. If there is any question regarding jurisdictional issues, the ADE consults with Director of Enforcement (“DOE”) and/or General Counsel (the consultation may occur during a complaint/case review: see Step #9).
- (4) Initial Review of the Complaint – After determining the complaint is a jurisdictional complaint, the ES determines whether TSBP must obtain a Complainant Waiver Form and/or a Medical Release to obtain the patient’s medical records. The ES routes the complaint/files to the AA to acknowledge the receipt of the complaint and obtain additional information, if applicable. The ES advises the AA as to “next step” with respect to the assignment of the complaint (see Step #6 below).
- (5) 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 review. If the complaint can be resolved/closed without the requested forms, the DOE assigns the complaint to an in-house investigator (“EO”) to handle. If the complaint involves a dispensing error, the DOE assigns the complaint to an EO who attempts to telephone the complainant to discuss the matter. If the complainant does not wish to cooperate, the complaint/file is returned to DOE, who closes the complaint and notifies the complainant of the decision.
- (6) Assignment of Complaint – See response to Question L (below) regarding the Board’s philosophy with respect to the approach the agency takes to handle complaints. In accordance with this approach, complaints may be assigned to an in-house investigator or a field investigator, depending upon the nature of the complaint/violation(s) alleged and the licensee’s prior complaint history on file with the Board. 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).

The ES reviews the nature of the complaint violations and the licensee’s previous complaint history, and recommends assignment of complaint in accordance with Board policy: if complaint allegations are egregious, the complaint is assigned to a field investigator (regardless of whether the licensee has prior complaint history); if licensee has no prior complaint history and the complaint allegations are not egregious, the complaint is assigned to an in-house investigator.

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- (A) Field Investigations – If the ES determines the complaint should be handled with a field investigation, the ES routes the complaint to the DOE for review. The DOE consults with the Chief of Investigations, who assigns the complaint to a field investigator.
- (B) In-House Investigations – If the ES determines the complaint should be handled with an in-house investigation, the ES routes the complaint to an EO.

If the ES has any question with regard to how the complaint is to be handled (e.g., either through an in-house investigation or through a field investigation), the ES consults with ADE and/or DOE, who makes assignment. If DOE has any question with regard to how the complaint is to be handled, the DOE consults with the Executive Director (“ED”) and/or Legal Staff (consultation may occur at a complaint/case review: see step #9 below).

- (7) 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. Investigations are prioritized. The Board sets the priorities for investigations each year, when it sets its annual goals and objectives. **See FY2003 Goals and Objectives, Enforcement Division, Ongoing Objective #3 (Attachment #E) for a list of investigative priorities for FY2003.**
- (8) Preliminary Complaint/Case Review – After the investigation has been completed and the report has been prepared, the complaint/file is submitted to and reviewed by a supervisor, as described below:
 - (A) Field Investigations – field investigators’ cases are initially submitted to the Chief of Investigations (non-pharmacist) for review; if the Chief determines that the investigation is complete, the Chief routes the case to the DOE (a pharmacist) for review; if the DOE determines that the investigation is complete, the DOE routes the case to the Legal Division for review; then the case is reviewed with the Executive Director (“ED”): see Step #9. If the Chief, DOE or General Counsel determines that the investigation is incomplete, the case is returned to the case agent for additional investigation.
 - (B) In-house Investigations –
 - in-house investigators’ cases are submitted to DOE for review, if the complaint is to be closed with a written warning per Board policy (DOE reviews and signs all warning letters); and
 - in-house investigators’ cases are submitted to ADE for review, if the complaint is to be closed with no written warning.

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If the DOE or ADE determines that the investigation is incomplete, the case is returned to the case agent for additional investigation. If investigation is complete, the complaint is closed by DOE (after written warning is mailed) or ADE (with final review by DOE). If there is any question with regard to how the complaint should be closed, a final review is conducted with E.D./Legal Staff (see Step #9).

- (9) Complaint/Case Review – These reviews are held approximately every two weeks and are attended by the ED, General Counsel, DOE and other staff of the Legal and Enforcement Divisions. The following types of decisions are made at complaint/case reviews: whether a complaint should be investigated; what type of investigation should be conducted (i.e., in-house or field investigation); whether additional investigation is needed to make a decision about the action to take on a complaint; and how the complaint should be closed, specifically, whether disciplinary action should be instituted.
- (10) Complaint Closed or Referred to the Legal Division for Institution of Disciplinary Action – If after a final review, the decision has been made not to institute disciplinary action, the complaint is closed and the complainant is notified of the decision. If the complaint is closed with a warning letter, the complainant receives a copy of the letter. If the decision has been made to institute disciplinary action, the complaint/file is routed to the Legal Division (see “Disciplinary Process”).

DISCIPLINARY PROCESS

- (1) Assignment of Case – After investigation has been completed and the Legal Division has accepted the case, the General Counsel assigns the case to one of two staff attorneys 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 first draft of 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. The PNL is reviewed by DOE and General Counsel before it is mailed to the respondent.
- (3) Informal Settlement Conference (ISC) – Multiple informal settlement conferences are held over the course of several days (approximately eight conferences are held each day for three consecutive days a month during eight months a year). The conferences are held at the TSBP office. One Board Member attends the ISC, along with the Executive Director, General Counsel, prosecuting attorney, and other applicable staff (e.g., DOE; Chief of Investigation). The TSBP General Counsel conducts the ISC and explains 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

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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. **See Attachment #F for a description of the informal settlement conference procedures.**

- (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.
- (5) Waiving the ISC – 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 ABO. In these cases, the respondent has the opportunity to attend an ISC or waive the ISC, by signing and returning the proposed ABO that is enclosed with the PNL. This procedure expedites the disciplinary process and saves the respondent's time and resources, as well as the agency's time and resources.
- (6) When Informal Settlement Fails – A case cannot be settled through informal proceedings if one of the following events occur: the respondent rejects the terms and conditions of the proposed ABO or does not sign/return the proposed ABO; the Board rejects the terms of the proposed ABO; or the respondent does not appear at an ISC. 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.
- (7) 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.
- (8) 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.

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- (9) 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 the ALJ’s recommended disciplinary sanction.
- (10) 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 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.

INSPECTION PROCESS

- (1) Regions – Each Compliance Officer is responsible for inspecting pharmacies in an assigned region of Texas. For purposes of inspections, the state is divided into seven regions. **See Attachment #G for map of regions.** Pharmacies in the seventh region (Harris County) are inspected by one of the two Compliance Officers who are located in Houston.
- (2) Scheduling of Inspections – Inspections are conducted on an unannounced basis and generally average one to two hours in length. Texas pharmacies are inspected approximately every two years. Compliance Officers determine their own weekly schedules and are expected to maximize efficiencies by managing time and travel. To assist in efficient routing, Austin headquarters provides a “region roster” to each Compliance Officer. 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).
- (3) Priorities for Inspections – Compliance Officers plan their itinerary based on established priorities. The Board sets the priorities for inspections each year, when it sets its annual goals and objectives. **See FY2003 Goals and Objectives, Enforcement Division, Ongoing Objective #2 (Attachment #E) for a list of inspection priorities for FY2003.**
- (4) Notice of Inspection and Inspection Report Form – When Compliance Officers 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. After the Notice is signed, the Compliance Officer checks the pharmacy’s environment, equipment, drug stock, records, and practices/procedures. The Compliance Officer determines the degree of compliance for each item on the

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Inspection Report Form and indicates “satisfactory” or “needs improvement” or “unsatisfactory.” **See Attachment #H for a copy of Notice of Inspection and Inspection Report Form.**

- (5) Unsatisfactory Conditions – TSBP uses two different methods to handle unsatisfactory conditions, as described below:
- (A) Written Warning Notice – Compliance Officers 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 or imminent risk to public health (e.g., animals in the pharmacy); 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). **See Attachment #I for a copy of Warning Notice form.**
 - (B) Refer Case to the Legal Division for Review – For certain types of violations, in accordance with established guidelines, Compliance Officers may become investigators and collect evidence. The Compliance Officer advises the pharmacist on duty that the case will be referred to the Legal Division for review. The Compliance Officer submits the evidence with a written report to the DOE. If case is complete, the case is reviewed at a case/complaint review (see Step #9 under “Complaint Process” above), whereupon the case may result in disciplinary action against the pharmacy and its pharmacist-in-charge.
- (6) Response to 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.
 - (B) Unsatisfactory Response – If the pharmacy does not specifically state that the pharmacy has corrected the condition, TSBP notifies the pharmacy in writing that the response is unsatisfactory and states that the response be re-submitted.
 - (C) No Response – If the pharmacy fails to respond to the Warning Notice by the specified due date, 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, a complaint is opened and referred to the Legal Division for review and possible institution of disciplinary action.
- (7) Follow-up Inspections – After the Compliance Officer receives notice that the pharmacy has satisfactorily responded to the Warning Notice, the Compliance Officer 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

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“abbreviated inspection” (i.e., Compliance Officer only checks the areas that were marked “needs improvement” or the “unsatisfactory” conditions that resulted in the Warning Notice being issued. If the pharmacy has not corrected the conditions as described in the pharmacy’s Response to Warning Notice, the Compliance Officer files a complaint with the Director of Enforcement and the case is referred to the Legal Division.

- (8) Pre-Licensure Inspections – These types of inspections are conducted prior to the issuance of a pharmacy license, to 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 explains in explicit detail 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 – The Director of Enforcement (DOE) notifies all field personnel of the orders that have entered on licensees. The DOE requests the applicable field compliance officer to conduct inspections of pharmacies that have been revoked or suspended, or pharmacies that employed a pharmacist whose license has been revoked, retired, or suspended, in order to determine if the licensee is practicing or operating a pharmacy during the period of revocation, retirement or suspension. The DOE also requests the applicable field compliance officer to conduct inspections of licensees who are on probation or other types of disciplinary orders which are necessary to determine if the licensee is in compliance with the terms of the disciplinary order.
- (3) Peer Assistance Program – TSBP has a contract with the Pharmacy Recovery Network (PRN), a “voluntary” peer assistance program administered by the Texas Pharmacy Association, to aid impaired pharmacists. ***See Attachment #J for information regarding the PRN Program.*** 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

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- (B) if this individual signs a PRN contract and experiences a relapse (e.g., positive drug screen for a controlled substance that has not been dispensed pursuant to a valid prescription).

After receiving a referral from the PRN Program, TSBP initiates a complaint, conducts an investigation, and if sufficient evidence is collected, institutes disciplinary action against the licensee.

- (4) Typical Terms and Conditions Imposed by Disciplinary Orders – In FY2001, 90% of the disciplinary orders entered by TSBP required some type of monitoring. In FY2002, 80% of the disciplinary orders entered by TSBP required some type of monitoring.

- (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., 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.
- requiring the impaired/recovering pharmacist to submit to random drug screens (see below).

- (B) Orders Imposing Drug Screens – TSBP has a contract with the National Confederation of Professional Services (NCPS) to administer a drug screening program for TSBP. NCPS 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");

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- an 800 number for probationers to telephone each weekday (the probationer enters his/her unique PIN number on the touch tone pad and the system will inform the caller 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 or positive).
- (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 report regarding the CE. If the licensee submits the required CE certificates, TSBP conducts an audit of CE records claimed on the licensee's renewal application to ensure that the licensee did not "double count" the CE (i.e., using the CE to satisfy the terms of the disciplinary order, as well as for license renewal purposes, which would be a violation of the terms of the order). CE audits are also conducted on probationers.
- (E) Orders Imposing Administrative Penalties – After the entry of a disciplinary order requiring the payment of an administrative penalty (fine) or probation fee, the Enforcement Division notifies the Administrative Services Division (Enforcement Division prepares a list of all licensees that owe a fine and/or probation fee, including the licensee's name, license number, amount due, and due date). The Administrative Services Division monitors whether a licensee pays his/her fine or probation fee by the due date. If the licensee does not pay his/her fine or fee by the due date, the Administrative Services Division notifies the DOE. The DOE or designee opens a complaint, telephones the licensee, and gives 10 days to submit payment. If payment is not received within 10 days, the complaint is referred to the Legal Division for the institution of disciplinary action.
- (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).

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- (6) Non-Compliance with Terms of Disciplinary Order –
- (A) Drug Screens – As explained above, NCPS monitors licensees' compliance with their drug screening requirements. TSBP would open 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 automatically generated each week. Enforcement Division staff use this report to identify a licensee's non-compliance. When Enforcement Division staff confirm 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. For additional information regarding agency task forces, see Section III, Question I.

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INFORMATION SERVICES

Regulatory Program staff provide 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 Web site (which provides voluminous amounts of information, including detailed data about licensees as well as extensive information about the agency); and
- (4) publications (e.g., *TSBP Newsletter*, TSBP Law Reference Manual; Consumer Brochure).

Regulatory Program staff make every effort to provide the requested information in the format or method requested by the customer (e.g., telephone, TSBP Web site, fax, email, U.S. mail, TSBP Exhibit, and speaking engagements). The following statements are applicable to the procedures used for the Regulatory Program's information services.

- (1) For procedures regarding how the agency responds to requests for public records, see Section VII, Question I.
- (2) TSBP pays additional monies for its telephone services in order to maintain a "queue system" for compliance calls (inquiries about pharmacy laws/rules or requests for technical assistance), in order to prevent callers from getting voice mail when they call TSBP with a question.
- (3) If information about pharmacy laws/rules is requested by email, the email is forwarded to the Director of Professional Services for reply. An email response is prepared and sent to the inquirer, if the response can be prepared easily and quickly. Otherwise, TSBP requests the customer to provide a telephone number so that TSBP may provide the information by telephone.
- (4) The *TSBP Newsletter* was published three or four times a year until budget reductions were mandated by the 78th Texas Legislature. The agency intends to make future issues of the *TSBP Newsletter* available through the agency's Web site.
- (5) Effective January 2003, as a result of budget reductions, TSBP discontinued providing the following information services:
 - (A) TSBP discontinued publishing the TSBP Law Reference Manual; the law reference manual is now outsourced and being published by Matthew Bender & Company, a member of the LexisNexis Group; and

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- (B) TSBP Exhibit was previously displayed during two professional meetings each year. However, TSBP discontinued this service in FY2003 because funding was not available to reimburse employees to attend the professional meetings or to pay the incidental costs related to the exhibit space/updating the exhibit.
- (6) Due to budget cutbacks, Regulatory Program staff may be unable to make presentations unless the requesting organization pays for all or part of the travel expenses.

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 Web sites, such as the Office of the Attorney General, the Texas Ethics Commission, and Secretary of State, for specific updates on opinions and law.

G. If the program or function works with local units of government, (e.g., Councils of Governments, Soil and Water Conservation Districts), please include a brief, general description of these entities and their relationship to the agency.

TSBP investigators work with local law enforcement agencies (e.g., police departments, sheriff departments, and narcotic task forces, local units of the Texas Department of Public Safety, and local offices of the Drug Enforcement Administration).

H. Identify all funding sources and amounts for the 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 Regulatory Program receives no federal funds. TSBP is self-supporting by generating sufficient revenues from licensure fees to support the agency's operations. See Section IV of this report for details regarding funding. TSBP is funded by the General Revenue Dedicated - Pharmacy Board Operating Account 523. The types of appropriation, appropriation authority and amounts for the Regulatory Program (Enforcement and Peer Assistance) are listed below:

Regulatory Program (Enforcement Strategy) General Revenue Dedicated-Pharmacy Board Operating Account No. 523	FY2002 Budget
Regular Appropriation	1,729,438.00
Rider Appropriation	
Article IX-96, Section 10.52(a) Contingency Appropriation SB 98 (2002-03 GAA)	125,216.00
Article IX-96, Section 10.52(b) Contingency Appropriation SB 768 (2002-03 GAA)	110,807.00

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Transfer	
Article IX, Section 10.12(a) Salary Increase (2002-03 GAA)	51,850.00
Article IX, Section 10.12(l) Longevity Increase (2002-03 GAA)	7,880.00
Article IX, Section 10.23 Contingency Appropriations HB 2976 (2002-03 GAA)	38,991.00
Article IX, Section 6.08 Appropriation Transfers (2002-03 GAA)	-59,772.00
Article IX, Section 6.17 UB - Capital Budget Transfer to Fiscal Year 2003 (2002-03 GAA)	-15,165.00
Other Funds	
Regular Appropriations - Appropriated Receipts	99,000.00
Rider Appropriations - Article IX-44, Section 6.16 Sale of Publication	36,700.00
Total Funding Sources - Enforcement Program	2,124,945.00

Regulatory Program (Peer Assistance Strategy)	FY2002 Budget
General Revenue Dedicated-Pharmacy Board Operating Account No. 523	
Regular Appropriation	160,325.00
Total Funding Sources - Enforcement Program (Peer Assistance Strategy)	160,325.00

I. Are current and future funding resources appropriate to achieve program mission, goals, objectives, and performance targets? Explain.

TSBP believes that additional funding is needed to carry out its mission, particularly in light of the budget cutbacks mandated by the 78th Texas Legislature. The Enforcement Division has only five field investigators and 5.25 inspectors for the entire state, resulting in each field employee having vast territories to regulate. Moreover, TSBP will be implementing a new program in FY2004 to register 26,500 pharmacy technicians. The pharmacy technician registration program will double the number of persons being regulated by the agency and will stretch the Regulatory Program's employees to the breaking point.

J. Identify any programs internal or external to the agency that provide identical or similar services or functions. Describe the similarities and differences.

- (1) Internal Programs – The Regulatory 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 Pharmacist Licensing Section 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;

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- (C) Enforcement Division and Legal Divisions work closely with the Pharmacy Licensing Section to ensure that applicants with a criminal history record are not licensed until the application has been thoroughly reviewed by the Enforcement and/or Legal Divisions;
 - (D) Enforcement Division works closely with the Pharmacist Renewal Licensing Section to ensure that pharmacists who have not completed the required CE for relicensure are referred to the Legal Division for institution of disciplinary action; and
 - (E) Licensing Section also provides information about agency services and information about public licensing records.
- (2) External Programs
- (A) Similar enforcement programs and functions are provided by state boards of pharmacy in other states. The Texas Pharmacy Act requires pharmacies that are located in other states (but dispense/deliver prescriptions to patients in Texas) to obtain a Class E (Non-Resident) Pharmacy license. These pharmacies must also be licensed in the state where they are located.
 - (B) The Texas Department of Health (TDH) licenses and regulates hospitals and ambulatory surgical centers. Class C (Institutional) Pharmacies are located in these facilities. TDH personnel may conduct inspections in hospitals, including the pharmacy.
 - (C) Health and Human Services Commission (HHSC) contracts with pharmacies to provide services to Medicaid patients. HHSC has regional pharmacists who conduct annual 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.

K. Discuss how the program or function is coordinating its activities to avoid duplication or conflict with the other programs listed in Question J 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 Joint Commission on Accreditation of Healthcare Organizations (JCAHO), a private non-profit organization, 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 employs regional pharmacists to conduct annual visits at pharmacies that are serving Medicaid patients. Not all pharmacies serve Medicaid patients and these annual visits are not complete inspections. HHSC regional pharmacists only check for contract violations (Medicaid Fraud). Their visits are annual, while TSBP inspections are conducted approximately every other year and constitute more in depth inspections. However, if HHSC regional pharmacists observe violations

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or items that are unsatisfactory during their visits, HHSC forwards the information to TSBP for review and possible action against the licensees involved. TSBP works closely with AGMFU on cases involving Medicaid Fraud by pharmacists/pharmacies.

- (3) Class E Pharmacies (pharmacies located in other states) – TSBP refers complaints on Class E Pharmacies to the state board of pharmacy where the pharmacy is located. If that state board does not take disciplinary action on the complaint within the time period set forth in Section 565.053 of the Texas Pharmacy Act, TSBP may do so.

L. Please provide any additional information needed to gain a preliminary understanding of the program or function.
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- (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.
- (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. Over the past 5 fiscal years (FY1998-FY2002), TSBP entered 744 disciplinary orders and 733 of the orders were Agreed Board Orders (an average settlement rate of 98.6% over the past 5 years).
- (4) Violations of Texas and Federal Drug Laws subject pharmacists and pharmacies to criminal penalties, as well as administrative sanctions against their licenses to practice and operate a pharmacy.

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- (5) The regulation of the practice of pharmacy is highly specialized and complex. Regulatory 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. The TSBP Rules, alone, span approximately 200 pages. In order to carry out their duties, Regulatory Program staff are required to have a thorough knowledge of all the aforementioned laws/rules.
- (6) TSBP issues five different types of pharmacy licenses:
- (A) Class A (Community) Pharmacies
 - (B) Class B (Nuclear) Pharmacies
 - (C) Class C (Institutional) Pharmacies
 - (D) Class D (Clinic) Pharmacies
 - (E) Class E (Non-Resident) 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. Until budget cuts mandated by the 78th Texas Legislature, TSBP employed pharmacists to conduct these inspections. The budget cuts will force the agency to replace pharmacist Compliance Officers with non-pharmacist inspectors.

- (7) TSBP employs five 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, except they may not carry a firearm or make 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.

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| <p>M. Regulatory programs relate to the licensing, registration, certification, or permitting of a person, business, or other entity. If this is a regulatory program, please describe:</p> <ul style="list-style-type: none">C why the regulation is needed;C the scope of, and procedures for, inspections or audits of regulated entities;C follow-up activities conducted when non-compliance is identified;C sanctions available to the agency to ensure compliance; andC procedures for handling consumer/public complaints against regulated entities. |
|--|

For response to why the regulation is needed, see responses in Section I of this report.

For responses to the remaining questions, see response to Question F above.

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N. Please fill in the following chart for each regulatory program. The chart headings may be changed if needed to better reflect the agency's practices.

Texas State Board of Pharmacy (Regulatory Program) Exhibit 15: Complaints <u>Against</u> Regulated Entities or Persons – Fiscal Years 2001 and 2002		
	FY 2001	FY 2002
Number of jurisdictional complaints received	1,642	1,787
Number of jurisdictional complaints resolved	1,614	2,090
Number of complaints dropped/found to be without merit	see footnote (1)	see footnote (1)
Number of sanctions (disciplinary orders)	145 see also footnote (2)	181 see also footnote (2)
Number of complaints pending from prior years	see footnote (3)	see footnote (3)
Average time period for resolution of a jurisdictional complaint	267 days	225 days
Number of entities inspected or audited by the agency	2,529	2,581
Total number of entities or persons regulated by the agency	26,282 see also footnote (4)	26,529 see also footnote (4)

Footnote (1) – TSBP interprets your definition of the term “dropped/found to be without merit” to mean complaints that are closed with an action other than a disciplinary order. However, in TSBP’s opinion, complaints that are closed without the entry of a disciplinary order are not considered “dropped” or “found to be without merit.” TSBP closes many complaints with non-disciplinary methods such as: verbal admonitions, written warnings, inspections and inspections with written warnings. See representative examples below; the statistics below pertain to all complaints received by TSBP (including both jurisdictional and non-jurisdictional complaints):

	FY2001	FY2002
Complaints Closed Following a Verbal Admonition	270	483
Complaints Closed Following a Written Warning	419	456
Complaints Closed Following an Inspection	59	25
Complaints Closed Following Entry of Disciplinary Order	173	211
Complaints Closed Following an Investigation (due to insufficient evidence or no violation)	185	379
Complaints Closed with No Action (due to no violation, insufficient information, etc.)	115	90
Complaints Closed with Other Type of Action (e.g., multiple actions; referrals, uncooperative complainants, complainants withdrew complaint, etc.)	446	493
Total Number of Complaints Closed (all complaints)	1,667	2,137

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Footnote (2) – The number of sanctions equals the number of disciplinary orders entered. However, the number of sanctions does not equal the number of complaints closed with a disciplinary order. Because one complaint may involve two licensees (i.e., one pharmacist and one pharmacy), one complaint may result in the entry of two disciplinary orders. Moreover, one disciplinary order against one licensee may close one or more complaints.

Footnote (3) – TSBP's computerized complaint tracking system allows the agency to query the number of active/pending complaints at the time of the query (i.e., the system does not have the ability for the agency to obtain the number of active/pending complaints for a date in the past). However, TSBP can provide an estimate of the number of active/pending complaints during the last month in each of the requested fiscal years. The estimate is based upon reports given to the Board at its meetings held in early August in 2001 and 2002. These reports indicate the following statistics:

- C As of August 8, 2001 = 1,074 active/pending complaints
- C As of August 7, 2002 = 764 active/pending complaints

Footnote (4) – This total does not include the number of pharmacist-interns that are registered by TSBP. The number of interns fluctuates each year from 1,300 to 1,800 persons.

VII. Agency Performance Evaluation

A. What are the agency's most significant accomplishments?

The Texas State Board of Pharmacy (TSBP) has an excellent state and national reputation for its stature and effectiveness as a state health regulatory agency. This reputation has been reinforced within Texas and throughout the nation, as evidenced by the following:

- (1) an exception-free audit on the Post-Payment & Procurement Audit by the Texas Building & Procurement Commission on service contracts in FY2003;
- (2) monetary exception-free financial audit by the State Comptroller in FY1999;
- (3) unqualified certification of the agency's FY2000 performance measures, conducted by the State Auditor;
- (4) achievement, over the past five years (FY1998-FY2002), of average settlement rate of approximately 99% of TSBP's contested cases (resulting in a disciplinary order against a licensee), which resulted in significant efficiencies, both in terms of complaint resolution time and costs; and
- (5) an exceptional Management Audit from the Office of the State Auditor in FY1993. The final report stated in part, ". . . *The Texas State Board of Pharmacy is operating efficiently. . . . The agency actively seeks ways to determine how to improve its operations. . . . We commend the agency's personnel for their efforts to improve both agency operations and the practice of pharmacy throughout the State.*"

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The agency has also been an innovator in the field of proactive health regulation. This recognition and stature is well-documented in that TSBP was the first or one of the first, pharmacy boards in the nation to:

- (1) use ad hoc task forces in its pre-rule-making process (the agency began using these task forces in 1981);
- (2) publish a *Newsletter* that is distributed to all licensees and other interested customers (the *Newsletter* has been continuously published since 1977 and is directed at educating pharmacists about the laws/rules relating to the practice of pharmacy; it also discloses the names of all pharmacists and pharmacies disciplined by the Board);
- (3) implement a preventive enforcement program that encourages pharmacists' voluntary compliance with governing laws and rules, through a combination of routine inspections and education efforts (the Compliance program began in 1977);
- (4) develop and implement a strategic plan (the first agency *Strategic Plan* was developed in 1986);
- (5) work with the regulated community to pass legislation to establish drug therapy management and immunizations by pharmacists, establish procedures to implement confidential peer review committees, and obtain funding for implementation of a pharmacy technician registration program;
- (6) establish a comprehensive and user-friendly Web site to improve services and accessibility to its customers. The site contains consumer information, including procedures regarding the complaint process, new and ongoing licensing information, a reference site for pharmacy-related information, and important information regarding the agency's laws and rules. Significant additions to the web site include: a license verification link that enables the public to verify the licensing and disciplinary status of TSBP licensees and a system that allows an individual to file a complaint online; and
- (7) implement an online pharmacist license renewal program.

<p>B. Describe the internal process used to evaluate agency performance, including how often performance is formally evaluated and how the resulting information is used by the policymaking body, management, the public, and customers.</p>
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Several internal processes are used to evaluate agency performance, as described below:

- (1) Strategic Planning Process – The Board updates its strategic plan every other year. During this process, the Board and staff evaluate the progress that the agency has made towards its long-term goals.
- (2) Annual Goals and Objectives – The agency uses a modified management by objective system to evaluate agency performance. Using the agency goals set forth in the TSBP Strategic Plan, the Board establishes detailed annual goals and objectives for the Office of the Executive Director and each organizational Division. **See Attachment #E for list of FY2003 Goals and Objectives.** The executive management team (Executive

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Director and Division Directors) establishes management systems to determine progress toward annual goals/objectives and constantly monitors the progress made toward achieving these goals/objectives. Some of the tools that the management team uses to determine progress include the following:

- (A) Reports on Output and Efficiency Performance Measures – TSBP submits quarterly reports to the Legislative Budget Board (LBB) and Governor’s Budget Office (GBO) regarding actual performance attained on Output and Efficiency Key Measures. TSBP submits an annual report to LBB and GBO regarding actual performance on Output, Efficiency, Explanatory and Outcome Key Measures. LBB/GBO and the agency use these reports to assess the performance of the agency against previously established performance targets;
 - (B) Executive Management Team Meetings – The management team holds periodic meetings (approximately every four to six weeks) to review activities of the divisions and discuss the agency’s progress toward annual goals;
 - (C) Manager’s Monthly Status Reports – Each one of the four Division Directors submits a monthly activity report to the Executive Director detailing division activities and progress made toward the annual goals of the division;
- (3) Annual Report of Goals and Objectives – Following the end of each fiscal year, a comprehensive annual report is made to the Board detailing the agency’s accomplishments and constraints in the prior fiscal year. The Board uses this information to evaluate the performance of the Executive Director; the Executive Director uses this information to evaluate the performance of the Division Directors, and the Division Directors use this information to evaluate the performance of Division employees. Performance evaluations of all employees are conducted annually. Upon request, TSBP distributes copies of the agency’s annual report to the public. The agency’s annual reports for the past two years are also posted on the TSBP Web site.
- (4) Customer Satisfaction Survey – See response to Question F (below).
- (5) Internal Audit – H.B.609, 77th Texas Legislature (2001), established the requirement for all state agencies to employ an Internal Auditor for the purpose of improving performance through identification/elimination of problems. In FY2002, the agency contracted with an outside consultant-C.P.A. firm who used a risk assessment model to rank and prioritize the identified risks associated with various business activities. Following their review of the Internal Audit plan, the TSBP Executive Committee determined that the agency’s complaint process and computer security should be audited by the Internal Auditor, due to the high risk potential of these activities. In FY2002, the Internal Auditor reviewed the agency’s complaint process. Statistical testing was employed to assess: adequacy of internal control over the complaint resolution process; content accuracy and sufficiency of complaint information file; timeliness of complainant notification; compliance with statutory requirements of the complaint resolution process; and compliance with statutory requirements of the disciplinary process. The Internal Auditor determined that TSBP had been “successful in investigating and resolving complaints filed with the Board in conformity with the Texas Occupation Code and Texas Administrative Code” and had “established and followed a sound complaint record retention procedure.” However, one deficiency was identified. Due to workload issues, the Enforcement Division was only in 85% compliance with

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notifying complainants every four months of the status of their complaints. Management instituted procedures to address the situation. In FY2003, the Internal Auditor reviewed computer security, the licensing process and the complaint process and found no deficiencies. Due to budget cutbacks in FY2004, the Internal Auditor function will be eliminated.

- (6) Survey of Organizational Excellence – Since 1994, TSBP has been participating in the biennial survey conducted by the University of Texas School of Social Work relating to organizational excellence. This survey is sent to all agency employees and asks for their opinions about the total work environment. The Executive Director encourages all employees to participate in the survey. Responses are anonymous. The Executive Director and Division Directors thoroughly read and review the report that is generated from the survey results, including the agency's strengths and areas that may need improvement. The agency's scores rate consistently higher than the statewide average for all workplace dimensions.
- (7) Agency Change Team (ACT) – To get agency staff more involved in reviewing and learning about the results of the Survey of Organizational Excellence, the Executive Director established the ACT committee in FY2003. This committee was composed of front-line staff members (one from each section within the agency). Committee members were asked to read the summary report regarding the agency's responses to surveys completed in FY2002. After an initial meeting, ACT members had team meetings with fellow employees. Following the team meetings, the ACT committee produced a 12-page report regarding 47 suggestions for changes to agency operations. The final report was given to the Executive Director in February 2003. The management team (Executive Director and Division Directors) held two meetings reviewing each suggestion listed in the ACT report (i.e., the management team spent approximately eight hours discussing the content of the ACT report). On May 16, 2003, the management team produced a 9-page written response listing the 23 changes that had been implemented as a result of the ACT report (i.e., management implemented 49% of the total number of suggestions made by the ACT committee); if a suggestion was not implemented, management's written response explained the reasons why a change was not made.

C. What are the agency's biggest opportunities for improvement?
--

With the recent budget cuts (7% for FY 2002 and 12.5% for the FY2004-2005 biennium) the agency is struggling to maintain its level of service. In addition, during the next biennium, the agency will begin to register approximately 25,000 pharmacy technicians. This number of registrants will double the agency's number of registrants/licenses. The agency is expected to accomplish this task with an increase in funding of approximately \$200,000 over the funding for the last biennium.

Other opportunities for improvement also relate to the budget and to personnel issues. With the existing structure, the agency is unable to adequately compensate its professional staff particularly the Executive Director. In each of the last three Legislative Sessions, the agency has asked the legislature to increase the salary of the Executive Director of the agency. This increase based on the following information:

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- (1) The person who is the executive director for the Board of Pharmacy is required not only to be a pharmacist, but also to be a person who has considerable experience in the management of an organization including strategic planning and budgeting, who is familiar with pharmacy and drug laws, and who is familiar with state and national issues affecting pharmacy practice.
- (2) The current salary of the Executive Director (\$70,000) is below the Texas average salary of a pharmacist working in Texas. 2002 Market data indicates that in the subregion which includes Arkansas, Louisiana, Oklahoma, and Texas, the average salaries are \$76,900 for staff pharmacists and \$82,000 for pharmacist managers.
- (3) The great majority of pharmacists working within the State of Texas, including those working for the Board of Pharmacy, are currently classified as Pharmacist III's, with a salary range of \$52,992 - \$82,140. The pharmacist positions that are within the Board of Pharmacy are a part of the succession planning for the Executive Director position. With this in mind, how will the Board of Pharmacy be able to hire an Executive Director if a pharmacist has to take a pay cut to become Executive Director?

The other personnel issue relates to the agency's high rate of turnover rate, especially in terms of its pharmacist staff. Again in each of the last three legislative sessions the agency has asked for additional appropriations to fund merit increases for agency employees. Without these additional appropriations, merit increases will not be available to all eligible employees. Given the rising cost of employee benefits (i.e., insurance), no substantive cost of living increases to state employees, and inadequate merit funding, staff turnover is expected to increase within the agency unless additional compensation shortcomings are addressed.

Agency employee turnover increased from 15% in FY96-97 to 20% in FY98-99 and dropped to 18% for the FY00-01 biennium. The pharmacist turnover rate for FY2001 was an alarming 53.33%. This loss of pharmacist staff is especially disturbing since the pharmacist staff are a part of the secession for the Executive Director position, in that the Executive Director is statutorily required to be a pharmacist.

In addition, during the last four years, the agency lost its Director of Investigations, three of its four field investigators, and one in-house investigator. These investigators had an average of 16.19 years of Pharmacy Board experience.

The reason for the high turnover rate in both the pharmacist and investigator job classes can be directly attributed to retirement, salary dissatisfaction, increased workload as a result of legislative initiatives, and lack of any intrinsic rewards. Employees are continually asked to do more with less. We expect that employee turnover will continue to be volatile and increase, unless additional compensation shortcomings are addressed.

D. How does the agency ensure its functions do not duplicate those of other entities?
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TSBP has taken a "lead agency" role in coordinating enforcement activities of federal, state, and local law enforcement agencies, with regard to the regulation of pharmacies and pharmacists. By keeping the lines of communication open between the various law enforcement agencies, by coordinating investigations involving pharmacies and pharmacists, by providing technical

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assistance to law enforcement officials and prosecutors, and by periodically meeting with the other entities, the agency has been able to develop a close working relationship with these agencies. This process, in turn, has fostered and promoted a cooperative regulatory environment, resulting in virtual elimination of duplication of efforts.

E. Are there any other entities that could perform any of the agency's functions?

No.

F. What process does the agency use to determine customer satisfaction and how does the agency use this information?

In FY2000 and FY2002, TSBP conducted a survey of agency customers regarding the quality of service delivered by the agency as specified in Chapter 2113 of the Government Code. The TSBP Executive Director read all written comments and suggestions that customers made on the surveys. Supervisors were advised if customers made comments about an employee and identified the employee by name; supervisors complimented specific employees when comments about them were positive, and counseled when comments were negative. In FY2002, the Enforcement Division Director read all comments made on customer service surveys, identified the comments that could be described as a "suggestion," and prepared a summary list of the suggestions for review and consideration/action by agency staff. **See Attachment #K for a copy of the report that was submitted to the Board Members, Governor and Legislative Budget Board in FY2002, including the summary list of suggestions.** At the time of report, agency staff had accomplished eight of the suggestions and taken action on four others. The suggestions made by the other 20 individuals were not acted upon due to the following reasons: funding not available (three suggestions from six individuals); statutory changes would be required (seven suggestions from eight individuals); suggestions not within TSBP's jurisdiction (four suggestions); and suggestions not in line with TSBP's mission (two suggestions).

G. Describe the agency's process for handling complaints against the agency, including the maintenance of complaint files and procedures for keeping parties informed about the process. If the agency has a division or office, such as an ombudsman, for tracking and resolving complaints from the public or other entities, please provide a description.

TSBP Rule 311.1 sets forth the procedures for handling complaints filed against a board employee. **See Attachment #B.** The TSBP Executive Director handles all written complaints against employees. The executive assistant to the Executive Director is the TSBP Customer Relations Representative and maintains files for the Executive Director. As indicated in the response to Question H (below), the agency did not have any written complaints filed against it or an employee in FY2001 or FY2002.

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H. Please fill in the following chart. For complaints Against the Agency - Fiscal Years 2001 and 2002.

There were no written complaints filed against the agency in FY2001 or FY2002. However, one written complaint against an employee was filed and resolved in FY2003. The complaint was resolved within 13 days of receipt.

I. What process does the agency use to respond to requests under the Public Information (Open Records) Act?

(1) Requests for Confidential Information

TSBP does not disclose social security numbers, pursuant to Section 56.001 of the Occupations Code. In addition, under the provisions of the Texas Pharmacy Act, the following information is confidential:

- (A) investigative files;
- (B) any information that would disclose the identity of the complainant or any person assisting TSBP in the investigation of a complaint; and
- (C) any records relating to pharmacists who have a chemical, mental or physician impairment.

If TSBP receives a written request for information that falls into one of the above categories, TSBP legal staff contact the requestor to determine if the request can be limited to providing public information only. If the requestor does not agree to narrowing the request, TSBP legal staff draft a request for an Attorney General Open Records Decision within 10 days of the receipt of the request.

(2) Requests for Licensure Information

- (A) TSBP Web site – The public can find licensure information on the TSBP Web site for pharmacies, pharmacists, and pharmacist-interns. Detailed information can be found by clicking on “License & Registration Verifications.” The public can search by name, license number, or city.
 - For pharmacists, the public can confirm the following information: name of licensee; place of employment; current status of license and expiration date of license; license number; date license issued; gender; degree at time of licensure; year of graduation; and college where degree was obtained; and licensure method (i.e., by examination or reciprocity).
 - For pharmacist-interns, the public can confirm the following information: name of intern; date intern registration became effective; current status of intern registration and expiration date of registration; gender; college of pharmacy that intern is attending; and anticipated date of graduation.

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- For pharmacies, the public can confirm the following information: name and address; license number; current status of license and expiration date; date license issued; names of pharmacists working at the pharmacy; name of owner of pharmacy; class of pharmacy; and type of pharmacy ownership.

(B) Other – If the public does not have access to the TSBP Web site, TSBP will also provide licensure information by telephone, provided the caller is only requesting licensure information for one or two individuals. Otherwise, TSBP requests that the caller submit his/her request in writing. TSBP accepts/processes requests for licensure information by email, telephone, fax, or U.S. mail.

(3) Requests for Information about Disciplinary Orders

The public can verify whether a licensee or intern has been the subject of a disciplinary order by going to the TSBP Web site and clicking on “License & Registration Verifications” [same process as described in (1) above]. The detailed information will indicate whether the licensee or intern has been the subject of a disciplinary order.

(A) Public Disciplinary Orders – If the Web site indicates “yes” (that the licensee or intern has been the subject of a disciplinary order), the public can call the TSBP office and speak with Regulatory Program staff regarding the details about the order (e.g., description of violations or alleged violations and description of sanction), provided the order is a public disciplinary order. A copy of the public disciplinary order is provided upon written request. The written request may be emailed or faxed to TSBP.

(B) Confidential Disciplinary Orders – Information about confidential disciplinary orders is restricted, pursuant to Section 564.002 of the Texas Pharmacy Act. In accordance with Section 564.003(a), TSBP may provide a copy of the confidential order (or disclose information about the order) only to another state board of pharmacy, in a disciplinary hearing before the board or in a subsequent trial or appeal of a board action or order, or under a court order. However, TSBP may and does disclose the status of the license if the confidential order revokes, cancels, restricts, or retires, or in any other manner limits the licensee’s practice of pharmacy.

(4) Requests for Information Regarding Complaints

All complaints remain on a licensee’s record in accordance with TSBP’s approved record retention schedule. Complaints are maintained a minimum of five years after the date of the closure of the complaint, regardless of how the complaint was closed. Exceptions include: complaints that result in disciplinary orders, in which case, complaints are maintained for 75 years after the entry of the order.

Information about complaints is provided only upon written request, and then only information about “public actions” is disclosed. Examples of “public actions” include: verbal admonition (verbal warning); dismissal letter (written warning); letter of explanation (advisory letter); and cease and desist letter. If a complaint (not involving an impaired pharmacist) was closed with a public action, the following information about the

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complaint is disclosed to the public, upon written request: the fact that a complaint was filed, the nature of the complaint, and the description of the public action (including copies of dismissal/warning letters that TSBP mailed to the licensee). If a complaint involves an impaired pharmacist, TSBP does not disclose the nature of the complaint nor provide copies of letters mailed to the licensee, except under limited circumstances as allowed under the Texas Pharmacy Act.

J. Please fill in the following chart with updated information and be sure to include the most recent email address if possible.

Texas State Board of Pharmacy Exhibit 17: 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 & Fax Numbers	Email Address
Texas Pharmacy Association Contact: Jim Martin	P.O. Box 14709 Austin, TX 78752	Telephone: 512/836-8350 FAX: 512/836-0308	jmartin@txpharmacy.com
Texas Society of Health-System Pharmacists Contact: Paul Davis	P.O. Box 15147 Austin, TX 78761	Telephone: 800/242-8747 FAX: 512/233-5288	tshp@tshp.org
College of Pharmacy The University of Texas at Austin Contact: Steven W. Leslie, Ph.D.	The University of Texas at Austin Austin, TX 78712-1074	Telephone: 512/471-3719 FAX: 512/471-8783	sleslie@mail.utexas.edu
School of Pharmacy Texas Tech University Contact: Arthur Nelson	Health Sciences Center 1300 S. Coulter Amarillo, TX 79106	Telephone: 806/356-4010 FAX: 806/356-4018	arthur@cortex.ama.tt.uhsc.edu
College of Pharmacy and Health Sciences Texas Southern University Contact: Barbara Hayes, Ph.D.	3100 Cleburne Avenue Houston, TX 77004	Telephone: 713/313-7164 FAX: 713/313-1091	hayes_be@tsu.edu
College of Pharmacy University of Houston Contact: Sunny E. Ohia, Ph.D.	Texas Medical Center 1441 Moursund Street Houston, TX 77030	Telephone: 713/795-8337 FAX: 713/795-8330	seohia@uh.edu
Texas Federation of Drug Stores Contact: Karen Reagan	504 West 12 th Austin, TX 78701	Telephone: 512/472-8261 FAX: 512/474-5011	kreagan@txretailers.org

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INTERAGENCY, STATE, OR NATIONAL ASSOCIATIONS (that serve as an information clearinghouse or regularly interact with the agency)			
Group or Association Name/ Contact Person	Address	Telephone & Fax Numbers	Email Address
National Association of Boards of Pharmacy Contact: Carmen Catizone	700 Busse Hwy. Park Ridge, IL 60068	Telephone: 847/698-6227 FAX: 847/698-0124	exec- office@nabp.net
Pharmacy Technician Certification Board Contact: Melissa Murer	2215 Constitution Avenue NW Washington, DC 20037	Telephone: 202/429-7576 FAX: 202/429-7596	mmm@ptcb.org
LIAISONS AT OTHER STATE AGENCIES (with which the 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 & Fax Numbers	Email Address
Office of the Attorney General Contact: Joe Pitner	P.O. Box 12548 Austin, TX 78711-2548	Telephone: 512/475-4199 FAX: 512/320-0167	joseph.pitner@oag.state.tx.us
Legislative Budget Board Contact: Thomas Galvan	P.O. Box 12666 Capitol Station Austin, TX 78711	Telephone: 512/463-1169 FAX: 512/475-2903	thomas.galvan@lbb.state.tx.us
Governor's Budget, Planning, & Policy Office Contacts: Budget - Heidi Lopez-Cepero Policy - Victoria Ford	P.O. Box 12428 Capitol Station Austin, TX 78711	Telephone: 512/463-2047 FAX: 512/463-1880	hlopez- cepero@governor.state.tx.us vford@governor.state.tx.us

VIII. 78th Legislative Session Chart

Texas State Board of Pharmacy Exhibit 18: 78th Legislative Session Chart		
Legislation Enacted - 78th Legislative Session		
Bill Number	Author	Summary of Key Provisions/Intent
H.B. 9	Rep. Flores	This bill adds a new Section 562.055 (titled Report to Texas Department of Health) to the Texas Pharmacy Act (Occupations Code, Subchapter J). This new section requires pharmacists to report to the Texas Department of Health "any unusual or increased prescription rates, unusual types of prescriptions, or unusual trends in pharmacy visits that may be caused by bioterrorism, epidemic or pandemic disease, or novel and highly fatal infectious agents or biological toxins that might pose a substantial risk of a significant number of human fatalities or incidents of permanent or long-term disability."

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Bill Number	Author	Summary of Key Provisions/Intent
H.B. 1095	Rep. Capelo	This bill amends the definition of practitioner in Section 551.003(34) of the Texas Pharmacy Act (Occupations Code, Subchapter J) and Section 483.001(12) of the Texas Dangerous Drug Act (Health and Safety Code, Chapter 483) to include the authority for advanced practice nurses and physician assistants to carry out prescriptions for controlled substances.
H.B. 1614	Rep. Chisum	This bill amends Section 562.108(a) of the Texas Pharmacy Act (Occupations Code, Subchapter J) to allow a Class E (Non-Resident) Pharmacy to maintain drugs in an emergency medication kit in a nursing home in this state provided the pharmacy is not more than 20 miles from the pharmacy.
H.B. 2292	Rep. Wohlgemuth/ Sen. Nelson	This bill adds a new Section 562.1085 (titled Unused Drugs Returned by Certain Pharmacists), which allows a consultant pharmacist in a nursing home to return to a pharmacy certain unused drugs, other than a controlled substance purchased from the pharmacy and a new Section 562.1086 (titled Limitation on Liability) to the Texas Pharmacy Act (Occupations Code, Subchapter J) that puts a limit on the liability of pharmacies returning these drugs.
H.B. 3486	Rep. Delisi	This bill also adds new Section 562.1085 (titled Unused Drugs Returned by Certain Pharmacists) and a new Section 562.1086 (titled Limitation on Liability) to the Texas Pharmacy Act (Occupations Code, Subchapter J). It appears that the language in HB 2292 will survive since Section 2.157 of HB 2292 states "In the event of a conflict between a provision of this Act and another Act passed by the 78 th Legislature, Regular Session, 2003, that becomes law, this Act prevails and controls regardless of the relative dates of enactment."
S.B. 144	Sen. Averitt/ Rep. McReynolds	<p>This bill adds a new Section 554.014 (titled Information Provided to License Holders) to the Texas Pharmacy Act (Occupations Code, Subchapter J) and new 554.015 (titled Poison Control Center Information).</p> <p>(1) Section 554.014 requires the Board of Pharmacy to provide information at least every two years to license holders on:</p> <ul style="list-style-type: none"> (a) prescribing and dispensing pain medications, with particular emphasis on Schedule II and Schedule III controlled substances; (b) abusive and addictive behavior of certain persons who use prescription pain medications; (c) common diversion strategies employed by certain persons who use prescription pain medications, including fraudulent prescription patterns; and (d) the appropriate use of pain medications and the differences between addiction, pseudo-addiction, tolerance, and physical dependence. <p>(2) Section 554.015 requires the Board of Pharmacy to provide to licensees, information regarding the services provided by poison control centers.</p> <p>(3) This bill requires this same information be provided to licensees by the Medical, Dental, Nursing, and Optometry Boards and requires the Boards by January 1, 2004, to:</p> <ul style="list-style-type: none"> (a) cooperate in developing the materials; and (b) ensure, to the extent possible, that the same information is contained in the materials used by each agency.

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Bill Number	Author	Summary of Key Provisions/Intent
S.B. 803	Sen. Janek	This bill adds a new Section 562.151 (titled Compounding Service and Compounded Drug Products). The new section specifies that a compounding pharmacist or pharmacy may advertise or promote: (1) non-sterile prescription compounding services provided by the pharmacist or pharmacy; and (2) specific compounded drug products that the pharmacy or pharmacist dispenses or delivers.
S.B. 939	Sen. Janek	This bill creates a new Section 568.006 (titled Ratio of Pharmacists to Pharmacy Technicians) of the Texas Pharmacy Act (Occupations Code, Subchapter J). The section allows the ratio of pharmacists to pharmacy technicians to be 1 to 5 in a pharmacy that dispenses not more than 20 different prescription drugs and does not produce intravenous or intramuscular drugs on-site.
S.B. 957	Sen. Van de Putte/Rep. Noriega	This bill also amends Section 562.108(a) of the Texas Pharmacy Act (Occupations Code, Subchapter J) to allow United States Department of Veterans Affairs pharmacy or another federally operated pharmacy to maintain drugs in an emergency medication kit in a veterans home.
S.B. 1315	Sen. Van de Putte/Rep. Capelo	This bill creates a new Section 560.063 (titled Establishment of Additional Pharmacy Classifications) of the Texas Pharmacy Act (Occupations Code, Subchapter J). The new section allows the Board of Pharmacy, by rule, to establish a new class of pharmacy licenses if the Board determines that: (a) the practice setting will provide pharmaceutical care services to the public; (b) the existing classifications of pharmacy licenses are not appropriate for that practice setting; and (c) establishment of a new classification of pharmacy license is necessary to protect the public health, safety, and welfare. This bill also adds a new subsection (g) to Section 562.101 of the Texas Pharmacy Act (Occupations Code, Subchapter J). This new subsection allows the Board to adopt rules regarding the pharmacist supervision of a pharmacy created under Section 560.063. The supervision must require at least continuous supervision by a pharmacist according to the needs of the pharmacy.
Legislation Not Passed - 78th Legislative Session		
Bill Number	Author	Summary of Key Provisions/Intent/Reason the Bill did not Pass
H.B. 129/ H.B. 963	Rep. Burnam	This bill would have regulated the sale of mercury, including a provision that requires pharmacists to dispense mercury fever thermometers only pursuant to a prescription.
H.B. 340	Rep. Uresti	This bill would have regulated the sale of products containing dextromethorphan (an ingredient included in many cough syrups).
H.B. 825	Rep. Marchant	This bill would have required pharmacies to place the manufacturer's expiration date for the drug on a prescription label.
H.B. 759	Rep. Wilson	This bill would have directed the Texas Department of Transportation to arrange for buses to take Texans to Mexico to purchase prescription drugs.

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Bill Number	Author	Summary of Key Provisions/Intent
H.B. 1381/ S.B. 1339	Rep. Thompson/ Sen. Wentworth	This bill would have amended the Medical Practices Act to allow a pharmacist to initiate emergency contraception under a collaborative drug protocol with a physician.
H.B. 1386/ S.B. 622	Rep. Hamrick/ Sen. Armbrister	This bill would have created an online customer service center at the Texas Department of Licensing and Regulation for all licensing agencies.
H.B. 1932	Rep. Capelo	This bill would have reversed the changes in the way a physician communicates instructions for generic substitution to a pharmacist made during the 77 th Legislative Session.
H.B. 2292	Rep. Wohlgemuth	The introduced version of this bill would have moved the Board of Pharmacy and most of the other health profession licensing agencies to the Department of Health.
H.B. 2802/ S.B. 1319	Rep. Giddings/ Sen. Nelson	This bill would have established a school of pharmacy at the University of North Texas Health Science Center at Fort Worth.
H.B. 2996	Rep. Capelo	This bill would have allowed the establishment of a mobile pharmacy that would operate under electronic supervision of a pharmacist.
H.B. 3092	Rep. Madden	This bill would have required pharmacies to notify the consumer of the actual cost of a prescription drug.
H.B. 3231/ S.B. 1353	Rep. Todd Smith/ Sen. Rodney Ellis	This bill would have established a sunset review of the Health Professions Council (HPC) and given HPC the authority to adopt rules and administrative policies for each of the member agencies.
H.B. 3302/ H.B. 3320/ S.B. 1746	Rep. Gutierrez/ Rep. Eiland/ Sen. Zaffirini	This bill would have established a regulatory scheme for Pharmacy Benefit Managers. TSBP was included, but the major requirements were to be established by the Department of Health and the Department of Insurance.
H.B. 3341/ S.B. 1540	Rep. Wohlgemuth/ Sen. Nelson	This bill would have allowed a pharmacy to receive and dispense prescription drugs that are part of a patient assistance program. The bill also specified if the quantity received by the pharmacy exceeded the quantity prescribed, the pharmacy could place the excess in the pharmacy's inventory for use in the normal course of business.
H.B. 3451	Rep. Noriega	This bill would have given psychologists authority to prescribe prescription drugs under a collaborative practice agreement with a physician.

IX. Policy Issues

PHARMACY PRACTICE ISSUES

ISSUE #1– DRUG THERAPY MANAGEMENT AUTHORITY

A. Should the authority for a pharmacist to perform drug therapy management under written protocol of a physician be modified to include the authority to “carry-out or sign” a prescription?

B. Discussion

The 74th Texas Legislature amended the definition of the practice of pharmacy to include performing for a patient a specific act of drug therapy management (DTM) delegated to a pharmacist by a written protocol from a physician. The Texas State Board of Pharmacy, in concert with the Texas State Board of Medical Examiners, has adopted rules for pharmacists engaged in DTM. These rules specify that DTM may include implementing or modifying drug therapy following diagnosis, initial patient assessment, and ordering of drug therapy by a physician as detailed in the protocol.

Through this authority, pharmacists are monitoring and adjusting a patient’s drug therapy. In most cases, the pharmacist who is monitoring the drug therapy is not the pharmacist that dispenses the patient’s prescriptions. Therefore, the DTM pharmacist calls in orders to adjust drug therapy under the delegated authority of the physician. However, the current law does not give pharmacists the authority to write an order to adjust drug therapy. This lack of authority sometimes delays therapy if the patient needs a written prescription. In these cases, the pharmacist has to obtain the physician’s signature on the prescription.

Patient care would be enhanced if the pharmacist had the authority to carry-out or sign prescriptions in the same manner as is allowed for advanced practice nurses and physician assistants under Chapter 157, Subchapter B, of the Texas Medical Practice Act.

Pharmacists have the knowledge and opportunity to help patients achieve better outcomes from drug therapy and, in turn, provide a significant cost savings to the Texas' healthcare system. The cost of this pharmaceutical care can possibly be recovered from the savings it generates. This can be realized only if an environment is created by healthcare reform that recognizes that the savings probably will not be generated at the pharmacist-patient level. The savings will be generated at the level of patients' therapeutic successes and from 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

Amend the Texas Pharmacy Act and Chapter 157 of the Medical Practice Act to allow pharmacists the authority to carry-out or sign prescription drugs.

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ISSUE #2 – ADMINISTRATION OF DRUGS

A. Should the definition of the practice of pharmacy be modified to clarify the authority a pharmacist has in administering drugs?

B. Discussion

The 75th Texas Legislature amended the definition of the practice of pharmacy to include the administration of an immunization or vaccination under a physician's written protocol. Section 554.004 of the Texas Pharmacy Act further specifies the conditions under which a pharmacist may administer drugs. This section is titled "Administration of Medication" and states that the Board shall specify conditions under which a pharmacist may administer medication, including an immunization and vaccination. This section was added by the 75th Legislature and the conditions listed were intended to apply to immunizations and vaccines. However, because the wording in this section applies to administration of any medication, it appears that pharmacists may not administer any medication without first complying with all of the provisions listed in the section.

C. Possible Solutions and Impact

Amend the Texas Pharmacy Act to clarify a pharmacist's authority to administer medications.

ISSUE #3 – PHARMACIST PROFESSIONAL DISCRETION

A. Should the Pharmacy Act be modified to clarify that pharmacists have professional discretion when deciding to dispense a prescription or medication order?

B. Discussion

The Pharmacy Act does not specifically state that pharmacists have the discretion to refuse to fill a prescription for any professional ground, such as if the pharmacist believes the prescription may present a danger to the patient. The Board has essentially interpreted the law in this manner since there is nothing to the contrary in the Pharmacy Act.

C. Possible Solutions and Impact

Clarify that pharmacists have professional discretion when deciding to dispense a prescription or medication order.

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ISSUE #4 – PHARMACY PEER REVIEW

A. Should Subchapter C of Chapter 564 be modified to give the Board the authority to require all pharmacies to establish a continuous quality improvement program that includes peer review?

B. Discussion

The 76th Texas Legislature, through the passage of S.B. 780, gave pharmacists and the Board a valuable tool 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. The bill specifies that a Pharmacy Peer Review Committee may be established to:

- (1) evaluate the quality of pharmacy services or the competence of pharmacists;
- (2) suggest improvements in pharmacy systems to enhance patient care; and
- (3) investigate disagreements or complaints, determine facts, and make recommendations or issue decisions in a written report.

Most importantly, this report makes the records of a pharmacy peer review committee confidential and not subject to disclosure, discovery, or subpoena. In May 2001, the Board published *Guidelines for Establishing Pharmacist Peer Review Committees* to assist pharmacists and pharmacy owners in establishing continuous quality improvement programs that include peer review. These programs should allow pharmacists to thoroughly study their dispensing and distribution systems in order to establish a safer system.

Since this bill became effective in September 1999, the Board has ordered pharmacies charged with dispensing errors to develop and implement a continuous quality assurance program to detect errors, to rectify errors that have occurred, and to prevent future errors. During this time period, the Board has placed this sanction on over 50 pharmacies. Information received from pharmacies that have implemented peer review programs indicates that the programs are successful in identifying problems that may lead to dispensing errors.

Recently, other states have implemented similar programs. California recently passed legislation that requires all pharmacies to establish or participate in “a *quality assurance program which documents and assesses medication errors to determine cause and an appropriate response as part of a mission to improve the quality of pharmacy service and prevent errors.*”

C. Possible Solutions and Impact

Currently, the Texas Peer Review authority does not include a provision that specifies the Board may require all pharmacies to establish peer review programs. Because of the broad authority for rule making included in the Pharmacy Act, the Board could adopt rules that require such a program. However, this authority would be clear if the Act were amended to specify the Board has the authority to mandate peer review.

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ISSUE #5 – PREVENTING MEDICATION ERRORS BY REQUIRING PRESCRIPTIONS TO BE LEGIBLE

A. Should the Pharmacy and other Practice Acts be amended to require written prescriptions to be legible?

B. Discussion

Illegible prescriptions continue to contribute to medication errors. Currently, Texas laws require that the name, address, and telephone number of the practitioner at the practitioner's usual place of business be legibly printed or stamped on the prescription, but they do not require the prescription itself to be legible. In 1999 a jury in Texas awarded a patient a large settlement and specifically noted in their decision that the bad handwriting of the physician contributed to the error.

C. Possible Solutions and Impact

Recently, Florida has passed a law that requires the practitioner to legibly print or type a prescription, so it is “capable of being understood by the pharmacists filling the prescription.” Texas laws could be structured in a similar fashion.

ISSUE #6 – VALID PRACTITIONER-PATIENT RELATIONSHIP

A. Should the Texas Pharmacy Act specify that a legal prescription must be based on a valid practitioner-patient relationship and define the requirements for such a relationship?

B. Discussion

The Texas Pharmacy Act does not currently define the professional responsibility of a pharmacist to dispense a prescription based on a valid practitioner-patient relationship.

The Board has adopted a rule in Section 291.34(b)(1), which requires a pharmacist to exercise professional judgment with respect to whether a prescription is valid and states that a pharmacist may not dispense a prescription he/she knows or should have known to be based on an Internet or telephonic consultation without a valid practitioner-patient relationship, unless an emergency situation exists. However, the rule relies on the interpretation of the Texas State Board of Medical Examiners of a valid practitioner-patient relationship.

The Controlled Substance Act Section 481.074 and the Dangerous Drug Act Section 483.021 have similar provisions which require a pharmacist to dispense a drug only when based on a valid prescription, and that the pharmacist cannot dispense the drug if he/she knows the prescription is without a valid practitioner-patient relationship.

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C. Possible Solutions and Impact

Amend the Texas Pharmacy Act and the Texas Medical Practice Act to specifically state that a pharmacist cannot dispense a drug he knows or should have known is not based on a valid practitioner-patient relationship, and define the parameters that constitute such a relationship.

ENFORCEMENT RELATED ISSUES

ISSUE #7 – DISCIPLINARY GROUNDS FOR PHARMACISTS

A. Would the protection of the public be enhanced by adding additional grounds for disciplinary action of pharmacists?

B. Discussion

Issues have arisen over the past several years during the prosecution of pharmacists and pharmacies that have raised the question as to whether additional disciplinary grounds would be appropriate in the Texas Pharmacy Act. At times during the disciplinary process, the agency's authority to take disciplinary action in certain situations was limited by the current statutory scheme governing disciplinary grounds.

(1) *Supervision of pharmacy technicians*

Current disciplinary grounds were developed at a time when pharmacists were the primary individuals involved in the dispensing process. Today, this situation has changed dramatically with the presence of the pharmacy technicians. Pharmacists have taken on a new role to oversee the processing of prescriptions and perform those duties that require a pharmacist's specific knowledge and input, leaving other more routine tasks to be performed by the pharmacy technicians. The current disciplinary scheme does not adequately take this situation into account, because the agency does not have the statutory authority to discipline a pharmacist for failing to adequately supervise the activities of the pharmacy technicians. The agency has implemented rules to address this situation [e.g. Section 291.32(c), applicable to Class A pharmacies, states that pharmacists are solely responsible for direct supervision of technicians], but a statutory change would also be beneficial in enforcement actions.

(2) *Violations of disciplinary orders*

When a pharmacist has been disciplined by the Board, the order often contains certain terms and conditions that are required of the licensee. The current disciplinary provisions do not specify that to violate the order would constitute a violation of the Pharmacy Act. When the Board issues an order with terms and conditions, these provisions are included in the order so that the licensee can continue to practice while the Board monitors the licensee. Without the ability to monitor the licensee, the Board

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cannot properly protect the public. Therefore, when the licensee violates the terms of the order, the Board should be able to take action based on the violation of the Board's previous order. Although the Board has adopted a rule under Section 281.7(a)(19), which defines "unprofessional conduct" to include violating the terms of a disciplinary order, the statutory change is considered beneficial.

(3) *Repeat disciplinary actions for impaired licensees*

The Pharmacy Act, Section 564.002, provides that the records and proceedings of the Board involving an impaired pharmacist are confidential and not subject to public disclosure. This confidentiality provision applies to disciplinary orders that contain terms and conditions in the order so that the licensee can continue to practice while the Board monitors the licensee. Often a licensee on such an order suffers from chemical dependence, and relapses while on the order or violates the order in some other way. Any subsequent order involving the impairment is also confidential under the current statute.

The Board does not have the discretion to make any subsequent disciplinary actions public, which could serve as a deterrent for impaired individuals and could prevent additional relapses. The licensee under a confidential disciplinary action has no incentive to avoid further action because each additional action will be confidential and not subject him/her to any further scrutiny by employers or the public.

(4) *Misdemeanor violations of the Dangerous Drug or Controlled Substances Acts and deferred adjudication of felony offenses*

The Texas Pharmacy Act authorizes the Board to discipline a pharmacist who has been **convicted** of a misdemeanor involving moral turpitude or a felony. Tex. Occ. Code Ann. § 565.001(a)(6).

The Texas Pharmacy Act allows the Board to suspend the license of a pharmacist who has received deferred adjudication or a suspended or probated sentence for certain felony drug offenses under the Controlled Substances Act, Dangerous Drug Act, or the federal Comprehensive Drug Abuse Prevention and Control Act of 1970. Tex. Occ. Code Ann. §565.060. The Board may revoke the license of a pharmacist who is imprisoned or may assess a fine under these particular felony drug offenses.

If a pharmacist is subject to a court order granting **deferred adjudication** based on a plea of guilty or of nolo contendere, the Board can only take action if the deferred adjudication is based on the **felony** drug offenses under the Controlled Substances Act, Dangerous Drug Act, or the federal Comprehensive Drug Abuse Prevention and Control Act of 1970. In addition, if a pharmacist receives deferred adjudication on any misdemeanor offense, including misdemeanors under these drug laws, the Board may not be able to impose disciplinary action unless there is also evidence that the licensee is impaired. Thus, if a licensee receives deferred adjudication on any felony, other than under the Controlled Substances Act, Dangerous Drug Act, or the federal Comprehensive Drug Abuse Prevention and Control Act of 1970, or on any misdemeanor, the Board currently may not be able to take disciplinary action.

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(5) *Disciplinary action in another state*

The disciplinary ground for pharmacists who have been disciplined in another state is limited to those whose licenses are canceled, revoked, surrendered, or suspended for conduct substantially equivalent to violations of the Texas Pharmacy Act.

When TSBP places a pharmacist on probation, the license is legally suspended and then placed on probation. In many other states, this practice is not followed. The state merely places the licensee on probation and does not first suspend or revoke the license. The procedure followed by the other states creates a problem when TSBP wants to discipline the pharmacist based on the findings in the out-of-state order. TSBP cannot use the order itself as a basis for discipline but must obtain the underlying information and prosecute the pharmacist based on that evidence.

The same problem arises when another state denies the license of a pharmacist. That pharmacist could come to Texas, and although he/she was not adequately qualified to practice in the other state, TSBP would have no grounds to deny the license in Texas.

C. Possible Solutions and Impact

- (1) Modify disciplinary grounds to allow the agency to discipline a pharmacist for the following:
 - (A) not properly supervising pharmacy technicians;
 - (B) violation of disciplinary order; and
 - (C) violation of contract with a committee of a professional society with a program to aid licensees impaired by chemical abuse or mental or physical illness.
- (2) Give the Board the option to make a second order against a person who has a chemical, mental or physical impairment non-confidential.
- (3) Allow the Board to discipline a licensee:
 - (A) who has been convicted of or received deferred adjudication for a misdemeanor or a felony involving a violation of the Dangerous Drug or Controlled Substances Acts;
 - (B) who has been convicted of or received deferred adjudication for a misdemeanor involving moral turpitude or a felony; and
 - (C) when a disciplinary action has been imposed in another state without limiting the type of disciplinary action.

The agency would have the ability to better fulfill its legislative purpose to promote, preserve, and protect the public health, safety, and welfare by having additional disciplinary grounds to discipline pharmacists.

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ISSUE #8 – DISCIPLINARY GROUNDS FOR PHARMACIES LOCATED IN TEXAS

A. Should the disciplinary grounds for pharmacies be expanded to allow the agency to be able to take disciplinary action against a pharmacy that has violated laws of another jurisdiction or when an owner or managing officer has violated a drug law of the state?

B. Discussion

(1) *Disciplinary action in another state*

Current disciplinary grounds were developed at a time when pharmacies were primarily processing prescriptions for patients located in the same area as the pharmacy. Today, some pharmacies (e.g., mail order pharmacies) have evolved to handling prescriptions for individuals around the state and in other states in the country. When a pharmacy sends prescriptions to other states, most of these states also require that the pharmacy have a license in that state (just as TSBP does for out-of-state pharmacies sending prescriptions to patients in Texas). If another state takes disciplinary action against a pharmacy located in Texas, TSBP has no authority to take disciplinary action against the pharmacy based on that action.

TSBP does currently have authority for such disciplinary action against Texas pharmacists disciplined in another state. If the action in the other state is based on conduct that would also be a violation in this state, TSBP can take action against a pharmacist whose license has been canceled, revoked, surrendered, or suspended in the other state.

(2) *Violation of drug law by owner or managing officer of a pharmacy*

The Pharmacy Act Section 565.002(1) allows for discipline of an applicant or holder of a pharmacy license if the applicant or license holder has been convicted of a misdemeanor involving moral turpitude or a felony, or if a managing officer of the pharmacy has been convicted of a misdemeanor involving moral turpitude or a felony. The Board has no ability to discipline a pharmacy if the owner or managing officer has received deferred adjudication or a suspended or probated sentence for any offense, including misdemeanor or felony drug offenses. Pharmacies routinely, as part of their standard operation, possess and handle controlled substances and other abusable drugs that are subject to diversion and sale on the street. Currently, the Board does not have the ability to deny a license or discipline a pharmacy that has an owner or managing officer who has committed criminal violations of the drug laws, unless the violations resulted in felony convictions.

(3) *Audit shortages of prescription drugs and/or controlled substances*

The current disciplinary grounds for pharmacies includes failing to maintain required pharmacy records as a violation in the Texas Pharmacy Act Section 565.002(8). This disciplinary ground is the violation used by the Board to allege that the pharmacy is responsible for audit shortages. Rather than using this vague ground, the preferable method of charging this type of violation would be to specifically state that the pharmacy

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is responsible for and can be disciplined for audit shortages of prescription drugs, including controlled substances.

C. Possible Solutions and Impact

Modify the disciplinary grounds for pharmacies to allow the agency to take disciplinary action when:

- (1) a pharmacy has been subject to disciplinary action by another jurisdiction's licensing agency. This change would allow the agency to take disciplinary action without having to prove the merits of the case, based on the due process received in another state, so long as the violation would also be a violation of Texas law;
- (2) the owner or managing officer has violated the drug laws under the Texas Controlled Substances Act, the Texas Dangerous Drug Act, the Comprehensive Drug Abuse Prevention and Control Act of 1970, and certain provisions of the Health and Safety Code relating to Abusable Volatile Chemicals; and
- (3) the pharmacy has audit shortages.

The agency would be able to more effectively discipline pharmacies in situations that warrant disciplinary action. When another state takes action against a pharmacy, TSBP should be able to take action based on the other state's action, just as TSBP can do for pharmacists. Additionally, the Board will be able to deny licensure or discipline a pharmacy when an owner or managing officer has violated drug laws, which currently may not have been possible if the individual was not also a pharmacist.

ISSUE #9 – DISCIPLINARY GROUNDS FOR PHARMACIES LOCATED OUTSIDE OF TEXAS

A. Should the disciplinary grounds for out-of-state pharmacies be expanded to allow the agency to prosecute those pharmacies for the same violations of law as pharmacies located in Texas?

B. Discussion

The current disciplinary scheme for out-of-state pharmacies does not adequately protect the public, because the laws governing the safety of the prescriptions from another state may not be as stringent as those in Texas. The disciplinary grounds for out-of-state pharmacies, i.e., Class E pharmacies, are substantially limited. For example, TSBP is unable to take action against Class E pharmacies that are disciplined by other states, which is similar to the situation for in-state pharmacies described above in #2.

Additionally, TSBP can only initiate action against the pharmacy if the other state's licensing agency fails to timely initiate or resolve the complaint.

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C. Possible Solutions and Impact

Modify the disciplinary grounds for pharmacies to allow the agency to take disciplinary action against an out-of-state pharmacy for the same reasons as a pharmacy located in Texas. An out-of-state pharmacy that ships into Texas should be required to follow the same laws as a pharmacy located in Texas, unless complying with Texas law would violate the other state's law. This change would place in-state and out-of-state pharmacies on a level playing field and allow the Board to consistently and fairly enforce the pharmacy laws of the state.

ISSUE #10 – DISCIPLINARY GROUNDS FOR PHARMACY TECHNICIANS

A. Should the disciplinary grounds for pharmacy technicians be expanded to include other violations similar to those of pharmacists?

B. Discussion

The current disciplinary scheme for pharmacy technicians in Section 568.003 of the Pharmacy Act allows TSBP to discipline for the following violations:

- (1) violated this subtitle or a rule adopted under this subtitle;
- (2) engaged in gross immorality, as that term is defined by the rules of the Board;
- (3) engaged in any fraud, deceit, or misrepresentation, as those terms are defined by the rules of the Board, in seeking a registration to act as a pharmacy technician;
- (4) been convicted of a misdemeanor involving moral turpitude or a felony;
- (5) a drug or alcohol dependency;
- (6) violated:
 - (A) Chapter 481 or 483, Health and Safety Code, or rules relating to those chapters;
 - (B) Sections 485.031-485.035, Health and Safety Code; or
 - (C) a rule adopted under Section 485.011, Health and Safety Code;
- (7) violated the pharmacy or drug laws or rules of this state, another state, or the United States; or
- (8) had a registration as a pharmacy technician issued by another state revoked, surrendered, or suspended for conduct substantially equivalent to conduct described by Subsections (1)-(6).

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The Board is unable to discipline a pharmacy technician for serious actions, such as when a pharmacy technician engages in unprofessional conduct or negligent actions. If a technician is involved in a dispensing error, or if he/she operates outside the scope of practice, the Board does not have statutory authority to take action.

C. Possible Solutions and Impact

Allow the Board to discipline a pharmacy technician for grounds similar to those of a pharmacist, including engaging in unprofessional conduct, as defined by Board rule, or acting in a negligent manner. This change would allow the Board to take action against a technician for those acts that the technician should be held responsible for, and would allow for a similar range of disciplinary grounds for all licensees.

ISSUE #11 – DISCIPLINARY SANCTIONS FOR PHARMACIES OR PHARMACISTS

A. Should the Board be able to impose the range of disciplinary sanctions authorized for violations of Board rule and should the Board be able to place terms and conditions on a licensee as part of a disciplinary action?

B. Discussion

(1) *Rule violation*

Section 565.051 of the Pharmacy Act sets forth the range of disciplinary sanctions the Board is authorized to impose on a pharmacist or pharmacy license. The sanctions include suspension, revocation, restriction, administrative penalty, denial, probation, reprimand, retirement, or any combination of the sanctions. However, if the Board finds that a licensee has violated a rule that is not also a violation of a statute, the Board is not authorized to revoke, deny, or retire a license. This scheme limits the Board's ability to discipline a licensee according to the severity of his/her actions. Even if a licensee violates a rule, the severity of the violation may be just as great as when a statutory violation exists. This statute contradicts the legislature's grant of authority to the Board to properly regulate the practice of pharmacy and adopt rules necessary to protect the public health and welfare. Tex. Occ. Code Ann. § 554.001.

(2) *Terms and conditions*

The discipline authorized allows the Board to impose a probation but then specifically lists the following actions that may be imposed by the Board. The licensee must:

- (A) report regularly to the Board on matters that are the basis of the probation;
- (B) limit practice to the areas prescribed by the Board;

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- (C) continue or review professional education until the license holder attains a degree of skill satisfactory to the Board in each area that is the basis of the probation; or
- (D) pay the Board a probation fee to defray the costs of monitoring the license holder during the period of probation.

The Board should be able to impose other terms and conditions on the licensee depending upon the violations that are alleged in the order, so that the Board can properly monitor the licensee and ensure the public safety.

C. Possible Solutions and Impact

Remove the restriction for limited sanctions for rule violations and allow the Board to determine the sanction based on the severity of the violation, and add the ability to impose general terms and conditions as part of a probation. These changes should result in overall fairness and consistency in disciplinary actions.

ISSUE #12 – DISCIPLINARY SANCTIONS FOR INTERNS

A. Should the Board be able to impose a broader range of disciplinary sanctions for pharmacist-interns than those currently authorized?

B. Discussion

The Pharmacy Act Section 557.004 allows the Board to deny, restrict, suspend, or revoke a pharmacist-intern's registration based on a violation of the Pharmacy Act. This scheme gives the Board little flexibility to allow an intern to begin an internship, but still impose some type of less severe disciplinary action for minor violations of the law.

C. Possible Solutions and Impact

Allow for a greater range of disciplinary sanctions, such as reprimand, administrative penalty, or probation, similar to the sanctions allowed for other licensees. This change allows the Board to discipline a pharmacist-intern for minor violations without either restricting the internship or denying the ability to participate in the internship completely.

ISSUE #13 – DISCIPLINARY SANCTIONS FOR PHARMACY TECHNICIANS

A. Should the Board be able to impose a broader range of disciplinary sanctions for pharmacy technicians than those currently authorized?

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B. Discussion

The Pharmacy Act, Section 568.003, allows the Board to deny, suspend, or revoke a pharmacy technician's registration based on various disciplinary grounds. This scheme gives the Board no flexibility to impose some type of disciplinary action for minor violations of the law while allowing a pharmacy technician to practice. Without additional types of sanctions, the Board will be faced with the choice of completely ignoring a violation of law or imposing a "death sentence" (i.e., resulting in the inability to practice at all).

Additionally, the Board does not currently have the authority to reinstate a registration once it has been revoked. This limitation would result in a permanent revocation for pharmacy technician registrations.

C. Possible Solutions and Impact

Allow for a greater range of disciplinary sanctions, such as reprimand, administrative penalty, restriction, or probation, similar to the sanctions allowed for other licensees. This change allows the Board to discipline a pharmacy technician without requiring that he/she cease practicing. Also, allow the Board to reinstate a registration if a pharmacy technician has demonstrated rehabilitation.

ISSUE #14 – EMERGENCY SUSPENSION PROCESS

A. Should the agency's emergency suspension procedure be modified to allow for a more efficient process that would result in a system that can be used to protect the public?

B. Discussion

Section 565.059 of the Pharmacy Act governs temporary suspension of license. The first problem arises because this section applies only to pharmacists, and not to pharmacies and pharmacy technicians. Therefore, when a dangerous situation arises with a pharmacy or pharmacy technician that constitutes a continuing threat to the public, the Board cannot take any immediate action, but rather must follow the standard procedure for disciplinary action, which can take several months to complete.

Secondly, the procedure for pharmacists is cumbersome and complicated. The entire Board must meet to determine from the evidence and information presented whether grounds exist to temporarily suspend the license of a pharmacist. The Board does have the ability to suspend the license without notice or hearing if a hearing is scheduled within 14 days, but again the entire Board must be present to vote on the suspension order and then presumably again to attend the hearing. This procedure creates a problem in that a quorum of the entire Board must be present to hold a hearing, and also, once the entire Board has heard both evidence and information on the temporary suspension, the pharmacist could certainly argue that the Board Members who were present to vote on the suspension should recuse themselves from any additional proceedings involving the same matter. This scenario would then create a serious

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quorum problem when a final order is presented to the Board, because there may never be enough Board Members to have a quorum for the vote on the final order.

C. Possible Solutions and Impact

Modify the procedure to allow a panel of the Board to hear the temporary suspension hearing and proceed to the State Office of Administrative Hearings for a hearing under the Administrative Procedure Act. The ability to suspend the license without notice or hearing should be maintained so long as disciplinary action is instituted at the same time and an informal conference is held within a specified period of time.

The ability for the panel to meet by telephone should also be included to expedite the hearing if the public is endangered by not acting immediately.

ISSUE #15 – MAINTENANCE OF PHARMACY RECORDS

A. Should a specific requirement be included in the Pharmacy Act mandating that pharmacy prescription records be maintained for five years from the date of dispensing in a pharmacy?

B. Discussion

The Pharmacy Act does not currently address any record retention periods for maintaining prescription records in the pharmacy. The Board has, however, adopted rules [e.g. Section 281.34(a) for Class A pharmacies] that require records to be maintained for a period of two years, which corresponds with the retention periods required by the Controlled Substances Act Section 481.067 (Records) and the Dangerous Drug Act Section 483.023 (Retention of Prescriptions).

A two-year time period may not be sufficient since the pharmacies are now required to report malpractice claims to TSBP. In turn, TSBP is then required to review malpractice claims if three claims are filed within five years. This investigation could result in possible disciplinary action. Without the proper dispensing records, TSBP will be unable to investigate or take disciplinary action. If a pharmacy is only required to maintain records for two years, the records required to undertake a proper investigation and disciplinary action may no longer exist.

C. Possible Solutions and Impact

Amend the Pharmacy Act to provide for a specific record retention period for prescription records maintained by a pharmacy of a minimum of five years from the date of dispensing.

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ISSUE #16 – CANCELLATION OF LICENSE

A. Should TSBP have the ability to cancel a license?

B. Discussion

During the 77th Legislative Session, the Pharmacy Act was codified under the Texas Occupations Code. In this process, the legislature removed the ability of the agency to cancel the license in a disciplinary procedure. Often, in negotiating a disciplinary action, a pharmacist would be willing to accept cancellation of his/her license and not revocation, although the effect of either is the same.

C. Possible Solutions and Impact

Return the ability to cancel a license by amending Section 565.051 of the Pharmacy Act.

ISSUE #17 – AUTHORIZATION FOR INSPECTIONS

A. Should inspections conducted by TSBP compliance officers be authorized for general regulation of pharmacies?

B. Discussion

The Pharmacy Act, Section 556.001, authorizes a representative of the Board to enter and inspect a pharmacy relating to: (1) drug storage and security, (2) equipment, (3) sanitary conditions, and (4) records, reports, or other documents required by federal and state drug laws. The authorized reasons for inspections limit the Board's ability to properly inspect and determine whether a pharmacy is truly compliant with the law and offering safe pharmacy services to the public.

The Board's focus for the past several years has been on outcome-based regulation, which means that the Board is primarily concerned with the outcome of the services provided. In order to enforce this policy, the Board should be able to inspect for such issues as verbal patient counseling, drug regimen review records, incident reports regarding dispensing errors, pharmacy procedures, or any other business record maintained by the pharmacy.

C. Possible Solutions and Impact

Expand the Board's inspection authority to include the ability to enter a pharmacy for general regulation purposes.

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ISSUE #18 – ACCESS TO FINANCIAL AND PRICING DATA

A. Should the limitation on inspections that prohibits the inspections extending to financial data, sales data, and pricing data be deleted?

B. Discussion

Section 556.054 of the Pharmacy Act places limitations on the inspections of facilities in that inspections may not extend to:

- (1) financial data;
- (2) sales data, other than shipment data; and
- (3) pricing data.

This restriction severely hampers prosecution of Internet pharmacies, in that pricing of prescription drugs is clearly relevant particularly when determining whether a valid physician-patient relationship exists for a physician to prescribe a medication. Without pricing data, it is more difficult to prosecute Internet pharmacies that are operating illegally and charging extremely high prices for abusable drugs, such as hydrocodone. For example, if a pharmacy charges a 1000% markup on a drug, this evidence may suggest that an invalid physician-patient relationship exists and the prescription issued by the physician is illegal. Without the ability to access pricing data, the Board would be unable to effectively establish such a violation.

In addition, the restriction against access to pricing data restricts the Board from properly enforcing the generic substitution laws in the Pharmacy Act, Section 562.011, which requires that a less expensive generically equivalent drug be substituted for the prescribed drug, and that the pharmacist may not charge a higher professional fee for the substituted drug than the brand name. Without access to financial data, the Board has no way to determine whether a violation exists or to ultimately prosecute this violation of law.

Finally, the Board does not have access to the required evidence to prosecute a charge of flagrant overcharging. Section 101.203 of the Occupations Code, which applies to member agencies in the Health Professions Council, which includes TSBP, specifically gives the Board the authority to regulate overcharging or overtreatment under Section 311.0025 of the Health and Safety Code. That statute provides that the appropriate licensing authority may audit the billings and patient records of a health care professional if a complaint is filed about a bill for treatment. However, under the Pharmacy Act, TSBP does not have the independent authority to obtain financial data, which would be required to properly investigate an overcharging issue.

C. Possible Solutions and Impact

Expand the Board's inspection authority to include the ability to inspect financial data, sales data, and pricing data.

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MISCELLANEOUS ISSUES

ISSUE #19 – LICENSING PROCEDURES

A. Should the requirements for licensure as a pharmacist or pharmacy technician include a provision that the applicant be in the United States legally and be legally able to work?

B. Discussion

The licensure requirements currently do not contain any requirements that an applicant be in the United States legally and be legally able to work. Therefore, assuming that all other licensure requirements are met, the Board would not have grounds to refuse to issue the license.

C. Possible Solutions and Impact

Modify Sections 558.051 and 558.101 of the Pharmacy Act for pharmacists' qualifications for license and Section 568.002 for pharmacy technicians to include a provision that the applicants be in the United States legally and be legally able to work prior to issuing a license for pharmacists and pharmacy technicians.

ISSUE #20 – BOARD MEMBER QUALIFICATIONS

A. Should the faculty members of colleges of pharmacy be able to serve as TSBP Board Members?

B. Discussion

Section 555.004(b) of the Pharmacy Act currently contains a restriction that faculty members of colleges of pharmacy cannot serve as TSBP Board Members. This restriction prevents qualified members of the pharmacy profession from serving on the Board, and prevents the Board from having input from the academic sector of the pharmacy profession.

C. Possible Solutions and Impact

Amend Section 555.004(b) of the Pharmacy Act to allow faculty members of colleges of pharmacy to serve on the TSBP. This change would allow for valuable input from a section of pharmacy practice that has not previously been represented on the Board.

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ISSUE #21 – CONFIDENTIALITY OF PHARMACIST HOME ADDRESSES

A. Should the home addresses of pharmacists be exempted from public disclosure under the Texas Public Information Act?

B. Discussion

Neither the Public Information Act nor the Texas Pharmacy Act contain any statutory provisions that would allow the TSBP to withhold the home addresses of its licensees. Therefore, since the home addresses, as well as the business addresses, are collected by TSBP, the home address would be subject to public disclosure. The home addresses are necessary information for the agency to maintain, because if a pharmacist cannot be located at his/her place of employment, the home address provides the agency an alternate means of contacting the licensee for the agency. Since a pharmacist may change employment, the home address provides a second mechanism to allow TSBP to locate the pharmacist.

The home address of a licensee is information that could be considered private and worthy of protection from public disclosure. Many reasons could exist that would justify allowing the TSBP to withhold this information, including safety of the pharmacist, protection of private information, etc.

C. Possible Solutions and Impact

Amend the Texas Pharmacy Act, or other appropriate act, to allow home addresses of pharmacists to be exempted from release under the Texas Public Information Act. This amendment would protect this private information from public disclosure.

ISSUE #22 – NON-PHARMACIST PRECEPTOR

A. Should a non-pharmacist be allowed to be a preceptor under certain limited circumstances in college-based internship programs?

B. Discussion

The Pharmacy Act currently requires that preceptors who supervise and train pharmacist interns be licensed pharmacists. In certain circumstances, when the pharmacist interns are actually being supervised by other healthcare professionals, the agency does not have the discretion to allow the preceptor to be another type of healthcare professional.

C. Possible Solutions and Impact

Amend the Texas Pharmacy Act to allow a non-pharmacist to be a preceptor under certain limited circumstances in college-based internship programs.

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ISSUE #23 – BOARD MEMBER PER DIEM

A. Should the Pharmacy Act clearly indicate that all Board Member travel expenses are reimbursable?

B. Discussion

The Pharmacy Act Section 552.009 states that a Board Member can be reimbursed for transportation expenses as prescribed by the General Appropriations Act, and that he/she may not be reimbursed for any other travel expenses, including expenses for meals and lodging.

This language is not consistent with the Appropriations Act, Article IX, Section 4.04, which indicates that reimbursement for actual expenses for meals and lodging are specifically included in the per diem of Board Members.

C. Possible Solutions and Impact

Amend the Pharmacy Act, Section 552.009, to indicate that all travel expenses, including meals and lodging, are reimbursable. This amendment would make the Pharmacy Act consistent with other state law, and allow for Board Members who are serving in the public interest to be reimbursed for expenses directly related to their service to the public.

ISSUE #24 – PEACE OFFICERS ABILITY TO CARRY A FIREARM AND ARREST

A. Should peace officers commissioned by the Board be able to carry a firearm or make an arrest?

B. Discussion

The Texas Pharmacy Act Section 554.011 authorizes the Board to commission peace officers to enforce the act if the employees have been certified as qualified to be peace officers by the Commission on Law Enforcement Officer Standards and Education. The act further specifies that the peace officer has the powers, privileges, and immunities of a peace officer, but may not carry a firearm or make an arrest.

The employees that are commissioned as peace officers by the Board are investigators who travel a majority of the time to perform their job functions. They have often requested to be allowed to carry a firearm while traveling for their personal safety. Additionally, peace officers have a duty to protect the public, particularly if they witness the commission of a crime. Without the ability to carry a firearm and make an arrest, they would be virtually powerless to ensure the safety of the public in such a situation.

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C. Possible Solutions and Impact

Amend the Pharmacy Act to allow peace officers to carry a firearm in limited situations and to make arrests. The ability to carry a firearm would be limited to carrying the firearm outside a pharmacy unless a life-threatening situation exists.

ISSUE #25 – REGISTRATION OF PHARMACY TECHNICIANS-IN-TRAINING

A. Should the Act be amended to give the agency the authority to register and regulate pharmacy technician trainees?

B. Discussion

Currently, Section 568.001 of the Texas Pharmacy Act specifies that the Board shall require a pharmacy technician to have passed a board-approved pharmacy technician certification examination. Thus, the Board may not register the technician until he/she has passed this examination. However, most pharmacy technicians work in a pharmacy while studying to take this examination. Current Board rules allow a person to work as a “pharmacy technician trainee” for up to one year while participating in a pharmacy’s technician training program in preparation for the exam. Because the “pharmacy technician trainee” cannot be registered by the Board, the agency has no authority to discipline these individuals even though they have access to prescription drugs.

C. Possible Solutions and Impact

Amend the Texas Pharmacy Act to allow the Board to register an individual while they are working in a pharmacy as a pharmacy technician-in-training, similar to the registration method currently used for pharmacist-interns.

ISSUE #26 – PHARMACY TECHNICIANS NOT WORKING IN A PHARMACY

A. Should the definition of a pharmacy technician be amended to clarify that the Board may register pharmacy technicians that are not currently working in a pharmacy?

B. Discussion

Currently the definition of a pharmacy technician specifies that a pharmacy technician is an 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. If this definition is read literally, it would require the Board to remove a pharmacy technician’s registration if that technician did not work in a pharmacy, even if the individual had left one job and was seeking another job as a pharmacy technician.

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C. Possible Solutions and Impact

Amend the Pharmacy Act to remove the requirement that a pharmacy technician be employed by a pharmacy.

X. Comments

None.