OVERVIEW OF AGENCY SCOPE AND FUNCTIONS

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.

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 Pharmac; 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.

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 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.

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 — directly, and indirectly through service to Texas Legislators who represent their constituents;
- Licensees — 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. In "A Summary of The Texas Challenge" by Dr. Steve H. Murdock, Department of Rural Sociology, Texas A & M University, the following statements are made:

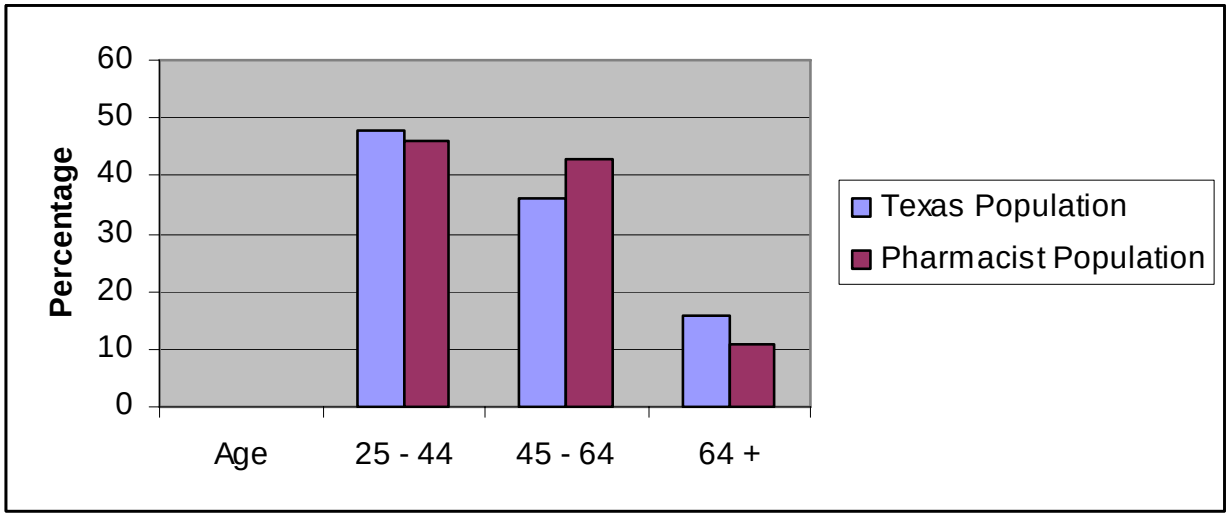
> *No factor is more important to Texas than the growth of its minority population. By 2008 Texas will be less than half Anglo and by 2030, the Texas State Data Center projects the State to be about 37 percent Anglo, about 9 percent African American, 46 percent Hispanic and about 8 percent of the population being from other racial/ethnic groups, primarily Asians. Roughly 87 percent of the net additions to the Texas population from 1990 to 2030 will be minority group members.*

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 2005 Texas Population of 22,859,968 (13,258,781 are 25 and older) and a Texas Pharmacist Population of 17,609.

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 48).

- 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 Nurse Examiners (BNE), 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.

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; and 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. 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, 1,176 of these “remote pharmacy services” are currently licensed.

In FY2003, the Texas Legislature gave the agency the authority to create new classes of pharmacy licenses. 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 emerging issue of 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, the funding for the program was not appropriated until the 78th Legislative Session, for 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.
As of the date of this report, the agency licenses approximately 22,000 pharmacists, 6,000 pharmacies, and registers 30,000 pharmacy technicians. The additional 30,000 pharmacy technicians have had a dramatic

effect on the agency's operations, since it more than doubled the number of licensees, bringing the total of all licensees to approximately 58,000.

From FY1995 - FY2005, the agency has experienced the following increases:

Performance Outputs – FY1995 – FY2005								
Year	Exams Administered	% Increase	# of Pharmacist Licensed	% Increase	# of Pharmacies Licensed	% Increase	# of Pharmacy Technicians Registered	% Increase
FY95	1,381	--	18,026	--	5,107	--	--	--
FY96	1,557	13%	18,450	2%	5,246	3%	--	--
FY97	1,698	9%	19,048	3%	5,404	3%	--	--
FY98	1,567	<8%>	19,429	2%	5,410	0%	--	--
FY99	1,162	<35%>	19,716	1%	5,422	0%	--	--
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%	26,644	20%
Cumulative Increases FY95-05		26%		26%		20%		20%

Online Application Process

In late October 2002, TSBP began implementing its license applications to the Texas Online Occupational License Application System. By year-end FY2005, all fee-paying applications of the agency were available electronically on Texas Online, with an overall adoption rate by agency customers of 75%. It is expected that with increased customer awareness, that adoption rate will grow.

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 6,100 pharmacies, with 5,730 of those pharmacies located in Texas and 370 pharmacies located in other states. TSBP employs six FTE's to conduct compliance inspections (e.g., follow-up to written warnings and disciplinary orders involving a pharmacy). With this staff, TSBP is able to inspect less than one-half 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. However, TSBP has limited resources to investigate complaints in a timely manner. Although TSBP closed/resolved more complaints in FY2005 than in the prior fiscal year, TSBP's average complaint time increased from 118 days in FY2004 to 196 days in FY2005 (see chart below).

Fiscal Year	Complaints Received	% Change Complaints Received Previous Year	Complaints Closed	% Change Complaints Closed Previous Year	% Complaints Closed	Resolution Time (Agency Average)	% Change Time
FY01	1683		1667		99%	262 Days	
FY02	1836	+9%	2137	+28%	116%	221 Days	-16%
FY03	1935	+5%	1887	-12%	97.5%	153 Days	-31%
FY04	4475	+131%	3018	+60%	67%	118 Days	-23%
FY05	3086	-31%	3327	+10%	108%	196 Days	+66%

The increased complaint resolution time is a direct result of the new program to register pharmacy technicians that began in FY2004. 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. 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 in FY2005.

The chart above shows that TSBP experienced an 83% increase in the number of complaints received over the past five fiscal years (i.e., the number of complaints received in FY2001 as compared to the number of complaints received in FY2005). Due to the criminal background checks of 26,000 individuals applying for a pharmacy technician registration in FY2004, TSBP experienced a dramatic increase in the number of complaints received in that particular year.

TSBP began to conduct quarterly criminal background checks of all registered technicians during the fourth quarter of FY2005 and determined that many of these technicians had committed criminal offenses during the year following the implementation of the technician registration program. TSBP anticipates that it will open an additional 500 complaints in FY2006 as a result of the quarterly background checks on pharmacists and technicians. Based upon mid-year statistics, TSBP anticipates that the agency will receive 3,550 complaints in FY2006 (a 15% increase in the number of complaints received when compared to FY2005 numbers).

In addition to the workload created by the quarterly criminal background checks, TSBP will begin registering pharmacy technicians-in-training in FY2006/2007. TSBP projects that it will open an additional 800 complaints in FY2006/2007 on these types of applicants, which will result in another dramatic "peak" during

the initial period of registering technician trainees. Without sufficient additional FTE's to handle this ever-increasing workload, TSBP anticipates that the complaint backlog and average complaint resolution time will continue to increase.

During the past five years, TSBP has also experienced increased demand for probation/monitoring services. In FY2005, the agency entered more disciplinary orders than in any prior fiscal year, based in large part on the additional cases against pharmacy technicians. A total of 552 disciplinary orders were entered, with approximately 95% of TSBP's disciplinary orders requiring some type of monitoring. TSBP currently has approximately two FTE's who monitor 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 purpose of the Council is to provide a means for the agencies represented to coordinate administrative and regulatory efforts. The Council is made up of representatives from the following agencies:

- Board of Chiropractic Examiners;
- Board of Dental Examiners;
- Texas Medical Board;
- Board of Nurse Examiners;
- Board of Occupational Therapy Examiners;
- Texas Optometry Board;

- Board of Pharmacy;
- Board of Physical Therapy Examiners;
- Texas Funeral Commission;
- Board of Podiatric Medical Examiners;
- Board of Examiners of Psychologists;
- Board of Veterinary Medical Examiners;
- Department of State Health Services, Professional Licensing and Certification Unit; and
- Office of the Governor.

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 FY1994-2005.

- 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.

- Use of a *purchasing pool* provides use of trained and certified purchasers to agencies too small to have such expertise.

- 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.

- Development of core policies and procedure statements for common areas such as travel, open records, and records retention. These statements are resources for Council agencies to use in developing individual agency manuals, saving staff time, and assuring consistent quality.

- Sharing an electronic imaging system for data storage.

- Completion of Complaint Study as mandated by the 77th 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. 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.

STATEWIDE BENCHMARKING

Michael Spendolini defines *Benchmarking* as *the continuous systematic process of evaluating the products, services, or work processes of organizations that are recognized as representing best practices for the purposes of organizational improvement* (Benchmarking Book, 1992). In January 1995, the Governor's Executive Development Program (Class XIII) published a Task Force Report entitled *Benchmarking and Customer Service Satisfaction as Measures of Governmental Effectiveness*, in which *Benchmarking* was defined as *a system of internal and external comparison, coupled with identification of best practices toward which agencies should strive to achieve.* This Task Force Report also quoted the International Benchmarking Clearinghouse's definition of *benchmarking* as *the practice of being humble enough to admit that someone else is better at something and being wise enough to try to learn how to match and even surpass them at it*.

Description of Agency Benchmarking Process

In an attempt to compare its performance with another agency or organization, TSBP reviewed the following sources for information:

- National Level — TSBP contacted the National Association of Boards of Pharmacy (NABP) to determine if national standards exist for any of the performance measures reported on a regular basis to the Legislative Budget Board (LBB) and Governor's Office (GO). NABP collects information from other state boards of pharmacy, but does not have data with regard to performance measures.

- Private Sector — The process of licensing and enforcing the laws and rules governing the practice of pharmacy are not carried out by the private sector. Accordingly, TSBP was unable to review similar service providers in the private sector.

- Other Agencies in Texas — TSBP conducts services similar to other health licensing boards in Texas, which are required to collect and report data to LBB with regard to performance. TSBP is a member of the Health Professions Council (HPC), as are all other Texas health licensing agencies. HPC publishes an annual report each year that includes the following information for each member agency: number of licensees, number of complaints resolved, average complaint resolution time, and number of disciplinary orders. When reviewing HPC Annual Reports and comparing statistics between HPC member agencies, TSBP appears to be either *best in class* or near to it when comparing TSBP to agencies having a similar size licensee population and/or similar workload (e.g., number of complaints received).

In addition, in an attempt to identify *best practices*, TSBP personnel continue to review applicable literature [*e.g.*, *Governing* (monthly publication)] and attend training sessions (*e.g.*, *Managing for Results*).