TEXAS STATE BOARD OF PHARMACY

STRATEGIC PLAN
For the Fiscal Years 2011-2015

June 18, 2010

STRATEGIC PLAN
For the Fiscal Years 2011-2015

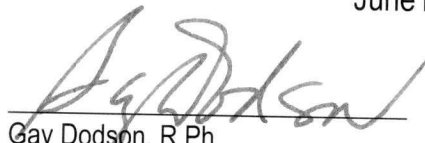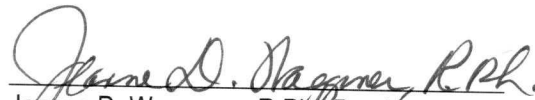| Board Member	Dates of Term	Hometown
Buford T. Abeldt, Sr., R.Ph.	5/9/2008-8/31/2013	Lufkin
Rosemary F. Combs	11/10/1999-8/31/2011	El Paso
W. Benjamin Fry, R.Ph., FIACP, FACS	4/14/2004-8/31/2015	San Benito
L. Suzan Kedron	5/9/2008-8/31/2013	Dallas
Alice G. Mendoza, R.Ph.	8/10/2006-8/31/2011	Kingsville
Joyce A. Tipton	1/6/2010-8/31/2015	Houston
Jeanne D. Waggener, R.Ph.	8/10/2006-8/31/2011	Waco
Charles F. Wetherbee	1/6/2010-8/31/2015	Boerne
Dennis F. Wiesner, R.Ph.	5/9/2008-8/31/2013	Austin

June 18, 2010

Signed: _____
Gay Dodson, R.Ph.
Executive Director/Secretary

Approved: _____
Jeanne D. Waggener, R.Ph., President

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THE VISION OF TEXAS STATE GOVERNMENT

- *Ensuring the economic competitiveness of our state by adhering to principles of fiscal discipline, setting clear budget priorities, living within our means, and limiting the growth of government;*

- *Investing in critical water, energy, and transportation infrastructure needs to meet the demands of our rapidly growing state;*

- *Ensuring excellence and accountability in public schools and institutions of higher education as we invest in the future of this state and ensure Texans are prepared to compete in the global marketplace;*

- *Defending Texans by safeguarding our neighborhoods and protecting our international border; and*

- *Increasing transparency and efficiency at all levels of government to guard against waste, fraud, and abuse, ensuring that Texas taxpayers keep more of their hard-earned money to keep our economy and our families strong.*

THE MISSION OF TEXAS STATE GOVERNMENT

Texas State Government must be limited, efficient, and completely accountable. It should foster opportunity and economic prosperity, focus on critical priorities, and support the creation of strong family environments for our children. The stewards of the public trust must be men and women who administer state government in a fair, just, and responsible manner. To honor the public trust, state officials must seek new and innovative ways to meet state government priorities in a fiscally responsible manner.

THE PHILOSOPHY OF TEXAS STATE GOVERNMENT

The task before all state public servants is to govern in a manner worthy of this great state. We are a great enterprise, and as an enterprise we will promote the following core principles.

- First and foremost, Texas matters most. This is the overarching, guiding principle by which we will make decisions. Our state, and its future, is more important than party, politics or individual recognition.

- Government should be limited in size and mission, but it must be highly effective in performing the tasks it undertakes.

- Decisions affecting individual Texans, in most instances, are best made by those individuals, their families, and the local governments closest to their communities.

- Competition is the greatest incentive for achievement and excellence. It inspires ingenuity and requires individuals to set their sights high. And just as competition inspires excellence, a sense of personal responsibility drives individual citizens to do more for their future, and the future of those they love.

- Public administration must be open and honest, pursuing the high road rather than the expedient course. We must be accountable to taxpayers for our actions.

- State government has a responsibility to safeguard taxpayer dollars by eliminating waste and abuse, and providing efficient and honest government.

- Finally, state government should be humble, recognizing that all its power and authority is granted to it by the people of Texas, and those who make decisions wielding the power of the state should exercise their authority cautiously and fairly.

RELEVANT STATEWIDE GOAL AND BENCHMARK

Priority Goal

To ensure Texans are effectively and efficiently served by high-quality professionals and businesses by:

- implementing clear standards;
- ensuring compliance;
- establishing market-based solutions; and
- reducing the regulatory burden on people and business.

Benchmarks:

- Percent of state professional licensee population with no documented violations.

- Percent of new professional licensees as compared to the existing population.

- Percent of documented complaints to professional licensing agencies resolved within six months.

- Percent of individuals given a test for professional licensure who received a passing score.

- Percent of new and renewed professional licenses issued via Internet.

- Number of new business permits issued online.

- Percent increase in utilization of the state business portal.

AGENCY MISSION

To promote, preserve, and protect the public health, safety, and welfare by fostering the provision of quality pharmaceutical care to the citizens of Texas, through the regulation of: the practice of pharmacy; the operation of pharmacies; and the distribution of prescription drugs in the public interest.

AGENCY PHILOSOPHY

The Texas State Board of Pharmacy will assume a leadership role in regulating the practice of pharmacy and act in accordance with the highest standards of ethics, accountability, efficiency, effectiveness, and open communication. We affirm that regulation of the practice of pharmacy is a public and private trust. We approach our mission with a deep sense of purpose and responsibility. The public and regulated community alike can be assured of a balanced and sensible approach to regulation.

EXTERNAL/INTERNAL ASSESSMENT

IDENTIFICATION OF ISSUES

In developing its Strategic Plan, the Board and agency staff sought to identify and analyze those trends and resulting issues expected to have the most significant impact on the profession and regulation of pharmacy over the next five years. As described in the *Description of Agency Planning Process (Appendix A)*, the Board conducted internal and external assessments, with the following four issues identified and detailed:

POLICY ISSUE #1 – The Changing Focus of Pharmacy Practice

POLICY ISSUE #2 – Increased Use of Technology in the Practice of Pharmacy

POLICY ISSUE #3 – Pharmacy Personnel and Working Conditions

POLICY ISSUE #4 – To Maintain the Agency's Leadership Position in Pharmacy Practice Regulation and Establish a Key Leadership Position for Addressing Public Needs

POLICY ISSUE #1 – THE CHANGING FOCUS OF PHARMACY PRACTICE

Issue Statement

The following forces are forging rapid changes in our healthcare system:

- the aging of Texas' population;

- advances in drugs, devices, and drug dosage forms;

- managed care;

- the public demand for safety in the healthcare system;

- the emergence of alternative medicine; and

- economics.

These forces both drive and are driven by new governmental strategies and marketplace issues, and are causing an evolution in the practice of pharmacy. These factors are causing pharmacists to change the focus of their practice to one that is more patient-oriented, where the pharmacist provides the prescription product as well as other pharmaceutical care services to meet needs of patients.

Pharmacists have the knowledge and opportunity to help patients achieve better outcomes from drug therapy and, in turn, provide a significant cost savings to Texas' healthcare system. The cost of this pharmaceutical care can very likely be recovered from the savings it generates. This outcome can be realized only if an environment is created by healthcare reform that recognizes that the savings are not likely to be generated at the pharmacist-patient level. The savings will be generated at the level of patients' therapeutic successes and the resulting reductions in hospitalizations, surgeries, repeated office visits, nursing home admissions, and prolonged illnesses that result from patients using their medications improperly.

Explanation of Issue

In recent years, the complexity of the healthcare system and the changing ways in which healthcare is delivered similarly changed the way pharmacists practice. Within the next five years the practice of pharmacy will continue to be changed by many factors, such as the aging of Texas' population, increasingly complex and expensive drugs, drug regimens, and diagnostic technologies emerging from the biotechnology industry, and healthcare reform. This will necessitate the viewing of pharmacy by professionals and patients in a way different from our century-old image of the pharmacist *behind the counter* inside the pharmacy.

The Texas Pharmacy Act recognizes this shift to a more patient-centered practice in the definition of the practice of pharmacy. This definition now includes activities associated with traditional dispensing of medication and:

- Provision of any act or service necessary to provide pharmaceutical care;

- Performance of drug therapy management under protocol of a physician (collaborative practice); and

- Administration of immunizations or vaccinations under a physician's written protocol.

The Act defines *pharmaceutical care* as the provision of drug therapy and other pharmaceutical services intended to assist in the cure or prevention of a disease, elimination or reduction of a patient's symptoms, or arresting or slowing of a disease process. These definitions make it clear that pharmacists need to be aware of, and committed to, the patients' interests and the direct outcomes of their individual drug therapies.

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

Although the Texas Pharmacy Act currently allows pharmacists to perform drug therapy management under written protocol of a physician and to administer immunizations and vaccines, there are limitations to these authorities. During the 2009, the Texas Legislature passed two bills that eliminated some of the limitations. In the case of drug therapy management under written protocol of a physician, pharmacists may initiate and modify drug therapy of patients but pharmacists were not allowed to sign written prescriptions in the same manner as physician assistants and advanced nurse practitioners are allowed. S.B. 381 passed by the 2009 Texas Legislature allows a physician to delegate the signing of a prescription to a pharmacist IF the pharmacist practices in a hospital, hospital-based clinic, or an academic health care institution.

Likewise, prior to the passage of H.B. 1409 by the 2009 Texas Legislature, the authority to administer medications was limited to immunizations and vaccines, and the patient must be 14 years of age or older. H.B. 1409 reduced the limitations by amending the law to allow pharmacists to administer an influenza vaccination (only) to a patient over seven years of age without an established physician-patient relationship. While the passage of these bills eliminated some of the barriers, further amendments to the act are necessary to remove the restrictions to allow pharmacists to more fully use these tools. In addition, for pharmacists to continue providing these expanded services, the buyers and sellers of healthcare must recognize and understand the pharmacist's value to the patient.

The buyers and sellers of healthcare will continue to scrutinize the system to ensure that care and product are being provided in the most *cost-effective* manner. The role of pharmacists will be viewed in the context of what level of care and services a patient receives. Financiers will be monitoring pharmacy practice in all settings to determine if pharmacists' services are cost-beneficial or if these services could be provided at reduced costs (*e.g.*, could pharmacist services be provided by another health professional?).

Policymakers, third-party payers, the public, and pharmacists need to be continually reminded that appropriate drug therapy is generally safer and more cost-effective than other forms of treatment and that the personal and economic consequences of inappropriate drug use are enormous.

If the profession of pharmacy does not move toward a cost-effective, patient-oriented practice, it can expect pharmacy technicians and/or technological advances to replace pharmacists who dedicate themselves solely to the dispensing and sale of medications and other products.

A big step to the recognition that appropriate drug therapy is cost-effective and necessary is the inclusion of medication therapy management programs (MTM) in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA). 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 is the first time that pharmacists have been allowed to bill for Medicare-related patient care services. Pharmacists were the only healthcare professionals specifically named in MMA to provide medication management services. However neither MMA nor the rules adopted to implement MMA specify that only pharmacists may provide these services.

During the last four years MTM has been required to be a part of Medicare Part D plans, and pharmacists are becoming more involved with the provision of this service. A Centers for Medicare and Medicaid Services (CMS) "Fact Sheet" on 2007 MTM programs states that "pharmacist intervention appears to be increasing as a preferred MTM strategy. In time, CMS expects MTM to drive improvements in quality of care and health outcomes.

A big step toward the reimbursement to pharmacists for MTM services occurred in July 2007, when the American Medical Association made the temporary pharmacist's' reimbursement codes a permanent part of the official list of procedures (three codes for MTM – initial service, subsequent service, and additional time, each in 15-minutes blocks). The Current Procedural Terminology (CPT) manual describes MTM, in part, *as a form of face-to-face assessment or intervention between a pharmacist and a patient or caregiver that is provided to optimize and improve the response to medications and to help avoid potential treatment-related medication interactions or complications.*

The CPT definition also notes that MTM is distinct from information at the point of dispensing and that it involves *a documented review of the patient, history, chief complaint or concern, medication profile (Rx and nonprescription), and any recommendations for improving health outcomes and the level of treatment compliance. These codes are to be used by pharmacists.*

MTM is a tool for pharmacists to use. The data generated from MTM documentation is being used to prove that drug therapy management is effective in improving patient's health. Over the next few years pharmacists will be challenged to provide these services and document their effect on the patient's health. As implementation of MTM moves forward, the Board will need to monitor its implementation and be ready to make modifications in agency rules and or law, if necessary, to allow pharmacists to improve patient care. The greatest need for regulation may be the adoption of minimum requirements for documentation of MTM activities. Thorough documentation is needed for pharmacists to validate their activities and to justify appropriate reimbursement as well as for the agency to monitor all provisions of pharmaceutical care.

In addition to providing drug therapy management and proving the value of their services, pharmacists must also work with other healthcare professionals to assure the safety of the healthcare system. The issue of the safety of the healthcare system has been the focus of numerous reports including a series of reports from the Institute of Medicine (IOM). The first report, issued in 1999 was titled: *To Err is Human: Building a Safer Health System.* This report identified medical errors as a significant problem and that medical errors kill 44,000 people in U.S. hospitals each year and cause more than 7,000 deaths annually, both in and out of hospitals. This study recognized the value of the pharmacist and stated: *The pharmacist has become an essential resource . . . access to pharmaceutical information must be available all the time.* Additionally, one of the IOM strategies calls for increasing pharmacy participation in medical rounds and in other areas to decrease the potential for error. The report recognized that errors were system and not individual failures and encouraged the use of continuous quality improvement (CQI) programs to prevent errors.

In 1999 Texas became the first state to pass legislation establishing pharmacy peer review committees for the establishment of CQI programs in pharmacies. The bill specifies that a pharmacy peer review committee may be established to:

- Evaluate the quality of pharmacy services or the competence of pharmacists;

- Suggest improvements in pharmacy systems to enhance patient care; and

- Investigate disagreements or complaints, determine facts, and make recommendations or issue decisions in a written report.

Most importantly, this legislation makes the records of a pharmacy peer review committee confidential and not subject to disclosure, discovery, or subpoena. Since passage of the peer review legislation, the Board has used this tool by ordering pharmacies, which have come before the Board for dispensing errors, to implement a CQI program that includes "peer review," for the identification and prevention of dispensing errors. The Board has no studies or data to indicate that pharmacies that establish CQI programs make fewer dispensing errors. However, pharmacies that have implemented such programs have indicated that the establishment of such programs has allowed management to identify problem areas and may have reduced the occurrence of serious errors. For example, one pharmacy chain used the data to determine that 80 percent of their errors occurred in 20 percent of the stores. This chain implemented changes in these stores and dramatically reduced errors chain-wide.

Since the passage of this legislation, the Board has ordered numerous pharmacies to implement CQI programs. However, because implementation of a CQI program is voluntary, not all pharmacies have implemented CQI programs. Therefore, the Board has suggested that the Pharmacy Act be amended to allow the Board to mandate all pharmacies implement CQI programs.

Implementation of CQI programs is crucial for pharmacies to develop a system to prevent medication errors; however, there are other actions that the Board could take to assist in preventing errors. For example, the Board could suggest that the legislature amend the Pharmacy and Medical Practice Acts to prohibit physicians from using "as directed" instructions on prescriptions and to strengthen the requirement for physicians to include an indication for use on the prescription. The use of clear and definitive instructions on prescriptions, including the indication for use, not only helps the patient understand how to take the medication, but also allows another check for a pharmacist to verify appropriate therapy. In addition, the Board should encourage the use of electronic systems for the transmission and receipt of prescriptions. These systems reduce the chance of "bad handwriting" causing errors. In addition, the Board should support initiatives by organizations such as the Institute for Safe Medication Practices and the Joint

Commission on Accreditation of Healthcare Organizations to eliminate the use of dangerous abbreviations and dose expressions. Symbols and abbreviations are frequently used to save time and effort when writing prescriptions. However, some symbols and abbreviations have the potential for misinterpretation or confusion. Examples of problematic abbreviations include "U" for "units" and "μg" for "micrograms." When "U" is handwritten, it can often look like a zero. Likewise, using the "μg" instead of "mcg" has also been the source of errors because when handwritten, the symbol "μ" can look like an "m."

In 2001, a second IOM report titled *Crossing the Quality Chasm: A New Health System for the 21st Century* was published. This report identified two additional issues that will affect the provision of pharmaceutical care, as described below.

(1)   Regulating the Profession – Within this issue IOM identified the following two areas:

    (A)   Assessment of the competence of a healthcare provider is identified as a *gap* in the regulatory scheme. The report states the following:

        In a field with a continually expanding knowledge base, there is no mechanism for ensuring that practitioners remain up to date with current best practices. Responsibility for assessing competence is dispersed among multiple authorities.

        Because of this *gap*, the Board may need to explore ways to ensure pharmacists' competence through periodic testing. An alternative to this testing may be for national and state professional pharmacy organizations to work together to develop other appropriate methods for assessing the continued competence of pharmacists.

        Recently a number of national pharmacy organizations have adopted policies stressing the importance of continuing professional development (CPD). In a CPD model a pharmacist would:

- Evaluate his or her personal needs and interests;

- Develop a plan that will foster his or her professional growth and development;

- Implement the plan;

- Document participation and execution; and

- Evaluate and refine the plan on an ongoing basis.

        CPD may include traditional continuing education (CE) and other learning/ work activities.

To assist pharmacists in developing a CPD plan, the National Association of Boards of Pharmacy has developed a Pharmacist Self-Assessment Mechanism (PSAM). PSAM is an evaluation tool intended to assist pharmacists in obtaining objective, non-punitive feedback on their knowledge base. The PSAM is based on a blueprint that is applicable to general pharmacy practitioners in all practice settings. On completion of PSAM the pharmacist will receive a report indicating the percentage of questions answered correctly in each of the five competency areas to allow pharmacists to see areas that may need further study.

Further validation for the use of CPD occurred In December 2009, when the Institute of Medicine (IOM) published a report titled: *Redesigning Continuing Education in the Health Professions.* This report proposes a new vision for continuing education that will be based on CPD, in which learning takes place over a lifetime and stretches beyond the classroom to the point of care. The IOM report provides five broad messages for all CE for Health Professionals as follows.

- There are major flaws in the way CE is conducted, financed, regulated, and evaluated. Among various problems, health professionals and their employers tend to focus on meeting regulatory requirements rather than identifying personal knowledge gaps and finding programs to address them. Many of the regulatory organizations that oversee CE also tend not to look beyond setting and enforcing minimal, narrowly defined competencies.

- The science underpinning CE for health professionals is fragmented and underdeveloped. These shortcomings have made it difficult, if not impossible, to identify effective educational methods and to integrate those methods into coordinated, broad-based programs that meet the needs of the diverse range of health professionals.

- Continuing education efforts should bring health professionals from various disciplines together in carefully tailored learning environments. As team-based health care delivery becomes increasingly important, such interprofessional efforts will enable participants to learn both individually and as collaborative members of a team, with a common goal of improving patient outcomes.

- A new, comprehensive vision of professional development is needed to replace the culture that now envelops continuing education in health care. Such a vision will be key in guiding efforts to address flaws in current CE efforts and to ensure that all health professionals engage effectively in a process of lifelong learning aimed squarely at improving patient care and population health.

- Establishing a national interprofessional CE institute is a promising way to foster improvements in how health professionals carry out their responsibilities. The committee proposes the creation of a public-private entity that involves the full spectrum of stakeholders in health care delivery and continuing education and that is charged with developing and overseeing comprehensive change in the way CE is conducted, financed, regulated, and evaluated.

(B)   With regard to the second area, scope-of-practice acts, the report states the following:

Although scope-of-practice acts are motivated by the desire to establish minimum standards to ensure the safety of patients, they also have implications for the changes to the healthcare system recommended in this report. Since any change can potentially affect scope-of-practice acts, it can be difficult to use alternative approaches to care, such as telemedicine, e-visits, non-physician providers, and multi-disciplinary teams, all of which can help in caring for patients across settings and over time.

Regulatory agencies and professional associations for all of the healthcare professions must work to identify methods to work together to provide the best healthcare to their patients. As the report identifies, healthcare practitioners and regulators must work through these scope-of-practice issues and design a regulatory scheme "that both protects the public's interest and supports the ability of healthcare professionals and organizations to innovate and change to meet the needs of their patients."

(2)   Use of Clinical Decision Support Systems (CDSS)

The second issue identified in *Crossing the Quality Chasm: A New Health System for the 21st Century* is use of clinical decision support systems (CDSS). The report defines CDSS as *software that integrates information on the characteristics of individual patients with a computerized knowledge base for the purpose of generating patient-specific assessments of recommendations designed to aid clinicians and/or patients in making clinical decisions.* Pharmacists have been the leader in the healthcare field in using computer support in daily practice. However, to make the best use of the systems, pharmacists must have access to the patients' medical records. Access to information could be provided through direct contact with the prescriber, a personalized patient ID card *(smart card),* centralized health information and patient profile, or other mechanisms. Concerns regarding intervention into the patient-doctor relationship and confidentiality of patient records will certainly emerge as issues to be addressed.

Medical confidentiality issues were addressed federally through the passage of the Health Insurance Portability and Accountability Act (HIPAA). During the 2001 Session, the Texas Legislature passed a comprehensive medical privacy act that encompasses the provisions of HIPAA and is more stringent than HIPAA in some areas. Both of these pieces of legislation appear to allow the sharing of medical information among healthcare providers, including pharmacists. It is important for pharmacists to monitor the implementing of regulations for these laws to assure that pharmacists may have access to important patient medical information.

A report from the Institute of Medicine (IOM) titled *Preventing Medication Errors* was issued in 2007. This report was the result of a direction from the Congress of the United States through the Medicare Modernization Act of 2003 for the Centers for Medicare and Medicaid Services (CMS) to contract with the IOM for a study to formulate a national agenda for reduction of medication errors.

The report provides guidance on how to implement error prevention strategies in hospitals, long-term care, and ambulatory care. The seven recommendations in the report follow on the recommendations included in the previous two IOM reports identified above. Specifically, Recommendation 7 states that <u>"Oversight and regulatory organizations and payers should use legislation, regulation, accreditation, and payment mechanisms and the media to motivate the adoption of practices and technologies that can reduce medication errors, as well as to ensure that professionals have the competencies required to deliver medications safely."</u>

In November 2007, the federal Food and Drug Administration (FDA) held a public meeting to obtain comments regarding behind-the-counter (BTC) availability of certain medications. In the announcement of the hearing FDA stated the following:

"The FDA is exploring the public health benefit of certain drugs being available behind-the-counter (BTC) that were previously prescription medications. A BTC class of drugs could be comprised of certain medications available behind-the-counter at the pharmacy without a prescription and require the intervention of a pharmacist before dispensing."

"Arguments in favor of BTC availability include pharmacist education and interaction with patients help ensure safe and effective use of medications, and increase patient access to medications that might otherwise be underutilized, particularly by patients without health insurance. Variations of BTC status are already in effect in other countries, including Australia, Canada, France, New Zealand, United Kingdom, Denmark, Germany, Italy, Netherlands, Sweden, and Switzerland. Typically, the pharmacist is required to ensure the patient meets certain criteria prior to dispensing, to provide education on proper use, and to monitor. In general, foreign countries have used the following criteria for switching a drug from prescription to intermediate class:

- *Indications suitable for self-medication, including self-diagnosis with pharmacist intervention.*

- *Low potential for side effects or overdose, pharmacist intervention could minimize risks.*

- *Other considerations include abuse potential, patient choice and accessibility, and public health issues."*

Pharmacy has long advocated for a BTC or "third class" of drugs. The board should monitor FDA's deliberations for the establishment of this new class of drugs and make changes to the Pharmacy Act and rules, if necessary, to allow pharmacists to engage in this activity.

Patients respect the information given to them by pharmacists. Pharmacists have consistently been rated as one of the most trusted professionals in the nation. Couple this with the fact that pharmacists are the most accessible healthcare professionals, and it follows that pharmacists are in an excellent position to fulfill an expanded service role to the public. With increased documentation showing that pharmaceutical care will benefit the patient, the expanding role of the pharmacist will be more widely accepted.

However, since non-pharmacists (corporate managers, some managed care officials, insurers, etc.) make many policy decisions about how pharmacy will be practiced, the delivery of true pharmaceutical care will be threatened unless healthcare policymakers and payers determine that pharmaceutical care is cost-effective and establish methods to compensate pharmacists for this service.

Pharmaceutical care will have a positive impact on public health by achieving desired medical outcomes, thereby improving patients' quality of life and reducing healthcare costs and perhaps by demonstrating that pharmaceutical care is indeed cost-effective.

Impact on Agency

The change of the focus of pharmacy practice to one that is more patient-oriented with pharmacists providing an ever-increasing number of expanded/nontraditional services to patients makes it imperative that Board members and staff continually monitor developments in pharmacy practice to be aware of any potential dangers to the public. If the agency is aware of potential dangers, it is better able to recommend laws and rules to assure that pharmacists are able – and willing – to competently provide these expanded services and provide advice and assistance to other health practitioners and to the patient.

Trends indicate that pharmacists do not have control over their pharmacy practice environment. Since corporate control exists in virtually all practice settings, non-pharmacists and non-dispensing pharmacists are making decisions about how pharmacy is to be practiced. Pharmacists should always consider the health of the patient when implementing procedures established by others. In addition, the agency must monitor the practice to assure that pharmacists are able to provide valuable pharmaceutical care services to patients. If the practice is limited or prohibited by corporate owners, the agency may be required, in the best interest of Texans, to implement rules mandating certain aspects of pharmaceutical care. In addition, the federal government could establish these standards in the absence of appropriate actions by state boards of pharmacy, given the precedent set by OBRA '90 and the recommendations of the Institute of Medicine.

The goals of healthcare reform include greater individual security, improved access to care, more cost-effective care, and maintenance of quality. This reform is an evolving process that will ultimately rewrite all the relationships in healthcare delivery and financing. Healthcare reform will also be occurring at the state level, as well as the federal level. The agency must monitor activities at the state level and provide input into any state legislation, ensuring that pharmaceutical care is incorporated into Texas' overall health plan.

As the role of the pharmacist expands to include shared responsibility for the quality of patient care and patient outcomes, the agency will need to adapt its enforcement efforts to ensure that pharmacists are effective. For example, the Board may need to implement measures to ensure that pharmacists are performing (and are competent to provide) such functions as:

- Drug utilization review;

- Drug therapy management;

- Monitoring their patients for drug abuse;

- Providing effective counseling;

- Directly monitoring drug use in certain settings; and

- Provision of behind the counter (BTC) drugs.

Such efforts would represent a departure from the traditional focus of pharmacy regulation, structure, and process to a focus on the results instead of the process. The goal would be not to abandon structure and process, but to link them with the final outcome. The Board is using the concept of *outcome-based regulation* in assessing disciplinary actions on pharmacists and pharmacies; for example, in the area of those who have committed dispensing errors. In addition to a sanction on the licensees involved, the Board has required the owner of the pharmacy license to review the dispensing process in the pharmacy and to develop and implement a quality assurance system to detect or anticipate errors, to rectify errors that have occurred, and to reduce the likelihood of future errors. Surely this type of sanction is better for the licensee and the public since it offers the potential for reducing the number of prescription errors.

Hospital pharmacists are currently defining quality of care in terms of outcomes as a result of standards from the Joint Commission on Accreditation of Healthcare Organizations (JCAHO). As community pharmacy practice moves to incorporate the concept of pharmaceutical care, regulatory and enforcement activities must also move to regulate based on quality assurance standards, not just performance of process-oriented tasks. The laws and rules must be structured such that they specify the desired outcome but not detail all of the steps necessary to obtain that outcome. This type of structure will allow pharmacists the flexibility to use innovative practice ideas while protecting the public by specifying positive patient outcomes.

The Texas State Board of Pharmacy's support of the use of outcome-based regulation may require retraining of enforcement personnel for review of quality-related records and procedures. The agency may need to employ *clinical consultants* or retrain pharmacist employees in these areas so they can assess whether clinical services provided by the pharmacist helped or harmed the patient.

Agency Strengths and Opportunities

(1)   The current definition of the *practice of pharmacy* in the Texas Pharmacy Act:

    (A)   Includes *provision of those acts or services necessary to provide pharmaceutical care*, *drug therapy management, and administration of immunizations and vaccines under the written protocol of a physician*, and

    (B)   Is broad enough to include new responsibilities and activities necessary for pharmacists to *dispense/administer* advanced technological drug products and devices in the delivery of pharmaceutical care.

(2)   In May 2001, the Board published *Guidelines for Establishing Pharmacist Peer Review Committees* to assist pharmacists and pharmacy owners in establishing continuous quality improvement programs that include peer review. These programs should allow pharmacists to thoroughly study their dispensing and distribution systems in order to establish a safer system.

(3)   The Texas Dangerous Drug Act gives the agency the authority to regulate prescription drugs and devices regardless of where these drugs are used or delivered.

(4)   A precedent exists for expanded roles for Texas pharmacists, because:

    (A)   The federal government, through the Department of Health and Human Services' Office of the Inspector General, has supported the clinical role of community pharmacists;

    (B)   The Texas Pharmacy Act now recognizes drug therapy management under protocol from a physician in any practice setting and the administration of drugs, under certain conditions, as a role of the pharmacist. In addition, this amendment to the Act was supported by the medical and nursing community; and

    (C)   The federal government, through the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, has recognized the value of pharmacist provision of medication therapy management programs.

(5)   Current Board rules require patient counseling for patients at the pharmacy, Drug Utilization Review (DUR), and provision of written information about prescription medications.

(6)   Current Board rules require patient outcome monitoring in some practice settings.

(7)   The Board of Pharmacy has embraced the concept of *outcome-based regulation* and is using it in imposing disciplinary action by requiring the licensee(s) to develop and implement a continuous quality assurance program to detect errors, to rectify errors that have occurred, and to prevent future errors.

(8)   The pharmacist's credibility with the public in terms of honesty and integrity will help the profession and the agency to move pharmacists toward new or expanded roles.

(9)   The agency has the authority to establish task forces composed of pharmacists and other professionals who have special expertise to advise the Board.

(10)   There is a vast pool of knowledgeable resource persons in Texas' pharmacy educational institutions and in its health professions available to the agency.

Agency Weaknesses and Constraints (Threats)

(1)   In spite of the need for healthcare to be based on a multi-disciplined healthcare delivery system, expanded roles for pharmacists may be perceived as threatening the *turf* of other health professionals such as physicians and nurses. Resolution of problems related to advanced technological drugs, devices, and dosage forms may, in some cases, be thwarted by *turf* battles between the health professions.

(2)   Some pharmacists may perceive that providing *pharmaceutical care* increases their liability. In addition, some pharmacists may be limited in the extent of *pharmaceutical care* services they are able to effectively provide because they don't have access to information in the patient's medical records (*e.g.*, pharmacists may not know the patient's diagnosis or the outcome sought by the physician).

(3)   If pharmacists are not allowed to fully use the assistance of technology and/or pharmacy technicians, but are required to provide *pharmaceutical care,* the cost of pharmacy services could rise significantly.

(4)   Although there is a documented need, the agency has virtually no resources to address the need for consumer education about the use, abuse, and misuse of prescription drugs so critical to positive patient outcomes.

(5)   The current definition of dangerous drugs includes *devices which require a prescription*, but does not include other types of devices.

(6)   Although the current definition of the *practice of pharmacy* in the Texas Pharmacy Act is broad enough to include new responsibilities and activities for pharmacists to *dispense/administer* advanced drug products and devices, the Act may have to be amended to clarify that these activities are included.

(7)   Some of the *corporate* (independent and chain) entities that own pharmacies in Texas talk about their *commitment* to the concept of pharmaceutical care, but the experience of the agency is that the main emphasis of these corporations is on the *bottom-line* or the number of prescriptions dispensed. Therefore, when it becomes apparent that additional resources are necessary to provide pharmaceutical care, these resources may not be readily provided.

Agency Initiatives

(1)   Continue to include outcome-based initiatives in the Board's disciplinary orders.

(2)   Work with the associations and the Legislature to amend the Pharmacy Act to give the Board the authority to mandate that all pharmacies implement continuous quality improvement programs that include peer review.

(3)   Develop a compliance inspection process based on the concept of outcome-based regulation.

(4)   Be an active participant with other healthcare providers, legislators, and regulators in establishing initiatives regarding protecting a patient's confidential healthcare information.

(5)   Be an active participant with other healthcare providers, legislators, and regulators in establishing initiatives regarding medication errors, including possibly amending the Pharmacy and Medical Practice Acts to prohibit physicians from using "as directed" instructions and problematic abbreviations on prescriptions and to strengthen the requirement for physicians to include an indication for use on the prescription. The use of clear and definitive instructions on prescriptions, including the indication for use, not only helps the patient understand how to take the medication but also allows another check for a pharmacist to verify appropriate therapy. In addition, the Board should encourage the use of electronic systems for the transmission and receipt of prescriptions. These systems reduce the chance of *bad handwriting* causing errors, as well as increase the breadth of information that is available to the healthcare providers at the time of care.

(6)   Monitor the progress of the profession in establishing continuous quality improvement programs and the effect these programs have on reducing medication errors.

(7)   Monitor the implementation of Medication Therapy Management Programs under the Medicare Part D legislation and be ready to make modifications in agency rules and/or law, if necessary, to allow pharmacists to improve patient care.

(8)   Work in partnership with other state and national pharmacy regulatory organizations and professional associations to ensure that the Act continues to provide the greatest protection for the citizens of Texas while not inhibiting the implementation of new and progressive healthcare and pharmaceutical care systems. It is crucial that the Texas pharmacy regulations not trigger federal preemption requirements in areas such as medication therapy management, electronic prescribing, and electronic medical records.

POLICY ISSUE #2 – INCREASED USE OF TECHNOLOGY IN THE PRACTICE OF PHARMACY

Issue Statement

The use of new technologies will continue to increase in the practice of pharmacy over the next five years. Current, new, and anticipated technologies include the expanded use of computers, PDA's (personal digital assistants), robotics, biometrics, bar codes, RFID (radio frequency identification), nanotechnology, voice recognition, telecommunication, automated prescription kiosks, and the Internet. It is clear that technology has the capacity to greatly enhance the provision of pharmaceutical services and provides opportunities to maximize the use of staff. It also creates some special challenges for the Board. Many issues cross jurisdictional boundaries between state agencies, federal agencies, and even international agencies.

The Board must find ways to support the increased use of technologies that enable pharmacists to better serve the public health, safety, and welfare. This includes finding ways to balance productivity with safety, automation with accountability, and pharmacy service with patient confidentiality.

Explanation of Issue

In November 2000, the Texas Pharmacy Congress organized a Summit 2000 meeting of all Texas pharmacy organizations and representatives of many of the non-pharmacy practitioner organizations. The consensus report was published as a white paper titled, *Summit 2000: Better Medication Outcomes Through Healthcare Collaboration*. One of many issues identified during this summit was the inadequate use of technology that could facilitate recognition of systems errors and potentials for error. Some of the recommendations for technology directly impact pharmacy practice and regulation, such as: sharing patient data and information, developing smart card systems containing comprehensive patient data, prescribing electronically, computerizing physicians' orders, centralizing distribution of bar-coded unit dosed pharmaceuticals, using scanning technologies, and integrating computer systems.

In 2000, the Institute for Safe Medication Practices (ISMP) published a white paper titled, *A Call to Action: Eliminate Handwritten Prescriptions within 3 Years!* Although the ISMP recognizes that electronic prescribing is not a panacea that will eliminate all prescription errors, their white paper makes the following statement. *Put simply, handwritten prescriptions ought to be a thing of the past. Healthcare practitioners and providers across the nation should rapidly and aggressively <u>take advantage of the electronic prescribing technology that will help prevent medication errors today</u>*. (Emphasis added). As a follow up to the 2000 call to action, in early 2003, ISMP issued a draft recommending guidelines for safe transmission of electronic medication orders.

In 2003, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) was passed by the United States Congress (see Issue #1 for a more detailed discussion of this legislation). MMA includes a provision that requires that all prescriptions issued to Medicare Part D patients be written and transmitted electronically. The provision of prescriptions through MMA became effective on January 1, 2006. Although prescribers were originally required to have prescription pads with at least one of three tamper-resistant characteristics by October 1, 2007, Congress voted to extend the deadline to April 1, 2008. Additionally, prescription pads were required to contain all three tamper-resistant characteristics by October 1, 2008. The Board needs to continue monitoring the implementation of this federal requirement to ensure that state laws are compatible with the federal regulations.

The American Recovery and Reinvestment Act of 2009 appropriated substantial funding to facilitate the development, electronic exchange, and use of electronic health information among healthcare providers. Such a national initiative has the potential to foster better communication among all healthcare providers, to improve efficiencies in the delivery of patient care, and to enhance the overall care provided to patients. The Board must consider regulations in the context of an evolving framework so as not to inadvertently hinder pharmacy's ability to adopt or participate in the development of electronic health records.

The National Association of Boards of Pharmacy (NABP) supports the call for electronic transmission of prescriptions in the Medicare bill. However, NABP believes that this initiative should be expanded to all prescriptions. NABP believes that electronic prescription transmission will be a benefit to both pharmacists and their patients because it is an easier, safer, and more efficient way of tracking patients' prescriptions, while at the same time making prescriptions easier to read and reducing the possibility of errors.

It is clear that appropriate, coordinated use of new technologies is necessary in pharmacy practice. New technology is appearing in many other areas of pharmacy practice as well.   Although there is overlap, this discussion will be divided into the following areas:

- receipt and data entry of prescriptions and patient information;

- storage of prescription information;

- delivery of pharmacy services;

- accountability for pharmacy services;

- patient confidentiality; and

- the use of the Internet.

The Board will be challenged to appropriately address each of these areas of *technological progress* due to the very limited practice sites in operation that may be used as true reference.

(1)   Receipt and Data Entry of Prescriptions and Patient Information

The profession will continue to seek ways to automate the prescription transmission process between practitioners and pharmacies. Besides written and verbally communicated prescriptions, the Board has, for many years, allowed prescriptions to be electronically transmitted between practitioners and pharmacies. Electronic prescribing may be one of the most effective methods to reduce dispensing errors due to illegible handwriting. However, the Board must be aware of the potential for other types of errors to occur when using electronic prescribing. Entrepreneurs have been monitoring this type of prescription transmission and are seeking ways to facilitate the process. This includes use of the Internet, e-mail, personal digital assistants (PDAs), fax-to-fax or fax-to-computer, prescription depositories, as well as direct computer-to-computer links between practitioners and pharmacies. This raises the concern of unauthorized access to the confidential healthcare information contained in these prescriptions. To ensure patients' confidentiality, prescribers should be required to produce an *audit trail* for prescriptions electronically submitted to pharmacies.

Data entry of prescription information into a pharmacy's computer system has traditionally occurred via a computer keyboard at the dispensing pharmacy. Other technologies, such as biometrics, bar coding, and voice recognition are being considered as methods for data entry of this information. Electronic transmission technology allows prescription data entry into a pharmacy's computer by any of these methods to occur at locations other than the dispensing pharmacy. Off-site data entry is currently being used as a way to alleviate some of the pharmacist's workload issues at the pharmacy level. It is important for the Board to monitor the changes in electronic prescribing and keep the Board's rules current with the technology.

(2)   Storage of Prescription Information

Currently, a pharmacy's prescription records are required to be maintained at the dispensing pharmacy. With the centralization of pharmacy services discussed under *Delivery of Pharmacy Services* (below), there is a desire to centralize prescription records. This would allow a single prescription record to be accessed by multiple pharmacies for dispensing purposes without actual transfer of the prescription between pharmacies. As a result, patients would have easier access to their prescriptions. There also exists *smart card* technology, where a computer chip is contained in a card carried by the patient. This card could carry patient and insurance information and also carry the patient's prescription information. However, at both the state and federal levels, these practices raise recordkeeping, confidentiality, and accountability concerns. Cooperation and agreement between federal and state agencies will be required as the Board addresses recordkeeping issues.

Some entrepreneurs have gone a step further and set up centralized prescription and patient information centers that are not licensed as pharmacies. These types of facilities should be licensed as pharmacies to protect the public. One such entity has promoted their service as a centralized location to which practitioners communicate their prescriptions. Once received, the prescriptions are either sent to a designated pharmacy or retrieved by a pharmacist for dispensing. In addition to the prescription information, system members have access to all of the prescription and healthcare information contained in the system. The Board needs to be diligent in assuring that the information contained by these systems is confidential and may only be accessed by authorized entities.

Pharmacies are also using electronic recordkeeping systems to scan or capture an unalterable electronic visual image of a prescription drug order. These systems save space and may improve a pharmacy's efficiencies by reducing time spent filing hard-copy prescriptions. These scanned images allow for a prescription to be viewed from alternative locations outside of the pharmacy where the record is stored. Currently, Board rules allow for the electronic storage of prescription records. However, federal regulations do not allow for the electronic storage of controlled substance prescriptions.

(3)   Delivery of Pharmacy Services

The Board will need to monitor and address entirely new methods for delivery of pharmacy services. This will include licensure requirements and enforcement strategies to protect public health.

(A)   Prescription Drug Products

- Robotics - Dispensing robots are becoming more affordable and prevalent. Because the cost for such robots is decreasing, some smaller pharmacies are able to justify the cost. However, the cost of the larger systems is still well beyond the means of most pharmacies. This has led to the desire to get the most out of the investment in robotics by attempting to fill prescriptions robotically for separately licensed pharmacies.

- Centralized Prescription Dispensing - This comes as an offshoot of robotics. Pharmacy managers see that centralized high volume robotics can take pressure off of individual high volume pharmacies. The concept has currently revealed itself as centralized dispensing centers where prescriptions are ordered through community pharmacies but filled in the highly automated central location. Prescriptions are then delivered to the community pharmacy for pick-up by the patient. When patients order refills early enough, this process will take the dispensing load out of the community pharmacy and place it in a very efficient automated pharmacy. In November 2002, the Board adopted rules for allowing centralized dispensing.

- Centralized Prescription Processing - In a continuing effort to take pressure off of individual high volume pharmacies, pharmacy managers are also developing the concept of processing prescriptions centrally. When a prescription is ordered from a pharmacy, the information is routed to a central processing location where personnel perform tasks closely related to dispensing a prescription without actually dispensing the prescription. These tasks may include obtaining and documenting refill authorizations, processing claims for third party payments, resolving managed care issues, and even data entry of the prescription into the dispensing pharmacy's prescription data base. In November 2002, the board adopted rules for centralized prescription processing.

- Remote Dispensing Systems - As this robotic technology develops and entrepreneurs look for ways to market their products, there will be a push to place remotely controlled dispensing systems in satellite locations. In the past, these remote locations may or may not have held pharmacy licenses or any other license that allowed possession of stock prescription drugs. However, under the provisions of S.B. 98 and S.B. 65, passed by the 77th Legislature (2001), these remote facilities must be registered by the Board.

  Currently, Texas pharmacy laws and rules allow a pharmacy to place an automated dispensing system that is remotely controlled by a pharmacist in a nursing home. A drug ordered for a patient is released only after the pharmacist has reviewed the order and conducted a drug regimen review. Other potential locations for remote dispensing systems include assisted living centers, personal care homes, adult day care centers, jails and detention centers, offsite clinics associated with hospitals, and even in schools.

Texas pharmacy laws and rules also allow a pharmacy to provide prescription services to remote medically underserved areas using a telepharmacy system. The telepharmacy system is a system that monitors the dispensing of prescription prepackaged unit of uses drugs to patients at the remote location by a nurse or pharmacy technician under the supervision of a pharmacist. The pharmacist supervises the activities at the remote site through the use of a telepharmacy system that uses audio and video, still image capture, and/or store and forward technology. The pharmacist also provides drug use review and patient counseling by electronic means. As telepharmacy systems become more accepted, there will be pressure to expand the types of sites that may use telepharmacy. The Board must monitor these initiatives to ensure that pharmacists are in control of the dispensing process and patients are receiving good pharmaceutical care.

- Bar-coding and Other Tracking Systems – The increased use of bar-coding and other tracking systems, such as radio frequency identification (RFI), may help to prevent the distribution of counterfeit drugs.

- Institutional Based Centralized Repackaging and Distribution of Medications - With the advent of DRGs (diagnosis related group codes) and mandated capitation costs, there is increasing pressure for institutions to become more financially fit, without compromising patient safety or patient care. Inventory management and distribution management are two areas that can possibly reduce associated overhead, while at the same time not compromise patient safety, but actually improve patient safety in some ways. Both regulations and statutes at the federal and state level must be modified. The 79th Legislature (2005) passed S.B. 492 that allows a hospital to prepackage medications for another hospital under common ownership. In August 2007, the Board adopted rules implementing the legislation.

(B) Drug Information Services

- Call Centers - These central locations receive verbally or electronically communicated prescriptions from practitioners, then process and forward the prescriptions to pharmacies within their network. These facilities may perform such activities as formulary reviews, drug regimen reviews, consults with physicians or patients, getting approval for generic substitution or therapeutic interchanges, and even drug therapy management under protocol. Currently, facilities performing these activities must be licensed as pharmacies and operate as such to some extent.

- Drug Information - Drug information has been available for a long time in the form of reference books that could be purchased or accessed through libraries, pharmacies, or drug information services, but the Internet has become a major source of drug information. Use of the Internet as a source for healthcare information has led to great concern by healthcare providers. Patients need accurate healthcare and drug information. Problems with the accuracy of information presented on the Internet, as well as accountability for the information, have prompted this concern.

Many of these new methods for delivery of pharmacy services may require statutory and/or regulatory changes. The Board will need to constantly monitor these current and future developments and take appropriate action to assist and not hinder appropriate advances in the delivery of pharmacy services.

(4)   Accountability for Pharmacy Services

The provision of pharmacy services has become fragmented and multiple personnel, licensed and unlicensed, assist in the dispensing process.   Automation and robotics can perform many of these same functions in some facilities. Centralized recordkeeping and multi-pharmacy involvement in a single dispensing process make it harder to establish individual responsibility. Although advances in technology may fragment the dispensing process, technology can also be used to enhance individual accountability. As the Board addresses technology issues in the future, it must also address individual accountability for decisions made in the dispensing and information provision processes.

(5)   Patient Confidentiality

Patient confidentiality, as viewed by a healthcare professional, may not be the same as that expected by a patient in the healthcare system. Whereas a healthcare professional may consider sharing confidential information with another healthcare professional caring for a patient as being in the best interest of that patient, the patient may have a much stricter interpretation of confidentiality where only those entities specifically noted by the patient may receive confidential information.

Many entrepreneurs seek to gather confidential patient information directly or as a byproduct of another endeavor. For example, the unlicensed facility promoting their centralized prescription transmission and recordkeeping business will have access to confidential patient information. Another example is a drug wholesaler who developed a program to identify certain prescriptions and make calls to the practitioner on behalf of the pharmacy to request a generic substitution or a therapeutic switch for the drug. Who will regulate their access to the information and how they use it?

Expanded use of information technology increases the opportunity for confidential patient health information to become public. As confidential patient information is routed between pharmacies, practitioners, and other healthcare professionals, the information goes through intermediaries, which may or may not have access to the confidential patient information. Much of this sharing of protected health information (PHI) is governed by specific documents outlined in HIPAA.

(6)   Internet Pharmacies

The Internet has received a tremendous amount of attention over the past few years. Internet pharmacies sprang up almost overnight. By and large, legitimate Internet pharmacies are simply mail-service pharmacies that use the Internet to advertise their pharmaceutical services. This has led to several ancillary issues.

Not all Internet pharmacies are licensed. Some entrepreneurs use the ever-changing fluidity of the Internet to offer prescription drugs illegally, closing up shop after a very short period of time only to appear again under a different facade. In addition, since the Internet is global in scope, an Internet pharmacy, which appears to be located in a city in another state, may in fact be located in Switzerland, or some other country. The issue of illegal sales of prescription drugs through the Internet crosses local, state, and international boundaries and will require the cooperation of many state, federal, and international agencies to resolve. The Board must continue to monitor this issue.

To assist consumers with determining whether an Internet pharmacy is legitimate, the National Association of Boards of Pharmacy (NABP) established a Verified Internet Pharmacy Practice Sites (VIPPS) program. In the VIPPS program, Internet pharmacies voluntarily agree to abide by certain high standards set by NABP. NABP, in turn, verifies proper pharmacy licensure, monitors compliance with the volunteer standards, and authorizes a VIPPS seal to be placed on the Internet pharmacy's web site.

Another related issue is that of Internet prescribing by practitioners. In this practice, practitioners examine patients through the use of a questionnaire completed by the patient on the Internet. If the patient meets certain parameters, the practitioner will issue a prescription for the patient. Internet pharmacies become involved because many of the practitioners prescribing in this manner are linked to Internet pharmacy sites. Although the prescribing component is not within the authority of the Texas State Board of Pharmacy, the Board should closely monitor the Texas Medical Board activities regarding this issue. The current U.S. administration is proposing that the federal Food and Drug Administration regulate Internet pharmacies. Although cooperation between state and federal government is essential to adequate regulation, there is a concern that state regulation of pharmacy practice may be diluted. The Board will be challenged to maintain a balance between regulatory authorities as the Board discharges its duty to the residents of Texas.

During the 79th Legislative Session (2005), the Texas Legislature passed S.B. 410 that contains a number of provisions related to the Internet as follows:

- Provisions that require the Board to maintain a list of all licensed pharmacies that maintain an Internet web site including the pharmacy's 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.

- A provision that adds to the Pharmacy Act language that requires a pharmacy to ensure that its agents and employees, before dispensing a prescription, determine in the exercise of sound professional judgment that the prescription is a valid prescription. The bill further states that a pharmacy may not dispense a prescription drug if an agent or employee of the pharmacy knows or should know that the prescription was issued on the basis of an Internet-based or telephonic consultation without a valid practitioner-patient relationship.

- 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. The law required the Board to designate from one to ten Canadian pharmacies as having passed inspection, and thus allow the pharmacies to ship prescription drugs into Texas. The Board was also mandated to provide information on these pharmacies on its web site to facilitate ordering of drugs by Texas residents. Because the Board had received a letter from the Federal Food and Drug Administration stating that this portion of S.B. 410 was in conflict with federal law, the Board asked the Texas Attorney General for an opinion on whether the law was, in fact, in conflict with federal law. On December 21, 2005, Attorney General Greg Abbott issued Opinion #GA-0384 in response to the Board's request. The opinion states that designating certain Canadian pharmacies, promoting them on the Board's web site, and permitting Texas consumers to import prescription drugs from Canada would violate federal law.

Impact on Agency

The agency must keep abreast of changes and advances in the uses of technology in pharmacy practice. In addition, the agency must continually strive to be educated about, to understand, and to monitor technological innovations in pharmacy practice.

The marketplace will increasingly demand *less regulation* in order to provide less costly services to the healthcare consumer. Therefore, as the use of technology expands, the agency will be tasked to determine the critical functions that must be controlled, supervised, or performed exclusively by pharmacists in order to promote, preserve, and protect the public health. By providing an environment that encourages the use of technology, pharmacies can continue to deliver services to the public in a form that meets the patient's needs and lifestyle while maintaining safety.

Agency Strengths and Opportunities

(1)   The Texas Pharmacy Act gives the agency authority to adopt rules regarding the use of technology in the practice of pharmacy. TSBP has used this authority to adopt rules for remote pharmacy services, central dispensing services, and central processing services.

(2)   TSBP has the authority to form task forces to study issues and make recommendations to the Board. As the need has arisen, several of these task forces have addressed automation and technology issues.

(3)   TSBP has continued to review, amend, and/or adopt rules for the expanded use of technology in the practice of pharmacy.

(4)   The agency's Compliance Section of the Enforcement Division is already in a position to observe the use of technology in the practice setting.

(5)   Texas has a wide variety of knowledgeable resource persons in pharmacy educational institutions and in the profession who can assist the Board in its decision-making process.

(6)   TSBP has developed and maintains good working relationships with those state and federal agencies whose jurisdiction overlaps pharmacy practice in Texas. TSBP should work with the Texas Medical Board to encourage physicians to electronically issue prescriptions and require physicians to produce and maintain audit trails for prescriptions submitted electronically to pharmacies.

(7)   TSBP has the opportunity to work with the Texas Department of Insurance (TDI) as TDI registers Pharmacy Benefit Managers (PBMs) and enforces the new confidentiality requirements for PBMs.

Agency Weaknesses and Constraints (Threats)

(1)   Board members, agency staff, and pharmacists in general, have limited expertise in technology, while the technology is rapidly becoming more and more complex. The agency will have to expend resources in getting and staying up to date.

(2)   Some statutory restrictions to the use of technology predate the application of technology to the practice of pharmacy. These restrictions at times become a barrier to the most efficient use of advancing technology.

(3)   TSBP does not have the authority to license or directly regulate entities that want to facilitate the prescription transmission process between practitioners and pharmacies.

(4)   There is a perception by some consumers that the use of robotics and other such automation makes the dispensing process too impersonal. Other consumers are afraid of the use of robotics and the perceived loss of human control in the dispensing process.

(5)   TSBP is unable to regulate the provision of drug information from facilities other than pharmacies.

(6)   Many of these issues cross political and jurisdictional boundaries resulting in inadequate, piecemeal, or patchwork solutions. Cooperation between various state and federal agencies to resolve problems is essential but takes time.

Agency Initiatives

(1)   Cooperate with state and federal agencies to establish an effective and efficient level of regulatory control over the use of technology in pharmacy practice.

(2)   Monitor the use of technology in healthcare in general and pharmacy in particular, including the use of technology as it applies to remote pharmacy services.

(3)   Actively participate with other healthcare providers, legislators, and regulators in establishing initiatives to advance the safe and appropriate use of technology in pharmacy practice.

(4)   Seek ways to increase individual accountability for the activities of personnel involved in the provision of pharmacy services.

(5)   Cooperate and actively participate with state and federal agencies to protect confidential patient information but still allow for the sharing of information between healthcare professionals necessary to the provision of pharmaceutical care.

(6)   Educate pharmacists, pharmacy owners, and other interested parties concerning:

- The legal use of technology in pharmacy practice; and

- Patient confidentiality.

POLICY ISSUE #3 – PHARMACY PERSONNEL AND WORKING CONDITIONS

Issue Statement

Current stressors in the pharmacy environment include the shortage of pharmacists; evolving roles and duties of registered pharmacy technicians, and working conditions [e.g., increased volume of prescriptions; working long hours; increased use and availability of technology; and increased professional responsibilities (e.g., patient counseling and drug regimen reviews)].

Expanded use of automation (as discussed in Policy Issue #2) and competent pharmacy technicians should help to reduce the stressors in the pharmacy. However, the strategic challenge for the Texas State Board of Pharmacy (TSBP) during the next five years will be to review its rules and procedures and to collaborate with other agencies and entities to improve working conditions in the pharmacy environment.

Explanation of Issue

(1)   Pharmacist Shortage

The six Texas institutions include four long-established colleges of pharmacy: Texas Southern University (College of Pharmacy in Houston); Texas Tech University Health Sciences Center (School of Pharmacy in Amarillo); University of Houston (College of Pharmacy in Houston); and The University of Texas at Austin (College of Pharmacy in Austin) and two new schools, University of the Incarnate Word (Feik School of Pharmacy in San Antonio) and Texas A&M University Health Science Center (Irma Lerma Rangel College of Pharmacy in Kingsville). University of the Incarnate Word is the first private institution in Texas to establish a pharmacy school. Both Texas A&M University Health Science Center (TAMHSC) and the University of the Incarnate Word (UIW) will graduate their first classes in May 2010. Although these institutions have experienced an increase in the number of applications to their pharmacy schools and an upturn in enrollment, TSBP records continue to indicate that most of the recent new licensees graduated from an out-of-state college/school of pharmacy. In FY2009, TSBP licensed 1074 new pharmacists from United States colleges/schools of pharmacy with 44% (469 persons) having graduated from one of the Texas colleges/schools of pharmacy. This percentage of in-state graduates has not changed from two years ago. In addition to graduates from domestic colleges/schools of pharmacy, Texas also licensed 133 new pharmacists who graduated from foreign colleges/schools of pharmacy.

Texas A&M Health Science Center in Kingsville and the University of the Incarnate Word in San Antonio combined will graduate approximately 150 students. This increase in new pharmacist graduates should have a positive impact on the number of in-state graduates who begin practicing in Texas.

The pharmacist shortage that has existed in Texas for several years appears to be improving. According to a report published by the Texas Higher Education Coordinating Board (THECB) in January 2009:

(A) Texas ranked 7th among the ten most populous states in average class size of pharmacy programs;

(B) from 1998 – 2008, applications to Texas schools/colleges of pharmacy increased 173 percent, and first-year entering enrollment increased 63 percent. The increase in first-year enrollment is attributed to expansion of existing programs and the creation of the two new programs at TAMHSC and UIW; and

(C) from 1999 – 2007, the number of Texas pharmacy graduates increased 49 percent.

In the same report, the THECB states:

(A) Texas has fewer pharmacists per 100,000 population (78) than the average of the 10 most populous states and that 41 states have more pharmacists per 100,000 population than does Texas; and

(B) the El Paso and the Big Bend region of West Texas has 48 pharmacist per 100,000 population, while the Gulf Coast and the Dallas-Ft. Worth Metroplex regions have 92 and 86 pharmacists per 100,000 population, respectively.

While not surprising that the pharmacist shortage is improving statewide compared with reports from previous years, there continues to be a relative shortage in rural areas of West and East Texas. Nonetheless, THECB does not recommend creation of a new pharmacy school and predicts that Texas will produce enough pharmacists from its own pharmacy schools to meet or exceed state workforce needs by the year 2014.

In March 2009, TSBP records indicated that 24,823 pharmacists held Texas licenses, but only 19,733 pharmacists resided in Texas. Of the pharmacists who resided in Texas, approximately 47% worked in community pharmacies, 19% worked in hospitals, and the remaining 34% worked in other types of settings (e.g., clinics, mail-service pharmacies, wholesalers, education, and government). The 2009 THECB report stated that Texas had 78 pharmacists per 100,000 population. The THECB study also indicated that pharmacists were not evenly distributed among the Texas population, with the Lower Rio Grande Valley (excluding Bexar County) and the El Paso area having the fewest pharmacists per 100,000 population.

Texas continues to import a large number of graduates from other states. In FY2009, 1207 persons were newly licensed as pharmacists by TSBP. This total represented 469 graduates from Texas colleges/schools of pharmacy; 605 graduates colleges/schools of pharmacy outside of Texas and 133 graduates from foreign colleges of pharmacy. This trend is similar to that in previous years; however, both new Texas pharmacy schools will graduate their first classes in 2010. These new Texas graduates should have a positive impact on the statistics of Texas graduates licensed as pharmacists.

The 2009 THECB study concluded:

The number of Pharm.D. graduates will increase markedly when new pharmacy schools in Kingsville and San Antonio begin producing graduates in 2010. The state's demand for additional pharmacists and the supply of new pharmacists from Texas pharmacy schools are expected to be balanced by 2014.

The study recommends:

As a remedy for those regions of the state where the ratio of pharmacists to residents is significantly lower than the state average, the Legislature could fund a pharmacist residency program to help bring practicing pharmacists to underserved communities in Texas.

(2)   **Applicants for Licensure**

(A)   Pharmacist-Interns

With the creation of two new pharmacy schools and the proposed change in the standards for internship that will require students to begin performing limited internship duties in the first professional year, there will be a dramatic increase in the need for internship sites and qualified preceptors. A majority of the internship rotations are within institutional settings, and these rotation sites may be faced with the prospect of having to increase positions for interns by as much as 75% within the next few years.

The Accreditation Council for Pharmacy Education (ACPE) now requires that students in the first professional year of a college/school of pharmacy program begin gaining experience in multiple pharmacy practice settings and models. To accommodate this new requirement, TSBP developed a second intern designation, the intern-trainee. Intern-trainees are students in the first year of the professional sequence of study who may only work during times and in sites assigned by a Texas college/school of pharmacy.

The addition of the intern-trainee registration has added an additional registration type to the registrants regulated by TSBP. The new intern-trainee designation has created an additional level of complexity for Board staff in that the Licensing Division must annually obtain lists of entering students from each college/school so that criminal background checks can be conducted on these students, and the registration process can begin in time for the students to obtain the introductory experiences as required by ACPE.

The new ACPE requirements for earlier practice experiences coupled with the two new colleges/schools of pharmacy needing to place students in both introductory and advanced pharmacy practice rotations will likely increase the need for qualified preceptors. As previously mentioned, Texas has 24,823 licensed pharmacists at the end of March 2009; however, only 5, 519 (22%) or approximately 1 in 5 are also registered with TSBP as a pharmacist preceptor. While TSBP rules currently allow certain non-pharmacists to be preceptors in specific situations, TSBP may need to review and modify its preceptor rules and guidelines further to accommodate the increased need for rotation sites.

(B)   Reciprocity Applicants for Pharmacist Licensure in Texas

Currently, an applicant for licensure in Texas by reciprocity may not serve in any capacity in a pharmacy until the applicant has passed the Texas Jurisprudence examination and received a Texas pharmacist license number. To be eligible for reciprocity applicants must have an active pharmacist license in another state. The reciprocity process works well for most applicants. However, TSBP, and other state Boards of Pharmacy have received requests for a *temporary license* from persons who are completing a one- or two-year pharmacy residency

program. The National Association of Boards of Pharmacy (NABP) is attempting to develop a set of qualifications that would allow persons registered in one state to practice in another state without having to be registered separately in that state. While this is not an attempt to create a single national license for pharmacists, the qualifications document resulting from NAPB's efforts may alleviate some of the concerns leading to the requests for temporary licensure. TSBP may wish to work with NABP in developing this set of national qualifications.

(3)   Pharmacy Technicians

Following the appropriation from the 78th Texas Legislature to fund the pharmacy technician registration program, TSBP promulgated rules to require pharmacy technicians to be registered by June 1, 2004. In 2005, the 79th Texas Legislature appropriated funds for TSBP to implement the registration of pharmacy technician trainees. TSBP promulgated rules to require pharmacy technician trainees to be registered by February 1, 2007. At the end of FY2009, TSBP had 51,584 active registered pharmacy technicians/technician trainees. The total number of technician/trainee registrants represents an increase of 36% of the total at the end of FY2007.

To become registered, a pharmacy technician must first be nationally certified. Pharmacy technicians are able to become certified, upon receipt of a high school diploma or the equivalent, and passing a national examination administered by the Pharmacy Technician Certification Board (PTCB). A pharmacy technician-trainee registration allows a person who desires to become a fully registered pharmacy technician to obtain practical experience in a pharmacy setting while preparing for the certification examination. A pharmacy technician-trainee registration is valid for 2 years from the date of issuance and cannot be renewed. If a pharmacy technician-trainee does not pass the PTCB examination within the two-year registration period, that person may not perform technician duties in a pharmacy licensed in Texas until he/she passes the PTCB examination and becomes registered as a pharmacy technician.

As of the end of FY2009, TSBP had 33,927 registered pharmacy technicians and 17,657 registered pharmacy technician trainees. During FY2009, TSBP received 4,394 pharmacy technician applications and 8,498 pharmacy technician trainee applications, an average of 1,074 applications for pharmacy technicians and pharmacy technician trainee applications per month. Of the 12,892 application received, 2,508 (approximately 19%) were submitted to the Enforcement Division to investigate criminal background.

A variety of issues regarding pharmacy technicians and technician trainees is likely to have an impact on TSBP in the next five years. Firstly, career opportunities for pharmacy technicians are expected to expand rapidly over the next few years. The Bureau of Labor Statistics' 2008-2009 report estimates employment for pharmacy technicians will increase by as much as 32% by 2016. This coupled with current and expanding duties being delegated to pharmacy technicians is likely have a substantial impact on the number of pharmacy technician and technician trainee applications received by TSBP.

Secondly, the 81st Texas Legislature passed House Bill HB1924 that greatly expands the authority pharmacy technicians will have to perform certain duties without the direct supervision of pharmacists in rural hospitals. HB 1924 defines a rural hospital as a hospital of 75 beds or less located in a county with a population of 50,000 or less, or has been designated by the Centers for Medicare and Medicaid Services as a critical access hospital, rural referral center, or sole community hospital. HB1924 allows the work of a registered pharmacy technician to be verified by a nurse, or practitioner, or a pharmacist by remote access. The bill also allows registered pharmacy technicians to (1) enter medications orders and drug distribution information into a data processing system; (2) prepare, package, or label a prescription drug according to a medication order if a licensed nurse or practitioner verifies the accuracy of the order before administration of the drug to a patient; (3) fill a medication cart used in the rural hospital; (4) distribute routine orders for stock supplies to patient care areas; (5) access and restock automated medication supply cabinets; and (6) perform any other duty specified by the Board by rule.

Thirdly, in 2008, a Task Force was convened by TSBP to review all of the rules pertaining to Class C (Institutional) pharmacies. One of the recommendations made by the Task Force was for the Board to consider requiring that all pharmacy technicians registered after 2015 be required to have completed a Board approved training program.

Fourthly, some members of the pharmacy profession feel strongly that an increase in educational requirements for pharmacy technicians is needed, while others disagree. As a result of the projected growth in career opportunities for pharmacy technicians and the expanding range of duties being delegated to pharmacy technicians, TSBP may wish to conduct a study of the need for additional pharmacy technician education. TSBP's mission is "to promote, preserve, and protect the public health, safety, and welfare by fostering the provision of quality pharmaceutical care to the citizens of Texas . . . ." To this end, TSBP should ensure that the training of pharmacy technicians supports the scope of services that they are expected to perform. Under the current law, technicians only have to have a high school diploma or high school equivalency certificate or be working to achieve an equivalent diploma or certificate. TSBP may want to seek legislation requiring a pharmacy technician to possess a minimum education beyond the high school diploma or equivalency.

(4)   Class C (Institutional) Rural Hospital Pharmacies

As discussed previously, HB1924, enacted in 2009 by the 81st Texas Legislature, created a third classification of hospital in Texas – the Rural Hospital. In addition to expanding the duties that may be performed by technicians in rural hospital, HB1924 requires TSBP to adopt rules regarding records that must be maintained in the pharmacy, policies and procedures for operation of a pharmacy when a pharmacist is not on-site, and the training requirements for pharmacy technicians. However, HB1924 does prohibit TSBP from establishing, prior to 2011, requirements for prospective and retrospective drug use review by a pharmacist in a rural hospital.

TSBP must adopt rules to implement HB1924 that provide proper patient care while developing appropriate rules to comply with the statutory requirement of the bill.

(5)   Working Conditions

For many years, working conditions in pharmacies has been a major issue in Texas, as well as in the nation. At its meeting held in February 1999, TSBP approved a position statement regarding working conditions. In the position statement, TSBP:

(A)   encouraged all employers to provide reasonable breaks during a regular work day for meals and rest;

(B)   discouraged employers from establishing working conditions that tend to increase the stress on dispensing pharmacists, such as setting quotas on the number of prescriptions that a pharmacist is required to dispense per hour in order to keep from being terminated or to achieve a favorable performance evaluation; and

(C)   encouraged increased communication between employees and management.

As another means of alleviating the demands on dispensing pharmacists, TSBP promulgated rules that increased the pharmacist-to-technician ratio from 1:2 to 1:3, providing one of the pharmacy technicians is registered. Recently, TSBP has had requests from the profession to increase the pharmacist-to-technician ratio in various practice settings. TSBP recently approved a pilot project to allow a ratio of 1 pharmacist to 6 technicians a call center setting. Another request was to allow a "discretionary" ratio in retail settings such that the pharmacist-in-charge would determine how many technicians he/she needed or could effectively supervise at various times during the day.

The Enforcement Division continues to receive complaints from consumers suggesting that many pharmacies are under staffed. Many of these consumers perceive that pharmacists are not able to concentrate properly on the act of dispensing medications because of constant interruptions. One consumer expressed concerns that the pharmacist was so overworked that she felt as if it were just a matter of time before a fatal error would be made.

Consumers often file complaints in which they express concerns that inadequately staffed prescription departments are the reason why pharmacists commit dispensing/medication errors. Research has shown that the causes of dispensing errors involve numerous factors, but are not necessarily a result of increased prescription volume. Accordingly, TSBP has not set a quota or limit of how many prescriptions per hour can be filled by a pharmacist. Although many would say that increasing the ratio of technicians to pharmacist would provide a "quick fix" to the staffing problem, many pharmacists say that they could not adequately supervise additional technicians and believe that an increased ratio could have negative effects on patient care. For further strategic issues relating to dispensing/medication errors, refer to Policy Issues #1 and #2.

Prescription volume has continued to increase at a very rapid pace. Some of the large pharmacy chains have developed workload distributing models that allow prescriptions to be entered at one location and verified at another. Other changes in practice models include more central fill facilities. Each new model requires TSBP to re-evaluate certain rules and laws to determine if the practice model meets regulatory requirement while maintaining proper patient care. While pharmacy automation and technology have helped pharmacies to keep pace with the prescription volume, some members of the profession have expressed concerns that the cost of technology may result in a reduction in pharmacist personnel to offset these increased costs of automation. While automation can help alleviate the increase in mechanical workload, it remains to be

determined what impact automation has on proper patient counseling and care. The large chains who have implemented major paradigm changes with technology and requests for increased pharmacist-to-technician ratios purport to be efforts to allow the pharmacist more time to counsel patients. However, TSBP continues to receive many complaints from consumers that they are not counseled, or are not able to speak to a pharmacist when they have questions.

Therefore, TSBP may wish to publish another position statement:

(A) discouraging employers from allowing increased automation and a desire to continue to increase the number of prescriptions filled per day or week to overshadow the continuing need for proper pharmaceutical care of their patients; and

(B) encouraging employers to develop patient-centric practice models through the use of new and improved automation.

Impact on Agency

As the role of pharmacy technicians continues to evolve, the need for trained and competent technician personnel will become even more critical. While reports are indicating that the pharmacist shortage statewide is improving and may no longer exist by 2016, the disparity between the overage of pharmacists in major metropolitan areas and the shortage of pharmacists in rural areas of the state is likely to continue as more people move to the metropolitan areas.

As of March 31, 2009, there were 24,823 persons registered as pharmacists in Texas. At the end of FY2009, there were 51,584 persons registered as either pharmacy technicians, or technician trainees. As a result of this increase in the number of regulated individuals, TSBP has seen a more than commensurate increase in cases referred to the Legal Division with a similar increase in Agreed Board Orders and Board Orders. Although this increased workload has had an enormous impact on agency operations, TSBP believes that registering pharmacy technicians and technician trainees is vitally important to protecting the public health, safety, and welfare, in that incompetent and unscrupulous technicians can be removed from practice. If reports such as the 2008-2009 report from the Bureau of Labor Statistics are correct and the opportunities for pharmacy technicians increases 32% by 2016, TSBP will likely see a significant impact on the workload in all Divisions.

Agency Strengths and Opportunities

(1)   The Texas Pharmacy Act gives the agency the authority to adopt rules regarding the role of pharmacy technicians and technology in the practice of pharmacy.

(2)   TSBP has continued to review, amend, and/or adopt rules for the expanded use of technology and pharmacy technicians in the practice of pharmacy.

(3)   TSBP has a vast storehouse of resources in academia and in the pharmacy profession to assist the Board in its decision and rule-making processes.

(4)   Through the use of Task Forces, TSBP will be able to examine questions of manpower, working conditions, and expanded roles of pharmacy technicians and their impacts on public health.

Agency Weaknesses and Constraints (Threats)

(1)   The nationwide shift in pharmacy education and mandates from the Accreditation Council for Pharmacy Education to introduce professional pharmacy students into practice experiences at an earlier point in the curriculum has created an increased need for qualified preceptors and a need for TSBP to work more closely with colleges/schools of pharmacy as students begin their professional education. The strategic impact of the new pharmacy educational requirements remains uncertain.

(2)   Opportunities for pharmacy technicians are expected to expand over the next several years. This, coupled with recent legislative mandates that pharmacy technicians be given additional authority in rural hospital settings provides TSBP with a unique opportunity to take a leading role in developing educational requirements, laws, and rules for new practice models for pharmacy technicians.

(3)   Regulating working conditions in pharmacies is extremely complex because each practice setting is unique, and the factors affecting the working conditions in each practice setting are different. However, TSBP should begin evaluating strategies that allow working conditions to reflect the changing pharmacy practice models and increases in technology.

Agency Initiatives

(1)   Be an active participant with colleges of pharmacy and professional associations in developing plans to increase practical educational opportunities for pharmacy students.

(2)   Establish minimum standards for pharmacy technician training programs.

(3)   Be proactive in developing educational and practice guidelines for well-qualified pharmacy technicians to facilitate the changing pharmacy practice paradigms.

(4)   Develop regulations that allow for unseen opportunities for pharmacists providing patient care.

POLICY ISSUE #4 – TO MAINTAIN THE AGENCY'S LEADERSHIP POSITION IN PHARMACY PRACTICE REGULATION AND ESTABLISH A KEY LEADERSHIP POSITION FOR ADDRESSING PUBLIC NEEDS

Issue Statement

The Board of Pharmacy needs to continue its partnership with the public and profession to aggressively promote the highest level of pharmacy services possible. In addition, opportunities exist for the Board to continue its national leadership role in progressive regulation. While being "out-front" is never comfortable, the pharmacy profession in Texas has come to expect the Board to act in a key leadership position while addressing public needs.

The Board of Pharmacy must be visionary in order to stay on the cutting edge of regulation. The Board must continue to play a public advocacy role as it relates to educating the public about the value of the pharmacist's role as a vital member of the healthcare team, especially in light of the major challenges facing pharmacy today. These challenges include the increasing demand for affordable healthcare services, the growing aging population, increased consumer demand for prescription drugs, the rising availability of prescription drugs over the Internet, and disaster planning and response. In order to accomplish these goals and still maintain its position of strength, the agency must identify areas for growth and opportunity, as well as challenges facing the agency. Additionally, the agency must aggressively pursue avenues to retain or preferably increase the number of highly-qualified personnel employed while continuing to implement quality management practices. Given the pace of technological advances, the agency must also carefully encourage and recognize the use of technology that will allow the public easier access to information, while at the same time not cause undue reporting requirements or workload constraints on the agency or practitioners. Finally, it is important for the agency to strike the appropriate balance in achieving its public protection mandate yet be flexible enough to develop regulations to facilitate pharmacy practice changes.

Explanation of Issue

(1)   The Board should continue to play a public advocacy role as it relates to educating the public about the value of pharmaceutical care, including the pharmacist's role as a vital member of the healthcare team along with pharmacy staff support personnel.

   (A)   The increasing demand for affordable healthcare services is influenced by increased prescription costs and the growing number of prescriptions for individuals, which may cause consumers to seek medications from nontraditional pharmacy sources. Consumers should be educated not only on the positive pharmacy facts like the importance of vaccines; dietary supplements; and prevention of medication errors, but also warned about the negative such as the proliferation of misinformation (e.g., Internet scams, e-mails offering prescription drugs without a prescription, and direct-to-consumer advertising); and the dangers of *look alike/sound alike* products. The many outlets offering easy access of drugs without pharmacist participation can cause great harm to the consumer.

(B)   Consideration must be given to the dramatic increase in the state's aging population and the associated growth in prescription volume. Not only is the current population aging, but also Texas is becoming home to an increasingly large number of retirees. Aging consumers often have decreased cognitive skills, eyesight, and mobility, which lead to increased demand on all healthcare providers. Consequently, as the senior population increases so will the workload associated with a higher volume of prescriptions. This will have a significant impact on pharmacists and pharmacy personnel to meet the consumers' needs.

(C)   Consumers, as well as healthcare professionals, are seeking information and advice concerning alternative medicines, including herbal and other nutritional supplements. Alternative drug/herbal therapies are increasingly prescribed by licensed physicians or recommended by other healthcare providers. Efforts should be made to incorporate complete drug histories into patient charts, including herbal medicines and other non-prescription medication products, to avoid the potential risk of an interaction with a prescription drug already prescribed. As more federal scrutiny and potential regulation of these agents occurs, it may be logical that the regulation of these drugs would fall to the Pharmacy Board. Pharmacists who are experienced in evaluating clinical studies and other types of substantiating health information, especially related to safety and effectiveness, are in a unique position to advice consumers.

(2)   The Board should focus on preparedness for public health emergencies where pharmacist participation is crucial.

Pharmacies and pharmacists have vital roles in front-line defense in the event of a public health emergency, such as an act of bioterrorism, natural disaster, or widespread disease such as a pandemic influenza. Pharmacists must be ready to be positioned to provide emergency care and medication delivery in response to such unplanned events. Currently, pharmacies are deeply involved in the administration of seasonal flu and H1N1 flu immunizations, placing pharmacy on the front line of healthcare in the nation. The immediate distribution of emergency refills of critical prescriptions, and assistance with the distribution of vaccines, antidotes, and other pharmaceutical agents is vital to ensure the continued safety of the public. This will require specialized knowledge, advance planning and integration of local, state and federal resources to achieve quick mobilization. Pharmacy is a key stakeholder in assuring appropriate and adequate response to disasters and as such should be present and a participant in all governmental preparedness meetings.

(3)   The Board should expand its partnerships with federal agencies, as well as other state agencies and boards. This can result in the sharing of key information, data sharing, training, as well as more effective enforcement and compliance.

An example of this partnership included the Board's joint investigation with the US Food & Drug Administration, Drug Enforcement Administration, Federal Bureau of Investigation, Internal Revenue Service, US Department Social Security Administration, US Department of Veteran Affairs, and the Texas Department of State Health Services. This case involving a major internet pharmacy fraud case, involved more than $200 million in fraudulently obtained pharmaceuticals, resulting in the guilty pleading of all 19 individuals charged in the 2011-count indictment.

These expanded partnerships will be especially crucial as the trend toward the abuse of prescription drugs continues to grow. In a May 2009 news release, Director Gil Kerlikowske of the National Drug Control Policy, reported that the *National Prescription Drug Threat Assessment (NPDTA)* finds non-medical use of prescription drugs a serious threat to public health and safety, with unintentional deaths involving prescription opioids increasing 114 percent from 2001 to 2005, and treatment admissions increasing 74 percent in a similar four-year period.   "Diversion and abuse of prescription drugs are a threat to our public health and safety similar to the threat posed by illicit drugs such as heroin and cocaine," said Director Kerlikowske. "In 2006, the last year for which data are available, drug-induced deaths in the United States exceeded firearm-injury deaths and ranked second only to motor vehicle accidents as a cause of accidental death. Law enforcement and healthcare communities must work together to help address prescription drug abuse, addiction, and the public safety consequences of diversion."

Despite strident regulations for dispensing controlled substances, prescriptions drugs, especially pain relievers, are acquired illegally, most frequently from friends or family or by doctor-shopping, prescription fraud, and theft. Rogue Internet pharmacies are also a significant source of diverted prescription drugs, and increasingly, street gangs are involved in the illicit distribution of diverted pharmaceuticals.

(4)   The regulation of certain records and regulatory functions relating to dispensing controlled substances by prescription may be transferred to the TSBP.

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 (DPS) 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. The transition plan is required to be submitted to the Legislature by January 1, 2011. The 82nd Texas Legislature will determine if the prescription monitoring program is transferred to TSBP or if it remains at DPS.

(5)   The Board should continue to be a leader in the growth and evolution of the profession by adopting regulations and encouraging legislation that allows pharmacists to use the full scope of their knowledge, skills, and abilities. Innovation will continue to be necessary in order to improve pharmacy systems to enhance patient care, in developing new methods and systems to monitor compliance with existing laws and rules, and/or expand compliance initiatives around the state. It is important to plan appropriately and address the growing volume of prescriptions and the additional professional services that pharmacy can provide as a key member of the healthcare team.

(6)   In order for the Board to continue to protect the citizens of Texas, it must be adequately funded and staffed. 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.

It is anticipated that the growth of the registration of pharmacy technicians 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. In order for the Board to continue to protect the citizens of Texas, it must be adequately funded & staffed.

The 2009 Texas Legislature approved appropriations for the agency that included all of the items requested by TSBP. As a result, the agency received 10 new positions and funding for the purchase of a new database system. However, due to a large projected short fall of revenue for the state over the current and next biennium, TSBP has been asked to identify a five percent cut in this biennium's appropriation and to anticipate entering the next biennium at ten percent below the current biennium's funding. These two actions will have a dramatic impact on TSBP's ability to properly do our job of protecting the public.

(7)   During this election year, Texas will face a hotly contested race for Governor. Each of the major candidates in the Republican primary has indicated that they support consolidating all of the health licensing agencies into one large Department of Health Professions. This consolidation will have a dramatic impact on the operation of the agency in that it will likely include less or no control by TSBP in developing and establishing its budget and loss of direct control of some agency functions such as licensing. A possible alternative to consolidation would be conversion to a self-directed semi-independent agency.

In 1999 and again in 2009, the Texas Legislature enacted legislation which transferred several professional and occupational licensing agencies to self-directed, semi-independent status. The self-directed, semi-independent status allows the Boards of these agencies to set and control the budgets for the agencies. Though the agencies are in control of their own budgets, they are still under the oversight of the legislature, governor, state auditor, state comptroller, and other state agencies. The self-directed, semi-independent status has allowed the agencies much more flexibility to react to changes in their respective professions. TSBP should consider seeking self-directed, semi-independent status during the next legislative session.

Impact on Agency

Given the growth in both size and complexity of pharmacy practice and healthcare, multiplied by the continued increase in demand for services and insufficient funding, the agency's ability to function efficiently and effectively in the public interest is severely challenged.

Any increase in the current demand for agency services without additional funding, personnel, and updated technology and without authority to be flexible with resource utilization such as the self-directed, semi-independent status may require a reassessment of the organization. This may require a shift in resources and, consequently, a realignment of agency priorities and initiatives. The net result could be a decrease in the quality and quantity of agency services vital to its mission.

Agency Strengths and Opportunities

(1)   Organizational structure, leadership, and management provide the mechanisms necessary to carry out the agency's mission and to accomplish its strategic and operational objectives.

(2)   The agency's position as an independent agency, along with its statutory authority, gives it the authority and flexibility needed to function as the *lead agency* for pharmacy regulation in Texas.

(3)   The agency generates its own revenue, primarily through licensure fees from pharmacists, pharmacies and pharmacy technicians. The agency does not use general tax revenues and is not directly subject to the problems of fluctuation in state revenue due to economic or political factors.

     Further, the regulated community fully supports this method of funding agency operations and would support an increased level of expenditure of the collected funds. While an increase in licensure fees is not needed, the regulated parties expect the agency to spend the money collected.

(4)   The Board members are dedicated to their role as policymakers, and the staff to its role as implementers of this policy. Through their complementary roles, the Board and staff form an efficient team, achieving consistently high-level agency performance in a customer-service oriented manner.

(5)   The agency is serving in a leading role within the Health Professions Council and is in a position to share the agency's successful operational strategies with the other regulatory agencies.

(6)   The agency is highly regarded by its customers, including consumers, legislators, and the regulated profession, as well as local communities throughout Texas. Additionally, the agency, staff, and Board are held in high esteem throughout the country as leaders in the pharmacy profession.

Agency Weaknesses and Constraints (Threats)

Among the challenges facing the agency are those associated with unfunded mandates and poorly-funded programs. Examples include:

(1)   **The provision of a significant education program**

     Despite the resounding national and state need for preventive patient care information, the agency continues to be placed in the position of having vital information that would protect or improve the health and safety of the citizens of Texas, but not able to effectively disseminate this information through a comprehensive public information service. Medication misuse not only costs the citizens of Texas billions of dollars, it seriously impacts their recovery from illness, their management of chronic illness, their productivity at work, their independent lifestyles, and even their lives.

     A significant educational effort is also vital to communicating important legislative issues, laws, and rules to the Board's licensee population. Given the continuous increase in the number of licensees the Board regulates, an educational effort to this target population is critical to a successful regulation program. Increasingly, informed consumers means the profession must be able to deliver public education on drug use, safety, and healthcare issues.

(2)   **The gap between current funding and 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. This demand has been compounded by the partially funded mandates of 2004 and 2006, and a looming state budget crisis expected in 2012-13. Any new population or increase in the level of services provided by the agency will significantly impact the agency's ability to provide quality customer service, information, and protection to the citizens of Texas.

(3)   **Proliferation of technology**

Proliferation of technological systems allows greater public access to agency information. Improvements in computer-related technology have had a significant impact on agency operations over the past several years, as the agency has modified and initiated new work processes to take advantage of these advances. Future developments will have an even greater impact, but these developments will require quality human resources and funding to implement. The expansion of the agency's web site as a tool to providing a significant education program about safety issues, the legal consequences of illegal purchases, and how to use the Internet wisely to obtain drug products and drug information, are just a few examples of current technology that is available.

Agency Initiatives

(1)   Continue to cultivate working relationships with members of the Texas Legislature in order to keep them better informed regarding the needs of the agency. Keep professional pharmacy associations and advocates abreast of critical issues to help promote favorable legislative action.

(2)   Continue to access the expertise of pharmacy educational institutions, associations, and related entities through networking and advisory committees on topics of increasing complexity.

(3)   Promote organizational change to meet the challenges of regulating the profession with limited resources.

(4)   Actively seek legislative authority to allow the agency to participate in the Self-Directed Semi-Independent Agency Project Act.

(5)   Remain progressive in initiatives focused on enhanced patient outcomes, with continued examination of those issues that are truly important, embracing current technology, gaining broad-based input, and acting aggressively and fairly to hold pharmacists accountable for the patient care they provide.

(6)   Advocate for key quality enforcement and consumer protection reforms at the state and national levels.

(7)   Participate in national and state-level pilot projects within the Board's areas of expertise.

By taking these initiatives, TSBP hopes to assure continuity of both the quality and quantity of agency services, thereby allowing the agency to move forward in fulfilling its mission.

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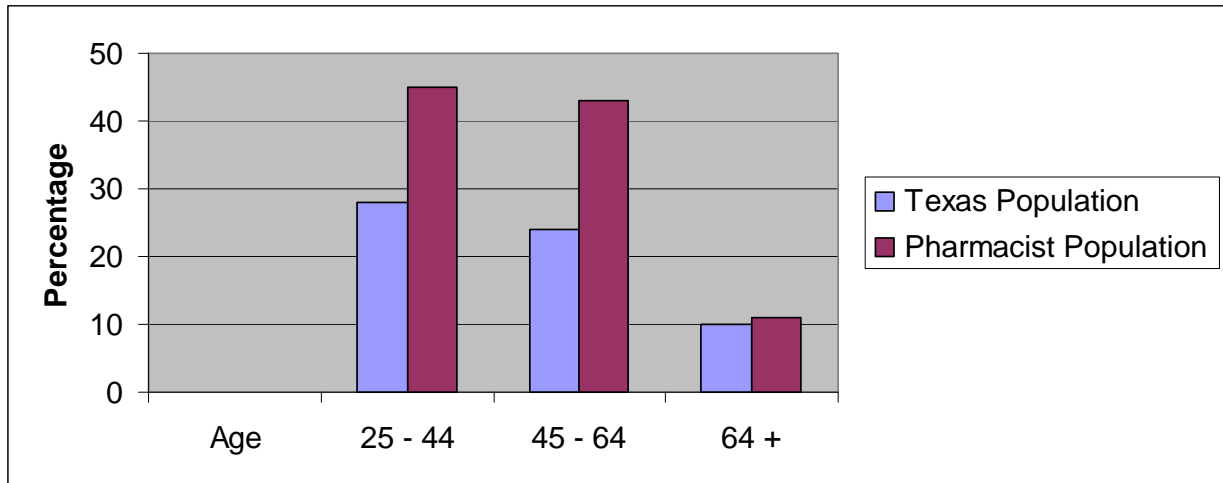
Data is based on 2009 Texas Population of 24,326,974 and a Texas Pharmacist Population of 20,508.

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 54).

- 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.

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 eight 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 80th 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.

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 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 81st 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 81st 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 81st 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 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 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

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 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*

Agency EEO Data	ANGLO		BLACK		HISPANIC		OTHER		TOTAL		GRAND
	M	F	M	F	M	F	M	F	M	F	TOTAL
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.

Texas State Board of Pharmacy
Revenue and Expenditures FY04 - FY09
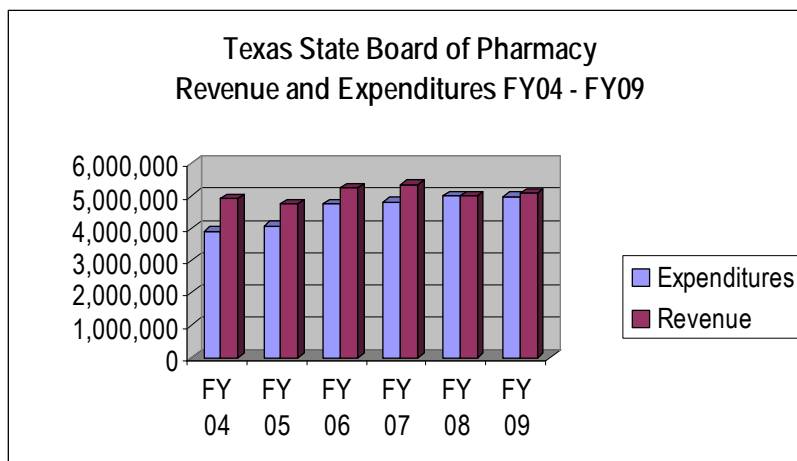
Degree to Which Current Funding Meets Current and Expected Needs

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 81st 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 82nd 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 81st 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 82nd Texas Legislature.

Additionally, in FY2010, all agencies are faced with an 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. The addition of these two programs has 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								% Chg over 7 years
	FY03	FY04	FY05	FY06	FY07	FY08	FY09	
Administrative Services and Licensing Division								
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%
Enforcement Division								
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%
Legal Division								
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 91.66% 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.

AGENCY GOALS

1. To establish and implement reasonable standards for pharmacist, pharmacy technician and pharmacy technician trainee education and practice, and for the operations of pharmacies to assure that safe and effective pharmaceutical care is delivered to the citizens of Texas [Texas Pharmacy Act (Occupations Code, Sec. 555-566 and 568-569)].

2. To assertively and swiftly enforce all laws relating to the practice of pharmacy to ensure that the public health and safety are protected from the following: incompetent pharmacists, pharmacy technicians and pharmacy technician trainees; unprofessional conduct, fraud, and misrepresentation by licensees; and diversion of prescription drugs from pharmacies; and to promote positive patient outcomes through the following: reduction of medication errors by encouraging or requiring licensees to implement self-assessment programs and continuous-quality improvement programs, including peer review processes; and enforcement of rules relating to patient counseling and drug regimen review, including prevention of misuse and abuse of prescription drugs. [Texas Pharmacy Act (Occupations Code, Sec. 551-569), and Health and Safety Code, Chapter 483, Dangerous Drugs.]

3. To establish and implement policies governing purchasing and public works contracting that foster meaningful and substantive inclusion of historically underutilized businesses (HUBs).

AGENCY OBJECTIVES AND OUTCOME MEASURES

OBJECTIVE   Continue to operate a licensure system for pharmacists, pharmacy technicians, pharmacy technician trainees, and pharmacies that will assure that all licensees and registrants meet minimum licensing standards through 2015.

Outcome Measure

- Percent of Licensees with No Recent Violations
- Percent of Licensees who Renew Online
- Percent of New Individual Licenses Issued Online

OBJECTIVE   Through 2015, deter and reduce the incidence of violations of the law through compliance inspections of 50% of the licensed pharmacies in Texas; through technical assistance to licensees; through education and increased licensee access to information by contacting all licensees; and to resolve complaints received within an average of 200 days.

Outcome Measures

- Percent of Complaints Resolved Resulting in Disciplinary Action

- Recidivism Rate of Those Receiving Disciplinary Action

- Percent of Documented Complaints Resolved Within 6 Months

- Recidivism Rate for Peer Assistance Program

- One-Year Completion Rate for Peer Assistance Program

OBJECTIVE   To include historically underutilized businesses (HUBs) in at least 20% of professional services contracts, 33% of other services contracts, and 12.6% of commodities contracts and subcontracts awarded annually by the agency in purchasing and public works contracting by fiscal year 2011.

Outcome Measure

- Percent of Total Dollar Value of Purchasing and Public Works Contracts and Subcontracts Awarded to HUBs

AGENCY STRATEGIES AND OUTPUT, EFFICIENCY, AND EXPLANATORY MEASURES

STRATEGY 01.01.01

Operate a timely, cost-effective application and renewal licensure system for pharmacies and pharmacists, pharmacy technicians and pharmacy technician trainees.

Output Measures

- Number of New Licenses Issued to Individuals

- Number of Licenses Renewed (Individuals)

- Number of New Registrations Issued to Individuals

- Number of Registrations Renewed (Individuals)

Efficiency Measures

- Percent of New Individuals Licensed Within Ten Working Days

- Percent of Individual License Renewals Issued Within Seven Working Days

Explanatory Measures

- Total Number of Individuals Licensed

- Total Number of Business Facilities Licensed

- Total Number of Individuals Registered

STRATEGY 02.01.01

Emphasize preventive enforcement by conducting compliance inspections of pharmacies, promote voluntary compliance by providing information, education and technical assistance to licensees; and protect public health and safety by receiving, investigating, and resolving complaints, disciplining licensees, and monitoring compliance with disciplinary orders resulting from board adjudication.

Output Measures

- Number of Inspections

- Complaints Resolved

Efficiency Measure

- Average Time for Complaint Resolution

Explanatory Measure

- Jurisdictional Complaints Received

STRATEGY 02.01.02

Operate a Peer Assistance Program by monitoring the growth, development, and compliance of a program to aid pharmacists and eligible pharmacy students impaired by chemical abuse or mental or physical illness, and monitor the success of individuals in the program.

Output Measure

- Number of Licensed Individuals Participating in Peer Assistance Program

STRATEGY

Develop and implement a plan for increasing the use of historically underutilized businesses through purchasing and public works contracts and subcontracts.

Output Measures

- Number of HUB Contractors and Subcontractors Contacted for Bid Proposals

- Number of HUB Contracts and Subcontracts Awarded

- Dollar Value of HUB Contracts and Subcontracts Awarded

TECHNOLOGY RESOURCE PLANNING

Part 1: Technology Assessment Summary

- Provide a brief description of the planned technology solutions that respond to the key factors that will affect the agency. Consider how those solutions align with the statewide technology goals reflected in the State Strategic Plan for Information Resources *(Advancing Texas Technology)*.

> Like many agencies, the Texas State Board of Pharmacy has increased demands for delivering services to the citizens of Texas while at the same time experiencing budget constraints. We expect to meet these demands through collaborative efforts with our fellow agencies and the use of existing enterprise services and infrastructure.

- Provide agency descriptions related to each statewide technology goal listed below. The criteria for these descriptions appear after each goal and are labeled 1.a, 1.b, 2.a, and so forth.

Statewide Technology Goal 1

Strengthen and Expand the Use of Enterprise Services and Infrastructure

1.1 Enhance Capabilities of the Shared Infrastructure
- Data Center Infrastructure
- Communications Technology Infrastructure
- Statewide Portal Infrastructure

1.2 Leverage Shared Applications
- Enterprise Resource Planning (ERP)
- Email Messaging

1.3 Leverage the State's Purchasing Power
- Product and Services Portfolio Expansion

1.a   Describe agency plans to strengthen and/or expand its capabilities through the initiatives described in Statewide Technology Goal 1.

> In a collaborative effort with five other state agencies, the Texas State Board of Pharmacy Is in the process of migrating its primary regulatory database, an aging legacy system, to a new platform to be housed at the state data center. Utilizing the Data Center Services infrastructure will immediately expand the agency's computing power, security resources, disaster recovery processes and reduce the cost of operations.

1.b   Describe agency plans to strengthen and/or expand its capabilities through other initiatives that leverage enterprise or multi-agency services and infrastructure, including managed services, shared applications, internal consolidation efforts, and procurement strategies.

The Texas State Board of Pharmacy will continue to evaluate potential collaborative efforts and expand our successful joint efforts like our shared regulatory and imaging systems. Messaging and web services are prime candidates to be leveraged as shared resources. We will watch closely as DIR enhances it's delivery of message and web hosting solutions.

DIR technology procurement contracts have been of great value to our agency. It would be difficult for an agency of or our size to negotiate the aggregate discounts present in these contracts. Utilizing these contracts has increased the Agency's technology purchasing power.

Statewide Technology Goal 2

Secure and Safeguard Technology Assets and Information

2.1 Align the State's Approach to Enterprise Security with other State and National Strategies
- State Enterprise Security Plan
- Vulnerability to Cyber Attacks
- Response and Recovery Capabilities

2.2 Integrate Identity Management, Credentialing, and Access Privileges
- Identity Management Services

2.a   Provide an update on the agency's progress in implementing strategies to align with the *State Enterprise Security Plan.*

In 2008 the Texas State Board of Pharmacy began actively participating in the DIR implemented secure web portal. This proactive system was put into place to enhance critical information-sharing regarding threats, vulnerabilities, and mitigation strategies. The Board also contracts annual penetration tests and most recently began participating in DIR's Security Information Management program. The SIM program provides external network monitoring and alerting of malicious traffic for our critical systems.

2.b   Describe the agency's identity management strategies in place or planned.

The Texas State Board of Pharmacy understands the benefits identity management could provide in enhanced security, efficiency of operations and ease of compliance. The agency will closely watch and evaluate other state and federal identity management initiatives.

Statewide Technology Goal 3

Serve Citizens Anytime, Anywhere

3.1 Expand and Enhance Access to Agency Services
- Multi-Channel Access
- Rural Broadband Expansion

3.2 Facilitate Open and Transparent Government
- Best Practices for Information Assets

3.a   Describe the agency's plans to expand or enhance access to its services and promote citizen engagement through online services and emerging technologies.

For many years now the Texas State Board of Pharmacy has utilized a traditional website as an important part of our service delivery. In 2009, the Agency began successfully investing resources into the emerging social networks that have become very popular. Future enhancements to our services delivery will include podcasts, blogs and streaming video.

3.b   Describe initiatives planned or in process that will facilitate access to agency information and public data.

Currently, the push of public data to our website occurs in batch mode updating overnight. The migration of our primary regulatory database in the fall of 2010 will have the added benefit of "real time" updates to our web services.

Statewide Technology Goal 4

Pursue Excellence and Foster Innovation across the Enterprise

4.1 Link Technology Solutions to Workplace Innovations
- Workplace Productivity and Collaboration

4.2 Pursue Leading-Edge Strategies for Application Deployment
- Cloud Computing
- Specifications, Toolkits, and the Application Marketplace
- Legacy Systems Modernization

4.3 Optimize Information Asset Management
- Best Practices for Managing Digital Information

4.4 Promote the Use and Sharing of Information
- Health Information Exchange
- Statewide Communications Interoperability
- Justice Information System Integration
- Enterprise Geospatial Services

4.a   Describe agency plans to implement or enhance workplace productivity and to leverage collaboration tools.

> The Texas State Board of Pharmacy promotes a flexible and adaptive workplace through the use of mobile computing technology such as laptops, PDAs and remote system access through the use of Virtual Private Networks. The agency will also expand the use of our existing imaging system to interface with the new regulatory database.

4.b   Describe agency strategies to develop and deploy applications more efficiently (i.e., through Cloud Computing, Software as a Service, Application Toolkits, Legacy System Modernization).

> In a collaborative effort with five other state agencies, the Texas State Board of Pharmacy is in the process of migrating its primary regulatory database, an aging legacy system, to a new platform to be housed at the state data center. In conjunction with the creation of this collaborative system, shared support staff is contracted with the Health Profession Council to provide a single efficient source for application deployment and support.

4.c   Describe agency strategies to enhance information asset management practices.

> In 2007 the Texas State Board of Pharmacy revised its employee email policy to include electronic records retention. Separate classes of email were created and retention policies assigned. These policies where then incorporated into the overall all records retention policy for the agency.
>
> The Agency has also started assigning retention dates, destruction date, to electronic documents filed in our imaging system.

4.d   Describe agency practices or plans to enhance the use and sharing of information with agency business partners.

> In a collaborative effort with five other state agencies, the Texas State Board of Pharmacy is in the process of migrating its primary regulatory database, an aging legacy system, to a new platform to be housed at the state data center. The new system will include interfaces that will allow the sharing of data with the Department of Public Safety, the FBI, the Texas Attorney General's office, the Emergency System for the Advanced Registration of Volunteer Health and the Texas Guaranteed Student Loan Corporation.

Part 2: Technology Initiative Alignment

The table below depicts the format and mapping of the Texas State Board of Pharmacy's current and planned technology initiatives to the agency's business objectives.

TECHNOLOGY INITIATIVE	RELATED AGENCY OBJECTIVE/(S)	RELATED SSP STRATEGY/(IES)	CURRENT OR PLANNED	ANTICIPATED BENEFIT(S)	INNOVATION, BEST PRACTICE, BENCHMARKING
1. Transformation and consolidation of agency data center operations into the State Data Center.	**All Objectives.**	1.1 1.2 1.3 2.1 3.1 4.1 4.2 4.3 4.4	Planned	Replacement of outdated mainframe computer; improved bulk print/mailing capability; enhanced disaster recovery mechanism; more efficient interfaces to business partners	Best Practice: Utilize DIR Consolidated Data Center and negotiated contracts
2. Refresh Agency computer systems according to established equipment replacement schedule	All Objectives	1.1 1.3 2.1	Current	Minimizes systems downtime. Enhanced security and productivity.	Best Practice: Utilized DIR negotiated contracts
3. Extend the functionality of existing shared imaging system by linking it to the new regulatory database.	Objective 1	1.1 1.2 1.3 3.1 4.3	Planned		Best practices: enhance capabilities of shared infrastructure

APPENDIX A

DESCRIPTION OF AGENCY PLANNING PROCESS

Internal/External Assessment and Issue Identification

In developing its *Strategic Plan*, Board and agency staff identified and analyzed those trends and resulting issues expected to have the most significant impact on the profession and regulation of pharmacy over the next five years. In 1986, 1990, 1998, and 1999/2000, the agency conducted research into these areas utilizing a contracted consultant-facilitator, who worked with the Board and agency staff.

This Strategic Plan has been the product of:

- overall review of the current *Strategic Plan* by the Board Members and agency staff (Internal Assessment) with a significant amount of input provided as to changes, issues, and updates that need to be addressed; and

- comments received from Board customers in response to a letter sent to:

  - the Deans of the Texas colleges of pharmacy;

  - the Executive Directors of the Texas pharmacy professional organizations;

  - the Executive Directors of national pharmacy professional organizations;

  - the Executive Director of the National Association of Boards of Pharmacy;

  - the Executive Director of the Pharmacy Technician Certification Board and the Institute for the Certification of Pharmacy Technicians;

  - the Executive Directors of five Texas consumer advocacy groups;

  - the Texas Commissioner of State Health Services; and

  - the Executive Directors of two health regulatory agencies.

A list of the individuals who received an invitation for input and whether they responded is found in this Appendix.

The questions asked in the External Assessment were the following:

- As the agency updates its *Strategic Plan*, what are the issues in general, but specifically in health care, that will affect the practice of Pharmacy and the regulation of the practice, about which the agency should be concerned?

- How will any of these issues affect the agency's ability to carry out its mission?

- Which of these issues poses the greatest challenge for the agency in its ability to respond, and why?

- How should the agency attempt to respond to these issues and challenges?

- What do you see as the greatest area of opportunity for the agency?

- What can this Board do to establish or maintain a position of strength for both the profession and the agency?

Resulting issues to be addressed by the *Strategic Plan* were identified as:

• The Changing Focus of Pharmacy Practice;

• Increased Use of Technology in the Practice of Pharmacy;

• Pharmacy Personnel and Working Conditions; and

• To Maintain the Agency's Leadership Position in Pharmacy Practice Regulation and Establish a Key Leadership Position for Addressing Public Needs.

The Board Members worked with staff to develop these Issue Statements and approved the final *Strategic Plan* at the May 2010 Board Business Meeting.

Request List for Comments on the Agency Strategic Plan	
Name/Address	Response Received
COLLEGES OF PHARMACY	
F. Lamar, Pritchard, Ph.D. College of Pharmacy The University of Houston 4800 Calhoun, SR-2.141 Houston, TX 77204	
Barbara Hayes, R.Ph., Ph.D., Dean College of Pharmacy and Health Sciences Texas Southern University 3100 Cleburne Ave. Houston, TX 77004	
M. Lynn Crismon, Pharm.D., Dean College of Pharmacy The University of Texas at Austin 1 University Station A1900 Austin, TX 78712-0120	
Arthur Nelson, Jr., Ph.D., Dean School of Pharmacy Texas Tech University Health Science Center at Amarillo 1300 Coulter Dr. Amarillo, TX 79106	September 16, 2009
Arcelia M. Johnson-Fannin, Ph.D., Dean Founding Dean, Feik School of Pharmacy University of the Incarnate Word 4301 Broadway, Box 99 San Antonio, TX 78209-6397	
Indra K. Reddy, Ph.D., Dean Professor and Dean Irma Lerma Rangel College of Pharmacy Texas A&M University Health Science Center MSC 131, 700 University Blvd. Kingsville, Texas 78363-8202	September 28, 2009

CONSUMER GROUPS	
Reggie James, Director Southwest Office Consumers Union 506 West 14th St., Suite A Austin, TX 78701	
A. Barry Rand, CEO American Association of Retired Persons 98 San Jacinto, St., Ste. 750 Austin, TX 78701	

Suzy Woodford, Executive Director Common Cause Texas 603 West 13th , Suite 2D Austin, TX 78701	
Tom "Smitty" Smith, Director Public Citizen Texas 1303 San Antonio St Austin, TX 78701-1636	
Kathy Tyler State Coordinator Gray Panthers 3710 Cedar Street # 15 Austin, TX 78705	
NATIONAL PHARMACY ORGANIZATIONS	
Thomas E. Menighan, Pharm.D., CEO and Executive Vice President American Pharmacists Association 1100 15th Street NW, Suite 400 Washington, DC 20005-1707	
Michael R. Cohen, RPh, MS, ScD, FASHP President Institute for Safe Medication Practices 200 Lakeside Drive; Suite 200 Horsham, PA 19044-2321	
Henri Manasse, Jr., P.D., Executive Vice President American Society of Health-System Pharmacists 7272 Wisconsin Avenue Bethesda, MD 20814	
William A Gouveia, President Accreditation Council for Pharmacy Education 20 North Clark Street Suite 2500 Chicago, Illinois 60602-5109	September 28, 2009
Steven C. Anderson, IOM, CAE President & CEO National Association of Chain Drug Stores 413 North Lee Street Alexandria, VA 22314	October 1, 2009
Carmen A. Catizone, MS., R.Ph., DPh. Executive Director/Secretary National Association of Boards of Pharmacy 1600 Feenhanville Drive Mt. Prospect, IL 60056	

Holly W. Henry, P.D. President National Community Pharmacists Association 100 Daingerfield Road Alexandria, VA 22314	
Melissa Murer Corrigan, R.Ph. Executive Director/CEO Pharmacy Technician Certification Board 1100 15th St, NW Suite 730 Washington, DC 20005-1707	
Rebecca M. Rabbitt, MS, Pharm.D., CEO Institute for the Certification of Pharmacy Technicians 2536 S Old Highway 94, Suite 224 St. Charles, MO 63303	
Lenora Holder, CPhT American Association of Pharmacy Technicians P.O. Box 1447 Greensboro, NC 27402	
Judith A. Cahill Executive Director Academy of Managed Care Pharmacy 100 North Pitt Street #400 Alexandria, VA 22314-3134	
Robin Luke, CPhT President National Pharmacy Technician Association PO BOX 683148 Houston, TX 77268	
TEXAS PHARMACY ORGANIZATIONS	
Gene Adams President Texas Pharmacy Association 12007 Research Blvd., Suite 21 Austin, TX 78759 Joe DaSilva Executive Director Texas Pharmacy Association 12007 Research Blvd., Suite 21 Austin, TX 78759	

Todd Canada, R.Ph., President Texas Society of Health-System Pharmacists 3000 Joe DiMaggio #30-A Round Rock, TX 7665-3994 Paul F. Davis, R.Ph. Executive Director Texas Society of Health-System Pharmacists 3000 Joe DiMaggio #30-A Round Rock, TX 7665-3994	
Scott Lason, R.Ph. Chair Texas Federation of Drug Stores 504 W. 12th St. Austin, TX 78701	September 30, 2009
STATE PUBLIC HEALTH OFFICIALS	
David L. Lakey, M.D. Commissioner Texas Department of State Health Services 1100 West 49th Street Austin, TX 78756	
Kathy Thomas, R.N. Executive Director Texas State Board of Nurse Examiners 333 Guadalupe St., Ste 3-460 Austin, TX 78701	
Mari Robinson, J.D. Executive Director Texas State Board of Medical Examiners 333 Guadalupe St., Ste. 3-610 Austin, TX 78701	

APPENDIX B

Texas State Board of Pharmacy
Fiscal Year 2010

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                    │ Executive Director/Secretary │
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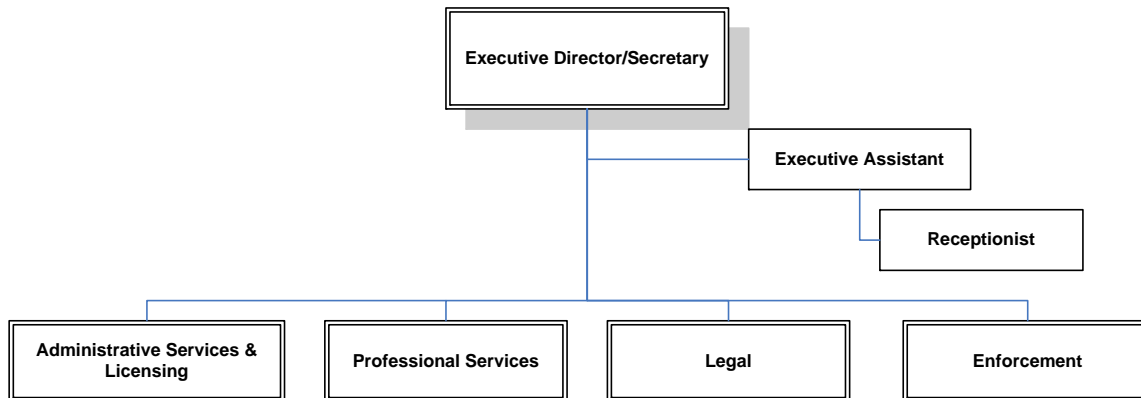
Texas State Board of Pharmacy
Administrative Services & Licensing Division
Fiscal Year 2010

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Texas State Board of Pharmacy
Professional Services Division
Fiscal Year 2010

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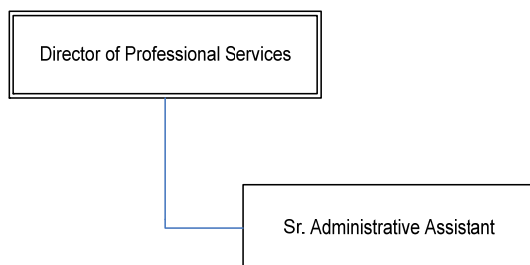
Texas State Board of Pharmacy
Legal Division
Fiscal Year 2010

General Counsel

Litigation Counsel

Staff Attorney - 2

Legal Program Specialist

**Legal Assistant
Hearings Coordinator**

Legal Assistant - 5
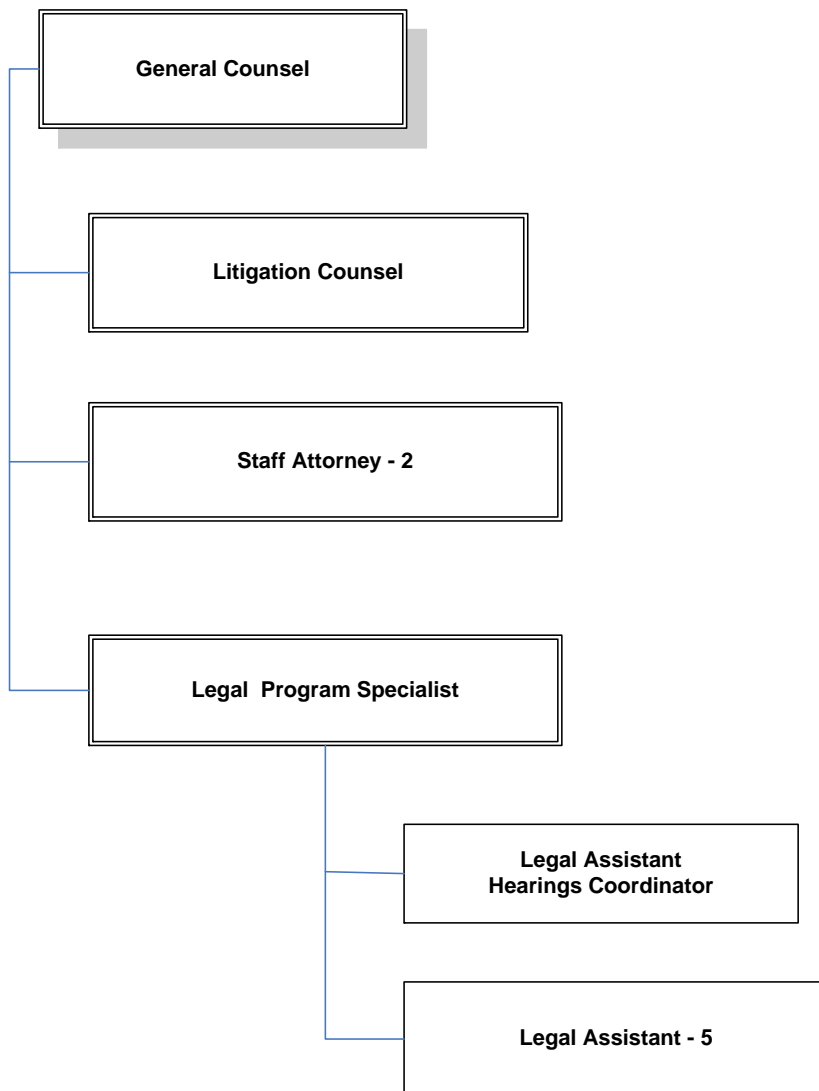
Texas State Board of Pharmacy
Enforcement Division
Fiscal Year 2010

Division Director

Enforcement Specialist

Chief of Investigations

Enforcement Program Specialist

Asst Dir of Enforcement

Enf Program Administrator

Investigative Case Manager

Enforcement Specialist - 2

Chief of Compliance

Enforcement Program Officer

Field Investigator – 7

Sr. Compliance Officer – 2

Enforcement Specialist - 2

Sr. Staff Investigator

Compliance Inspector - 5

Administrative Assistant

Enforcement Specialist - 2

Compliance Specialist

Administrative Assistant

Enforcement Officer - 3

Enforcement Technician - 3

Administrative Assistant

APPENDIX C

FISCAL YEARS 2011-2015
PROJECTED OUTCOMES

OUTCOME	2011	2012	2013	2014	2015
Percent of Licensees (Pharmacists and Pharmacies) With No Recent Violations (Disciplinary Action)	95%	95%	95%	95%	95%
Percent of Licensees Who Renew Online	84%	85%	85%	85%	85%
Percent of (Jurisdictional) Complaints Resolved Resulting in Disciplinary Action	10%	10%	10%	10%	10%

APPENDIX D

PERFORMANCE MEASURE DEFINITIONS FOR FY2011/2015

Licensing - Outcome Measures

(1) Percent of Licensees with No Recent Violations

Short Definition: The percent of the total number of licensees (pharmacists and pharmacies) at the end of the reporting period who have not been subject to a disciplinary order within the current and preceding two years (three years total). Note: The number of disciplined licensees is expressed as a percentage of the total number of licensees at the end of the reporting period (i.e., persons who obtained a new pharmacy or pharmacist license, during the reporting period, or who renewed a pharmacist or pharmacy license during the reporting period).

Purpose/Importance: Licensing individuals helps ensure that these persons meet legal standards for professional education and practice, which is a primary agency goal. This measure is an indication of the percentage of licensees who have not committed substantive violations of the laws and/or rules governing the practice of pharmacy. This measure is important because it indicates how effectively the agency's activities deter violations of professional standards established by statute and rule.

Source/Collection of Data: Data regarding the denominator (number of licensees during the reporting period) is generated by the agency's computerized data base. Data regarding the information needed to calculate the numerator (number of licensees who have been the subject of a disciplinary order within the past three fiscal years) is determined by a manual review of all disciplinary orders entered during the three-year reporting period (i.e., manually counting all of the orders contained in the notebooks for current and preceding two fiscal years). If a Disciplinary Order is reviewed and approved by the Board at a Board Meeting that falls in one fiscal year, but the Order does not get signed by a Board Member until a date that falls into a subsequent fiscal year, the Order will be considered as entered in the fiscal year that the Board reviews/approves the Order. The Orders are maintained in readily retrievable notebooks.
Disciplinary Orders include the following two types of Orders:

(1)   Agreed Board Orders (consent orders that are entered by the Board, in which the licensee neither admits nor denies the allegations contained in the Order, but agrees to the sanctions imposed by the Board); and

(2)   Board Orders [includes: Orders which are entered by the Board after a public hearing has been conducted by the State Office of Administrative Hearings (SOAH), and may impose a sanction on the licensee; also includes Orders temporarily suspending a license (summary suspensions) or court-ordered suspensions (e.g., due to failure to pay child support)].

TSBP Director of Administrative Services & Licensing is responsible for the licensure data. TSBP Director of Enforcement is responsible for the disciplinary data and calculating the measure.

Methodology:

Method of Calculation: This measure is calculated by dividing the numerator by the denominator and multiplying by 100 to achieve a percentage.

The following method is used to calculate the Numerator:

NUMERATOR - Denominator minus "X"

"X" is the total number of pharmacists, pharmacies who have been the subject of a Disciplinary Order within the current fiscal year and the two prior fiscal years (a total of three fiscal years). This number includes applicants who have a pharmacist, pharmacy license granted (with or without restrictions) under the terms of a Disciplinary Order.

Types of disciplinary orders included in this calculation would be orders imposing the following types of sanctions: granting a license (with or without restrictions), revocation, suspension with or without probation, cancellation, retirement, restriction, administrative penalty (fine), reprimand, or a combination of any of these sanctions. Warning letters are not considered as sanctions and are not included in this calculation.

There are some types of disciplinary orders that are NOT included in this calculation. These types of "excluded" Orders, for purposes of this performance measure only, are described below.

(1)   Disciplinary Orders would not be included in this calculation if the order resulted in the Board granting or denying the reinstatement of a previously revoked license, unless the order included allegations of "new" violations (violations committed or allegedly committed by the licensee after the date the license was revoked, or not included in the prior order). Orders reinstating a license will generally not be included in this calculation because these types of orders generally do not include allegations (charges) of violations of laws/rules. Orders that deny a petition for reinstatement may include allegations or findings of new violations.

(2)   Disciplinary Orders would not be included in the calculation if the order resulted in the Board denying an individual's application to obtain a new or to renew a pharmacist or pharmacy license. Since this type of order would not result in the person being counted in the denominator (in that the person would not be a licensee), the order should not be counted in the numerator.

(3)   Disciplinary Orders would not be included in this calculation if the order resulted in the Board (a) denying an internship registration; or (b) granting an internship registration (with or without conditions), but not granting a pharmacist license. Since this type of order would not result in the person being counted in the denominator (in that the person would not be a licensee), the order should not be considered in the numerator.

(4)   Disciplinary orders would not be included in this calculation if the order resulted in the Board granting or denying the modifications of a previously entered order, unless the order included allegations of "new" violations (violations committed or allegedly committed by the licensee after the date the order was entered, or not included in the prior order). Orders that grant modifications will generally not be included in this calculation because these types of orders generally do not include allegations (charges) of violations of laws/ rules. Orders that deny modifications may include allegations or findings of new violations.

(5)   Disciplinary orders would not be included in this calculation if the order would result in "double counting" of a licensee. For example, pharmacists who were subject to more than one order during the three-year period will be counted only once. If a facility was subject to more that one order during the three-year period, it will be counted only once if it maintained the same license number during the three-year period. If a facility changed ownership (obtained a new license number), it will be included in this calculation.

DENOMINATOR - total number of licensees (pharmacists and pharmacies) licensed by the agency in this reporting period. This number is calculated by adding the totals of the following categories of licenses:

(1)   Number of new licenses issued to individuals (pharmacists) in current fiscal year (reporting period);

(2)   Number of new licenses issued to facilities (pharmacies) in current fiscal year (reporting period);

(3)   Number of pharmacist licenses renewed in current fiscal year (reporting period); and

(4)   Number of pharmacy licenses renewed in current fiscal year (reporting period).

Data Limitations: With regard to the Denominator, the agency has no control over the number of persons who wish to obtain or renew a license to operate a pharmacy in Texas, or who wish to obtain or renew a license to practice pharmacy in Texas. With regard to the Numerator, the number of disciplinary orders (that are entered by the Board each year) is limited by (1) the number of applicants/licensees who commit substantive violations of the laws and/or rules governing the practice of pharmacy; (2) the number of complaints filed (TSBP has no control over the number of complaints that are filed with TSBP each year); and (3) the quantity of agency staff who investigate complaints and institute disciplinary action against an applicant or licensee.

Calculation Type	Non-cumulative.
New Measure	No.
Desired Performance	Higher than Target.

(2) Percent of Licensees Who Renew Online

Short Definition: Percent of the total number of licensed, registered, or certified individuals who renewed their license, registration, or certification online during the reporting period.

Purpose/Importance: To track use of online license renewal technology by the licensee population.

Source/Collection of Data: The TSBP computerized data base calculates the total number of licenses or registrations renewed for a specific period of time, including the number of renewals that are issued as a result of the user accessing an online application system.

Methodology: Total number of individual licenses, registrations, or certifications renewed online divided by the total number of individual licenses, registrations, or certifications renewed during the reporting period. The result should be multiplied by 100 to achieve a percentage.

Data Limitations: TSBP has no control over the number of individuals who choose to submit an online license, registration, or certification.

<u>Calculation Type</u>	Non-Cumulative.
<u>New Measure</u>	No.
<u>Desired Performance</u>	Higher than Target.

(3) *Percent of New Individual Licenses Issued Online*

Short Definition: Percent of all new licenses, registrations, or certifications issued to individuals during the reporting period, using online technology for initial payment. (Denominator = number of all new licenses issued, regardless of whether they have paid in any manner. Because TSBP issues a 30 day initial license, the payment for that license may not occur in the quarter reported. Numerator = number of initial license payments using online technology for payment.)

Purpose/Importance: To track use of online license renewal application technology by the licensee population.

Source/Collection of Data: The TSBP computerized data base can calculate the total number of new licenses or registrations issued for a specific period of time.

The TSBP computerized data base calculates the total number of initial licenses or registrations issued for a specific period of time, including the number that was issued as a result of the user using an online application system.

Methodology: Total number of new licenses, registrations, or certifications issued to individuals online divided by the total number of new licenses, registrations, or certifications issued to individuals during the reporting period. The result should be multiplied by 100 to achieve a percentage.

Data Limitations: TSBP has no control over the number of individuals who choose to submit an online license, registration, or certification.

<u>Calculation Type</u>	Non-Cumulative.
<u>New Measure</u>	No.
<u>Desired Performance</u>	Higher than Target.

Licensing - Output Measures

(1) Number of New Licenses Issued to Individuals

Short Definition: The number of licenses issued to previously unlicensed individuals during the reporting period.

Purpose/Importance: To determine the number of new licenses issued to Texas pharmacists. This measure can be used to assist in determining the extent of a pharmacist surplus or shortage in Texas.

Source/Collection of Data: The licensing computer applications as developed and maintained by agency database system under master contract with the Department of Information Resources. TSBP Director of Administrative Services & Licensing is responsible for data.

Method of Calculation: The unduplicated number of individuals initially licensed in a reporting period.

Data Limitations: Data is dependent on the actual number of individuals who are initially licensed as a Texas pharmacist. This measure is only useful as an explanatory piece of information. The data can give the reader an idea of the workload in the licensing area. The data (number of people who choose Texas as their state of licensure) however, is not a factor that can be controlled by the agency.

Calculation Type	Cumulative.
New Measure	No.
Desired Performance	Higher than Target.

(2) Number of New Registrations Issued to Individuals

Short Definition: The number of registrations issued to previously unregistered individuals during the reporting period.

Purpose/Importance: To determine the number of new registrations issued to Texas pharmacy technicians and technician trainees. This measure can be used to assist in determining the extent of a pharmacy technician surplus or shortage in Texas.

Source/Collection of Data: The licensing computer applications as developed and maintained by agency database system under master contract with the Department of Information Resources. TSBP Director of Administrative Services & Licensing is responsible for data.

Method of Calculation: The unduplicated number of individuals initially registered in a reporting period.

Data Limitations: Data is dependent on the actual number of individuals who are initially registered as a Texas pharmacy technician and technician trainee. This measure is only useful as an explanatory piece of information. The data can give the reader an idea of the workload in the licensing area. The data (number of people who choose Texas as their state of registration) however, is not a factor that can be controlled by the agency.

<u>Calculation Type</u>	Cumulative.
<u>New Measure</u>	No.
<u>Desired Performance</u>	Higher than Target.

(3) Number of Licenses Renewed (Individuals)

Short Definition: The number of licenses issued to previously-licensed individuals during the reporting period.

Purpose/Importance: To determine the number of pharmacists who renew their Texas license. This measure can be used to assist in determining the extent of a pharmacist surplus or shortage in Texas, and determine the impact to the agency workload as this number increases.

Source/Collection of Data: The licensing computer applications, as developed and maintained by agency database system under master contract with the Department of Information Resources. TSBP Director of Administrative Services & Licensing is responsible for data.

Method of Calculation: The unduplicated number of individuals who renew a license in a reporting period.

Data Limitations: Data is dependent on the actual number of individuals who choose to continue their Texas pharmacist license. This measure is only useful as an explanatory piece of information. The data can give the reader an idea of the workload in the licensing area. The data (number of people who choose Texas as their state of licensure) however, is not a factor that can be controlled by the agency.

<u>Calculation Type</u>	Cumulative.
<u>New Measure</u>	No.
<u>Desired Performance</u>	Higher than Target

(4) Number of Registrations Renewed (Individuals)

Short Definition: The number of registrations issued to previously-registered individuals during the reporting period.

Purpose/Importance: To determine the number of pharmacy technicians who renew their Texas registration. This measure can be used to assist in determining the extent of a pharmacy technician surplus or shortage in Texas, and determine the impact to the agency workload as this number increases.

Source/Collection of Data: The licensing computer applications, as developed and maintained by agency database system under master contract with the Department of Information Resources. TSBP Director of Administrative Services & Licensing is responsible for data.

Method of Calculation: The unduplicated number of individuals who renew a registration in a reporting period.

Data Limitations: Data is dependent on the actual number of individuals who choose to continue their Texas pharmacy technician registration. This measure is only useful as an explanatory piece of information. The data can give the reader an idea of the workload in the licensing area. The data (number of people who choose Texas as their state of registration) however, is not a factor that can be controlled by the agency.

Calculation Type   Cumulative.
New Measure   No.
Desired Performance   Higher than target.

Licensing - Efficiency Measures

(1) Percent of New Individual Licenses Issued Within 10 Working Days

Short Definition: The percentage of initial individual license applications that were processed during the reporting period within 10 working days, measured from the time in working days elapsed from the receipt of all required documentation (e.g., applicable fees, application, supporting documents, examination scores) until the date the license is mailed.

Purpose/Importance: This measures the ability of the agency to process new applications in a timely manner and its responsiveness to a primary constituent group.

Source/Collection of Data: Data from a computer application program as developed and maintained by agency database system under master contract with the Department of Information Resources as well as manual licensing records are used to determine this calculation.   At the end of each fiscal quarter, the Director of Licensing prints a report from the computer application program, listing all dates and new licenses issued in that quarter. This date is compared to the date the final required documentation is received and a turnaround time in working days is established. TSBP Director of Administrative Services & Licensing is responsible for the data.

Method of Calculation: The performance measure is calculated by dividing the numerator by the denominator and multiplying by 100 to achieve a percentage.

NUMERATOR - Total number of individuals licensed during the reporting period. This number is obtained from data developed from a computer program developed by agency database system under master contract with the Department of Information Resources.

DENOMINATOR - Using the total number of individual licenses mailed during the reporting period, the sample size is determined by using an approved statistical sampling method. The number of licenses to be sampled (sample size) is divided into the number of licenses mailed during the quarter to identify the sampling interval. The number of initial individual licenses in the sample that were mailed in 10 working days or less from the date of all required documentation is determined by comparing the date on the final piece of required documentation of each individual license to the initial date of license. This number is multiplied by the sample interval to estimate the total number of individual licenses mailed in 10 working days. The resulting number is the denominator.

Data Limitations: In most cases of pharmacist licensure, the final piece of documentation is the passing grade on either the NAPLEX or MPJE examination. The agency has no control over the date the applicant sits for either of these examinations, or the date these grades are reported to the agency. Therefore, the date that the examination grades are downloaded to the agency computer system is used.

<u>Calculation Type</u>	Non-cumulative.
<u>New Measure</u>	No
<u>Desired Performance</u>	Higher than Target.

(2) Percent of Individual License Renewals Issued Within 7 Working Days

Short Definition: The percentage of individual license renewal applications that were processed during the reporting period within 7 working days measured from the time in working days elapsed from the receipt of all required documentation (e.g., applicable fees, application, supporting documents) until the date the license is mailed.

Purpose/Importance: This measures the ability of the agency to process renewal applications in a timely manner and its responsiveness to a primary constituent group.

Source/Collection of Data: Data from a computer application program, as developed and maintained by agency database system under master contract with the Department of Information Resources, as well as manual licensing records are used to determine this calculation.   At the end of each fiscal quarter, the Director of Licensing prints a report from the computer application program, listing all dates and licenses renewed in that quarter. This date is compared to the date the final required documentation is received and a turnaround time in working days is established. TSBP Director of Administrative Services & Licensing is responsible for the data.

Method of Calculation: The performance measure is calculated by dividing the numerator by the denominator and multiplying by 100 to achieve a percentage.

NUMERATOR - Total number of individuals licensed (renewed) during the reporting period. This number is obtained from data developed from a computer program developed by agency database system under master contract with the Department of Information Resources.

DENOMINATOR - Using the total number of individual licenses mailed during the reporting period, the sample size is determined by using an approved statistical sampling method. The number of licenses to be sampled (sample size) is divided into the number of licenses mailed during the quarter to identify the sampling interval. The number of individual licenses renewed in the sample that were mailed in 7 working days or less from the date of all required documentation, is determined by comparing the date on the final piece of required documentation of each individual license to the renewal date of license. This number is multiplied by the sample interval to estimate the total number of individual licenses mailed in 7 working days. The resulting number is the denominator.

<u>Data Limitations</u>:	None.
<u>Calculation Type</u>	Non-cumulative.
<u>New Measure</u>	No
<u>Desired Performance</u>	Higher than Target.

LICENSING - EXPLANATORY MEASURES

(1) Total Number of Individuals Licensed

Short Definition: The unduplicated number of individuals currently licensed (active and inactive) by the agency.

Purpose/Importance: An information tool to report the number of pharmacists who are currently licensed by the agency, at any given point in time.

Source/Collection of Data: This number is obtained from licensing computer applications, as developed and maintained by agency database system under master contract with the Department of Information Resources. TSBP Director of Administrative Services & Licensing is responsible for the data.

Method of Calculation: See Collection of Data above.

Data Limitations: Data is dependent on the actual number of individuals who choose to continue their Texas pharmacist license. This measure is only useful as an explanatory piece of information. The data can give the reader an idea of the workload in the licensing area. The data (number of people who choose Texas as their state of licensure) however, is not a factor that can be controlled by the agency.

Calculation Type	Non-Cumulative.
New Measure	No.
Desired Performance	Higher than Target.

(2) Total Number of Business Facilities Licensed

Short Definition: The unduplicated number of facilities currently licensed by the agency.

Purpose/Importance: An information tool to report the number of pharmacies that are currently licensed by the agency, at any given point in time.

Source/Collection of Data: This number is obtained from licensing computer applications as developed and maintained by agency database system under master contract with the Department of Information Resources. TSBP Director of Administrative Services & Licensing is responsible for the data.

Method of Calculation: See Collection of Data above.

Data Limitations: Data is dependent on the actual number of pharmacies that choose to continue their licensure status in Texas. This measure is only useful as an explanatory piece of information. The data can give the reader an idea of the workload in the licensing area. The data (number of people who choose to operate a pharmacy in Texas) however, is not a factor that can be controlled by the agency.

Calculation Type	Non-Cumulative.
New Measure	No.
Desired Performance	Higher than Target.

(3) Total Number of Individuals Registered

Short Definition: The unduplicated number of individuals currently registered by the agency.

Purpose/Importance: An information tool to report the number of pharmacy technicians and pharmacy technician trainees who are currently registered by the agency, at any given point in time.

Source/Collection of Data: This number is obtained from licensing computer applications, as developed and maintained by agency database system under master contract with the Department of Information Resources. TSBP Director of Administrative Services & Licensing is responsible for the data.

Method of Calculation: See Collection of Data above.

Data Limitations: Data is dependent on the actual number of individuals who choose to initiate or continue their Texas pharmacy technician registration. This measure is only useful as an explanatory piece of information. The data can give the reader an idea of the workload in the licensing area. The data (number of people who choose Texas as their state of registration) however, is not a factor that can be controlled by the agency.

Calculation Type	Non-Cumulative.
New Measure	Yes.
Desired Performance	Higher than Target.

ENFORCEMENT - OUTCOME MEASURES

(1) Percent of Complaints Resulting in Disciplinary Action

Short Definition: Percent of documented jurisdictional complaints that were resolved (closed) through the entry of a Disciplinary Order during the reporting period.

Purpose/Importance: This measure is intended to show the extent to which the agency exercises its disciplinary authority in proportion to the number of complaints received. It is important that both the public and licensees have an expectation that the agency will work to ensure fair and effective enforcement of the laws and rules governing the practice of pharmacy. This measure seeks to indicate the agency's responsiveness to this expectation, as well as serves as an indication of the agency's workload with regard to investigations resulting in disciplinary actions as compared to investigations not resulting in disciplinary actions.

Source/Collection of Data: Data is obtained from the agency's computerized data base (complaint-tracking system). Disciplinary Orders are maintained in readily retrievable notebooks. The TSBP Director of Enforcement is responsible for the data.

Method of Calculation: The performance measure is calculated by dividing the numerator by the denominator and multiplying by 100 to achieve a percentage.

The following method is used to calculate the Numerator:

NUMERATOR - Total number of complaints (jurisdictional only) that are resolved (closed) during the reporting period in which at least one licensee has been the subject of a Disciplinary Order. See performance measure entitled "Percent of Licensees with No Recent Violations" for description and explanation of the term "Disciplinary Order." See performance measure entitled "Complaints Received" for description and explanation of the term "Jurisdictional Complaint." All Disciplinary Orders would be included in this calculation, including: (1) orders that grant or deny an application for a pharmacist or pharmacy license, intern registration, or technician registration; (2) petition to reinstate a previously revoked license; and (3) petition to modify a previously entered order.

A complaint may involve two licensees (one pharmacist and one pharmacy). Such a complaint may result in Disciplinary Orders against both licensees, only one licensee, or neither licensee. If the complaint results in a Disciplinary Order on one licensee (e.g., pharmacist) in one fiscal year (or reporting period) and a non-disciplinary action (i.e., no Disciplinary Order) on the second licensee (e.g., pharmacy) in another fiscal year (or reporting period), the complaint will be counted in the numerator as of the date the Disciplinary Order was entered (signed). If the complaint results in a Disciplinary Order on one licensee in one fiscal year (or reporting period) and a second Disciplinary Order on the second licensee in another fiscal year (reporting period), the complaint will be counted in the fiscal year (reporting period) as of the last date the Disciplinary Order was entered (signed). If the complaint is not closed with the entry of a Disciplinary Order on at least one licensee, the complaint will not be counted in the numerator. If the complaint results in two Disciplinary Orders, the complaint will still be counted as only one complaint. If the Board enters a Disciplinary Order that closes more than one complaint (as a result of multiple complaints being filed on the licensee), all complaints will be counted in the numerator.

DENOMINATOR -- Total number of jurisdictional complaints that are resolved (closed) during the reporting period, regardless of how the complaint was resolved (closed). This is the same number that will be reported for the performance measure entitled "Complaints Resolved."

Data Limitations: TSBP has no control over the number of complaints it receives, and consequently, has no control over the number of complaints that require disciplinary action to be taken (i.e., complaints that, following an investigation, produce evidence to prove that a licensee or applicant has committed a substantive violation of the laws and/or rules governing the practice of pharmacy).

<u>Calculation Type</u>   Non-cumulative.
<u>New Measure</u>   No.
<u>Desired Performance</u>   Higher than Target.

Note: this statement is based upon the assumption that a greater percentage of disciplinary actions is an indication of "better" (more effective) enforcement. However, this assumption may or may not be true.

(2) Recidivism Rate of Those Receiving Disciplinary Action

Short Definition: The number of "repeat offenders" at the end of the reporting period as a percentage of all offenders during the most recent three-year period. For purposes of this measure, the term "repeat offender" is defined as a person who has been the subject of two or more disciplinary orders within the past three fiscal years.

Purpose/Importance: This measure is intended to show how effectively TSBP enforces the laws and rules governing the practice of pharmacy. It also gives an indication of the workload on the agency's enforcement/legal staff that is caused by ▲repeat offenders." It is important that TSBP enforce its laws and rules strictly enough to ensure consumers are protected from unsafe, incompetent, and unethical practice by licensees.

Source/Collection of Data: Data is obtained from the agency's computerized data base (complaint-tracking system). Disciplinary Orders are maintained in readily retrievable notebooks. The TSBP Director of Enforcement is responsible for the data.

Method of Calculation: This performance measure is calculated by dividing the numerator by the denominator and multiplying by 100 to achieve a percentage.

The following method is used to calculate the Numerator:

NUMERATOR - Total number of persons who were the subject of more than one Disciplinary Order during the current fiscal year and the two prior fiscal years. See the performance measure entitled "Percent of Licensees with No Recent Violations" for description and explanation of the term ▲Disciplinary Order." Warning Letters are not disciplinary orders and are not included in this calculation.

For purposes of calculating the numerator of this performance measure only, the following types of Disciplinary Orders would not be included: (1) Orders that grant or deny an application for a license or registration, unless the disciplinary action to deny/grant an application involved a repeat offense; (2) Orders that grant or deny a petition to modify a previously entered Order, unless the disciplinary action to deny/grant the petition involved a repeat offense; and (3) Orders that would result in ▲double counting."

See performance measure entitled "Percent of Licensees with no Recent Violations" for description and explanation of the term "double counting."

"Repeat offenders" are determined by manually reviewing Disciplinary Orders (that are maintained in notebooks) to determine the license numbers and registration numbers that were subject to Orders entered during the current fiscal year; then entering those license and registration numbers into the agency's computerized data base to determine if the person was subject to another Order that was entered in the prior two fiscal years. If the individual does not have a license number (e.g., applicant), matching of names will be required.

DENOMINATOR - The number of persons who have been the subject of a Disciplinary Order during the past three fiscal years. For purposes of calculating the denominator of this performance measure only, the following types of Disciplinary Orders would not be included: (1) Orders denying the reinstatement of license, unless the Order included allegations of "new" violations; (2) Orders granting or denying the modification of a previously entered Order, unless the Order included allegations of "new" violations; and (3) Orders that would result in "double counting." See performance measure entitled "Percent of Licensees with No Recent Violations" for description and explanation of the terms "new violations" and "double counting."

Data Limitations: TSBP aggressively monitors persons who are on probation (as a result of a sanction imposed by a Disciplinary Order). However, a person may violate the laws/rules governing the practice of pharmacy, despite the fact that the person knows the action will be a probation violation and will likely result in additional, more severe disciplinary sanctions. TSBP has no control over the licensee's intentions to violate the laws/rules governing the practice of pharmacy.

Calculation Type   Non-cumulative.
New Measure   No.
Desired Performance   Lower than Target.

Note: this statement is based upon the assumption that a lower percentage of repeat offenders is an indication of the agency's effectiveness of enforcement. This assumption may or may not be true.

(3) Percent of Documented Complaints Resolved Within Six Months

Short Definition: The percent of documented jurisdictional complaints resolved (closed) during the reporting period, that were resolved (closed) within a six-month period (180 calendar days) from the date of the receipt of the complaint by the agency.

Purpose/Importance: This measure gives an indication of the agency's timeliness in resolving (closing) complaints. It is important to ensure the swift enforcement of the laws and rules governing the practice of pharmacy, which is an agency goal.

Source/Collection of Data: Data is generated by the agency's computerized data base (complaint tracking system). The TSBP Director of Enforcement is responsible for the data.

Method of Calculation: This performance measure is calculated by dividing the numerator by the denominator and multiplying by 100 to achieve a percentage.

NUMERATOR - Total number of jurisdictional complaints closed within six months (or less) from the date of the receipt of the complaint.

DENOMINATOR - This number is the same as the number reported for the performance measure entitled "Jurisdictional Complaints Resolved."

The date of the receipt of the complaint is documented on the complaint form and is entered into the agency's computerized complaint tracking system. The date the complaint is closed by the agency is also documented on the complaint form and entered into the agency's computerized complaint tracking system. The computer calculates the total number of days it took the agency to resolve (close) each one of the complaints closed during the reporting period. The computer also calculates the number of complaints closed within six months and the number of complaints that were not closed within six months, as well as the percentage for each. The computer generates a report that: (a) lists all jurisdictional complaints closed during the reporting period, by complaint number; (b) identifies the complaints that took only six months to close; and (c) produces the information with regard to the percentage of complaints closed within six months.

Data Limitations: Because the agency prioritizes complaints, more serious complaints are handled before less serious complaints. In addition, the size of TSBP's complaint backlog has an impact on the number (percentage) of complaints that can be closed in a timely manner. When TSBP receives more complaints than it resolves (closes), a backlog of complaints is formed. Each year that TSBP is unable to close 100% of the complaints it receives, the backlog continues to mount and complaints get older before agency staff can begin to work on the new complaints being received. Most significantly, the swiftness of resolution is dependent on the number and efficiency of enforcement staff who are handling the resolution of complaints.

<u>Calculation Type</u>	Non-cumulative.
<u>New Measure</u>	No.
<u>Desired Performance</u>	Higher than Target.

ENFORCEMENT - OUTPUT MEASURES

(1) Number of Inspections

Short Definition: Total number of compliance inspections/visits during the reporting period.

Purpose/Importance: This measure is an indication of the output of the agency's field Compliance Officers/Inspectors. In addition, the number of inspections/visits can be reflective of compliance with requirements. The more often an inspection occurs in a facility, the more likely they are to be in compliance.

Source/Collection of Data: Data is generated by the agency's computerized data base and is verified through a manual reporting system. TSBP Director of Enforcement is responsible for data.

Method of Calculation: The date of the inspection or inspection-visit is entered into the agency's computerized system. The computer calculates the number of inspections per reporting period. Compliance Officers/Inspectors complete weekly activity reports, indicating the number of pharmacies that were inspected or visited. The two reports are checked/verified against each other.

Data Limitations: The number of inspections conducted is dependent on the number of field Compliance Officers/Inspectors who are available to conduct the inspections. If the agency experiences any turnover in this area, the number of inspections conducted is decreased.

Calculation Type   Cumulative.
New Measure   No.
Desired Performance   Higher than Target.

(2) Number of Complaints Resolved

Short Definition: The total number of jurisdictional complaints resolved (closed) during the reporting period.

Purpose/Importance: This measure is an indication of the agency's workload with regard to the number of complaint investigations conducted and final actions taken by the agency.

Source/Collection of Data: Data is generated by the agency's computerized data base (complaint tracking system). TSBP Director of Enforcement is responsible for data.

Method of Calculation: All jurisdictional complaints resolved (closed) during the reporting period will be included in this calculation, regardless of the method of resolution. If a complaint is referred to the TSBP Legal Division for review (for possible institution of disciplinary action), the complaint will not be considered closed until final action is taken (e.g., entry of a disciplinary order, adjudicative warning letter, closing of complaint with no formal action, or institution of disciplinary action with subsequent dismissal). For these complaints, the date of the adjudication action will be the date that the complaint is closed (e.g., date of the disciplinary order, date of the warning letter, date of the informal conference in which the decision was made to dismiss the case). If the complaint is not referred to the Legal Division for review, the complaint will be considered closed as of the date of action (e.g., date of warning letter, if complaint was closed with a warning letter; date of the telephone call, if the complaint was closed with a telephone call; date of the final review by the division director, or designee, such as when a complaint is closed with investigation/no violation).

Data Limitations: TSBP has no control over the number of complaints that it receives, which has a direct relationship to the number of complaints it resolves (closes). Most significantly, the quantity of complaints closed is dependent on the number and efficiency of enforcement staff who are handling the resolution of complaints.

Calculation Type   Cumulative.
New Measure   No.
Desired Performance   Higher than Target.

ENFORCEMENT - EFFICIENCY MEASURES

(1) Average Time for Complaint Resolution

Short Definition: The average length of time to resolve (close) a jurisdictional complaint, for all jurisdictional complaints resolved (closed) during the reporting period.

Purpose/Importance: This measure gives an indication of the agency's timeliness in closing complaints.

Source/Collection of Data: Data is generated by the agency's computerized data base (complaint tracking system). TSBP Director of Enforcement is responsible for data.

Method of Calculation: The date of the receipt of the complaint is entered into the agency's computerized complaint tracking system. The date the complaint is closed by the agency is also entered into the agency's computerized complaint tracking system. For each complaint, the agency's computer system calculates the total number of calendar days elapsed from the date of the receipt of the complaint by the agency to the date that the complaint is closed (i.e., the date final action is taken by the agency). Then the computer calculates the total number of calendar days for all closed complaints and divides this number by the total number of complaints closed by the agency (resulting figure is the average time for complaint resolution).

Data Limitations: When the agency receives many more complaints than it resolves (closes), a backlog of complaints is formed. Each year that the agency is unable to close 100% of the complaints it receives, the backlog continues to mount and complaints get older before agency staff can begin to work on the new complaints being received. This situation has a major impact on the average complaint resolution time. Most significantly, the swiftness of resolution is dependent on the number and efficiency of enforcement staff who are handling the resolution of complaints.

Calculation Type	Non-cumulative.
New Measure	No.
Desired Performance	Lower than Target.

ENFORCEMENT - EXPLANATORY MEASURES

(1) Number of Jurisdictional Complaints Received

Short Definition: The total number of jurisdictional complaints received by TSBP during the reporting period. See explanation of "jurisdictional complaint" below.

Purpose/Importance: This measure is an indication of the workload on the agency's enforcement staff.

Source/Collection of Data: Data is generated by the agency's computerized data base (complaint tracking system). TSBP Director of Enforcement is responsible for the data.

Method of Calculation: After a complaint is received and evaluated, agency staff determine whether the complaint is a jurisdictional complaint or a non-jurisdictional complaint. Jurisdictional complaints include complaints filed against persons licensed or registered by TSBP or persons who are applying for a license/registration that is issued by TSBP, regardless of the allegations made in the complaint. Jurisdictional complaints also include complaints filed against persons who are not licensed or registered by TSBP, if the complainant has alleged that the subject of the complaint has violated the Texas Pharmacy Act or the Texas Dangerous Drug Act (TSBP has the jurisdiction and authority to enforce these two Acts). Agency staff enter the jurisdictional status in the agency's computer system. The computer calculates the number of jurisdictional complaints received during the reporting period and produces a report that (1) lists the total number of jurisdictional complaints received; (2) identifies all jurisdictional complaints received during the reporting period, by complaint number; and (3) lists the number of non-jurisdictional complaints. Although TSBP keeps track of the total number of non-jurisdictional complaints, TSBP does not use that figure in its calculation of this performance measure.

Data Limitations: TSBP has no control over how many complaints it receives. The Texas Pharmacy Act requires pharmacies to post a sign informing the consumer how to file a complaint (the sign lists the agency's address, telephone number, and toll-free number). TSBP also requires pharmacies who deliver (mail) prescriptions to advise customers of the same information contained in the aforementioned sign. This information has increased consumer awareness.

Calculation Type   Cumulative.
New Measure   No.
Desired Performance   Higher than Target, provided the agency has sufficient staff to handle the increased workload.

PEER ASSISTANCE - OUTCOME MEASURES

(1) Recidivism Rate for Peer Assistance Program

Short Definition: The percent of individuals who relapse within three years of the end of the reporting period as part of the total number of individuals who participate in the program during the previous three years.

Purpose/Importance: This measure is intended to show the three-year recidivism rate for those individuals who are participating in a peer assistance program. It is important because it indicates that consumers are being protected from unsafe, incompetent, and unethical (professional) practice as a result of the peer assistance program.

Source/Collection of Data: The PRN program will review its records and report the following numbers to TSBP: Data regarding the denominator [total number of individuals who have been reported to the PRN program in X-4 (where X is the current fiscal year), and who achieved a one-year sobriety date during X-3] is determined by a manual review of contracts entered during the reporting period. Data regarding the information needed to calculate the numerator (any individual who became the subject of a related disciplinary order anytime between the end of the one-year sobriety date and the end of the current fiscal year) is determined by a manual review of individuals' files.

TSBP will review its records and determine the following numbers: Data regarding the denominator [number of individuals who have been the subject of a disciplinary order in X-4 (where X is the current fiscal year), and who achieved a one-year sobriety date during x-3] is determined by manual review of disciplinary orders entered during the reporting period. Data regarding the information needed to calculate the numerator (any individual who became the subject of a related disciplinary order anytime between the end of the one-year sobriety date and the end of the current fiscal year) is determined by a manual review of disciplinary orders.

TSBP will add the PRN numbers to its numbers and calculate totals. TSBP Enforcement Administrator is responsible for the collection of data. The data is maintained in manual files.

Method of Calculation: Of all individuals successfully completing the program in fiscal year X-3, (where X is the current fiscal year), the percent of individuals receiving related disciplinary action from the Board anytime between the beginning of the fiscal year X-3 and the end of fiscal year X (i.e., the current fiscal year).

This measure is calculated by dividing the numerator by the denominator and multiplying by 100 to achieve a percentage.

The following method is used to calculate the Numerator:

NUMERATOR - "X" is any individual who became the subject of a related Disciplinary Order anytime between successfully completing the program and the end of the current fiscal year. Applicable terms are defined below:

(1)   "Individuals" are defined as pharmacists licensed by TSBP, applicants for licensure, and eligible pharmacy students (students enrolled in the professional sequence of an accredited pharmacy degree program approved by TSBP), who are participating in the PRN program or are subject of a Disciplinary Order.

(2)   The term "Disciplinary Order" is defined in the performance measure entitled "Percent of Licensees with no Recent Violations."

(3)   A "related" Disciplinary Order would be an Order containing one or more violations or alleged violations (i.e., charges or counts) that directly relate to relapse of impairment (e.g., unauthorized use of controlled drugs for personal use). An "unrelated" Order would not be included in this figure. Unrelated Orders would include the following types of disciplinary orders: (a) orders based upon an individual's failure to submit to a drug screen (i.e., a "no-show" is not considered a "relapse"); (b) orders based upon an individual's failure to submit required reports (e.g., self performance reports and reports from supervising pharmacist and/or mental health professional); and (c) orders based upon violations or alleged violations of the laws and rules governing the practice of pharmacy, other than impairment (e.g., failure to produce required continuing education records upon audit).

(4)   "Successfully completing the program" means individuals who have completed one-year sobriety (i.e., 12 months of sobriety from "start date" - see explanation of "start date" below).

The following method is used to calculate the Denominator:

DENOMINATOR - Total number of individuals who have been reported to the PRN program (regardless of the referral source) or who were the subject of a disciplinary order in X-4 (where X is the current fiscal year), and who achieved a one-year sobriety date during X-3.

These figures would include individuals in the PRN known only to the PRN program, as well as individuals in the PRN program known to the PRN program and TSBP. Year-end figures would not include individuals who did not participate in the program ("dropped out" of the program) during the reporting period because: (a) the individual allowed his/her pharmacist license to expire during the reporting period (i.e., the individual no longer holds a valid license and thereby, is not under TSBP's jurisdiction); and (b) the individual dies during the reporting period (regardless of the reason for the death of the individual). Accordingly, such an individual may be included in the calculations during one or two of the three-year reporting period, but not in the remaining years of the reporting period.

If an individual was reported to the PRN program in one fiscal year, and reported to TSBP in a subsequent fiscal year (or vice versa), the following is applicable:

(A)   the individual would be counted only once;

(B)   for individuals reported to TSBP, the "start date" (for calculating the one-year sobriety period) would be the date of the entry of the Disciplinary Order*;

(C)   for individuals reported to PRN program, the "start date" (for calculating the one-year sobriety period) would be the date the individual signed a contract with the PRN program, or an equivalent date*;

(D)   for purposes of calculating the one-year sobriety period, the "start date" would be earlier of (B) or (C).

* If an individual is subject to a new/revised PRN contract or a second related Disciplinary Order (other than revocation, cancellation, or retirement), the date of the entry of the second contract or order would serve as a new "start date" for calculating the one-year sobriety period.

Data Limitations: With regard to the Denominator, TSBP has no control over the number of individuals who enter into PRN contracts. With regard to the numerator, the number of disciplinary orders (that are entered by TSBP each year) is limited by the number of individuals who commit violations involving relapse or impairment.

Calculation Type   Non-cumulative.
New Measure   No.
Desired Performance   Lower than target.

(2) One-year Completion Rate for Peer Assistance Program

Short definition: Percent of individuals who successfully completed the peer assistance program during the year prior to the reporting period and have not relapsed during the one-year period.

Purpose/Importance: It is important because it indicates that consumers are being protected from unsafe, incompetent, and unethical (professional) practice as a result of the peer assistance program.

Source/Collection of Data: The PRN program will review its records and report the following to TSBP: Data regarding the denominator (number of individuals who have entered contracts with the PRN program in the prior fiscal year) is determined by a manual review of contracts entered during the reporting period. Data regarding the information needed to calculate the numerator (the number of individuals who achieved their one-year sobriety date in the current fiscal year) is determined by a manual review of individuals' files. For individuals on PRN contracts only (not subject to TSBP Disciplinary Orders), the PRN program will determine if the individual relapsed.

TSBP will review its records and determine the following numbers: Data regarding the denominator (total number of individuals subject to TSBP Disciplinary Order for impairment during the prior fiscal year) is determined by manual review of disciplinary orders entered during the prior fiscal year. Data regarding the information needed to calculate the numerator (number of individuals who were subject to an order during the prior fiscal year and who achieved one-year sobriety) is determined by a manual review of individuals' files.

TSBP will add the PRN numbers to its number and calculate totals. TSBP Enforcement Administrator is responsible for the collection of the data. The data is maintained in manual files.

Method of Calculation: Of all the individuals who have been referred to the peer assistance program in fiscal year X-1 (where X is the current fiscal year), the percent who have successfully participated in the program for one year with no relapses. For the purposes of this performance measure, the definition of the term "individual" is the same definition contained in the performance measure entitled "Recidivism Rate for Peer Assistance Programs."

This measure is calculated by dividing the numerator by the denominator and multiplying by 100 to achieve a percentage.

NUMERATOR - the total of (A) and (B), and who achieved a one-year sobriety during the current fiscal year. (A) = the number of individuals who entered into a PRN contract in the prior fiscal year; and (B) = the number of individuals who were subject to a disciplinary order during the prior fiscal year. To avoid counting an individual twice, the following guidelines are applicable: if the individual signs a PRN contract prior to the entry of a disciplinary order, the individual would be considered in group (A). If the individual signs a PRN contract after the entry of the disciplinary order, the individual would be considered in group (B). Applicable terms are defined below:

(1)   "Participation in the peer assistance program" - individuals who have signed a contract with the PRN program or been the subject of a disciplinary order during FYX-1.

(2)   "One-year sobriety date" - this term refers to individuals who have not had a relapse within 12 months of the entry of their contract or their disciplinary order. Individuals who die (regardless of the reason for the death of the individual) within 12 months of the entry of their contract or disciplinary order would not be considered as not having achieved their one-year sobriety date). Individuals who have had their pharmacist license revoked within 12 months of the entry of their contract or their disciplinary order, regardless of the reason, would be considered as not achieving their one-year sobriety date.

DENOMINATOR - The number of all individuals who signed a contract with the PRN program during the prior fiscal year and all individuals who were subject to a TSBP Disciplinary Order for impairment during the prior fiscal year. For purposes of this performance measure, unrelated Disciplinary Orders would not be included in this calculation (i.e., Disciplinary Orders not related to relapse).

Data Limitations: TSBP has no control over the number of individuals who enter into PRN contracts or the number of individuals who relapse.

<u>Calculation Type</u>	Non-cumulative.
<u>New Measure</u>	No.
<u>Desired Performance</u>	Higher than target.

PEER ASSISTANCE - OUTPUT MEASURES

(1) Number of Licensed Individuals Participating In a Peer Assistance Program

Short Definition: The number of licensed individuals who participated in a peer assistance program sponsored by the agency during the reporting period.

Purpose/Importance: This measure shows licensed individuals who continue to practice in their respective field who are participating in a substance abuse program.

Source/Collection of Data: The PRN program will manually review its records and report the following to TSBP: the total number of licensed individuals who have signed a contract during the reporting period and are being monitored by the PRN program (minus any TSBP program participants). TSBP will manually review its records and determine the following: the number of licensed individuals who have had disciplinary orders entered during the reporting period and are being monitored by TSBP and add the TSBP number to the PRN number.

TSBP will add the PRN numbers to its numbers and calculate totals. The TSBP Enforcement Administrator is responsible for the collection of the data. The data is maintained in manual files.

The first quarter's report will include all licensed individuals carried forward from the prior year as well as those individuals who have had Disciplinary Orders entered/signed contracts during the quarter. However, the report for the second, third, and fourth quarters will be only the number of licensed individuals who have had Disciplinary Orders entered/signed contracts during the respective quarter, in order for the cumulative number to be the total number of licensed individuals who participated in the peer assistance program during the current fiscal year.

Method of Calculation: The summation of all the licensed individuals who are listed as participating in the program during the reporting period.

PRN program will determine the total number of licensed individuals who are being monitored by the PRN program (i.e., individuals who have signed a contract with the PRN program). TSBP will determine the total number of licensed individuals who are being monitored by TSBP (i.e., individuals who have been subject to a Disciplinary Order requiring the individual to participate in the PRN program, and/or that includes allegations or findings of one or more counts of impairment) during the current fiscal year.

The term "licensed individuals" refers only to pharmacists licensed by TSBP including pharmacists who have been subject to an order reinstating their license. If an individual is licensed as a pharmacist as of September 1 of the current fiscal year, the individual will be counted as being licensed, for the purpose of this performance measure. Pharmacists licensed by TSBP include individuals who have the following licensure status: active, inactive, delinquent, suspended, probation, or restricted. Licensed individuals do not include expired pharmacists, applicants for licensure, or potential applicants for licensure.

Data Limitations: TSBP has no control over the number of licensed individuals who develop a physical, mental, or chemical impairment. In addition, the agency has no control over the number of licensed individuals reported to and monitored by PRN program.

Calculation Type	Cumulative
New Measure	No.
Desired Performance	Higher than target.

APPENDIX E

FISCAL YEAR 2011-2015 WORKFORCE PLAN

I. Agency Overview

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 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).

In terms of the coverage of regulation, 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 distribution of dangerous drugs (prescription drugs that are not classified as controlled substances). In addition, the Board has responsibility for the administration and the enforcement of the Texas Pharmacy Act and Texas Dangerous Drug Act.

The agency licenses approximately 25,507 pharmacists, 6,516 pharmacies, and 51,584 pharmacy technicians 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 Executive Director/Secretary serves as the executive officer of the agency, and as such is 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.

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.

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 the Strategic Plan, *Appendix B*.

A. Agency Mission

To promote, preserve, and protect the public health, safety, and welfare by fostering the provision of quality pharmaceutical care to the citizens of Texas, through the regulation of: the practice of pharmacy; the operation of pharmacies; and the distribution of prescription drugs in the public interest.

B. Strategic Goals and Objectives

GOAL 1	To establish and implement reasonable standards for pharmacist, pharmacy technician, and pharmacy technician trainee education and practice, and for the operations of pharmacies to assure that safe and effective pharmaceutical care is delivered to the citizens of Texas [Texas Pharmacy Act (Occupations Code, Sec. 555-566 and 568-569)].
Objective	Continue to operate a licensure system for pharmacists, pharmacy technicians, pharmacy technician trainees, and pharmacies that will assure that 100% of pharmacists, 100% of licensees and registrants meet minimum licensing standards through 2015.
Strategy	Operate a timely, cost-effective application and renewal licensure system for pharmacies and pharmacists, pharmacy technicians and pharmacy technician trainees.
GOAL 2	To assertively and swiftly enforce all laws relating to the practice of pharmacy to ensure that the public health and safety are protected from the following: incompetent pharmacists, pharmacy technicians and pharmacy technician trainees; unprofessional conduct, fraud, and misrepresentation by licensees; and diversion of prescription drugs from pharmacies; and to promote positive patient outcomes through the following: reduction of medication errors by encouraging or requiring licensees to implement self-assessment programs and continuous quality improvement programs, including peer review processes; and enforcement of rules relating to patient counseling and drug regimen review, including prevention of misuse and abuse of prescription drugs. [Texas Pharmacy Act (Occupations Code, Sec. 551-569), and Health and Safety Code, Chapter 483, Dangerous Drugs].

Objective	Through 2015, deter and reduce the incidence of violations of the law through compliance inspections of 50% of the licensed pharmacies in Texas; through technical assistance to licensees; through education and increased licensee access to information; and to resolve/close complaints received within 200 days of receipt.
Strategy 1	Emphasize preventive enforcement by conducting compliance inspections of pharmacies, promote voluntary compliance by providing information, education and technical assistance to licensees; and protect public health and safety by receiving, investigating, and resolving complaints, disciplining licensees, and monitoring compliance with disciplinary orders resulting from board adjudication.
Strategy 2	Operate a Peer Assistance Program by monitoring the growth, development, and compliance of a program to aid pharmacists and eligible pharmacy students impaired by chemical abuse or mental or physical illness, and monitor the success of individuals in the program.

C. Anticipated Changes in Strategies

The Texas State Board of Pharmacy (TSBP) has identified several agency initiatives that are contained in the *Strategic Plan*, some of which may significantly impact the agency's business and workforce. A sample of these initiatives is listed below (see the TSBP *Strategic Plan* for a complete listing, found under each *Policy Issue*).

- Work with associations and the Legislature to amend the Pharmacy Act to give the Board the authority to mandate that all pharmacies implement continuous quality improvement programs that include peer review.

- Work in partnership with other state and national pharmacy regulatory organizations and professional associations to ensure that the Act continues to provide the greatest protection for the citizens of Texas while not inhibiting the implementation of new and progressive healthcare and pharmaceutical care systems.

- Actively participate with other healthcare providers, legislators, and regulators in establishing initiatives to advance the safe and appropriate use of technology in pharmacy practice.

- Be proactive in developing educational and practice guidelines for well-qualified pharmacy technicians to facilitate the changing pharmacy practice paradigms.

- Remain progressive in initiatives focused on enhanced patient outcomes, with continued examination of those issues that are truly important, embracing current technology, gaining broad-based input, and acting aggressively and fairly to hold pharmacists accountable for the patient care they provide.

II. Current Workforce Profile (Supply Analysis)

A. Critical Workforce Skills

There are several critical skills and knowledge areas that are important to the agency's ability to operate. Without these skills and knowledge areas, the TSBP could not provide basic business functions. They are as follows:

- extensive knowledge of healthcare systems and the practice of pharmacy and drug distribution, including legal and regulatory requirements;

- extensive knowledge of state administrative rules and regulations, including the management of human resources, budgetary, and appropriations process;

- extensive knowledge of information resource systems, including web-based applications;

- thorough knowledge of the Texas Administrative Procedures Act, rules of evidence, and other administrative and criminal laws and procedures;

- thorough knowledge of investigative procedures; and

- strong interpersonal skills and customer service.

Additionally, a license to practice pharmacy by the TSBP is a critical requirement for many of the agency's positions, including the Executive Director/Secretary.

B. Workforce Demographics

The following **Table 1** profiles the agency's workforce as of August 31, 2009. The TSBP workforce is comprised of 23% males and 77% females. 68 percent of our employees are over the age of 40 and 49% of employees has less than five year's agency service. These percentages are high enough to warrant strong training programs to ensure our employees are able to assume key positions in the event of unexpected turnover.
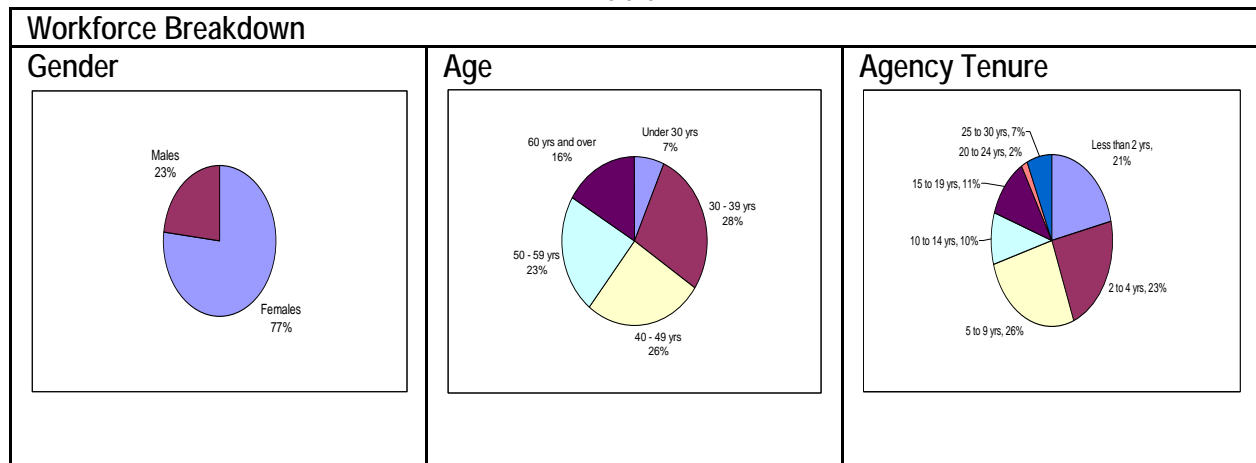
Table 1

Workforce Breakdown

Gender — Males 23%, Females 77%

Age — Under 30 yrs 7%, 30 - 39 yrs 28%, 40 - 49 yrs 26%, 50 - 59 yrs 23%, 60 yrs and over 16%

Agency Tenure — Less than 2 yrs 21%, 2 to 4 yrs 23%, 5 to 9 yrs 26%, 10 to 14 yrs 10%, 15 to 19 yrs 11%, 20 to 24 yrs 2%, 25 to 30 yrs 7%

Table 2

Race	Texas Population Race Distribution	Texas Pharmacists Population Race Distribution
Anglo	48.3%	58%
Hispanic	35.7%	8%
Black	11.4%	14%
Other	4.6%	20%

The agency's overall workforce profile, as shown in **Table 3**, indicates that the agency needs to increase its efforts to recruit and retain qualified minority applicants at all levels of job categories.

Table 3

Agency EEO Data	WHITE		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.

C. Employee Turnover

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 is 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.

D. Retirement Eligibility
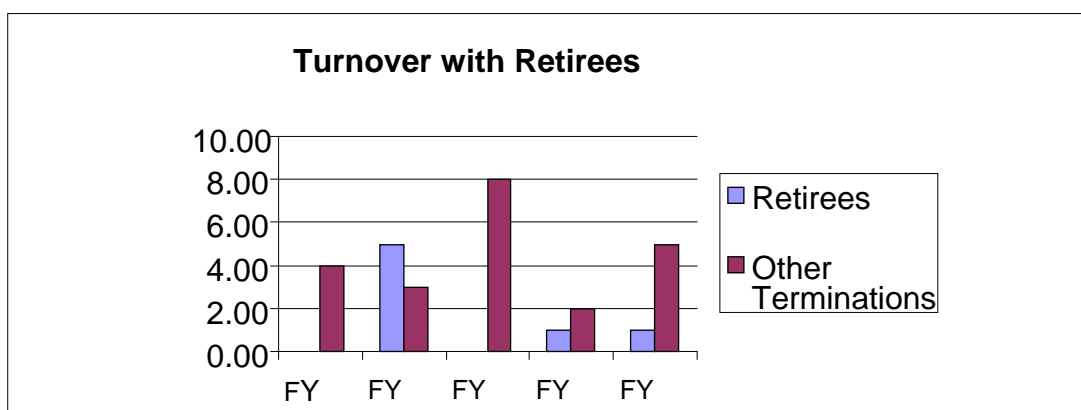
III. Future Workforce Profile (Demand Analysis)

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 the *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.

IV. Gap Analysis

After analyzing the workforce information, TSBP has determined that there are two main gaps between the agency's workforce supply and demand that must be addressed.

-        Key positions in management, including the Executive Director/Secretary position, are not being targeted for succession planning although three of the five management staff have been identified as eligible for retirement immediately.

-        The TSBP cannot attract and retain qualified pharmacists due to the significant differences in salaries compared to private sector employment.

V. STRATEGY DEVELOPMENT

GAP	LACK OF SUCCESSION PLANNING FOR THE EXECUTIVE DIRECTOR/SECRETARY AND KEY MANAGEMENT STAFF
Goal	Develop a competent, well-trained workforce.
Rationale	The training and development of current employees is critical to the success of the agency. TSBP should continue analyzing existing staff to determine which employees demonstrate the potential or interest to develop new competencies and assume new or modified positions.
Action Steps	• Request additional funding in the next legislative session to increase the compensation of the exempt line item position of Executive

Director/Secretary. • Expand training programs to include programs such as effective leadership and contemporary management training skills, effective project management, and assessing and managing risks. • Conduct an assessment of the level of risk facing the agency regarding the potential loss of knowledge particularly in areas where loss is likely due to the imminent loss of key employees.	

GAP	TSBP CANNOT ATTRACT AND RETAIN QUALIFIED PHARMACISTS
Goal	Become an employer of choice.
Rationale	If the agency is to recruit and retain qualified pharmacists, TSBP must take affirmative actions with the legislature to increase agency appropriations to secure qualified pharmacists. TSBP will also continue to re-examine its organizational structure and requirements to see if other job classifications could meet the needs of these positions.
Action Steps	Request additional appropriations to enhance employee compensation, especially in the recruitment and retention of pharmacists.

Survey of Employee Engagement

Board of Pharmacy

Executive Summary

2010

Executive Summary
Table of Contents

515-Board of Pharmacy

Introduction

Thank you for your participation in the Survey of Employee Engagement (SEE). We trust that you will find the information helpful in your leadership planning and organizational development efforts. As an organizational climate assessment, the SEE represents an employee engagement measurement tool based on modern organizational and managerial practice and sound theoretical foundations. In short, the SEE is specifically focused on the key drivers relative to the ability to engage employees towards successfully fulfilling the vision and mission of the organization.

Participation in the SEE indicates the willingness of leadership and the readiness of all employees to engage in meaningful measurement and organizational improvement efforts. The process is best utilized when leadership builds on the momentum initiated through the surveying process and begins engagement interventions using the SEE data as a guide. Contained within these reports are specific areas of organizational strengths and of organizational concern.

The SEE framework initially consists of a series of items to ascertain the demography of the respondents. The purpose is to measure whether or not a representative group of respondents participated. The second section contains 71 primary items. These are used to assess essential and fundamental aspects of how the organization functions, the climate, potential barriers to improvement, and internal organizational strengths. The items are all scored on a five-point scale from Strongly Disagree(1) to Strongly Agree(5) and are averaged to produce various summary measures - Constructs, Climate indicators, and the Synthesis Score.

The SEE has 14 Constructs which capture the concepts most utilized by leadership and those which drive organizational performance and engagement. These constructs are: Supervision, Team, Quality, Pay, Benefits, Physical Environment, Strategic, Diversity, Information Systems, Internal Communication, External Communication, Employee Engagement, Employee Development, and Job Satisfaction. In the Climate section of the reports are the Climate indicators: Atmosphere, Ethics, Fairness, Feedback, and Management.

The overall survey score, or Synthesis score, is a broad indicator for overall comparison with other entities and when available, over time.

Survey Administration Profile:

Collection Period:
01-25-2010 through 02-12-2010

Collection Method:
All employees took the survey online.

Additional Items and Categories (if applicable) may be used to target areas specific to the organization. Refer to the Appendix of the Data Report for a complete listing.

Survey Liaison:
Becky Damon
333 Guadalupe, Ste 3-600
Austin, TX   78701

becky.damon@tsbp.state.tx.us

Organization Profile

Board of Pharmacy

Organizational Leadership:

ID: 515

- Gay Dodson , R.Ph., Exec. Director/Secretary

Synthesis Score: 3.93

The Synthesis Score is an average of all survey items and represents the overall score for the organization. For comparison purposes, Synthesis scores typically range from 3.25 to 3.75.
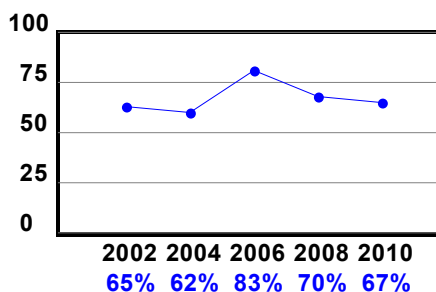
Response Rates

Overall Response Rate

Out of the 69 employees who were invited to take the survey, 46 responded. As a general rule, rates higher than 50 percent suggest soundness. Rates lower than 30 percent may indicate problems. At 67%, your response rate is considered average. Average rates mean that many employees have a reasonable investment in the organization, want to see the organization improve and generally have a sense of responsibility to the organization. Other employees may suffer from feelings of alienation or indifference.
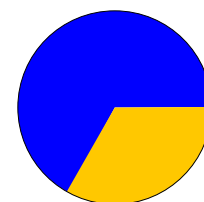
Responded 67%
Did Not Respond 33%

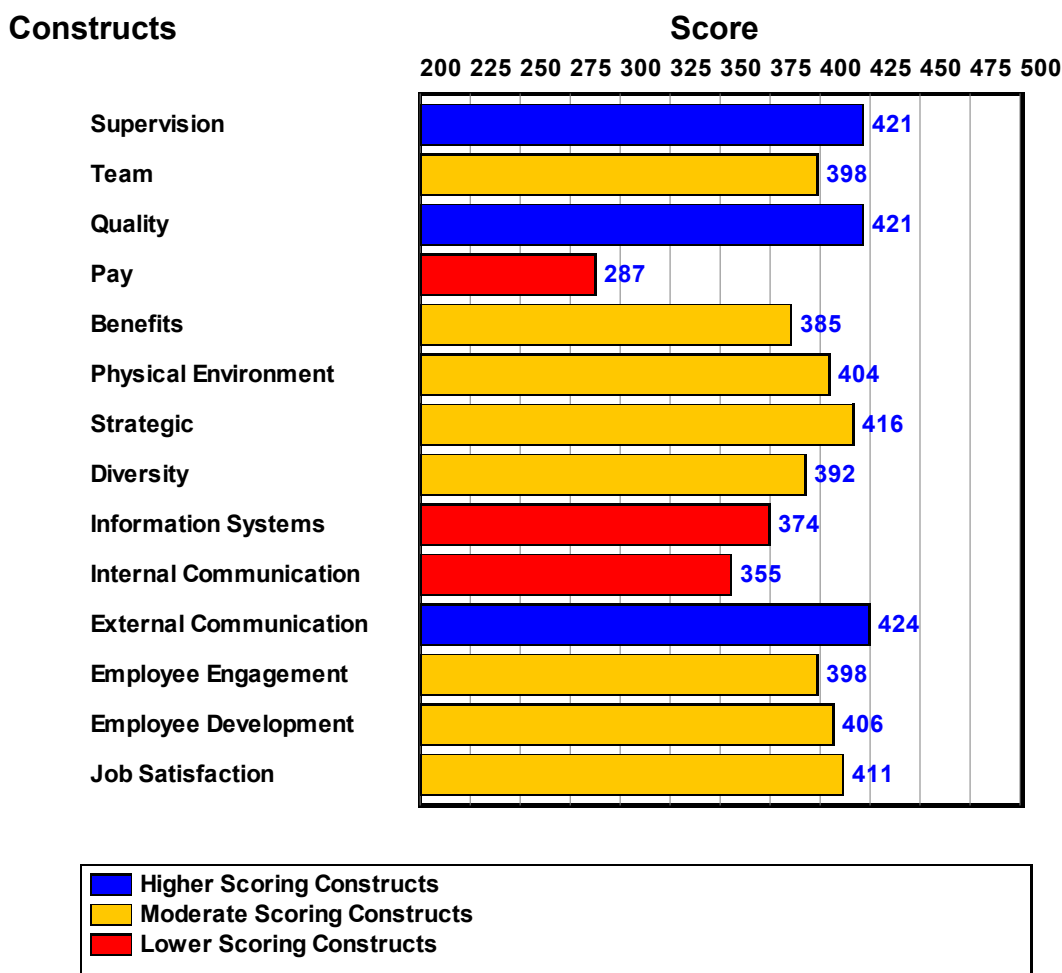|	2002	2004	2006	2008	2010
	65%	62%	83%	70%	67%

Response Rate Over Time

One of the values of participating in multiple iterations of the survey is the opportunity to measure organizational change over time. In general, response rates should rise from the first to the second and succeeding iterations. If organizational health is sound and the online administration option is used, rates tend to plateau around the 60 to 65 percent level. A sharp decline in your response rate over time can be a significant indicator of a current or potential developing organizational problem.

Construct Analysis

Constructs have been color coded to highlight the organization's areas of strength and areas of concern. The 3 highest scoring constructs are blue, the 3 lowest scoring constructs are red, and the remaining 8 constructs are yellow.

Each construct is displayed below with its corresponding score. Highest scoring constructs are areas of strength for this organization while the lowest scoring constructs are areas of concern. Scores above 350 suggest that employees perceive the issue more positively than negatively, and scores of 375 or higher indicate areas of substantial strength. Conversely, scores below 350 are viewed less positively by employees, and scores below 325 should be a significant source of concern for the organization and should receive immediate attention.

Constructs   **Score**

200 225 250 275 300 325 350 375 400 425 450 475 500

Construct	Score
Supervision	421
Team	398
Quality	421
Pay	287
Benefits	385
Physical Environment	404
Strategic	416
Diversity	392
Information Systems	374
Internal Communication	355
External Communication	424
Employee Engagement	398
Employee Development	406
Job Satisfaction	411

- ■ Higher Scoring Constructs
- ■ Moderate Scoring Constructs
- ■ Lower Scoring Constructs

Organizational Typology: Areas of Strength

The following Constructs are relative strengths for the organization:

External Communication   Score: 424

The External Communication construct looks at how information flows into the organization from external sources, and conversely, how information flows from inside the organization to external constituents. It addresses the ability of organizational members to synthesize and apply external information to work performed by the organization.

High scores indicate that employees view their organization as communicating effectively with other organizations, its clients, and those concerned with regulation. Maintaining these high scores will require leadership to be alert to change and maintain strong and responsive tools to assess the external environment.

Supervision   Score: 421

The Supervision construct provides insight into the nature of supervisory relationships within the organization, including aspects of leadership, the communication of expectations, and the sense of fairness that employees perceive between supervisors and themselves.

High Supervision scores indicate that employees view their supervisors as fair, helpful, and critical to the flow of work. Maintaining these high scores will require leadership to carefully assess supervisory training and carefully make the selection of new supervisors.

Quality   Score: 421

The Quality construct focuses upon the degree to which quality principles, such as customer service and continuous improvement are a part of the organizational culture. This construct also addresses the extent to which employees feel that they have the resources to deliver quality services.

High scores indicate that employees feel the organization delivers superior products and services to its customers. In general, quality is a result of understanding the needs of customers or clients coupled with a continuous examination of products and processes for improvement. Essential to maintaining high levels of quality are the clear articulation of goals, the careful attention to changes in the environment that might affect resources or heightened competition, and the vigorous participation by all members.

Organizational Typology: Areas of Concern

The following Constructs are relative concerns for the organization:

Pay   **Score: 287**

The Pay construct addresses perceptions of the overall compensation package offered by the organization. It describes how well the compensation package 'holds up' when employees compare it to similar jobs in other organizations.

Low scores suggest that pay is a central concern or reason for satisfaction or discontent. In some situations pay does not meet comparables in similar organizations. In other cases individuals may feel that pay levels are not appropriately set to work demands, experience and ability. Cost of living increases may cause sharp drops in purchasing power, and as a result, employees will view pay levels as unfair. Remedying Pay problems requires a determination of which of the above factors are serving to create the concerns. Triangulate low scores in Pay by reviewing comparable positions in other organizations and cost of living information. Use the employee feedback sessions to make a more complete determination for the causes of low Pay scores.

Internal Communication   **Score: 355**

The Internal Communication construct captures the organization's communications flow from the top-down, bottom-up, and across divisions/departments. It addresses the extent to which communication exchanges are open, candid, and move the organization toward goal achievement.

Average scores suggest that employees feel information does not arrive in a timely fashion and often it is difficult to find needed facts. In general, Internal Communication problems stem from these factors: an organization that has outgrown an older verbal culture based upon a few people knowing "how to work the system", lack of investment and training in modern communication technology and, perhaps, vested interests that seek to control needed information. Triangulate low scores in Internal Communication by reviewing existing policy and procedural manuals to determine their availability. Assess how well telephone systems are articulated and if e-mail, faxing, and Internet modalities are developed and in full use. Use the employee feedback sessions to make a more complete determination of factors influencing your Internal Communication score.

Information Systems   **Score: 374**

The Information Systems construct provides insight into whether computer and communication systems enhance employees' ability to get the job done by providing accessible, accurate, and clear information. The construct addresses the extent to which employees feel that they know where to get needed information, and that they know how to use it once they obtain it.

Average scores suggest that room for improvement exists and there is frustration with securing needed information. In general, a low score stems from these factors: traditional dependence on word of mouth, low investment in appropriate technology, and possibly some persons using their control of information to control others. Remedying Information Systems problems requires careful study to determine the correct causative factors. Have each program group list what information is needed and how they access it. Use the employee feedback sessions to make a more complete determination of the factors that influence your Information Systems score.
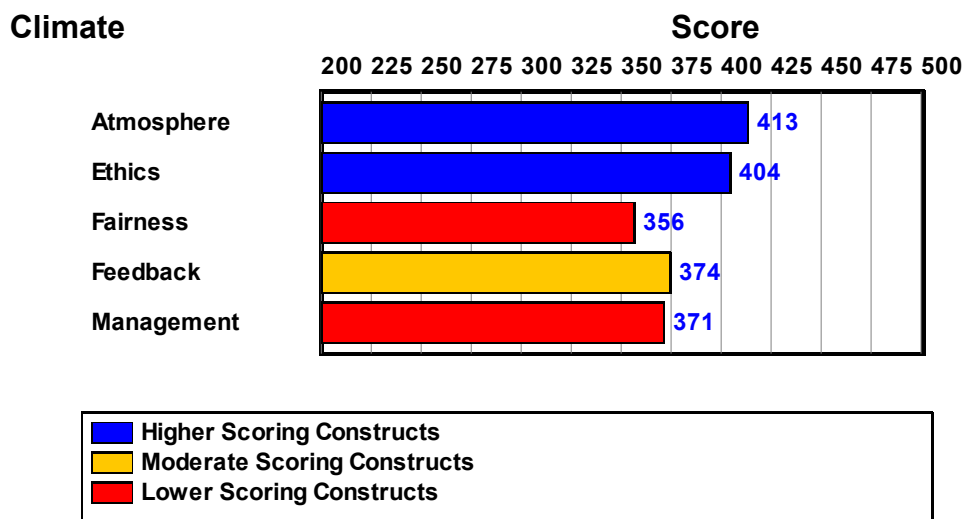
Climate Analysis

The climate in which employees work does, to a large extent, determine the efficiency and effectiveness of an organization. The appropriate climate is a combination of a safe, non-harassing environment with ethical abiding employees who treat each other with fairness and respect. Moreover, it is an organization with proactive management that communicates and has the capability to make thoughtful decisions. Climate Areas have been color coded to highlight the organization's areas of strength and areas of concern. The 2 highest scoring climate areas are blue (Atmosphere, Ethics), the 2 lowest scoring climate areas are red (Fairness, Management), and the remaining climate area is yellow (Feedback).

Each Climate Area is displayed below with its corresponding score. Scores above 350 suggest that employees perceive the issue more positively than negatively, and scores of 375 or higher indicate areas of substantial strength. Conversely, scores below 350 are viewed less positively by employees, and scores below 325 should be a significant source of concern for the organization and should receive immediate attention.

Climate   **Score**

Climate	Score
Atmosphere	413
Ethics	404
Fairness	356
Feedback	374
Management	371

Legend:
- Higher Scoring Constructs (blue)
- Moderate Scoring Constructs (yellow)
- Lower Scoring Constructs (red)

Climate Definitions:

Atmosphere: The aspect of climate and positive Atmosphere of an organization must be free of harassment in order to establish a community of reciprocity.

Ethics: An Ethical climate is a foundation of building trust within an organization where not only are employees ethical in their behavior, but that ethical violations are appropriately handled.

Fairness: Fairness measures the extent to which employees believe that equal and fair opportunity exists for all members of the organization.

Feedback: Appropriate feedback is an essential element of organizational learning by providing the necessary data in which improvement can occur.

Management: The climate presented by Management as being accessible, visible, and an effective communicator of information is a basic tenant of successful leadership.
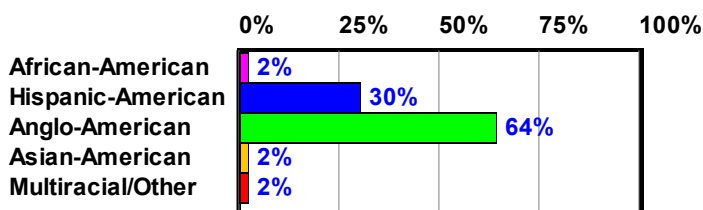
Participant Profile

Demography data help one to see if the Survey response rate matches the general features of all employees in the organization. It is also an important factor in being able to determine the level of consensus and shared viewpoints across the organization. It may also help to indicate the extent to which the membership of the organization is representative of the local community and those persons that use the services and products of the organization. Charts and percentages are based on valid responses.

*Please note that there may be a slight variation between the percentages presented here and those found in the Data Report. This is due to respondents who chose not to answer particular demographic items. All available demographic responses are reported in your Data Report.
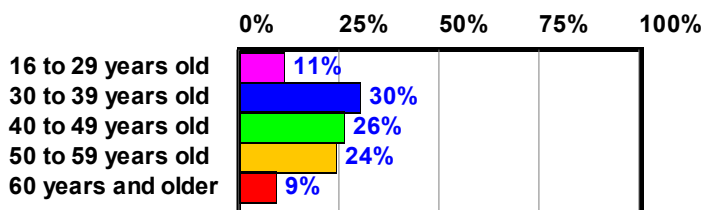
Race/Ethnic Identification

Racial/Ethnic diversity within the workplace provides resources for innovation. A diverse workforce helps ensure that different ideas are understood, and that the community sees the organization as representative of the community.

|	0%	25%	50%	75%	100%
African-American	2%				
Hispanic-American	30%				
Anglo-American	64%				
Asian-American	2%				
Multiracial/Other	2%				

Age

Age diversity brings different experiences and perspectives to the organization, since people have different challenges and resources at various age levels. Large percentages of older individuals may be a cause of concern if a number of key employees are nearing retirement age.

	0%	25%	50%	75%	100%
16 to 29 years old	11%				
30 to 39 years old	30%				
40 to 49 years old	26%				
50 to 59 years old	24%				
60 years and older	9%				

Gender

The ratio of males to females within an organization can vary among different organizations. However, extreme imbalances in the gender ratio when compared to actual gender diversity within your organization should be a source of concern and may require immediate attention as to why one group is responding at different than anticipated rates.

Female 82%
Male 18%
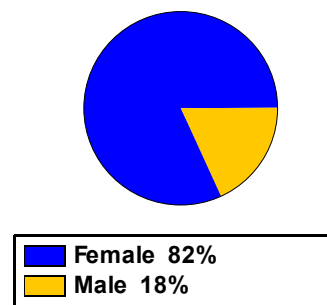
Benchmark Data and Other Resources

Benchmark Categories:

Benchmark Data composed of the organizations participating in the survey are provided in your reports. Benchmarks are used to provide a unit of comparison of organizations of similar mission and size. If you selected to use organizational categories, internal benchmarks between categories as well as over time data illustrate differences and changes along item and construct scores. Our benchmark data are updated every two years and are available from our website at www.survey.utexas.edu. The most current benchmark data are provided in your report. To get a better idea of how this organization compares to others like it, we provide three types of benchmark data: organizations with a similar size, similar mission, and organizations belonging to a special grouping. **The Benchmark Categories for this organization are:**

Organization Size: Size category 2 includes organizations with 26 to 100 employees.

Mission Category: Mission 8 (Regulatory)
The Regulatory category includes organizations involved in the regulation of medical, financial, and other service industries.

Special Grouping: None

Reporting and Other Resources:

A Data Report accompanies this summary. The data report provides greater detail than the executive summary. The data report is largely a quantitative report of the survey responses. Demographic data are presented in percentages and real numbers. Construct means and benchmark comparison numbers are provided on all variables. Item data are broken into mean, frequency counts, standard deviations, and number of respondents. Item benchmark data are also displayed.

Electronic Reports are provided in two formats. First, all executive and data reports are included in pdf files for ease in distribution and for clear printability. This file format is widely used, and a free pdf reader called Adobe Acrobat reader is available from www.adobe.com. The second type of electronic reports are in Microsoft Excel format. These reports are construct and item survey data in a flat spreadsheet format. This allows the user to sort highs and lows, search for individual items, or create custom reports from the survey data.

Using the Survey as a Catalyst for organizational improvement is essential to the survey process. The survey creates momentum and interest. At the end of the executive summary report is a series of suggested next steps to assist in these efforts. Also, we have captured several presentations from other organizations that have used the data in strategic planning, organizational improvement, and employee engagement initiatives. Please visit us at www.survey.utexas.edu for addtional survey resources.

Additional Services are available from our group. We conduct 360-Degree leadership and supervisory evaluations, special leadership assessments, customer and client satisfaction surveys along with the ability to create and administer a variety of custom hardcopy and online survey instruments. Consultation time for large presentations, focus groups, or individual meetings is available as well. For additional information, please contact us at anytime.

Next Steps: Interpretation and Intervention

After the survey data has been complied, the results are returned to the survey liaison, executive director, and board or commission chair approximately one to two months after data collection stops. These individuals are strongly encouraged to share results with all survey participants in the organization. Survey results are provided in several formats to provide maximum flexibility in interpreting the data and sharing the data with the entire organization. The quick turnaround in reporting allows for immediate action upon the results while they are still current.

The Executive Summary provides a graphical depiction of the data. Graphical data can easily be reproduced in a company newsletter or website. For additional detailed data, the Data Report is useful for examining survey data on the individual item level. Response counts, averages, standard deviations, and response distributions are provided for each item. Excel files provide electronic access to scores. Scores can be sorted in various ways to help determine strengths and areas of concern. The electronic data can also be used by Excel or other software to create additional graphs or charts. Any of these formats can be used alone or in combination to create rich information on which employees can base their ideas for change.

Benchmark data provide an opportunity to get a true feel of the organization's performance. Comparing the organization's score to scores outside of the organization can unearth unique strengths and areas of concern. Several groups of benchmarks are provided to allow the freedom to choose which comparisons are most relevant. If organizational categories were used, then internal comparisons can be made between different functional areas of the organization. By using these comparisons, functional areas can be identified for star performance in a particular construct, and a set of "best practices" can be created to replicate their success throughout the organization.

These Survey Data provide a unique perspective of the average view of all that took the Survey. It is important to examine these findings and take them back to the employees for interpretation and to select priority areas for improvement. This also provides an opportunity for the organization to recognize and celebrate areas that members have judged to be areas of relative strength. By seeking participation and engaging people on how the organization functions, you have taken a specific step in increasing organizational capital. High organizational capital means high trust among employees and a greater likelihood of improved efforts and good working relationships with clients and customers.

Ideas for getting employees involved in the change process:

- Hold small focus groups to find out how the employees would interpret the results
- Conduct small customized follow-up surveys to collect additional information including comments
- Provide employees with questionnaires/comment cards to express their ideas

Ideas for sharing data with the organization:

- Publish results in an organizational newsletter or intranet site
- Discuss results in departmental meetings
- Create a PowerPoint presentation of the results and display them on kiosks

Timeline

March and April: Interpreting the Data

- Data are returned to survey liaisons, executive directors and board members
- Review Survey data including the Executive Summary with executive staff
- Develop plans for circulating all the data sequentially and provide interpretations for all staff

May: Distributing Results to the Entire Organization

- Implement the plans for circulating the data to all staff
- Create 3 to 4 weekly or monthly reports or organization newsletters
- Report a portion of the constructs and items, providing the data along with illustrations pertinent to the organization
- Select a time to have employees participate in a work unit group to review the reports as they are distributed to all staff, with one group leader assigned to every group. The size of the groups should be limited to about a dozen people at a time. A time limit should be set not to exceed two hours.

June: Planning for Change

- Designate the Change Team composed of a diagonal slice across the organization that will guide the effort
- Identify Work Unit Groups around actual organizational work units and start each meeting by reviewing strengths as indicated in the data report. Brainstorm on how to best address weaknesses
- Establish Procedures for recording the deliberations of the Work Unit Group and returning those data to the Change Team
- Decide upon the Top Priority Change Topic and Methods necessary for making the change. Web-based Discussion Groups and Mini-Surveys are convenient technologies
- First change effort begins
- Repeat for the next change target

July and Beyond: Implementation and Interventions

- Have the Change Team compile the Priority Change Topics and Methods necessary for making the change and present them to the executive staff
- Discuss the administrative protocols necessary for implementing the changes
- Determine the plan of action and set up a reasonable timeline for implementation
- Keep employees informed about changes as they occur through meetings, newsletters, or intranet publications
- Resurvey to document the effectiveness of the change