

# OVERVIEW OF AGENCY SCOPE AND FUNCTIONS

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## STATUTORY BASIS AND HISTORICAL PERSPECTIVE

The Texas State Board of Pharmacy is an independent state health regulatory agency, operating under the authority of its enabling legislation, the Texas Pharmacy Act (Texas Occupations Code Ann., Chapters 555-566 and 568-569) and the Texas Dangerous Drug Act (Health and Safety Code, Chapter 483).

The Pharmacy Act states:

*It is the purpose of this Act to promote, preserve, and protect the public health, safety, and welfare by and through the effective control and regulation of the practice of pharmacy and the licensing of pharmacies engaged in the sale, delivery, or distribution of prescription drugs and devices used in the diagnosis and treatment of injury, illness, and disease.*

The Act goes on to say:

*The board shall enforce this Act and all laws that pertain to the practice of pharmacy and shall cooperate with other state and federal governmental agencies regarding any violations of any drug or drug-related laws.*

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

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- 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. The Texas Legislature created the Triplicate Prescription Program, requiring special forms for a patient to receive a Schedule II controlled substance.
- 1983 Texas Legislature, through amendments to the Texas Pharmacy Act, established a program to address the 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.
- 1995 Texas Legislature, after creating the Health Professions Council in 1993, required all health regulatory boards to collocate 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.
- 2000 The American Council on Pharmaceutical Education revised its standards to require all graduates of approved colleges of pharmacy to complete a six-year doctoral program, which is titled Pharm.D.
- 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.
- 2005 Texas Legislature, through amendments to the Texas Pharmacy Act, extended the agency's existence for another 12 years following the agency's review by the Sunset Advisory Commission. Other significant amendments to the Act include the following.
- Abolishment of the dedication of the Board of Pharmacy fund.

- Amendments regarding pharmacy technicians, including a requirement that TSBP register pharmacy technician trainees; an increased range of disciplinary sanctions, such as probation and administrative penalties that the Board may impose on pharmacy technicians; and expanded grounds for discipline, including deferred adjudication for misdemeanor offenses involving moral turpitude and any felony offenses.
- A requirement that the Board maintain a list of all licensed pharmacies that maintain an Internet web site, including the pharmacy name, license number, and state in which it is located. In addition, the bill requires all pharmacies that maintain a web site to post information on how a consumer may file a complaint regarding the pharmacy with the Board.
- Amendments to the Act regarding Class E (Non-Resident Pharmacies) to make these pharmacies subject to the same grounds for discipline as in-state pharmacies and allow the Board to take action on complaints immediately, rather than after referral and action by the Board in the home state.
- Amendments to the provisions of the Act regarding Temporary Suspension of a License/Registration that allows a panel of three Board members to hear temporary suspension cases rather than the whole Board when the public is in immediate danger. This change makes the process more feasible.
- Amendments to the Act concerning pharmacy compounding that allow Class A & Class C Pharmacies to compound prescription drugs for *Office Use* by a practitioner; Class A Pharmacies to compound prescription drugs for a Class C Pharmacy; and Class C Pharmacies to “prepackage” prescription drugs for use by other Class C pharmacies under common ownership. In addition, the amendments clarify that TSBP may inspect pharmacies relative to components used in compounding and sample these items.
- A provision that required the Texas State Board of Pharmacy to inspect and authorize Canadian pharmacies to sell prescription medications to patients in the state of Texas. On December 21, 2005, Attorney General Greg Abbott issued Opinion #GA-0384, which states that designating certain Canadian pharmacies, listing them on the Board's web site, and permitting Texas consumers to import prescription drugs from Canada would violate federal law. As a result of this opinion, the Board will not implement the Canadian pharmacy provisions of the Act.

2007 Texas Legislature, through amendments to the Texas Pharmacy Act, gave the agency the authority to register a new entity, pharmacy technician trainees. Other significant amendments to the Texas Pharmacy Act include the following.

- An provision that requires a Joint Committee made up of three members of the Texas State Board of Pharmacy and three members of the Texas Medical Board to review and make recommendations to the Board of Pharmacy regarding the addition of five transplant immunosuppressant drugs to a list of Narrow Therapeutic Index drugs that be refilled only with the same drug product by the same manufacturer last dispensed, unless otherwise agreed to by the prescribing practitioner.
- A provision that allows the Board of Pharmacy to adopt rules governing the flavoring of

prescriptions as a part of compounding.

- A provision that allows the return and re-dispensing of prescription drugs from penal institutions.

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

- A provision that requires all regulatory agencies to conduct a preliminary evaluation of a person's eligibility to be licensed.
- Amendments to the Health & Safety Code to allow for the licensing and regulation of "Freestanding Emergency Medical Care Facilities" by the Department of State Health Services. This action ultimately required the TSBP to adopt rules for a new class of pharmacy in these centers.
- Amendments to the Texas Pharmacy Act that defines a rural hospital and allows a pharmacy technician to perform certain duties without the direct supervision of a pharmacist.
- Amendments to the Medical Practices Act which ultimately allowed the TSBP to adopt rules to allow a pharmacist to implement or modify a patient's drug therapy pursuant to a physician's delegation and to sign a prescription.
- Amendments to the Texas Pharmacy Act to allow TSBP investigators who are commissioned peace officers to carry weapons and make arrests.
- Amendments to the Texas Controlled Substances Act that makes Carisoprodol (Soma) a Schedule IV controlled substance; and allows a physician to issue multiple prescriptions to one patient authorizing the patient to receive a total of 90-days supply of a Schedule II drug.
- Amendments to the Texas Pharmacy Act that specifies conditions that the Board may discipline a pharmacy technician, and gives the Board the authority to order a pharmacy technician to submit to a mental or physical evaluation.

## IMPACT OF FEDERAL STATUTES/REGULATIONS

### 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 re-importation of prescription drugs produced in the US, and banned sale, trade, or purchase of samples.
- 1990 Safe Medical Devices Act required “device user facility” to report any death or serious injury of patient probably due to device. The act also required adoption of a device tracking method and post-marketing surveillance of devices.
- 1997 FDA Modernization Act created exemption to ensure availability of compounded drugs prepared by pharmacists in forms not commercially available.
- 1999 OTC Labeling Requirements made for a new standardized format and supplying more detailed product information to the consumer to make over-the-counter medicines safer for consumers. The provisions will be fully enacted by 2005.
- 2002 United States Supreme Court decision (*Western States Medical Center v. Shalala*, 99-17424, February 6, 2001), which struck down the pharmacy compounding provisions of the federal Food, Drug, and Cosmetic Act.
- 1966 Federal Hazardous Substances Act, administered by the Consumer Product Safety Commission, regulates all hazardous substances. Labeling must have a warning statement; pharmacists must

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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.
- 1996 Health Insurance Portability and Accountability Act (HIPAA) set up privacy protections for individually identifiable health information as applied to health plans, healthcare clearinghouses, and healthcare 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 healthcare delivery.
- 2003 Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), recognized that appropriate drug therapy is cost-effective and necessary in the inclusion of medication therapy management programs (MTM). The passage of this legislation is the first time that Congress recognized in national legislation the importance of pharmacist-provided drug therapy management. In addition, it was the first time that pharmacists would be allowed to bill for Medicare-related patient care services.
- 2006 Medicare Part D, prescription drug coverage for all Medicare recipients began on January 1, 2006. Implementation of this program is expected to dramatically increase the number of prescriptions filled by pharmacies in the United States.

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

## THE KEY SERVICE POPULATION PERSPECTIVE

As identified in the agency's Mission Statement and the agency Internal and External Assessment, our key service populations are, in priority order:

- **The Citizens of Texas** C directly, and indirectly through service to Texas Legislators who represent their constituents;
- **Licensees** C pharmacists and pharmacy owners; pharmacy students and pharmacist interns; pharmacy technician trainees and pharmacy technicians;
- **Executive and Judicial Officials and Other State and Federal Agencies;**
- **The Pharmacy Education Community; and**
- **Health-Related Corporations and Professional Associations.**

In focusing on our primary key service population, the citizens of Texas, TSBP recognizes the changing demographics of the state's population. Highlights from the Texas State Data Center Projections for Texas, include the following statements:

*"Projections from the Texas State Data Center and Office of the State Demographer indicate that Texas is likely to grow rapidly and to become increasingly diverse and, like the remainder of the nation, to show a general aging of its population. Texas will be a state with a population that is at least twice as large projected for 2040 as in 1990, and may be more than three times as large.*

*Texas population will also be increasingly diverse with estimates indicating that it was already less than one-half Anglo by July 1, 2004, suggesting that Texas will be more than 50 percent Hispanic by no later than 2035.*

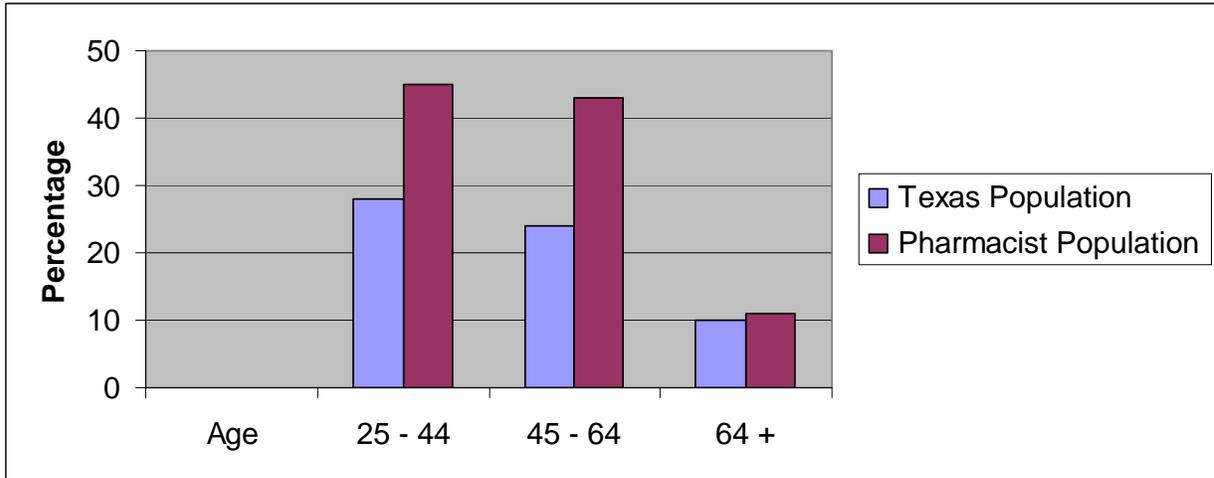
*Similarly Texas will become older with the percentage of the population that is 65 years of age increasing from 9.9 percent in 2000 to at least 15.9 percent by 2040."*

The Texas Comptroller of Public Accounts goes on to state that:

*Over the next 20 years, the number of Texans older than 65 will increase 81 percent. That means more people of retirement age and more products and services geared towards them. With an older population, there will be a growing need for alternative housing, transportation and healthcare.*

With the above trends, the agency is presented with a challenge and a demand that we explore and respond to the patient care needs of every age and ethnic group, literacy level, and income level. Chart 1 below shows a comparison of age distribution among the overall Texas civilian labor force, and the Texas pharmacist population.

Chart 1



Data is based on 2009 Texas Population of 24,326,974 and a Texas Pharmacist Population of 20,508.

## MAIN FUNCTIONS

Of paramount consideration to the agency are the vitality and health of Texas' citizens, with a particular emphasis on consumer protection. The agency is acutely aware of its overall responsibility to regulate the practice of pharmacy in the state of Texas in the public interest.

In fulfilling its statutory mandate (and mission), the agency emphasizes three primary services that are delivered to a variety of customers:

- **Information** - the provision of information to pharmacies, pharmacists, pharmacy technicians, and related laws and rules; information on consumer issues, such as generic drugs, patient counseling requirements; the concept and implementation of pharmaceutical care; and the provision of public information regarding complaint and disciplinary actions.
- **Licensing** - the licensing of pharmacists and pharmacies; certification of pharmacist preceptors; registration of interns, pharmacy technician trainees, and pharmacy technicians, to ensure uniform standards, competency, and public safety (see *Licensing Services* on page 53).

- **Enforcement**
  - the inspections of pharmacies, including the review of interns, pharmacists, and pharmacy technicians and trainees, for compliance with the laws and rules, including specialized requirements regarding the handling, safeguarding, and distribution of prescription drugs and devices;
  - the oversight of the complaint process and investigation of alleged violations of pharmacy laws and rules; and monitoring licensees who are subject to disciplinary orders; and
  - the adjudication of licensees found in violation of pharmacy laws and rules, and the rendering of legal advice and support to Board and staff.

## The Agency Approach

The Texas Pharmacy Act gives TSBP exclusive responsibility in licensing services, but does not give such exclusivity in its Information or Enforcement Services areas. Information Services regarding the profession are, in part, provided by the colleges of pharmacy, professional associations, and consumer advocacy groups. Enforcement Services are provided by the agency, together with other state, federal, and local agencies associated with law enforcement, such as the Texas Department of State Health Services, the Department of Public Safety, the Federal Food and Drug Administration, the Drug Enforcement Administration, and local police departments. Although other law enforcement agencies have specific jurisdiction over various aspects of the practice of pharmacy in Texas, their jurisdictions do not usurp or preclude the authority of the agency in carrying out its responsibilities. In fact, licensure of pharmacists and pharmacies by the agency is a prerequisite to other agencies' jurisdiction and regulation. As a result, and in line with the agency's statutory responsibility, the Board has historically taken a *lead agency* role in the regulation of the practice of pharmacy.

The agency has also developed excellent working relationships with the Texas Medical Board (TMB), Board of Nursing (BON), and other state health profession regulatory agencies.

This *lead agency* approach implements Section 554.001 of the Texas Pharmacy Act which states: *The Board shall 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.*

In the meantime, the agency continues (and aspires) to build ever-increasing, dynamic partnerships and coalitions in meeting the challenges that lie ahead for the agency as a whole and in the addressing of each of the policy issues previously identified in this plan. One of the greatest strengths the agency has, in being able to form these coalitions, is the fact that the agency is an independent state agency.

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## SUCCESS OF AGENCY IN MEETING DEMAND

### Licensing 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 registrations to qualified applicants for pharmacy technician trainee registration;
- (4) Issuing registrations to qualified applicants for pharmacy technician registration;
- (5) 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;
- (6) Issuing registrations to qualified applicants to provide remote pharmacy services;
- (7) Issuing registrations to qualified pharmacist-interns;
- (8) Issuing certifications to qualified pharmacist-preceptors;
- (9) Renewing licenses of pharmacists on active and inactive basis;
- (10) Renewing registrations of pharmacy technicians;
- (11) Renewing licenses of pharmacies that do not have a registration to provide remote pharmacy services;
- (12) Renewing licenses of pharmacies that have a registration to provide remote pharmacy services;
- (13) Renewing certifications of qualified pharmacist-preceptors;
- (14) Monitoring pharmacists' compliance with continuing education requirements;
- (15) Updating pharmacists' licensing and pharmacy technician registration records with respect to change of name, change of employment, and change of address;
- (16) Processing applications from pharmacies for a change of name and/or change of location;
- (17) Processing notifications from pharmacies regarding permanent closings; change of managing officers, updating licensing records; and

- (18) 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.

### Pharmacist Licensure

The licensee population continues to grow, directly resulting in increased workload in all areas of licensing (examination, internship, continuing education, changes of address/employment records), and licensure renewals, as well as all related telephone calls and correspondence. In order to partially address this increasing workload, the Board has implemented such initiatives as the biennial renewal of licenses, online initial and renewal of licenses, a web-based mechanism to verify licensure status, and an online change of address and employment feature. The Board will continue to look toward implementing other initiatives, as a means to reduce workload and more efficiently serve the public.

### Pharmacy (Facility) Licensure

While the number of pharmacies has increased at a slower pace than pharmacist licenses, quantity issues do not reflect the complexity of regulating pharmacies. The agency licensed four different Classes of Pharmacy during FY1988-1991, increasing to five Classes of Pharmacy in FY1992 and seven Classes in FY2010. In addition, in FY2002, the agency added a new category of pharmacy regulation - Remote Pharmacy Services - emergency kits in nursing homes, automated pharmacy systems and telepharmacy systems. Although this license is viewed as an extension of an existing pharmacy license, 1,323 of these "remote pharmacy services" are currently licensed.

As mechanisms for providing pharmacy services to patients continue to diversify, the agency fully expects that the number of pharmacies (and possibly the classes of pharmacy) will continue to increase over the next five years.

### Pharmacy Technician Registration

Patient safety and professional competence will remain a prime focus of the agency's Licensing and Enforcement efforts. The registration of pharmacy technicians will play a key role in the overall patient care issue. Pharmacy technician training and regulation issues have had a dramatic impact on not only the agency, but educators and practitioners as well.

During the 76th Legislative Session, S.B. 730 was passed, which required TSBP to begin registering pharmacy technicians effective September 1, 2001. However, due to appropriation issues, the program was not funded until FY2004/2005. The project began in October 2003, and by the end of the fiscal year, 22,164 pharmacy technicians were successfully registered with TSBP. In FY2007, as a result of the 80<sup>th</sup> Legislative Session, the agency was charged with the implementation of another new program – the registration and enforcement of the Pharmacy Technician Trainee Program. That project began in October 2006, and by the end of the FY2009, 17,657 pharmacy technician trainees had successfully registered with TSBP.

At year end FY2009, as a result of these new programs, the agency has more than doubled its licensee population. At the end of FY2003, the total agency licensee population was 28,064 – at year end FY2009, this number has increased 207%, to 84,659 (25,507 pharmacists, 1,052 pharmacist intern, 6,516 pharmacies, and 51,584 pharmacy technicians and trainees). The additional 51,584 pharmacy technicians have had a dramatic effect on the agency’s operations and that number is expected to continue growing. According to the Bureau of Labor Statistics, employment of pharmacy technicians is expected to increase by 32% from 2006 to 2016, much faster than the average for all occupations.

Fingerprint-based criminal background checks were implemented on all new pharmacist applicants in October 2008, and all new pharmacy technician and technician trainee applicants in March 2009. Approximately 6,300 FBI histories were received and stored in the TSBP consolidated pool within the Department of Public Safety’s (DPS) secured database. The implementation of these programs, along with a new pharmacy technician trainee application fee requirement in FY2010, appears to have had an impact on the number of new applications filed. Specifically, the rate of increase dropped from 20% in FY2008, to 1% in FY2009.

From FY1999 - FY2009, the agency has experienced the following increases:

Performance Outputs – FY1999 – FY2009								
Year	Exams Administered	% Increase/ <Decrease>	# of Pharmacist Licensed	% Increase	# of Pharmacies Licensed	% Increase	# of Pharmacy Technician & Trainees Registered	% Increase
FY99	1,162	--	19,716	--	5,422	--	--	--
FY00	1,363	17%	20,085	2%	5,496	1%	--	--
FY01	1,430	5%	20,679	3%	5,603	2%	--	--
FY02	1,387	<3%>	21,106	2%	5,681	1%	--	--
FY03	1,576	14%	21,570	2%	5,794	2%	--	--
FY04	1,543	<2%>	22,111	3%	6,014	4%	22,164	--
FY05	1,742	13%	22,661	3%	6,107	2%	26,664	20%
FY06	1,820	4.4%	23,323	3%	6,201	1.5%	30,091	13%
FY07	1,877	3.1%	23,939	2.6%	6,315	1.8%	42,505	41%
FY08	1,991	6%	24,586	2.7%	6,424	1.7%	51,007	20%
FY09	2,656	33.4%	25,507	3.7%	6,516	1.4%	51,584	1.1%
Cumulative Increases FY99-09		129%		29%		20%		133%

**Online Application Process**

In October 2002, TSBP began implementing its license applications to the Texas Online Occupational License Application System and by year-end FY2005, all fee-paying applications of the agency were available electronically on Texas Online. At year end FY2009, the overall adoption rate by agency customers was 83%. It is expected that with increased customer awareness, that adoption rate will grow.

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## Enforcement Services

The key function of the Enforcement 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 Enforcement 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.

TSBP has a two-pronged approach to enforcement. One approach is based upon *prevention*, because TSBP believes that 95-98% of its licensees will obey the laws and rules governing the practice of pharmacy, if the licensees are well-informed. A review of prior reports of TSBP performance measure *Percent of Licensees with No Recent Violations* proves that preventive enforcement is working well. The preventive program includes:

- (1) Compliance inspections (of pharmacies);
- (2) Publication of *TSBP Newsletter*, which contains information about new laws and rules; Q&A (most frequently asked questions); Disciplinary Orders (names of licensees and brief description of allegation and sanction); and helpful articles relating to practicing pharmacy in compliance with pharmacy laws/rules; and
- (3) Technical assistance (available by telephone, e-mail, via web site, live presentations, and professional exhibits).

As of the date of this report, TSBP licenses approximately 6,634 pharmacies, with 6,109 of those pharmacies located in Texas and 525 pharmacies located in other states. TSBP employs seven FTE’s to conduct compliance inspections (e.g., random un-announced inspections, follow-up to written warnings, and disciplinary orders involving a pharmacy). With this staff, TSBP is able to inspect approximately than one-third of the in-state pharmacies each year. As a result, there is a lengthy gap between inspections for most pharmacies. For some pharmacies, it may be as many as three to five years between inspections. TSBP would prefer to inspect pharmacies more often than it does now, because a longer period of time between inspections generally results in greater number of pharmacies being in non-compliance with the Texas Pharmacy Act and Texas Drug Laws. If TSBP is to continue its preventative enforcement through routine, unannounced inspections, additional inspectors must be authorized and funded.

TSBP’s other approach to enforcement is through investigation of complaints, and if substantive evidence is obtained, the institution of disciplinary action against the applicable person. As indicated in the chart below, TSBP has experienced a 72% increase in the number of jurisdictional complaints received over the past five fiscal years (i.e., the number of jurisdictional complaints received in FY2005 as compared to the number of jurisdictional complaints received in FY2009).

Year	Jurisdictional Complaints Received	% Change Complaints Received Previous Year	Jurisdictional Complaints Closed	% Change Complaints Closed Previous Year	% Complaints Closed	Resolution Time (Agency Average)	% Change Time
FY05	3,047		3,288		108%	196 Days	
FY06	3,501	+15%	3,338	+2%	95%	207 Days	+6%
FY07	5,793	+66%	4,931	+48%	85%	185 Days	-11%
FY08	5,687	-2%	5,303	+8%	93%	196 Days	+6%
FY09	5,226	-8%	6,120	+15%	117%	211 Days	+8%

The increased number of complaints is a direct result of new programs to register pharmacy technicians (that began in FY2004) and pharmacy technician trainees (that began in FY2007), as described below:

- (1) During FY2004, TSBP received approximately 24,000 applications from individuals applying for a pharmacy technician registration. Approximately 10-15% of the initial applicant pool had a criminal record which required further review/investigation by TSBP staff and necessitated the opening of a complaint.
- (2) During FY2007, TSBP received approximately 10,000 applications from individuals applying for a pharmacy technician trainee registration. Approximately 25% of the initial applicant pool had a criminal record which required further review/investigation by TSBP staff and necessitated the opening of a complaint.
- (3) TSBP conducts quarterly criminal background checks on all licensees and registrants. Each time a check indicates that a licensee or registrant has been the subject of a criminal offense, TSBP opens a complaint and conducts further review/investigation. As the agency’s licensed/registered population increases, TSBP continues to experience an increase in the number of complaints received as a result of the quarterly criminal background checks.

In FY2009, TSBP opened 865 complaints due to the information received from quarterly background reports, as compared to FY2008 when TSBP opened 346 complaints on quarterly reports (150% increase). Approximately 90% of these reports involve a criminal offense allegedly committed by a technician or technician trainee, with the remaining 10% reports involving a criminal offense allegedly committed by a pharmacist or pharmacist-intern.

Prior to the 81<sup>st</sup> Texas Legislative session, the number of FTEs was not sufficient to keep up with the massive increase in workload, which in turn had a negative impact on the agency's complaint resolution time and has resulted in a very large backlog, as described below:

- (1) Due to state-mandated budget cuts in FY2003-2004, the Enforcement Division experienced a loss of two FTE's prior to the implementation of the technician registration program in FY2004. During the initial start-up year of the technician registration program, the Enforcement Division received only one additional FTE. As a result, the Enforcement Division had a net loss of minus one employee in FY2004 to handle all of the calls and the new complaints generated from the technician registration program. Accordingly, TSBP delayed the investigation of complaints handled by in-house Enforcement staff, while they investigated the complaints that were opened on applicants for a pharmacy technician registration due to the applicant's criminal history. This delay, in turn, caused the pending complaints to become a year older, which increased the agency's complaint backlog and had a negative impact on the agency's average complaint resolution time in FY2005 and FY2006.
- (2) In FY2007, when TSBP began to register pharmacy technician trainees, the Enforcement Division once again was faced with prioritizing complaints that were opened on applicants for a pharmacy technician trainee registration due to the applicant's criminal history. These types of complaints (background checks) generally can be resolved more quickly than other types of complaints handed by TSBP. As a result, the agency's complaint resolution time in FY2007 dropped to 185 days. However, because the investigation of other complaints were delayed, the agency's backlog has continued to grow, which in turn, has resulted in an increase of the agency's average complaint resolution time in FY2009 to 211 days (a 14% increase from FY2007).
- (3) At the end of FY2003 (the year prior to the implementation of the technician registration program), the agency had a backlog (pending complaints) of approximately 800 complaints. At the end of FY2007, the agency had a backlog (pending complaints) of approximately 2,800 complaints (a 250% increase over the FY2003 level). As of mid-year FY2010, the agency had a backlog (pending complaints) of approximately 2,323 complaints. However, when compared to mid-year FY2009 when the backlog was approximately 3,140 complaints, the agency has substantially decreased its backlog by 27% within that 12 month period. This improvement was a direct result of the following two factors: the additional FTEs which were authorized by the 81<sup>st</sup> Texas Legislature (the increased number of Enforcement/Legal personnel was able to close more complaints than received during this period) and the agency received fewer complaints in FY2009 than in the prior fiscal year. Specifically, TSBP received 5,687 complaints in FY2008, as compared to 5,226 complaints that TSBP received in FY2009 (8% decrease).

During the past seven years, TSBP has also experienced a 247% increase in disciplinary orders from 213 in FY2003 to 737 in FY2009, as indicated in the chart below:

	Orders Entered by TSBP on RPh/Pharmacy	Ordered Entered by TSBP on Technicians by TSBP	Total Number of Disciplinary Orders
FY2003	213	n/a	213
FY2004	235	234	469*
FY2005	172	380	552
FY2006	207	268	475
FY2007	300	348	648**
FY2008	253	310	563
FY2009	334	403	737

\* TSBP began registering Technicians.

\*\* TSBP began registering Technician Trainees.

In FY2009, the agency entered 171 orders revoking a license or registration (14 pharmacist licenses; 8 pharmacy licenses; and 149 technician registrations). The orders entered on technicians were primarily due to theft of prescription drugs from the pharmacies where they were employed or the technician received a deferred adjudication or conviction for a felony offense. The diversion of prescription drugs by technicians is an ever increasing problem.

Due to the increased number of disciplinary orders being entered by TSBP, the agency has also experienced increased demand for probation/monitoring services. In FY2009, TSBP entered 633 disciplinary orders that required some type of monitoring, as compared to FY2006 when TSBP entered 457 disciplinary orders that required monitoring (39% increase). TSBP currently has two FTEs whose primary duty is the monitoring of probationers.

TSBP believes that its two-pronged approach to enforcement is cost-effective. However, to ensure that the public health and safety are not compromised, TSBP needs adequate human resources to enforce the laws and rules governing the practice of pharmacy.

## HEALTH PROFESSIONS COUNCIL - A MODEL FOR REGULATION

As stated in the Texas Sunset Advisory Commission Staff Report (October 1992), efforts throughout the past 40 years to create a centralized licensing agency in Texas have received only lukewarm support. During development of legislation to implement the recommendations of the Texas Performance Review, the Sunset Commission took another approach, and questioned what result the consolidation efforts were trying to achieve, other than simply that of ending up with one large, bureaucratic organization. The Sunset staff analysis indicated that a majority of the following positive benefits can be achieved in a constructive manner:

- Coordination of overall policy;
- Economies of scale;
- Standardization of functions;
- Improved public access to services; and

- The potential for better enforcement.

A further review indicated, however, that a majority of these measures could be achieved in a constructive manner, without consolidating regulatory agencies under one *super-agency*.

With these thoughts in mind, the *Health Professions Council (Council)* was created during the 73rd Legislative Session. The Council provides a unique solution for the multiple challenges of state regulation of health professions. The purpose of the Council is to provide a means for the agencies represented to coordinate administrative and regulatory efforts. The Council has a membership of 15 agencies currently representing 35 professional licensing boards, certification programs, documentation programs, permit programs or registration programs, and the Governor's Office. The Council consists of one representative from each of the following:

- (1) Board of Chiropractic Examiners;
- (2) Board of Dental Examiners;
- (3) Texas Medical Board;
- (4) Board of Nurse Examiners;
- (5) Board of Occupational Therapy Examiners;
- (6) Texas Optometry Board;
- (7) Board of Pharmacy;
- (8) Board of Physical Therapy Examiners;
- (9) Texas Funeral Commission;
- (10) Board of Podiatric Medical Examiners;
- (11) Board of Examiners of Psychologists;
- (12) Board of Veterinary Medical Examiners;
- (13) Department of State Health Services, Professional Licensing and Certification Unit;
- (14) Office of the Governor; and
- (15) Office of the Attorney General.

The Council has provided a valuable forum for health licensing agencies to discuss and reach consensus on ways for agencies to operate together in a more effective and efficient manner, without sacrificing the independent efficiency and effectiveness of each agency.

The Council has made tremendous strides in accomplishing efficiency and effectiveness through administrative sharing and cooperative teamwork. Eleven Council committees, involving approximately 40 staff members from member agencies, were appointed to study and make recommendations on the functional and programmatic assignments of the priority objectives. The following is a summary of accomplishments from FY1994-2009.

- Shared Database System: In July 2006, the Texas Department of Information Resources notified agencies that they will no longer be providing cold site recovery floor space as part of their Master Service Agreement. Moreover, agencies were informed that legacy databases would no longer be supported under upcoming contracts with IBM. HPC took the lead in finding enterprise Licensing and Regulatory software for the management of licensing, enforcement, legal and some accounting functions. The 81<sup>st</sup> Legislature awarded funding and implementation of a shared regulatory database system began in FY2010.
- Implementation of a plan to collocate the Council agencies to the state-owned William P. Hobby Jr., Building. The accomplishment of this objective was a major success for the Council agencies during fiscal years 1994 and 1995.
- Establishment of a "1-800" complaint system to provide assistance and referral services for persons initiating a complaint related to a health profession regulated by the state. Approximately 2,250 consumers call the toll-free complaint line each month. Of these, approximately 1,700 are routed to member agencies to request complaint forms and 500 per month receive other assistance from the HPC administrative staff.
- Development of a Training Manual for board and commission members.
- Sharing of administrative functions, such as accounting, purchasing, and payroll. These are typically back-up arrangements for occasions when employees are ill, on vacation, or for an extended vacancy.
- Shared services such as courier service, storage space, Employee Assistance Program, and legislative tracking.
- Training/Information Dissemination Opportunities exist for new employee EEO training and other opportunities through the State Auditor's Office and Employee's Retirement System. In addition, the National Certified Investigator/Inspector Training (NCIT) program of the Council on Licensure, Enforcement, and Regulation is provided to HPC members employing investigators.
- Coordination of Legal Services to discuss legal issues of joint concern to Council agencies.
- Information technology sharing utilizes two staff to provide direct ongoing services to eight of the smaller member agencies.

- Policy and Procedure Development. In the past, the Council through its committees, developed model policies and procedures for risk management, disaster recovery, and workforce policy/procedures. When new reporting requirements are mandated, member agency staff meets on an ad hoc basis to review the requirements, clarify expectations and seek further clarification to facilitate quality reporting.
- Sharing an electronic imaging system for data storage.
- Completion of Complaint Study as mandated by the 77<sup>th</sup> Texas Legislature.

In its December 1995 report entitled *Reforming Health Care Workforce Regulation*, the Pew Health Professions Commission cited the Health Professions Council as an innovation in regulation. The results of this cooperative structure have already been demonstrated by the many aspects described previously. As the Council pursues additional opportunities for improvement among member agencies, the primary goals envisioned by the legislative leadership should be met.

# THE ORGANIZATIONAL PERSPECTIVE

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## BOARD STRUCTURE - POLICY-MAKING BODY

The policy-making body of the agency is a nine-member Board appointed by the Governor, with concurrence of the Senate, for staggered six-year terms. Six members must have been registered pharmacists in Texas for five years immediately preceding appointment, be in good standing with the Board, and continue to actively practice pharmacy while serving. In addition, the Board must have representation for licensed pharmacists who are primarily employed in community and institutional pharmacies. Three members of the Board must be representatives of the general public (i.e., non-pharmacist, consumer representatives).

The Board has the responsibility for the administration and the enforcement of the Texas Pharmacy Act and Texas Dangerous Drug Act. Through the jurisdiction provided in these acts, the Board has the responsibility of regulating three distinct but interrelated and inseparable elements - 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 delivery of dangerous drugs (prescription drugs that are not classified as controlled substances).

Given the unique responsibilities of the Board, input regarding issues under the jurisdiction of the agency is obtained through a myriad of sources, including the following:

- (1) Task Forces – an ongoing significant part of the policy-making structure of the agency is the Board's use of professional ad hoc task forces in its pre-rulemaking process. These ad hoc task forces are composed of individuals who possess expertise helpful to the Board, both in the initial development and modification of agency rules. The result is that the rules governing pharmacy practice are formulated in the best interest of the public and, at the same time, represent an appropriate level of regulation.
- (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 six 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 – Beginning in FY2000, the TSBP has conducted surveys 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.
- (6) Individuals – Board Members are individually contacted about issues and the agency receives visits, letters, and telephone calls regarding issues. These issues may be addressed at Board meetings, which may result in rule changes.

## AGENCY DIVISIONS AND STAFF MANAGEMENT

The agency's office headquarters is located at 333 Guadalupe Street, Suite 3-600, Austin, Texas, in the central quadrant of the city. In FY2010, agency staff totaled 72 positions, consisting of five management, 18 professionals, 33 para-professionals, and 16 administrative support staff. Fourteen employees (seven Compliance Officers/Inspectors and seven Investigators) operate in field areas outside the main office and function under the supervision of their respective Division Directors.

Pharmacy practice regulation is unique since it regulates individuals (pharmacists and pharmacy technicians), facilities (pharmacies), and products (prescription drugs). Therefore, interaction and coordination between the divisions of the agency and their staff members are crucial and integral parts of the effectiveness of our efforts.

As of August 2009, the agency licenses approximately 25,507 pharmacists, 6,516 pharmacies, and registers 51,584 pharmacy technicians and trainees over a land area of approximately 270,000 square miles. The agency's limited numbers of Compliance and Investigative staff are challenged in the regular monitoring of these licensees by travel distances. All geographic regions are served by the agency. The field staffs of seven Compliance Officers/Inspectors and seven Investigators are assigned regions that encompass the entire state, including the Texas border regions. In addition, medically under-served areas present specific challenges for comprehensive inspection/investigative efforts. These areas are defined as locales where medical care and, specifically, pharmacy services may be inaccessible due to distance and lack of transportation, and lack of (or inadequate) insurance coverage. Such situations may occur in rural, sparsely populated areas of the state and, conversely, in some densely populated urban areas of Texas.

The agency operates under a modified system of Management-By-Objectives (MBO). Goals and objectives are reviewed and approved annually by the Board Members. These objectives are directly tied to the agency's *Strategic Plan* and "operationalize" the *Strategic Plan*. The Executive Director manages the staff to accomplish the adopted objectives.

The Executive Director/Secretary serves as the executive officer of the agency and, as outlined in the Pharmacy Act, serves as an ex-officio member of the Board. The Executive Director/Secretary is responsible for advising the Board on policy matters, implementing Board policy, and managing the agency on a day-to-day basis.

Regarding management structure, the Director of Administrative Services and Licensing is responsible for overall supervision of the Licensing and Administrative Services programs. The Directors of Enforcement and Professional Services, and the General Counsel are responsible for their respective programs and personnel. Information program services are shared among the divisions of the agency. An organizational chart of the agency can be found in *Appendix B*.

## HUMAN RESOURCE INVESTMENTS

Human resource investments are crucial to the continued efficiency and effectiveness of agency operations. In Texas government, as in the private sector, we must pay adequate wages if we expect to attract and retain quality employees. *Our employees are our most valuable resource and Texas cannot afford to have less than the best.* In addition to the initial investment of hiring qualified staff, the meeting of each employee's ongoing professional development and training needs is also crucial to the success of agency operations.

Human resource investments, such as provision of up-to-date technology and ongoing training for agency staff, help position the agency as public and private sector employers compete for the same work force pool. The agency has a distinct advantage in that it has a highly-educated and qualified staff who carry out their responsibilities in an efficient and effective, customer-service oriented manner. This proactive, progressive work environment, along with the general reputation of the agency, has definitely been an asset when recruiting staff. However, the fact that state salaries are not competitive with those in the private sector continues to hinder recruiting of qualified staff.

## STAFFING PATTERN AND PROFILE

Agency employee turnover increased from 7.2% in FY2006, to 14.2% in FY2007, but dropped to 8.5% in FY2008 and 5% in FY2009. The turnover in pharmacist staff is a much more significant number and has more serious consequences. Turnover of pharmacist staff has been high in past years – 57% in FY2001, 60% in FY2003, and 33.33% in FY2004. Even more dramatic is the number of pharmacist service years that have been lost – in FY2001, a total of 32.2 years of experience, with one pharmacist taking nearly 26 years of agency experience with him. In FY2003, a total of 52 pharmacist service years were lost. The agency is rapidly being depleted of talent in this crucial area – from a total of ten pharmacists (non-management) in FY2000, to a total of four pharmacists (non-management) in FY2010. This loss of pharmacist staff is especially disturbing since the pharmacist staff are a part of the succession for the Executive Director position, which is statutorily required to be a pharmacist. The reason for the high turnover rate can be directly attributed to an agency lack of funding for salaries. During the 2009 Legislative Session the legislature increased the salary range for a Pharmacist II to \$81,529 - \$134,524 and the range for a Pharmacist III to \$98,651 - \$162,773. However, even though the Legislature established these new salary ranges, the agency was not funded to hire pharmacists at the increased salaries.

The growth in Texas' minority populations may also have significant ramifications for the agency's workforce, specifically in the pharmacist (Compliance/Enforcement Officer) category. Attempts to recruit qualified minority pharmacists have been difficult due to the significant differences in salaries compared to private sector employment, and to the pool of licensed pharmacists who are minorities. Table 1 shows a comparison of race distribution among the overall Texas civilian labor force, the Texas pharmacist population, and the agency non-executive pharmacist positions for FY2008-09.

Table 1\*

Race	Texas Population Race Distribution	Texas Pharmacists Population Race Distribution	TSBP Non-Executive Pharmacists Population Race Distribution
Anglo	46.63%	60%	50%
Hispanic	37.48%	09%	25%
Black	11.61%	13%	25%
Other	4.29%	18%	0%

The agency's overall workforce profile, as shown in Table 2, indicates that the agency needs to increase its efforts to recruit and retain qualified minority applicants at all levels of job categories.

Table 2\*

<u>Agency EEO Data</u>	ANGLO		BLACK		HISPANIC		OTHER		TOTAL		GRAND TOTAL
	M	F	M	F	M	F	M	F	M	F	
Administrators	0	5	0	0	0	0	0	0	0	5	5
Professional	5	9	0	1	2	0	0	1	7	11	18
Para-Prof	6	12	1	0	0	6	0	0	7	18	25
Admin Support	0	6	0	2	0	5	0	0	0	13	13
TOTALS	11	32	1	3	2	11	0	1	14	47	61

\*Data reflects actual staff as of 8/31/09. Unfilled positions are not reflected.

## HISTORICALLY UNDERUTILIZED BUSINESSES

It is the intent of the Legislature that each state agency receiving appropriations shall, in acquiring, constructing, or equipping new or existing facilities, and in the operational implementation of each strategy funded, make a good-faith effort to include historically underutilized businesses (HUB) in the following categories:

Category	Actual FY09	Agency Goal for FY10
Professional Service Contracts	100%	20%
Other Services Contracts	19.4%	33%
Commodities Contracts	45%	12.6%

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 Annual Non-Financial Report.

The agency has made a dedicated effort to satisfy the requirement for soliciting at least two HUB-certified minorities and one women-owned business in the three bids solicited for each delegated spot purchase. The above constraints notwithstanding, the agency will increase its good-faith efforts by using an agency HUB Policy as the basis for obtaining the HUB participation goals.

## **CAPITAL IMPROVEMENT NEEDS**

### **Technological Development**

The use of technology has become integral to the operational success of the Texas State Board of Pharmacy. When appropriate, the agency deploys current and emerging cost effective information technologies to increase efficiencies within the agency and to improve service delivery to our constituents. Web-based applications, electronic payment and the imaging of paper documents are just a few of the technologies currently in use.

The agency Website has over 70,000 visitors each month. It has proven to be a valuable tool in disseminating information to the public and increasing the accessibility of the agency. The Website is also linked to Texas Online and allows the agency to accept electronic payment of renewal fees. Renewal forms are scanned into our imaging system making storage and retrieval much more efficient.

The primary technological challenge facing the Board of Pharmacy is the current migration of the Licensing, Enforcement and Cash database systems to a new shared regulatory database system. This conversion will occur in FY2010 and it is hoped that the new system will prove to be a cost effective, functional and compliant solution.

A complete discussion of the agency's Information Resources needs can be found in the agency Technology Initiative Alignment.

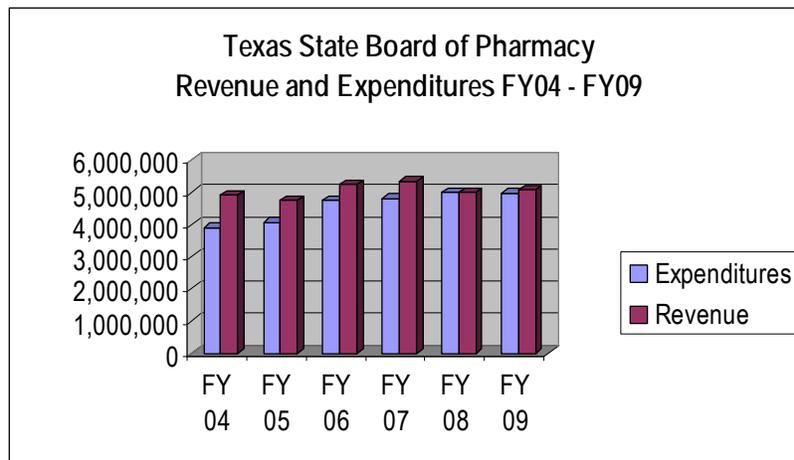
## **THE FISCAL PERSPECTIVE**

### **Current Funding**

The agency's operating budget for fiscal year 2009 was approximately \$3.3 million, which includes all Legislative appropriations. In addition, other direct and indirect costs are charged to the agency such as the agency's payroll-related costs, bond debt service payments, and indirect costs relating to the Statewide Cost Allocation Plan.

The agency is totally self-supporting, in that the operations of the agency are supported primarily from statutory fees related to licensing, reciprocity, and examinations. Until 2005, the general operating fund of the Board was a general revenue dedicated account within the State Treasury. The 2005 Texas Legislature, passed legislation that abolished the Board of Pharmacy fund dedication, transferred \$5,948,256 to the General Revenue Fund, and placed the agency funds into the General Revenue Fund.

The chart below shows the agency's revenues and expenditures for a six-year period (FY2004- FY2009). The agency also maintains a Fines Account for fines collected by the agency that are deposited in the State's General Revenue Fund. From FY2004 through FY2009, the agency collected and deposited \$1.3M of fine revenue into the General Revenue Fund.



### Degree to Which Current Funding Meets Current and Expected Needs

One key factor that continues to affect the ability of the agency to serve and protect the public interest is the increased demand for agency services in every area of its operation. Dramatic increases in the demand for licensing, enforcement, and information services are well-documented throughout this *Strategic Plan* and in the agency's budget requests. This continued increase in demand for services, together with the increase in the complex nature of modern health and pharmaceutical care, is taxing the agency's ability to respond not only to future challenges, but to maintain its current level of service.

The agency has the authority and mechanisms necessary to generate the revenue needed to support its *Strategic Plan* and Budget Requests. The TSBP was successful in obtaining additional appropriations for the requested exceptional items during the 81<sup>st</sup> Legislative session. During that same session however, a number of unfunded mandates passed which increased costs to the agency. These included:

- Increased per diem for travel and mileage to employees and board members.
- Changes to the State's Position Classification Plan resulted in mandatory increased salary adjustments to a number of agency positions.
- Passage of Senate Bill 646 relating to a study regarding the confidentiality of prescription information. A fiscal impact statement was submitted, but was not funded.
- Legislation enacted in 2009 has directed the TSBP, the Texas Department of Public Safety, and the

Texas Medical Board to develop a transition plan for the orderly transfer from the Department of Public Safety to the Texas State Board of Pharmacy of certain records and regulatory functions relating to dispensing controlled substances by prescription under Chapter 481, Health and Safety Code. This initiative will be addressed by the 82<sup>nd</sup> Texas Legislature.

Additionally, in FY2010, all agencies are faced with a 5% budget reduction for the FY2010 and FY2011 biennium. In light of this budget reduction and potential future decreases in the State of Texas budget for 2012-2013, the impact to the agency's ability to provide quality customer service, information, and protection to the citizens of Texas will be severely tested.

It is anticipated that the growth of the registration of pharmacy technicians and pharmacists will continue to challenge the agency. The Bureau of Labor Statistics' 2008-09 report estimates employment for pharmacy technicians will grow much faster than for the average occupation – up to a 32 percent increase by 2016. Additionally, the Bureau of Labor Statistics' reports that “employment of pharmacists is expected to grow by 17% between 2008 and 2018, which is faster than the average for all occupations.”

Operation of the agency has been dramatically affected by the unprecedented growth of registrants as a result of legislation requiring the registration of pharmacy technicians in 2004 and pharmacy technician trainees in 2006. Since FY2003, the licensee population exploded from 28,064 licensees to 84,659 licensees in FY09 (202% cumulative increase). Of particular concern to the agency is the explosive growth in the number of complaints received, which has a direct impact on the protection of the health and safety of the citizens of Texas. Since FY2003, the agency has experienced a 176% increase in the number of complaints; a 246% increase in the number of disciplinary orders and a 38% increase in the number of days to resolve a complaint. Each area of growth is directly attributed to the increase in registrants.

If the agency is to accomplish its mission and be *proactive* rather than *reactive* in its mission to protect the public health, it must be funded at an adequate level. Failure to receive this funding will severely impact the agency's ability to provide quality customer service, information, and protection to the citizens of Texas.

# AGENCY SELF EVALUATION

## KEY AGENCY EVENTS/AREAS OF CHANGE AND IMPACT SINCE THE LAST UPDATE OF THE STRATEGIC PLAN

Since the publication of the 2008 agency *Strategic Plan*, the following events and changes have had a major impact on the strategic and operational planning of the agency, and are referenced (where applicable) within this *Strategic Plan* where they are specifically addressed:

- The TSBP was successful in obtaining additional appropriations for all the requested exceptional items during the 81<sup>st</sup> Legislative session. During that same session however, a number of unfunded mandates passed which increased costs to the agency. These included:
  - Increased per diem for travel and mileage to employees and board members.
  - Changes to the State's Position Classification Plan resulted in mandatory increased salary adjustments to a number of agency positions.
  - Passage of Senate Bill 646 relating to a study regarding the confidentiality of prescription information. A fiscal impact statement was submitted, but was not funded.
  - Legislation enacted in 2009 has directed the TSBP, the Texas Department of Public Safety, and the Texas Medical Board to develop a transition plan for the orderly transfer from the Department of Public Safety to the Texas State Board of Pharmacy of certain records and regulatory functions relating to dispensing controlled substances by prescription under Chapter 481, Health and Safety Code. This initiative will be addressed by the 82<sup>nd</sup> Texas Legislature.

Additionally, in FY2010, all agencies are faced with a ordered 5% budget reduction for the FY2010 and FY2011 biennium. In light of this budget reduction and potential future decreases in the State of Texas budget for 2012-2013, the agency's ability to provide quality customer service, information, and protection to the citizens of Texas will be severely tested.

In 2004 and 2007 the agency began new programs to register pharmacy technicians and pharmacy technician trainees. These addition of these two programs have had the most dramatic impact to agency operations since the initial registration and licensing of pharmacists began in 1907. Certainly, it must be stated that the registration of pharmacy technicians and trainees has had positive benefits for the public by requiring that this critical member of the pharmacy healthcare team be regulated. However, this regulation has severely taxed the resources of the agency as indicated below:

Increases in Workload Caused by the Pharmacy Technician Registration Program								
	FY03	FY04	FY05	FY06	FY07	FY08	FY09	% Chg over 7 years
<b>Administrative Services and Licensing Division</b>								
Total Number of Licensees	28,064	51,041	56,236	60,437	73,645	82,942	84,659	202%
Number of Telephone Calls Received	10,000	19,737	20,600	26,500	26,500	24,880	30,560	206%
Number of Email Inquiries Answered	4,000	10,880	13,000	19,500	16,000	9,854	18,337	358%

<b>Increases in Workload Caused by the Pharmacy Technician Registration Program</b>								
	<b>FY03</b>	<b>FY04</b>	<b>FY05</b>	<b>FY06</b>	<b>FY07</b>	<b>FY08</b>	<b>FY09</b>	<b>% Chg over 7 years</b>
<b>Enforcement Division</b>								
Number of Jurisdictional Complaints Received	1,893	4,436	3,047	3,501	5,793	5,687	5,226	176%
Number of Jurisdictional Complaints Resolved	1,850	2,982	3,288	3,338	4,931	5,303	6,120	231%
Number of Compliance Queue Calls Received	6,706	8,661	7,995	10,492	11,498	14,326	15,466	131%
Number of Disciplinary Orders Entered that Required Monitoring	185	444	531	457	599	488	633	242%
Number of Days to Resolve a Complaint	153	118	196	207	185	196	211	38%
<b>Legal Division</b>								
Number of Disciplinary Orders Entered	213	469	552	475	648	563	737	246%
Number of Days of Informal Conferences	23.5	30	30	33	31	32	36	53%
Number of Preliminary Notice Letters Mailed	240	652	618	654	792	799	942	293%

- The TSBP, five other regulatory agencies and the Health Professions Council were successful in receiving funding from the 2009 Texas Legislature to replace the database system and migrate to a new Shared Regulatory Database System. The projected date for migration to the new Shared Regulatory Database System is September 1, 2009.
- TSBP continues development of a comprehensive and user-friendly Website to improve services and accessibility to its customers. Major features include:
  - comprehensive consumer information, including procedures regarding the complaint process and an online complaint form; new and ongoing licensing information; a reference site for pharmacy related information; and important information regarding the agency's laws and rules;
  - a license verification link that enables the user to verify the licensing and disciplinary status of pharmacists, pharmacies, interns, and pharmacy technicians; and
  - the implementation of all agency fee paying applications available electronically on Texas Online.

## Evaluation Process

As covered in the section titled *The Organizational Perspective*, the agency continually operates by implementing and measuring performance against strategic and operational *Goals and Objectives* and through customer feedback. Therefore, the agency is continually self evaluating, through each division and every employee. In addition to this continuous process, and in preparation for this *Strategic Plan*, the agency sought the input of Board Members, staff, officials of national and state pharmacy organizations, pharmacy academicians, and officials of state consumer advocacy groups. The list of the recipients of the survey letters is included in *Appendix A* with a list of the questions asked of these *interested parties*.

The strategy for the continued success of the agency consists of three distinct but interrelated elements:

- Leadership – The creative process comes from the ability of the organization and all its members to learn, improve, and innovate. The Board and management staff must establish a climate that allows the creative process to continue.
- Feedback from Employees – The *Survey of Employee Engagement (Appendix F)* (Survey), administered by the School of Social Work at The University of Texas at Austin provides a uniform benchmark for all Texas government to compare employees' perceptions of organizational achievement from agency to agency and over time. The agency's scores are consistently higher than the statewide average for all workplace dimensions.
- Feedback from External Customers – The agency has developed customer service standards, and has been conducting a survey of agency customers regarding the quality of service delivered by the agency since FY2000.

Customer satisfaction can also be measured by the agency's progress in establishing credibility and recognition. The Texas State Board of Pharmacy 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:

- The agency met or exceeded 83% of its 12 key performance measures listed in the Appropriations Act and required to be reported on an annual basis to the Legislative Budget Board for FY2009.
- Monetary exception-free financial audit by the State Comptroller of Public Accounts;
- Continuous exception-free audits by the Texas Building and Procurement Commission on the Delegated Service Certification Program (now the Texas Procurement and Support Services {TPASS} division of the State Comptroller) of TSBP's purchasing process.

- A recent audit of the *“Complaint Processing and Enforcement at the Board of Pharmacy”* conducted by the State Auditor’s Office concluded that the Board of Pharmacy:
  - imposes sanctions and disciplines licensees and registrants in accordance with state laws and regulations.
  - has processes in place to monitor compliance with Board-ordered disciplinary actions.
  - follows its complaint handling process that prioritizes the assignment and investigation of complaints relative to the seriousness of the allegations.
- Achievement, over the past five years (FY2005-FY2009), of an average settlement rate of approximately 98% of TSBP’s contested cases resulting in a disciplinary order against licensees/registrants; this results in significant efficiencies, both in terms of complaint resolution time and costs;
- The agency’s continued success with the licensee/registrant acceptance of the Texas Online application system (87% for pharmacists and pharmacy technician renewals). All fee-paying applications are now available through Texas Online; and
- Comments from external customer organizations, both national and statewide, were solicited in the Strategic Plan external assessment. The comments received were not only instructive, but extremely positive and complimentary to the agency.

The agency has also been an innovator in the field of proactive health regulation. This is well-documented in that Texas was the first state in the nation to:

- Pass legislation to establish drug therapy management and immunizations by pharmacists (2001);
- Pass laws that allowed for the remote provision of pharmacy services using automated dispensing systems and telepharmacy systems (2001); and
- Pass legislation to establish peer review committees that may be used to suggest improvements in pharmacy systems to enhance patient care, assess system failures, and make recommendations for continuous quality improvement processes (1999). Guidelines for Establishing Pharmacy Peer Review Committees were adopted by the Board in FY2000.

The Texas State Board of Pharmacy was the first board of pharmacy in the nation to:

- Use ad hoc task forces in its pre-rule-making process (The agency began using these task forces in 1981);
- Publish a *Newsletter* that is distributed to all pharmacies and other interested customers (The *Newsletter* has been continuously published since 1977 and is directed at educating pharmacists about the laws and rules relating to the practice of pharmacy. It also discloses the names of all pharmacists, pharmacies, and pharmacy technicians disciplined by the Board);

- 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); and
- Develop and implement a strategic plan (the first agency *Strategic Plan* was developed in 1986).

The Texas State Board of Pharmacy is in a unique position to be able to impact the delivery of pharmaceutical care to the citizens of Texas. We constantly strive to improve on our performance and responsiveness to our customers. In order to fulfill that goal, we hope to see advancement in expanding and enhancing our capabilities for encouraging the delivery of pharmaceutical care to improve the quality of life for Texas consumers.

The agency's opportunities in these areas are virtually boundless. It is an exciting and demanding era, because of the uncertainty in the environment due to healthcare reform and quickly changing market conditions. Never before in the nation's – or profession's history – have we been presented with such an opportunity to positively impact the healthcare of the citizens of Texas and the promotion of pharmaceutical care through proactive regulatory initiatives.

The agency has built credibility, momentum, and innovation in the advancement of patient care. Organizations don't stand still – they either progress or regress. For the agency to take advantage of its momentum, it must have the necessary resources.