

EXTERNAL/INTERNAL ASSESSMENT

IDENTIFICATION OF ISSUES

In developing its Strategic Plan, 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 an exhaustive internal and external assessment, with the following four issues identified and detailed:

POLICY ISSUE #1 - THE CHANGING FOCUS OF PHARMACY PRACTICE

Issue Statement

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 are all forging rapid change in our healthcare system. 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 possibly be recovered from the savings it generates. This can be realized only if an environment is created by healthcare reform that recognizes that the savings are likely to be generated not 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-oriented 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
- the 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 is currently occurring in Texas in that many pharmacists are currently providing 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. In the case of drug therapy management under written protocol of a physician, pharmacists may initiate and modify drug therapy of patients. However, pharmacists cannot sign written prescriptions in the same manner as physician assistants and advanced nurse practitioners are allowed. Likewise, the authority to administer medications is limited to immunizations and vaccines, and the patient must be 14 years of age or older. To more fully use these tools, the Act should be amended to remove these restrictions.

In addition, for pharmacists to continue providing these expanded services, the buyers and sellers of healthcare must recognize and understand their 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?).

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.

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.

Proving the value of pharmacists' services is not a new issue in pharmacy. Numerous studies have focused on the issue, including a study published in the July 21, 1999, issue of the *Journal of the American Medical Association*, which found that the presence of a pharmacist on rounds as a full member of the patient care team in a medical intensive care unit reduced adverse drug events caused by dispensing

errors by 66%. This same study estimated the cost savings in this single unit would be approximately \$270,000 per year.

In addition to proving the value of their services, pharmacists must work with other healthcare professionals to assure the safety of the healthcare system. The issue of the safety of the healthcare system was the focus of a November 1999 report from the Institute of Medicine (IOM). This report titled: *“To Err is Human: Building a Safer Health System”* states that medical errors kill some 44,000 people in U.S. hospitals each year. The report further states medication errors cause more than 7,000 deaths annually both in and out of hospitals. It is encouraging that the IOM 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 76th Texas Legislature, through the passage of S.B. 780, gave pharmacists and the Board a valuable tool to use in assessing medication errors and creating safer systems. This bill was the first in the nation to set up pharmacy peer review committees. The bill specifies that a pharmacy peer review committee may be established to:

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

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

Over the last two years, the Board used this tool by ordering most pharmacies who have come before the Board for dispensing errors, to implement a continuous quality improvement program (CQI) 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.

During the last two years, the Board has ordered a total of 60 pharmacies to implement CQI programs. This number represents less than 1 percent of the pharmacies licensed by TSBP. The Board had hoped that the owners of multiple pharmacies would see the benefit of the CQI program and voluntarily implement the program in all of the pharmacies they owned. This has not generally occurred. Therefore, the Board

has suggested that the Pharmacy Act should be amended to allow the Board to mandate all pharmacies implement a CQI program.

A follow-up report to the Institute of Medicine's 1999 report titled *"To Err is Human: Building a Safer Health System"* identified two additional areas that will affect the provision of pharmaceutical care. The two issues identified in the 2001 report titled *"Crossing the Quality Chasm: A New Health System for the 21st Century"* are:

- Regulating the Professions; and
- Use of Computer-Based Clinical Decision Support Systems.

The report identifies the following two areas regarding regulating the profession:

- Assessment of competence of the healthcare provider; and
- Restrictive scope-of-practice acts.

Assessment of the competence of a healthcare provider is identified as a "gap" in the regulatory scheme and 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.

One method to monitor continuing competence of pharmacists is through voluntary certification. Traditionally, certification is provided by a non-governmental entity, such as a professional association, in recognition that an individual practitioner has met certain predetermined standards or qualifications. However, not all pharmacists participate in voluntary programs. In addition, there is a lack of standards for the numerous certification programs available. To address this problem, the 76th Texas Legislature passed an amendment to the Texas Pharmacy Act that gave the Board of Pharmacy the authority to set minimum standards for pharmacist certification programs. The Board responded to this legislation by adopting rules that define the Board certification programs that will be recognized by the agency.

The second regulatory issue identified in the second IOM report is 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 tele-medicine, 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.”*

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 for 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*), a 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 regulations for these laws to assure that pharmacists may have access to important patient medical information.

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/non-traditional 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 being 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; and
- directly monitoring drug use in certain settings.

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 action on pharmacists and pharmacies that 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.

Finally, although many studies are being conducted to prove the cost benefit of pharmaceutical care, if these studies do not result in the development of methods to adequately compensate pharmacists for providing pharmaceutical care, the number of pharmacists providing this care will decrease. The agency may be faced with deciding if it is reasonable to require pharmacists to provide a service (pharmaceutical care) when the marketplace is not willing to pay for this service.

Agency Strengths and Opportunities

- The current definition of the *practice of pharmacy* in the Texas Pharmacy Act:
 - 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*
 - 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.
- 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.
- The Board has adopted rules that set standards for recognition and approval of pharmacist certification programs.
- 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.

- The National Council on Patient Information and Education conducts public information campaigns and prepares/distributes promotional materials on an ongoing basis, such as "*Communicate Before You Medicate*," "*Communication is the Best Medicine*," and "*Medicine: Before You Take It, Talk About It*."
- A precedent exists for expanded roles for Texas pharmacists, because:
 - the federal government, through the Department of Health and Human Services' Office of the Inspector General, has supported the clinical role of community pharmacists;
 - 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
 - the federal government, through the Omnibus Budget Reconciliation Act (OBRA '90), mandated prospective drug utilization review (DUR) by pharmacists (patient counseling and maintenance of patient profiles) for patients receiving Medicaid assistance.
- Current Board rules require patient counseling for patients at the pharmacy, Drug Utilization Review (DUR), and provision of written information about prescription medications. The agency's support for expanded roles, coupled with its reputation and credibility, may lend to the acceptance by consumers, legislators, and the profession of expanded roles for pharmacists.
- Current Board rules require patient outcome monitoring in some practice settings.
- 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.
- 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.
- All Texas pharmacy schools have completed the transition to a six-year curricula, conferring the Doctor of Pharmacy (Pharm. D.) degree upon successful graduates. The new curricula provides a knowledge base on which pharmacists can expand their current and future roles, such as those in education/training in patient assessment skills. In addition, the Texas colleges of pharmacy are offering a uniform "*external*" degree program for current pharmacists to obtain the Doctor of Pharmacy degree.
- The agency has the authority to establish task forces composed of pharmacists and other professionals who have special expertise to advise the Board.

- 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)

- Pharmacists may not be compensated for expanded pharmaceutical care services. Can the Texas State Board of Pharmacy require services for which the pharmacist will not be reimbursed, even if those services are crucial to the public health? Policymakers may view pharmaceutical care as *too expensive* to include in federal or state healthcare reform initiatives, and thus, the fragmented delivery of healthcare will continue even in *managed care* settings. The agency must encourage and educate policymakers to recognize the value of pharmaceutical care and its benefit to the public and its contribution to significantly reduce healthcare costs.
- 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.
- 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).
- 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.
- 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.
- The current definition of dangerous drugs includes *devices which require a prescription*, but does not include other types of devices.
- 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.
- Some of the “*corporate*” (independent and chain) entities that own pharmacies in Texas give a great deal of “*lip-service*” 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

- Continue to include outcome-based initiatives in the Board's disciplinary orders.
- Work with the associations and the legislature to amend the Pharmacy Act to give the Board the authority to mandate all pharmacies implement continuous quality improvement programs that include peer review.
- Develop a compliance inspection process based on the concept of outcome-based regulation.
- Be an active participant with other healthcare providers, legislators, and regulators in establishing initiatives regarding protecting a patient's confidential healthcare information.
- Be an active participant with other healthcare providers, legislators, and regulators in establishing initiatives regarding medication errors.
- Monitor the progress of the profession in establishing continuous quality improvement programs and the effect these programs have on reducing medication errors.

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, optical scanners, bar codes, RFID (radio frequency identification), nanotechnology, voice recognition, telecommunication, and the Internet. It is clear that technology has the capacity to greatly enhance the provision of pharmaceutical services. 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. Additionally, the National Association of Boards of Pharmacy (NABP) and the Food and Drug Administration (FDA) are both working on rule language to facilitate the use of electronic transmission of prescription data. TSBP should work with these agencies to enhance the tools available to prescribers and pharmacists.

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 take advantage of the electronic prescribing technology that will help prevent medication errors today." (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.

Also in the summer of 2003, a Medicare Reform bill was introduced in the United States House of Representatives that includes electronic prescribing as a way to minimize medical errors. This bill describes an electronic prescription program and requires that all prescriptions be written and transmitted electronically, except in emergency cases.

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. The phrase "new technology" is currently associated most frequently with the use of the Internet and electronic prescribing. However, 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:

- (1) receipt and data entry of prescriptions and patient information;
- (2) storage of prescription information;
- (3) delivery of pharmacy services;
- (4) accountability for pharmacy services;
- (5) patient confidentiality; and
- (6) 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 several years allowed prescriptions to be electronically transmitted between practitioners and pharmacies. Entrepreneurs have been monitoring this type of prescription

transmission and are seeking ways to facilitate the process. This includes use of the Internet, email, 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 optical scanning, bar coding, and voice recognition are being considered as methods for data entry of this information. Current electronic transmission technology could allow prescription data entry into a pharmacy's computer by any of these methods, to occur at locations other than the dispensing pharmacy. Pharmacy managers will look at off-site data entry as a possible way to alleviate some of the pharmacist's workload issues at the pharmacy level.

In addition to the information necessary to process a prescription, pharmacy personnel must data enter information necessary to process prescriptions through third party claims processors. Prescription insurance cards currently containing this information may carry the information electronically in the future, possibly through the magnetic strip or an implanted computer chip. This will permit faster and more accurate data entry into the pharmacy's computer system.

(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*, 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 as mentioned previously, but it could also carry the patient's prescription information. However, at both the state and federal levels, these practices raise record keeping and accountability concerns for an individual pharmacy's ability to survive a drug audit, should an audit become necessary. Cooperation and agreement between federal and state agencies will be required as the Board addresses record keeping 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. It also appears that the system is set up such that the unlicensed centralized facility maintains the prescription drug records for access and dispensing by multiple pharmacies.

(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.

Prescription Drug Products

- (A) Robotics - Dispensing robots are becoming more affordable and prevalent. Although the cost for such robots is decreasing, it 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.
- (B) Centralized Pharmacy Services (Central Fill) - 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 refill 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 Central Fill Pharmacies.
- (C) Centralized Prescription Processing (Central 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 Central Processing Pharmacies.
- (D) Satellite (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 satellite locations may or may not have held pharmacy licenses or any other license that allows 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. Under S.B. 98, a pharmacy may place an automated dispensing system that is remotely controlled by a pharmacist in a separately-located pharmacy 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 satellite 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. Under the provisions of S.B. 65, a pharmacy may provide prescription services to

remote areas using a telepharmacy system. The telepharmacy system is a system that monitors the dispensing of prescription drugs and provides for related drug use review and patient counseling by electronic means.

- (E) 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. This area parallels the Centralized Prescription Processing (Central Processing).

Drug Information Services

- (A) 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.
- (B) 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. Multiple personnel, licensed and unlicensed, assist in the dispensing process. Automation and robotics can perform many of these same functions in some facilities. Centralized record keeping 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. The issue of patient confidentiality is a hot topic at both the state and federal levels, as demonstrated by the Health Insurance Portability and Accountability Act (HIPAA), followed by Texas law (S.B. 11), and will be an evolving issue during the next five years.

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 record keeping 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) will be governed by specific documents outlined in HIPAA.

(6) The Internet

The Internet has received a tremendous amount of attention over the past few years. What are called "Internet Pharmacies" have sprung 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 Phoenix, AZ, 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.

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 website.

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 State Board of Medical Examiners 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.

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 which must be controlled, supervised, or performed exclusively by pharmacists in order to promote, preserve, and protect the public health.

Agency Strengths And Opportunities

- 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.
- 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.
- TSBP has continued to review, amend, and/or adopt rules for the expanded use of automated technology in the practice of pharmacy.
- The agency's Compliance Section of the Enforcement Division is already in a position to observe the use of technology in the practice setting.
- 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.
- TSBP has developed and maintains good working relationships with those state and federal agencies whose jurisdictions overlap pharmacy practice in Texas. TSBP should work with the Texas State Board of Medical Examiners to require physicians to produce and maintain audit trails for prescriptions submitted electronically to pharmacies.

- 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)

- Board members, agency staff, and pharmacists in general, have limited expertise in automated 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.
- 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.
- TSBP does not have the authority to license or directly regulate entities that want to facilitate the prescription transmission process between practitioners and pharmacies.
- 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.
- TSBP is unable to license many facilities where automation and technology could facilitate good patient care.
- TSBP is unable to regulate the provision of drug information from facilities other than pharmacies.

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

- Cooperate with state and federal agencies to establish an effective and efficient level of regulatory control over the use of technology in pharmacy practice.
- 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.
- Actively participate with other healthcare providers, legislators, and regulators in establishing initiatives to advance the safe and appropriate use of technology in pharmacy practice.
- Seek ways to increase individual accountability for the activities of personnel involved in the provision of pharmacy services.
- 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.

- 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; shortage of trained certified technicians; working conditions [e.g., working long hours, increased administrative functions resulting from requirements by third party payors, 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

Pharmacist Shortage/Overage

There are 89 accredited colleges/schools of pharmacy in the United States with four of these pharmacy education institutions being located in Texas: Texas Southern University (College of Pharmacy in Houston); Texas Tech University (School of Pharmacy in Amarillo); University of Houston (College of Pharmacy in Houston); and University of Texas (College of Pharmacy in Austin). Although these institutions have experienced an increase in the number of applications to their pharmacy colleges/school and an upturn in enrollment, TSBP records indicate that most of the recent new licensees graduated from an out-of-state college/school of pharmacy. In FY2003, TSBP licensed 806 individuals with only 41% (330 persons) having graduated from a Texas college/school of pharmacy.

The pharmacist shortage that the state of Texas is currently experiencing can be attributed, in part, to the following factors:

- (1) due to higher educational standards, pharmacy degree programs changed from a five-year to a six-year program; this change, which affected all colleges/schools of pharmacy in the nation, reduced the number of students graduating from pharmacy college/school during the transition, which in turn had a negative impact on the available pool of persons eligible to become licensed; and

- (2) Texas pharmacy colleges/school have limited resources, causing these institutions to limit the number of students that are accepted into their programs, which in turn results in finite numbers of persons being eligible for licensure in Texas.

According to a preliminary report published by the Texas Higher Education Coordinating Board (THECB) in December 2003, the following statistics suggest that Texas has room for improvement, in terms of average class size and number of pharmacy schools:

- (1) Texas ranked 8th among the 10 most-populous states in average class size of pharmacy programs; and
- (2) Texas residents had less opportunity than residents of nine of the 10 most-populous states to attend an in-state pharmacy school. Texas would need to accommodate 80 new students annually to meet the average in the other populous states.

However, this condition is going to be somewhat alleviated with the addition of a fifth and possibly a sixth pharmacy school, as listed below:

- (1) Texas A&M University/Kingsville plans to open a pharmacy school in the fall of 2005. The 78th Texas Legislature named the Kingsville facility the Irma Rangel Pharmacy School and construction began in April 2003. In December 2003, Governor Rick Perry announced \$4.28 million in funding that should allow the Kingsville school to hire faculty and administrators in time for its scheduled opening and to graduate its first class of students by the spring of 2009. Dr. Indra K. Reddy was selected as the first dean of this school, effective February 2, 2004. The Board, all the professional associations, and the colleges of pharmacy in the state have committed to assisting Texas A&M in establishing a first-class college of pharmacy at Kingsville.
- (2) University of the Incarnate Word (San Antonio) plans to open a pharmacy school in 2006. If plans are met, this institution anticipates graduating 50 to 55 students by 2010.

In January 2004, TSBP records indicated that approximately 20,000 pharmacists hold “active” Texas licenses, but only 16,000 pharmacists reside in Texas. Of the pharmacists who reside in Texas, approximately 50% work in community pharmacies, 21% work in hospitals, and the remaining 29% work in other types of settings (e.g., clinics, mail-service pharmacies, wholesalers, education, government). The THECB report stated that Texas ranked 39th among the 50 states in the number of pharmacists per 100,000 population (based upon 2000 data). The THECB study also indicated that pharmacists are not evenly distributed among the Texas population, with the Lower Rio Grande Valley and the El Paso area having the fewest pharmacists per 100,000 population.

Texas imports a large number of graduates from other states through the reciprocity process. In FY2003, 32% of the new licensees were licensed by reciprocity (i.e., of the 806 persons that TSBP licensed to practice pharmacy in Texas in FY2003, 260 had a license in another state that was used to reciprocate to Texas). This trend will need to continue if Texas pharmacy owners are to keep up with the growing need for pharmacists.

Until the colleges of pharmacy are able to meet the demands of the pharmacist shortage, this issue will continue to be a strategic challenge for TSBP. However, according to the THECB study, the annual

increase in the number of pharmacists in Texas has kept pace or outpaced the state's annual increase in population during the past decade (except in 2000). This study concluded:

“Demand issues, such as the rapid growth in the number of prescriptions filled and the aging population, most likely play a more pivotal role in assessing the current and future demand for pharmacists. Changes in the profession's scope of practice also may affect demand but are expected to develop more slowly. At the same time, centralized prescription fill services and automated fill systems are becoming more commonplace and are increasing efficiency in the dispensing of routine medications. The confluence of all of these factors makes it difficult to project the need for pharmacy education and leaves open a variety of options for resolving the current and any future pharmacist shortage.”

Pharmacy Technicians

In 1996, TSBP promulgated rules requiring pharmacy technicians to be certified by January 1, 2001. During the 76th Legislative Session, the Texas Pharmacy Act was amended to:

- (1) require pharmacy technicians to be certified by January 1, 2001;
- (2) give TSBP the ability to consider certain exemptions from the certification requirement; and
- (3) give TSBP the authority to register pharmacy technicians and to take disciplinary action against technicians.

At the TSBP August 2000 meeting, rules were adopted to allow technicians to petition for exemption. The rules allow the following types of pharmacy technicians to petition for the exemption:

- (1) pharmacy technicians who on September 1, 2001, had been continuously employed as pharmacy technicians at pharmacies in Texas for at least ten years; and
- (2) pharmacy technicians working in rural communities with a population of 50,000 or less. As of January 2004, 235 technicians had been granted exemptions.

The 78th Texas Legislature (2003) appropriated \$726,269 to fund the pharmacy technician registration program. In the fall of 2003, TSBP established an online registration system to enable the agency to quickly and efficiently process the applications from the potential 25,000-30,000 individuals seeking registration. In December 2003, TSBP promulgated rules to require pharmacy technicians to be registered by June 1, 2004.

To become registered, a pharmacy technician must first be certified. Pharmacy technicians are able to become certified, following graduation from high school, by passing a national examination administered by the Pharmacy Technician Certification Board (PTCB). According to PTCB data, Texas has more certified pharmacy technicians than any other state. As of November 30, 2003, there were 163,793 certified pharmacy technicians in the nation, with 29,110 in Texas. The state of Florida is second behind Texas, with only 9,542 certified pharmacy technicians (approximately 66% fewer certified pharmacy technicians than Texas).

TSBP rules specify that all certified pharmacy technicians must take and pass either the PTCB examination or “other examination approved during an open meeting by the Board.” Until late 2003, the PTCB examination was the only exam available for technician certification. The Institute for the Advancement of Community Pharmacy recently contacted TSBP regarding the development of a state-specific examination, and made a presentation to the Board at its May 2004 meeting.

Working Conditions

Working conditions in pharmacies have become a leading issue in Texas, as well as the nation. At its meeting held in February 1999, TSBP approved a position statement regarding working conditions. In the position statement, TSBP (1) encouraged all employers to provide reasonable breaks during a regular work day for meals and rest; (2) 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 (3) encouraged increased communication between employees and management. This position statement was published in the Summer 1999 issue of the *TSBP Newsletter*. Subsequently, at its May 2000 meeting, TSBP approved rules that allow pharmacists to be temporarily absent from the pharmacy without having to close the pharmacy department.

As another means to alleviate 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 certified. This change was consistent with the recommendations made by the Task Force on Standards for Pharmacy Technician Training Programs, as well as the Task Force on Working Conditions. Providing pharmacists with additional assistance in the prescription filling process and with administrative tasks will enable pharmacists to spend more time on patient care services.

Individuals frequently attribute poor working conditions (inadequately staffed prescription departments) as 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. For further strategic issues relating to dispensing/medication errors, refer to Policy Issues #1 and #2.

Impact on Agency

As the use of pharmacy technicians evolves, and as they are allowed to perform more technical and critical tasks, the need for trained and competent ancillary personnel will become even more critical. With the uncertainty regarding pharmacists manpower, TSBP will have to monitor the availability of pharmacists in the work force closely. If Texas continues to have a shortage of pharmacists, there will be an increase in the demand for pharmacists to use pharmacy technicians to assist in the technical aspects of the practice of pharmacy.

As a result of the new pharmacy technician registration program, TSBP will double the number of individuals that it regulates. Although this increased workload will have an enormous impact on agency operations, TSBP believes this program is important to protect the public health, safety, and welfare, in that incompetent and unscrupulous technicians can be removed from practice.

Agency Strengths and Opportunities

- The Texas Pharmacy Act was amended during the 76th Legislative Session to give TSBP the authority to register pharmacy technicians and take disciplinary action on the technicians. The technician registration program was funded in 2003 and will be implemented/operational in 2004.
- TSBP has continued to review, amend, and/or adopt rules for the expanded use of pharmacy technicians in the practice of pharmacy.

Agency Weaknesses and Constraints (Threats)

- The shift from a B.S. degree to a Pharm.D. degree for all graduates of all colleges of pharmacy in Texas has reduced the labor pool over the last few years. The strategic impact of the all-Pharm.D. program is unknown.
- 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.

Agency Initiatives

- Be an active participant with colleges of pharmacy and professional associations in developing plans to reduce the shortage of pharmacists.
- Establish minimum standards for pharmacy technician training programs.
- Encourage the use of Peer Review Committees.
- 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 perception of the Board of Pharmacy by its customers is that the Board has a progressive approach to current regulatory issues. 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 pharmaceutical care. 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 increase and retain highly qualified

personnel while continuing to implement quality management practices. Given the pace of technological advances, the agency must also carefully encourage 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. Finally, it is important for the agency to strike the appropriate balance in achieving its public protection mandate yet being flexible enough to develop regulations to facilitate pharmacy practice changes.

Explanation of Issue

Some of the areas identified by the Board in its external assessment include the following observations by board customers.

- The Board should continue to play a public advocacy role as it relates to educating the public about the value of pharmaceutical care.
- Consumers should be educated on the proliferation of misinformation (e.g., Internet scams, mail order services dispensing HIV medications with multiple side effects, and direct-to-consumer advertising); the importance of vaccines; dietary supplements; and prevention of medication errors at home, to name a few.
- The Board should focus on preparedness for public health emergencies in which pharmacist participation is crucial.
- Pharmacies and pharmacists will have vital roles in the front-line defense in the event of a public health emergency, such as an act of bioterrorism. Pharmacists will be needed to assist with the distribution of vaccines, antidotes, and other pharmaceutical agents to the public.
- Consumers, as well as healthcare professionals, are seeking information and advice concerning alternative medicine, including herbal and other nutritional supplements. Alternative drug/herbal therapies are increasingly prescribed by licensed physicians or recommended by other healthcare providers. 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 advise consumers.
- 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.
- In 1999, Texas became the first state in the nation to 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. The Board should continue this kind of innovation in developing new methods and systems to monitor compliance with existing laws and rules, and/or expand its compliance initiatives around the state.

- The Board may want to consider amending the law to allow membership to a pharmacist who is on the faculty at a Texas college of pharmacy. A pharmacy educator could make significant contributions to Board discussions on a wide variety of issues.

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 coupled with the recent legislative budget reductions, the agency's ability to function efficiently and effectively in the public interest is challenged.

Any increase in the current demand for agency services without additional funding, personnel, and updated technology may require a major 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

- Organizational structure, leadership, and management provide the mechanisms necessary to carry out the agency's mission and to accomplish its strategic and operational objectives.
- 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.
- The agency generates its own "tax" revenue primarily through licensure fees from pharmacists and pharmacies. 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.
- 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.
- The agency has an approved *Strategic Plan for Information Management* that addresses its technology needs for the next five years.
- 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.
- 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 underfunded programs in process. Examples include:

- The inability to provide significant consumer education.

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. Countless agencies have similar efforts, sometimes quite extensive, to disseminate public information about parks, recreation, land usage, environmental issues, immunization concerns for children, and child and adult protective issues.

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. Possibilities exist for receiving grant monies, both private and public, and for forming effective, dynamic coalition-based efforts across Texas; however, the agency's hands are tied due to lack of program and human resource funding. This is an area where a small investment of time and money could grow exponentially and reach the entire state.

- 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, coupled with recent legislative budget reductions. With the recent budget reductions (7% in FY2003 and 12.5% in FY2004-2005), the agency is struggling to maintain its level of service. Significant reductions occurred in the areas of travel, salaries, information resource technologies, vehicles, agency newsletter, registration and training, and merit pay. The budget reductions (\$789,696 for FY2004-2005) occurred at the same time that new funding (\$726,269 for FY2004-2005) was approved to implement an existing agency statutory mandate. The mandate to register a new population of applicants, the pharmacy technician, requires the agency to double its population of licensees in FY2004 and will cause a dramatic increase in the public's demand for agency services in every area of its operation. The impact of this new population on the level of services provided by the agency will significantly impact the agency's ability to provide quality customer service, information, and protection to the citizens of Texas. Lacking the ability to expend the funds collected from pharmacist and pharmacy license holders, the agency is unable (1) to maintain the previous level of professional for compliance and enforcement positions, (2) to pay the executive director a comparable professional salary, or (3) allow modest travel to professional pharmacy meetings. These gaps potentially weaken the agency's leadership position in the national pharmacy practice arena.

- 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 website to provide public education about safety issues, the legal consequences of illegal purchases, who to turn to with complaints or inquiries, 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

- 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.
- Continue to access the expertise of pharmacy educational institutions, associations, and related entities through networking and advisory committees on topics of increasing complexity.
- Promote organizational change to meet the challenges of regulating the profession with limited resources.
- 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 give.
- Advocate for key quality enforcement and consumer protection reforms at the state and national levels.
- 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 551-569) 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 at that time).
- 1934 Texas Pharmacy Act was amended to set the minimum education requirement as graduation from a recognized college of pharmacy having four terms of eight months each.
- 1943 Texas Pharmacy Act was amended to include the following: required one year of practical experience prior to registration as a pharmacist; clarified the reasons for revocation and suspension of licenses; and set forth in detail the penalties for violation of the law.
- 1977 Board initiated a comprehensive reorganization of the agency’s internal organization and functions, which resulted in upgrading and refining examination process, computerization of licensure records, initiation of a voluntary compliance program (including random, unannounced inspections of pharmacies, as well as publication of an agency newsletter).

- 1981 Texas Legislature repealed and replaced the Texas Pharmacy Act with a new practice Act and extended the agency's existence for another 12 years, following the agency's first review by the Sunset Advisory Commission. The new Texas Pharmacy Act changed the composition and number of Board Members from six pharmacists to nine members (seven pharmacists and two public members); created four classes of pharmacy licenses; began regulation of institutional (hospital) pharmacies and clinic pharmacies; and allowed drug product selection (generic substitution) for the first time under conditions. Texas Legislature created Triplicate Prescription Program, requiring special forms for a patient to receive a Schedule II controlled substance.
- 1983 Texas Legislature, through amendments to the Texas Pharmacy Act, established a program to address the issue of pharmacists who are chemically, mentally, or physically impaired (eligible pharmacy students added to the program in 1985).
- 1989 Texas Legislature, through amendments to the Texas Pharmacy Act, established continuing education requirements for pharmacists to help assure continuing competency. Agency promulgated rules to expand the duties of pharmacy technicians.
- 1991 Texas Legislature, through amendments to the Texas Pharmacy Act, established a new class of pharmacy license (Class E or Non-Resident Pharmacy) for mail service pharmacies located in other states.
- 1993 Texas Legislature, through amendments to the Texas Pharmacy Act, included the concept of pharmaceutical care, which established the legal basis for pharmacists' increased involvement in patient care. Subsequent rules promulgated by the Board required pharmacists to provide written and verbal counseling to patients and conduct drug regimen reviews. Agency's existence was extended another 12 years, following a successful review by the Sunset Advisory Commission. A requirement that one-third Board Membership must be public members changed the composition of the nine-member Board from seven pharmacists and two public members to six pharmacists and three public members.
- 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 website to improve services and accessibility to its customers.
- 2001 Texas Legislature, through amendments to the Texas Pharmacy Act, established remote pharmacy services; increased the number of continuing education hours required for pharmacist biennial renewal to 30 hours; and changed requirements for prescribers who wish to prohibit generic substitution.
- 2002 Agency implemented online pharmacist renewal system.
- 2003 Texas Legislature, through amendments to the Texas Pharmacy Act, authorized the agency to create new classes of pharmacy licenses; required the agency to provide information to licensees regarding the prescribing and dispensing of pain medications; set forth procedures for the reuse of certain unused prescription drugs dispensed to nursing home patients; permitted compounding pharmacists to promote and advertise compounding services; required pharmacists to report to the Texas Department of Health any situation that poses a risk to homeland security; and authorized advanced practice nurses and physician assistants to issue prescriptions for controlled substances. In addition, the Texas Legislature provided funding for TSBP to initiate the Pharmacy Technician Registration Program.

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.

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- 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.

TSBP does not anticipate any changes in federal law or court cases to impact the agency’s key functions. However, there has been federal interest with regard to the following issues, which are fully described in the previous Issue Statements.

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

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;
- **Licenseses** — pharmacists and pharmacy owners; pharmacy students and pharmacist interns; pharmacy technicians;
- **Executive and Judicial Officials and Other State and Federal Agencies;**
- **The Pharmacy Education Community;** and
- **Health-Related Corporations and Professional Associations.**

In focusing on our primary key service population, the citizens of Texas, TSBP recognizes the changing demographics of the state's population. In "A Summary of The Texas Challenge" by Dr. Steve H. Murdock, Department of Rural Sociology, Texas A & M University, the following statements are made:

"Texas will very likely enter the next century with more than 20 million persons, compared to 7.7 million in 1950 and 16.9 million in 1990. In just the first 8 years of this decade, Texas has added nearly 2.9 million persons. In the 1990s Texas has had the second largest numerical increase and the eighth largest percentage increase of any state in the nation. If current rates of growth continues, Texas will increase its population by nearly 100 percent between 1990 and 2030 and have nearly 34 million persons by 2030.

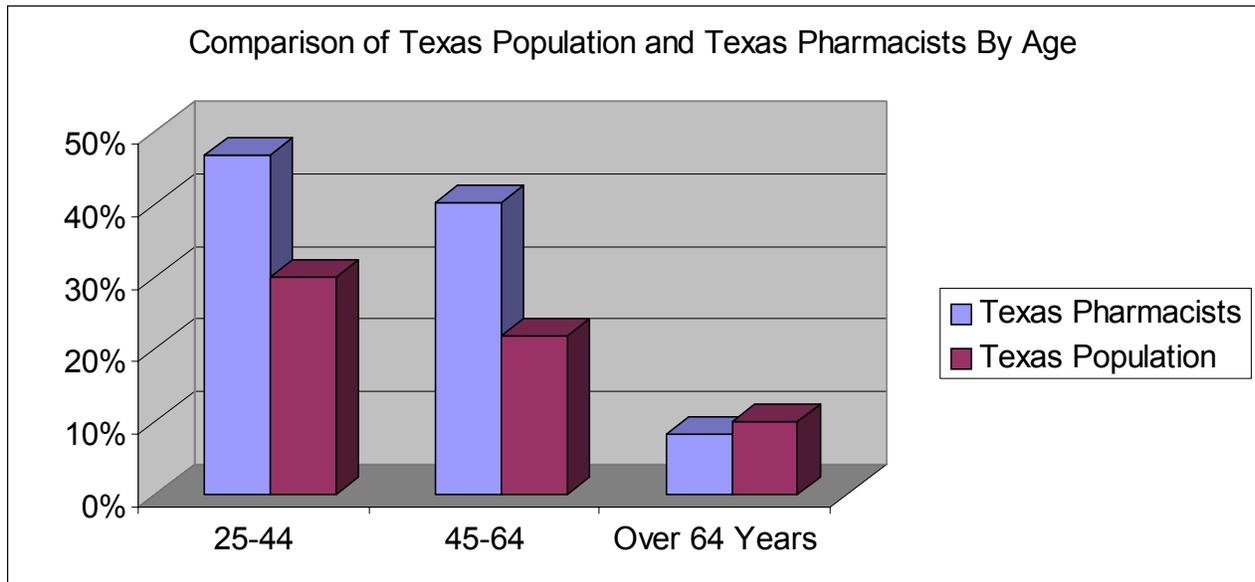
No factor is more important to Texas than the growth of its minority population. By 2008 Texas will be less than half Anglo and by 2030, the Texas State Data Center projects the State to be about 37 percent Anglo, about 9 percent African American, 46 percent Hispanic and about 8 percent of the population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

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

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

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

Chart 1



Data is based on 2003 Texas Population of 21,439,995 and a Texas Pharmacist Population of 16,793.

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 five primary services that are delivered to a variety of customers:

- **Information** — the provision of information on pharmacies, pharmacists, pharmacy technicians, and related laws and rules; information on consumer issues such as generic drugs, patient counseling requirements; and the concept and implementation of pharmaceutical care;
- **Licensing** — the licensing and review of interns, pharmacists, pharmacist preceptors, pharmacy technicians, and pharmacies, to ensure uniform standards, competency, and public safety;
- **Enforcement**
 - the monitoring of pharmacies, interns, pharmacists, and pharmacy technicians for compliance with the laws and rules, including specialized requirements regarding the handling, safeguarding, and distribution of prescription drugs and devices; and

- the oversight of the complaint process and investigation of alleged violations of pharmacy laws and rules; monitoring licensees who are subject to disciplinary orders; the provision of public information regarding complaint and disciplinary actions;
- Legal — the prosecution 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, Enforcement or Legal Services areas. Information Services regarding the profession are, in part, provided by the colleges of pharmacy, professional associations, and consumer advocacy groups. Enforcement and Legal Services are provided by the agency, together with other state, federal, and local agencies associated with law enforcement.

Although agencies such as the Texas Department of Health, the Department of Public Safety, the Federal Food and Drug Administration, the Drug Enforcement Administration, and local police departments 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 State Board of Medical Examiners (TSBME), Board of Nurse Examiners (BNE), and other state health profession regulatory agencies.

This *lead agency* approach implements Section 554.001 of the Texas Pharmacy Act which states: *The Board shall "cooperate with other state and federal agencies in the enforcement of any law relating to the practice of pharmacy or any drug or drug-related law."*

In the meantime, the agency continues (and aspires) to build ever-increasing, dynamic partnerships and coalitions in meeting the challenges that lie ahead for the agency as a whole and in the addressing of each of the Policy Issues. 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 registration;
- (4) issuing licenses to qualified applicants for initial licensure of pharmacies, including pharmacies that are new business operations or existing pharmacies that undergo a change of ownership;
- (5) issuing registrations to qualified applicants to provide remote pharmacy services;
- (6) issuing registrations to qualified pharmacist-interns;
- (7) issuing certifications to qualified pharmacist-preceptors;
- (8) renewing licenses of pharmacists on active and inactive basis;
- (9) renewing registrations of pharmacy technicians;
- (10) renewing licenses of pharmacies that do not have a registration to provide remote pharmacy services;
- (11) renewing licenses of pharmacies that have a registration to provide remote pharmacy services;
- (12) renewing certifications of qualified pharmacist-preceptors;
- (13) monitoring pharmacists' compliance with continuing education requirements;
- (14) updating pharmacists' licensing records with respect to change of name, change of employment, and change of address;
- (15) processing applications from pharmacies for a change of name and/or change of location; processing notifications from pharmacies regarding permanent closings; and updating licensing records; and
- (16) 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, pharmacists' 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 renewal of pharmacist licenses, and a web-based mechanism to verify licensure status. The Board will continue to look toward implementing other initiatives, as a means to reduce workload and more efficiently serve the public.

Pharmacy (Facility) Licensure

While the number of pharmacies has increased at a slower pace than pharmacist licenses, quantity issues do not reflect the complexity of regulating pharmacies. The agency licensed four different Classes of Pharmacy during FY1988-1991, increasing to five Classes of Pharmacy in FY1992. In addition, in FY2002, the agency added a new category of pharmacy regulation - Remote Pharmacy Services – using automated pharmacy systems and telepharmacy systems. Although this license is viewed as an extension of an existing pharmacy license, 1,200 of these “satellite pharmacies” are currently licensed and require monitoring.

In FY2003, the Texas Legislature gave the agency the authority to create new classes of pharmacy licenses. As mechanisms for providing pharmacy services to patients continue to diversify, the agency fully expects that the number of pharmacies (and possibly the classes of pharmacy) will continue to increase over the next five years.

Pharmacy Technician Registration

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

During the 76th Legislative Session, S.B. 730 was passed, which required TSBP to begin registering pharmacy technicians effective September 1, 2001. However, the funding for the program was not appropriated until the 78th Legislative Session, for FY2004/FY2005. The agency has adopted rules to begin the pharmacy technician registration process and the registration process has begun, with an anticipated 27,000 certified technicians awaiting registration.

Currently, the agency licenses approximately 21,000 pharmacists and 5,700 pharmacies. The additional 27,000 pharmacy technicians will have a dramatic effect on the agency's operations, since it would almost double the number of licensees in one year, bringing the total of all licensees to approximately 54,000.

From FY1993 - FY2003, the agency has experienced the following increases:

Performance Outputs - FY1993 - FY2003						
Year	Exams Administered	% Increase	# of Pharmacists Licensed	% Increase	# of Pharmacies Licensed	% Increase
FY93	1,394	—	17,312	—	4,963	—
FY94	1,472	6%	17,681	2%	5,096	3%
FY95	1,381	<6%>	18,026	2%	5,107	1%
FY96	1,557	13%	18,450	2%	5,246	3%
FY97	1,698	9%	19,048	3%	5,404	3%
FY98	1,567	<8%>	19,429	2%	5,410	0%

Performance Outputs - FY1993 - FY2003						
Year	Exams Administered	% Increase	# of Pharmacists Licensed	% Increase	# of Pharmacies Licensed	% Increase
FY99	1,162	<35%>	19,716	1%	5,422	0%
FY00	1,363	17%	20,085	2%	5,496	1%
FY01	1,430	5%	20,679	3%	5,603	2%
FY02	1,387	<3%>	21,106	2%	5,681	1%
FY03	1,576	14%	21,570	2%	5,794	2%
Cumulative Increases FY93-03		13%		25%		17%

Online Renewal

In late October 2002, TSBP implemented the pharmacist online renewal system through the Texas OnLine system. As of April 2004, approximately 30% of all pharmacists have renewed their licenses using the Texas OnLine method.

In January 2004, TSBP began implementing the pharmacy technician online applicant system, and it is expected that approximately 99% of all pharmacy technicians will become initially registered using the Texas OnLine method. Other applications, such as the pharmacy applicant and renewal system, examination applicant system, and pharmacy technician renewal system, are scheduled for implementation during this biennium.

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, email, and via website, live presentations, and professional exhibits). In FY2003, TSBP met its performance measure relating to the number of inspections conducted (approximately 2,500 inspections per year). However, TSBP would prefer to inspect pharmacies more often than it does now (which is approximately every two to three years), because a longer period of time between inspections generally results in a greater number of pharmacies being in non-compliance with the Texas Pharmacy Act and Texas Drug Laws. Currently, TSBP licenses approximately 5,700 pharmacies and employs five Compliance officers to inspect these pharmacies. If TSBP is to continue its preventive enforcement efforts through routine, unannounced inspections, additional field Compliance staff must be obtained.

TSBP’s other approach to enforcement is through investigation of complaints, and if substantive evidence is obtained, the institution of disciplinary action against the applicable person. However, TSBP has limited resources to investigate complaints in a timely manner. Although TSBP was able to decrease the average complaint resolution time during the past two fiscal years, the complaint backlog continues to have an effect on timeliness (see chart below).

Fiscal Year	Complaints Received	% Change Complaints Received Previous Year	Complaints Closed	% Change Complaints Closed Previous Year	% Complaints Closed	Resolution Time (Agency Average)	% Change Time
FY99	1533		1335		87%	221 Days	
FY00	1577	+3%	1513	+13%	96%	220 Days	-0.45%
FY01	1683	+7%	1667	+10%	99%	262 Days	+19%
FY02	1836	+9%	2137	+28%	116%	221 Days	-16%
FY03	1935	+5%	1887	-12%	97.5%	153 Days	-31%

The number of complaints that were received by TSBP have increased 26% from FY1999 to FY2003, due to the following four factors:

- (1) as of FY2000, TSBP began to receive Professional Liability Claim Forms (malpractice reports);
- (2) ability for complainants to file online complaints. TSBP experienced a significant increase in the number of complaints received via the TSBP website in FY2003 as compared to FY2002.

Specifically, TSBP received 214 complaints via the Internet in FY2002 as compared to FY2003, when TSBP received 318 complaints via the Internet (49% increase).

- (3) beginning in FY2004, TSBP began to register pharmacy technicians; and
- (4) TSBP is opening an increased number of complaints due to non-compliance with disciplinary orders.

The impact of the malpractice reports is beginning to be felt by the agency. In FY2001, the agency received 55 malpractice reports and in FY2002-2003, the agency received 470 reports. This increase has a “domino effect” (e.g., more claims mean more investigations, more disciplinary actions, and more monitoring of compliance with disciplinary orders). The registering of pharmacy technicians is going to have a dramatic effect on enforcement services. As previously explained, this change will double the agency’s licensee population, which will, more likely than not, double the workload on the agency’s investigators (to investigate complaints involving technicians), as well as double the workload on the agency’s attorneys (to adjudicate/discipline technicians). Accordingly, for TSBP to be able to swiftly investigate and adjudicate licensees, additional investigators will be needed.

During the past five years, TSBP has also experienced increased demands for the following enforcement-related services:

- (1) Probation/Monitoring services — For the past several years, approximately 80-90% of TSBP’s disciplinary orders have required some type of monitoring. TSBP has approximately one FTE who monitors probationers.
- (2) Requests for Public Information — As indicated in the chart below, TSBP experienced a 20% increase in the number of requests for enforcement records in FY2003, as compared to FY2002. Since TSBP implemented its website in 1998, the Agency has experienced a decrease in requests for information, particularly verbal requests (e.g., inquirers telephoning the agency for information regarding disciplinary orders entered against a pharmacist or pharmacy). (See chart below).

OPEN RECORDS REQUESTS HANDLED BY ENFORCEMENT DIVISION — FY99 through FY03										
Fiscal Year	Verbal Requests		Written Requests		Total # of Requests		Monthly Average		% Change from Prior Fiscal Year	
	# of Requests	# of Licensees	# of Requests	# of Licensees	# of Requests	# of Licensees	# of Requests	# of Licensees	# of Requests	# of Licensees
FY99	544	841	413	4953	957	5794	80	483	-37%	+36%
FY00	168	177	339	2078	507	2255	42	188	-47%	-61%
FY01	124	125	276	3642	400	3767	33	314	-21%	+67%
FY02	82	82	385	2121	467	2203	39	184	+17%	-42%
FY03	108	108	452	1569	560	1677	47	140	+20%	-24%

Because TSBP has no FTEs who are specifically employed to handle requests for enforcement information, persons who are assigned these duties must respond to the requests in addition to their “regular” duties.

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.

Telecommunication System Services

Information services, and the demand for such, arise partly out of constant and complex changes occurring in pharmacy practice and partly due to the continued rise in the population of licensed pharmacists in Texas, and more recently, with the addition of the pharmacy technician registration program. However, the primary demand for information services is due to the increased awareness of the public, both pharmacists and consumers, of the role of the agency.

In today's environment, every state agency is expected to do more with less. In order to address the number of inquiries being received by TSBP, particularly the Licensing and Enforcement divisions, TSBP established a comprehensive and user-friendly website to improve services and accessibility to its customers. The site contains consumer information, including procedures regarding the complaint process and an online complaint form; new and ongoing licensing information, including an online application for pharmacy technician registration; a reference site for pharmacy-related information; and important information regarding the agency's laws and rules. One important feature of the website (for consumers as well as licensees), is a license verification link that enables the user to verify the licensing and disciplinary status of pharmacists, pharmacies, interns and pharmacy technicians. More recent agency accomplishments include the implementation of the Pharmacist Online license renewal system; Pharmacy technician online application system; wireless handheld devices for the inspection program; and active computer virus monitoring and firewall installation.

In FY2003, TSBP received 160,937 website inquiries (average of 13,411 "hits" each month). This compares to prior years as follows:

Fiscal Year	Number of Website Inquiries	Cumulative Increase Since FY2000
FY00	64,476	—
FY01	90,701	40.67%
FY02	112,184	73.93%
FY03	160,937	149.60%

Although public access to this website has reduced the number of telephone calls received by the Licensing Division, the number of electronic inquiries (emails) has grown dramatically, as more and more customers realize the ease and accessibility of electronic communication.

In FY2003, the Department of Information Resources (DIR) ran a controlled penetration test to assess the security of the agency's computer systems network, and a test of dial-up lines for modem access. DIR was unable to penetrate the firewall's defenses that protect the internal network, and no vulnerabilities were found through the test of dial-up lines.

As computer virus and hacker activity continue to dramatically increase, the agency has been successful in keeping security incidents extremely low. Upgrading anti-virus software, implementing automatic updates,

weekly scans, and taking an assertive stance towards user passwords, as well as aggressively maintaining recommended security updates on the web server and firewall, have limited agency exposure to a single low-impact web defacement and virus infection to zero.

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 by the 73rd Legislative Session. The purpose of the Council is to provide a means for the agencies represented to coordinate administrative and regulatory efforts. The Council is made up of representatives from the following agencies:

- Board of Chiropractic Examiners;
- Board of Dental Examiners;
- Board of Medical Examiners;
- Board of Nurse Examiners;
- Board of Vocational Nurse Examiners;
- Executive Council of Physical Therapy & Occupational Therapy Examiners;
- Texas Optometry Board;
- Board of Pharmacy;
- Texas Funeral Commission;
- Board of Podiatric Medical Examiners;
- Board of Examiners of Psychologists;
- Board of Veterinary Medical Examiners;
- Department of Health, Professional Licensing and Certification Division; and
- Office of the Governor.

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

The Council has made tremendous strides in accomplishing efficiency and effectiveness through administrative sharing and cooperative teamwork. Eleven Council committees involving approximately 40 staff members from member agencies were appointed to study and make recommendations on the functional and programmatic assignments of the priority objectives. The following is a summary of accomplishments from FY1994-2003.

- 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.
- Use of a "purchasing pool" provides use of trained and certified purchasers to agencies too small to have such expertise.
- Training/Information Dissemination Opportunities exist for new employee EEO training and other opportunities through the State Auditor's Office and Employee's Retirement System. In addition, the National Certified Investigator/Inspector Training (NCIT) program of the Council on Licensure, Enforcement, and Regulation is provided to HPC members employing investigators.
- Sharing of legal library resources through the issuance of library cards to key staff for access to the legal libraries of the Pharmacy and Medical boards.
- Coordination of Legal Services to discuss legal issues of joint concern to Council agencies.
- Information technology sharing utilizes two staff to provide direct ongoing services to eight of the smaller member agencies.
- Development of core policies and procedure statements for common areas such as travel, open records, and records retention. These statements are resources for Council agencies to use in developing individual agency manuals, saving staff time, and assuring consistent quality.
- Sharing an electronic imaging system for data storage.
- Completion of Complaint Study as mandated by the 77th Texas Legislature.

The 78th Texas Legislature passed HB 2985, which requires the Health Professions Council to establish a new Office of Patient Protection (OPP). The OPP will represent the interests of consumers before the licensing agencies, and will serve as an ombudsman for consumer complaints at licensing agencies and help consumers obtain information about the status of their complaint.

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

STATEWIDE BENCHMARKING

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

Description of Agency Benchmarking Process

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

- National Level — TSBP contacted the National Association of Boards of Pharmacy (NABP) to determine if national standards exist for any of the performance measures reported on a regular basis to the Legislative Budget Board (LBB) and Governor’s Office (GO). NABP collects information from other state boards of pharmacy, but does not have data with regard to performance measures.
- Private Sector — The process of licensing and enforcing the laws and rules governing the practice of pharmacy are not carried out by the private sector. Accordingly, TSBP was unable to review similar service providers in the private sector.
- Other Agencies in Texas — TSBP conducts services similar to other health licensing boards in Texas, which are required to collect and report data to LBB and GO with regard to performance. TSBP is a member of the Health Professions Council (HPC), as are all other Texas health licensing agencies. HPC publishes an annual report each year that includes the following information for each

member agency: number of licensees, number of complaints resolved, average complaint resolution time, and number of disciplinary orders. When reviewing HPC Annual Reports and comparing statistics between HPC member agencies, TSBP appears to be either “best in class” or near to it when comparing TSBP to agencies having a similar size licensee population and/or similar workload (e.g., number of complaints received).

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

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 overlapping 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 the sole responsibility for the administration and the enforcement of the Texas Pharmacy Act and Texas Dangerous Drug Act.

Given the unique responsibilities of the Board, input regarding issues under the jurisdiction of the agency are 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 four colleges of pharmacy in Texas, the three major professional associations in Texas, and TSBP. The Congress meets quarterly to discuss issues of mutual concern. Each entity reports on activities and programs, and together the group addresses problems and recommends solutions.
- (4) Pharmacy Organizations – TSBP receives input from these groups on a regular basis; any suggested issues are scheduled for discussion at Board meetings.

- 5) Customer Service Survey – In FY2000 and FY2002, TSBP conducted a survey of agency customers regarding the quality of service delivered by the agency as specified in Chapter 2113 of the Government Code. Following each survey, a report was made to the Board regarding comments and recommendations that had been made on a myriad of issues. Many of the customers' suggestions resulted in changes to agency operations.
- (6) Individuals – Board Members are individually contacted about issues; the agency receives visits, letters, and telephone calls regarding issues. These issues may be addressed at Board meetings, which may result in rule changes.

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. Agency staff totals 48 positions, consisting of five management, 23 professionals, and 20 administrative support staff. Ten employees (five Compliance Officers and five Investigators) operate in field areas outside the main office and function under the supervision of their respective Division Directors. In FY2004, due to budget reductions, one of the in-house pharmacist positions was eliminated and two of the five pharmacist-field personnel were replaced with non-pharmacists.

Pharmacy practice regulation is unique since it regulates individuals (pharmacists), 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.

The agency licenses approximately 21,000 pharmacists and 5,600 pharmacies over a land area of approximately 270,000 square miles. Limited 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 staff of five Compliance Officers and five 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 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.

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.

Board members are dedicated to their role as policy-makers, and the staff to their role as implementers of this policy. Through these complementary roles, the Board and staff form an efficient team, achieving consistently effective agency performance.

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 workforce 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 impact agency operations. This impact is most keenly evidenced by the agency staff turnover rate and by the hours of staff overtime required to cope with the work overload of the agency.

STAFFING PATTERN AND PROFILE

Agency employee turnover had decreased from 25% in FY2000 to 11.2% in FY2002, but increased again to 18.7% in FY2003. The pharmacist turnover rate for FY2001 was an alarming 53.33% and 48% for FY2003. Even more dramatic are the number of pharmacist service years that have been lost - in FY2001, a total of 32 1/5 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. This loss of pharmacist staff is especially disturbing since the pharmacist staff are a part of the succession for the Executive Director position since the Executive Director is statutorily required to be a pharmacist.

The reason for the high turnover rate can be directly attributed to retirement, salary dissatisfaction, increased workload as a result of legislative initiatives, and lack of any intrinsic rewards. Employees are continually asked to do more with less.

The growth in Texas' minority populations may have significant ramifications for the agency's workforce, specifically in the pharmacist (Compliance/Enforcement Officer) category. Attempts to recruit qualified minority pharmacists have been difficult due to the significant differences in salaries compared to private sector employment, and to the pool of licensed pharmacists who are minorities. Table 1 shows a comparison of race distribution among the overall Texas civilian labor force, the Texas pharmacist population, and the agency non-manager pharmacist positions for FY2003.

Table 1

Race	Texas Population Race Distribution	Texas Pharmacists Population Race Distribution	TSBP Non-Manager Pharmacists Population Race Distribution
Anglo	52%	66%	75%
Hispanic	33%	09%	12.5%
Black	12%	11%	12.5%
Other	3%	14%	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	White			Black			Hispanic			Other			Total		
	M	F	Tot	M	F	Tot	M	F	Tot	M	F	Tot	M	F	Tot
Administrators	1	4	5	0	0	0	0	0	0	0	0	0	1	4	5
Professionals	7	8	15	0	1	1	1	2	3	0	0	0	8	11	19
Para-Professionals	3	10	13	0	2	2	0	5	5	0	0	0	3	17	20
Admin Support	0	1	1	0	0	0	0	1	1	0	0	0	0	2	2
TOTALS	11	23	34	0	3	3	1	8	9	0	0	0	12	34	46

*Data reflects actual staff as of 8/31/03. 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 FY03	Agency Goal for FY04
Professional Service Contracts	6.32%	20%
Other Services Contracts	3.25%	33%
Commodities Contracts	61.9%	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 minority 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

The agency projects one-time expenditures in the area of renovations of building and other facilities due to the projected increase of in-house staff from 54 FTE's to 58 FTE's in FY2006-07. In addition, the agency's information resources budget for the next biennium will include capital budget items relating to the replacement of existing hardware/software and new hardware/software due to the addition of new personnel. A complete discussion of the agency's Information Resources needs can be found in the agency Information Resources Strategic Plan.

INFORMATION RESOURCES MANAGEMENT STRATEGIC PLANNING

The agency Strategic Plan for Information Resources, as well as the Agency Biennial Operating Plan, outlines any additional or updated information resources necessary to continue to regulate effectively in the coming years. This document is submitted under separate cover.

THE FISCAL PERSPECTIVE

Current Funding

The agency's operating budget for fiscal year 2004 is approximately \$3.2 million, which includes all Legislative appropriations. In addition, other direct and indirect costs of approximately \$779,282 are charged to the agency. The indirect costs include such items 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. The general operating fund of the Board is considered a special revenue fund account within the State Treasury.

Chart 2 analyzes the agency's revenues and expenditures for a six-year period (FY1998 - FY2003). The agency also maintains a Fines Account for fines collected by the agency that are deposited in the State's General Revenue Fund. From FY1998 through FY2003, the agency collected and deposited \$559,924 of fine revenue into the General Revenue Fund.

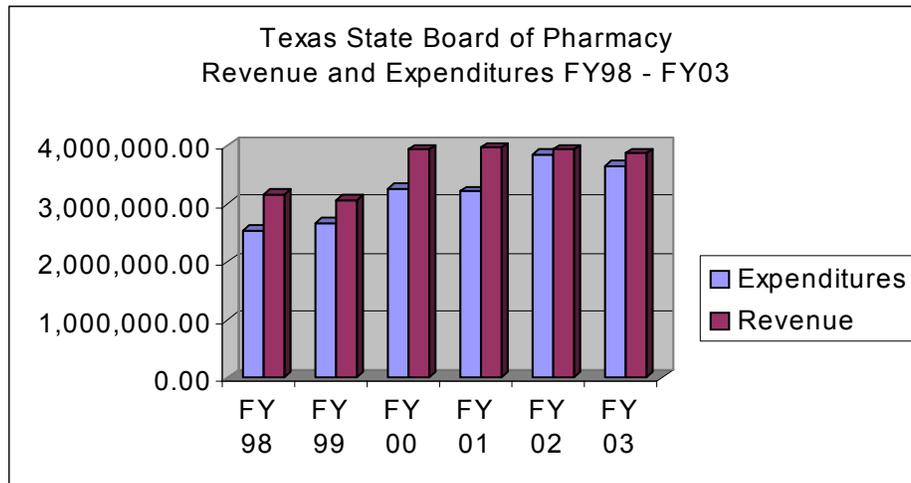
Degree to Which Current Funding Meets Current and Expected Needs

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

The agency has the authority and mechanisms necessary to generate the revenue needed to support its *Strategic Plan* and Budget Requests. However, in the past, Legislative appropriations have represented a level of funding that is hampering the agency's ability to maintain an acceptable level of performance.

The agency believes that additional funding is needed to carry out its mission, particularly in light of the budget cutbacks mandated by the 78th Texas Legislature and the new agency program to register 27,000 pharmacy technicians in FY2004. The Enforcement Division currently has only five field investigators and five inspectors for the entire state, resulting in each field employee having vast territories to regulate. With the addition of three new field positions in FY2005, we anticipate a slight improvement in the regulation of these territories.

Chart 2



The agency currently licenses approximately 5,600 pharmacy locations and 1,200 remote facilities that provide pharmacy services using an automated pharmacy system or a telepharmacy system in Texas. Our goal is to inspect every location approximately every two years. With only five field inspectors, in FY2003, we were able to inspect approximately 2,500 pharmacy locations and no remote facilities.

In addition, the pharmacy technician registration program will double the number of persons being regulated by the agency and will stretch the regulatory program's employees to the breaking point. 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 2002 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) to areas within this *Strategic Plan* where they are specifically addressed:

- Budget reductions imposed by the 78th Texas Legislature of 7% in FY2003 and 12.5% in FY2004.
- The passing of amendments to the Pharmacy Act in 2003 that:
 - gave the agency the authority to create new classes of pharmacy licenses;
 - appropriated funding for the agency to register pharmacy technicians;
 - gave the agency the authority to run federal criminal history background checks for applicants for licensing and licensees;
 - 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.
- TSBP began to receive complaints regarding “pharmacy storefront operations” that were assisting patients to receive drugs from Canadian pharmacies. TSBP has serious concerns regarding the legality, safety, and efficacy of drugs that are imported to Texas patients.
- TSBP promulgated rules that required pre-inspections of pharmacy applicants, under certain conditions. In addition, the Board approved the implementation of an expanded application process in order for the agency to obtain sufficient background information to help ensure that the applicant intended to operate a bona fide pharmacy.
- Bioterrorism and the role of pharmacists with regard to the delivery of prescription drugs during national crisis.
- The success of the Health Professions Council in accomplishing efficiency and effectiveness through administrative sharing and cooperative teamwork.
- Continued 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 the pharmacist online license renewal system and pharmacy technician online application system.

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 Organizational Excellence (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 rate consistently higher than the statewide average for all workplace dimensions.

Agency Change Team (ACT) – To get agency staff more involved in reviewing and learning about the results of the Survey of Organizational Excellence, the Executive Director established the ACT committee in FY2003. This committee was composed of front-line staff members who were asked to read the summary report regarding the agency's responses to surveys completed in FY2002. After an initial meeting, ACT members had team meetings with fellow employees. Following the team meetings, the ACT committee produced a 12-page report regarding 47 suggestions for changes to agency operations. Following review, the management team produced a 9-page written response listing the 23 changes that had been implemented as a result of the ACT report (i.e., management implemented 49% of the total number of suggestions made by the ACT committee); if a suggestion was not implemented, management's written response explained the reasons why a change was not made.

- Feedback from External Customers — The agency has developed customer service standards, and in FY2000 and FY2002, conducted a survey of agency customers regarding the quality of service delivered by the agency.

Customer satisfaction can also be measured by the agency's progress in establishing credibility and recognition. The Board of Pharmacy has been recognized for its efficiency and effectiveness within Texas through:

- Monetary exception-free financial audit by the State Comptroller and continuous exception-free audits by the Texas Building and Procurement Commission on the Delegated Service Certification Program;
- Unqualified certification of the agency's performance measures, conducted by the State Auditor;
- An exceptional Management Audit from the Office of the State Auditor in FY1993. The final report stated in part, ". . . *The Texas State Board of Pharmacy is operating efficiently. . . . The agency actively seeks ways to determine how to improve its operations. . . . We commend the agency's personnel for their efforts to improve both agency operations and the practice of pharmacy throughout the State.*"
- Achievement, over the past five years (FY1998-FY2002), of average settlement rate of approximately 99% of TSBP's contested cases (resulting in a disciplinary order against a licensee), which resulted in significant efficiencies, both in terms of complaint resolution time and costs; and
- 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:

- In 2001, pass legislation to establish drug therapy management and immunizations by pharmacists;
- In 2001, pass laws that allowed for the remote provision of pharmacy services using automated dispensing systems and telepharmacy systems; and
- In 1999, 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. 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 licensees 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 and pharmacies 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);
- Develop and implement a strategic plan (the first agency *Strategic Plan* was developed in 1986);
- Hold full membership in the National Council on Patient Information and Education, a national, non-profit, consumer health advocacy organization in Washington, D.C.

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.