

EXTERNAL/INTERNAL ASSESSMENT

TRENDS IN PHARMACY PRACTICE AND REGULATION

The Changing Focus of Pharmacy Practice

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

- the aging of Texas' population;
- advances in drugs, devices, and drug dosage forms;
- managed care;
- the public demand for safety in the healthcare system;
- the emergence of alternative medicine; and
- economics.

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

Pharmacists have the knowledge and opportunity to help patients achieve better outcomes from drug therapy and, in turn, provide a significant cost savings to Texas' healthcare system. The cost of this pharmaceutical care can very likely be recovered from the savings it generates.

This outcome can be realized only if an environment is created by healthcare reform that recognizes that the savings are not likely to be generated at the pharmacist-patient level. The savings will be generated at the level of patients' therapeutic successes and the resulting reductions in hospitalizations, surgeries, repeated office visits, nursing home admissions, and prolonged illnesses that result from patients using their medications improperly.

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

- provision of any act or service necessary to provide pharmaceutical care;
- performance of drug therapy management under protocol of a physician (collaborative practice); and
- administration of immunizations or vaccinations under a physician's written protocol.

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

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

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

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

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

Promoting Patient Safety through Continuous Quality Improvement Programs

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

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

- Evaluate the quality of pharmacy services or the competence of pharmacists;
- Suggest improvements in pharmacy systems to enhance patient care; and
- Investigate disagreements or complaints, determine facts, and make recommendations or issue decisions in a written report.

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

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

Pharmacist’s Continuing Competency

In 2001, a second IOM report titled “*Crossing the Quality Chasm: A New Health System for the 21st Century*” was published. This report identified assessment of the competence of a healthcare provider as a *gap* in the regulatory scheme. The report states the following:

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

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

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

- Evaluate his or her personal needs and interests;
- Develop a plan that will foster his or her professional growth and development;
- Implement the plan;
- Document participation and execution; and
- Evaluate and refine the plan on an ongoing basis.

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

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

- There are major flaws in the way CE is conducted, financed, regulated, and evaluated. Among various problems, health professionals and their employers tend to focus on meeting regulatory requirements rather than identifying personal knowledge gaps and finding programs to address them. Many of the regulatory organizations that oversee CE also tend not to look beyond setting and enforcing minimal, narrowly defined competencies.
- The science underpinning CE for health professionals is fragmented and underdeveloped. These shortcomings have made it difficult, if not impossible, to identify effective educational methods and to integrate those methods into coordinated, broad-based programs that meet the needs of the diverse range of health professionals.
- Continuing education efforts should bring health professionals from various disciplines together in carefully tailored learning environments. As team-based health care delivery becomes increasingly important, such inter-professional efforts will enable participants to learn both individually and as collaborative members of a team, with a common goal of improving patient outcomes.
- A new, comprehensive vision of professional development is needed to replace the culture that now envelops continuing education in health care. Such a vision will be key in guiding efforts to address flaws in current CE efforts and to ensure that all health professionals engage effectively in a process of lifelong learning aimed squarely at improving patient care and population health.

Increased Use of Technology in the Practice of Pharmacy

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, smart phones, tablet computers, robotics, biometrics, bar codes, RFID (radio frequency identification), nanotechnology, voice recognition, telecommunication, automated prescription kiosks, and the Internet. It is clear that technology has the capacity to enhance the provision of pharmaceutical services and provides opportunities to maximize the use of staff. It also creates some special challenges for the Board. Many issues cross jurisdictional boundaries between state agencies, federal agencies, and even international agencies. The Board must find ways to support the increased use of technologies that enable pharmacists to 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.

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

- receipt and data entry of prescriptions and patient information;
- storage of prescription information;
- delivery of pharmacy services;
- accountability for pharmacy services; and
- use of the Internet.

(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 allowed prescriptions to be electronically transmitted between practitioners and pharmacies for many years. The electronic transmission of prescriptions is growing rapidly and in January 2014, Surescripts reported that the number of prescriptions transmitted electronically is approximately six billion. This number is expected to increase greatly with more and more practitioners adopting electronic prescribing. Electronic prescribing may be one of the most effective methods to reduce dispensing errors due to illegible handwriting. However, the Board must be aware of the potential for other types of errors to occur when using electronic prescribing.

Data entry of prescription information into a pharmacy's computer system has traditionally occurred via a computer keyboard at the dispensing pharmacy. Electronic transmission technology allows prescription data entry into a pharmacy's computer by any of these methods to occur at locations other than the dispensing pharmacy. Off-site data entry is currently being used as a way to alleviate some of the pharmacist's workload issues at the pharmacy level. It is important for the Board to monitor the changes in electronic prescribing and keep the Board's rules current with the technology and to ensure that the Board is able to identify the pharmacists and pharmacy technicians involved in the process of dispensing a prescription as discussed in (4) below.

(2) Storage of Prescription Information

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

Some entrepreneurs have gone a step further and set up centralized prescription and patient information centers that are not licensed as pharmacies. The Board believes these types of facilities should be licensed as pharmacies to protect the public and have created a new Class G Pharmacy that establishes standards for entities that centrally process prescription drug or medication orders.

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

(3) Delivery of Pharmacy Services

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

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

The Board has adopted rules to implement these laws to allow a:

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

- pharmacy to provide prescription services to remote medically underserved areas using a telepharmacy system. Pharmacists monitor dispensing of prepackaged unit of use prescription drugs to patients at the remote location. The pharmacist supervises the activities at the remote site with a telepharmacy system that uses audio and video, still image capture, and/or store and forward technology. The pharmacist also provides drug use review and patient counseling by electronic means.

As telepharmacy systems become more accepted, there will be pressure to expand the types of sites that may use telepharmacy. The Board must monitor these initiatives to ensure that pharmacists are in control of the dispensing process and patients are receiving good pharmaceutical care.

- Centralized Prescription Dispensing: As the number of prescriptions dispensed by a pharmacy increase, many chain pharmacies are establishing centralized dispensing centers where prescriptions are ordered through community pharmacies but filled in the highly automated central location. Prescriptions are then delivered to the community pharmacy for pick-up by the patient.

This process takes some of the dispensing load out of the community pharmacy and places it in a very efficient automated pharmacy. In November 2002, the Board adopted rules allowing centralized dispensing.

(4) Accountability for Pharmacy Services

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

(5) Internet Pharmacies

The Internet has received a tremendous amount of attention over the past few years. Internet pharmacies sprang up almost overnight. Mostly, 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 only to appear again under a different facade. In addition, since the Internet is global in scope, an Internet pharmacy, which appears to be located in a city in another state, may in fact be located in Switzerland, or some other country. The issue of illegal sales of prescription drugs through the Internet crosses local, state, and international boundaries and will require the cooperation of many state, federal, and international agencies to resolve. The Board must continue to monitor this issue.

Pharmacy Personnel and Working Conditions

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

Expanded use of automation 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.

(1) Pharmacy Technicians

The addition of the registration of pharmacy technicians and pharmacy technician trainees has more than doubled the number of persons/entities licensed by TSBP. The almost 60,000 pharmacy technicians and trainees the agency registers have had a dramatic effect on the agency's operations and the impact on the profession is expected to continue for the following reasons. The Board established a Pharmacy Technician Task Force to review all issues relating to pharmacy technicians including minimum education requirement, duties of pharmacy technicians, and the ratio of pharmacy technicians to pharmacists. This Task Force should make recommendations to the Board in the summer of 2014.

- Increase in the demand for Pharmacy Technicians: Career opportunities for pharmacy technicians are expected to expand rapidly over the next few years. The Bureau of Labor Statistics' 2010 report estimates employment for pharmacy technicians will increase by as much as 32% between 2010 and 2020. This coupled with current and expanding duties being delegated to pharmacy technicians is likely have a substantial impact on the number of pharmacy technician and technician trainee applications received and processed by TSBP.
- Demand for Expanding the Duties of Pharmacy Technicians: The Board is continually receiving requests from various organizations to increase the duties of pharmacy technicians and/or to allow pharmacists to supervise more pharmacy technicians. In 2009, the 81st Texas Legislature passed House Bill HB1924 that greatly expands the authority pharmacy technicians will have to perform certain duties without the direct supervision of pharmacists in rural hospitals. H.B. 1924 defines a rural hospital as a hospital of 75 beds or less located in a county with a population of 50,000 or less, or has been designated by the Centers for Medicare and Medicaid Services as a critical access hospital, rural referral center, or sole community hospital. H.B.1924 allows the work of a registered pharmacy technician to be verified by a nurse, or practitioner, or a pharmacist by remote access. The bill also allows registered pharmacy technicians to perform the following duties without the supervision of a pharmacist:
 - enter medications orders and drug distribution information into a data processing system;
 - prepare, package, or label a prescription drug according to a medication order if a licensed nurse or practitioner verifies the accuracy of the order before administration of the drug to a patient;

- fill a medication cart used in the rural hospital;
- distribute routine orders for stock supplies to patient care areas;
- access and restock automated medication supply cabinets; and
- perform any other duty specified by the Board by rule.

A Pharmacy Technician Task Force was convened by TSBP in November 2013 and held its first meeting on January 14, 2014. This Task Force is studying the duties of pharmacy technicians and will be making recommendations for some changes to the Pharmacy Act to allow pharmacy technicians to perform additional duties.

- Education of Pharmacy Technicians: In 2013, the Pharmacy Technician Certification Board (PTCB) announced changes to their certification program that will require individuals to have completed an accredited training program prior to taking the PTCB examination by 2020. A Task Force was convened by TSBP to review all of the rules pertaining to Class C (Institutional) pharmacies. In early 2013, the American Society of Health-System Pharmacists (ASHP) and the Accreditation Council for Pharmacy Education (ACPE) collaborated to form the Pharmacy Technician Accreditation Commission (PTAC). PTAC will serve as the accrediting review committee for pharmacy technician education and training programs. This new entity will add standardization to pharmacy technician education programs.

TSBP’s mission is “to promote, preserve, and protect the public health, safety, and welfare by fostering the provision of quality pharmaceutical care to the citizens of Texas” To this end, TSBP must ensure that the training of pharmacy technicians supports the scope of services that they are expected to perform. Under the current law, technicians only have to have a high school diploma or high school equivalency certificate or be working to achieve an equivalent diploma or certificate. TSBP may want to seek legislation that would require a pharmacy technician to possess a minimum education beyond the high school diploma or equivalency.

(2) Working Conditions

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

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

- encouraged increased communication between employees and management.

As another means of alleviating the demands on dispensing pharmacists, in November 2013, TSBP promulgated rules that increased the pharmacist-to-technician ratio from 1:3 to 1:4, providing one of the pharmacy technicians is registered and increased the pharmacist-to-technician ratio in a call center setting where prescription drugs are neither stored nor dispensed from 1:6 to 1:8. In August 2013, TSBP proposed rules to eliminate the ratio of pharmacists to pharmacy technicians. However, after extensive comments were received on the issue with the comments split almost equally between those favoring no ratio to those favoring maintaining a ratio, the Board withdrew the rules and established a task force to look at all issues relating to pharmacy technicians including education, duties and ratio. This Task Force should make recommendations to the Board in the summer of 2014.

Consumers often file complaints in which they express concerns that inadequately staffed prescription departments are the reason why pharmacists commit dispensing/medication errors. Research has shown that the causes of dispensing errors involve numerous factors, but are not necessarily a result of increased prescription volume. Accordingly, TSBP has not set a quota or limit on the number of prescriptions a pharmacist can fill per hour or day. Although many would say that increasing the ratio of technicians to pharmacist would provide a “quick fix” to the staffing problem, many pharmacists say that they could not adequately supervise additional technicians and believe that an increased ratio could have negative effects on patient care.

Maintain the Agency’s Leadership Position in Pharmacy Practice Regulation and Establish a Key Leadership Position for Addressing Public Needs

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

The Board of Pharmacy must be visionary in order to stay on the cutting edge of regulation. The Board must continue to play a public advocacy role as it relates to educating the public about the value of the pharmacist’s role as a vital member of the healthcare team, especially in light of the major challenges facing pharmacy today. These challenges include the following:

- increasing demand for affordable healthcare services;
- the growing aging population;
- increased consumer demand for prescription drugs;
- rising availability of prescription drugs over the Internet; and
- disaster planning and response.

In order to accomplish these goals and still maintain its position of strength, the agency must identify areas for growth and opportunity, as well as the challenges facing the agency. Additionally, the agency must

aggressively pursue avenues to retain or preferably increase the number of highly qualified personnel employed while continuing to implement quality management practices. Given the pace of technological advances, the agency must also carefully encourage and recognize the use of technology that will allow the public easier access to information, while at the same time not cause undue reporting requirements or workload constraints on the agency or practitioners. Finally, it is important for the agency to strike the appropriate balance in achieving its public protection mandate yet be flexible enough to develop regulations to facilitate pharmacy practice changes.

(1) Value of Pharmaceutical Care

The Board should continue to play a public advocacy role as it relates to educating the public about the value of pharmaceutical care, including the pharmacist's role as a vital member of the healthcare team.

- The increasing demand for affordable healthcare services may cause consumers to seek medications from nontraditional pharmacy sources. Consumers should be educated not only on the positive facts like the importance of vaccines, dietary supplements, and prevention of medication errors, but also warned about the negatives such as the proliferation of misinformation (e.g., Internet scams and e-mails offering prescription drugs without a prescription) and the dangers of lookalike/sound alike products.
- Consideration must be given to the dramatic increase in the state's aging population and the associated growth in prescription volume. Not only is the current population aging, but also Texas is becoming home to an increasingly large number of retirees. Aging consumers often have decreased cognitive skills, eyesight, and mobility, which lead to increased demand on all healthcare providers. Consequently, as the senior population increases so will the workload associated with a higher volume of prescriptions. This will have a significant impact on pharmacists and pharmacy personnel to meet the consumers' needs.
- Consumers, as well as healthcare professionals, are seeking information and advice concerning alternative medicines, including herbal and other nutritional supplements. Efforts should be made to incorporate complete drug histories into patient charts, including herbal medicines and other nonprescription medication products, to avoid the potential risk of an interaction with a prescription drug already prescribed. As more federal scrutiny and potential regulation of these agents occurs, it may be logical that the regulation of these drugs would fall to the Pharmacy Board. Pharmacists who are experienced in evaluating clinical studies and other types of substantiating health information, especially related to safety and effectiveness, are in a unique position to advise consumers.

(2) Preparedness for Public Health Emergencies

The Board should focus on preparedness for public health emergencies where pharmacist participation is crucial. Pharmacies and pharmacists have vital roles in front-line defense in the event of a public health emergency, such as an act of bioterrorism, natural disaster, or widespread disease such as a pandemic influenza. Pharmacists must be ready to be positioned to provide emergency care and medication delivery in response to such unplanned events. Currently, pharmacies are deeply involved in the administration of seasonal flu immunizations, placing pharmacy on the front line of healthcare in the nation. The immediate distribution of emergency

refills of critical prescriptions, and assistance with the distribution of vaccines, antidotes, and other pharmaceutical agents is vital to ensure the continued safety of the public. This will require specialized knowledge, advance planning, and integration of local, state, and federal resources to achieve quick mobilization. Pharmacy is a key stakeholder in assuring appropriate and adequate response to disasters and as such should be present and a participant in all governmental preparedness meetings.

(3) Partnerships with Federal Agencies and Other State Agencies and Boards.

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 effective enforcement and compliance.

An example of this partnership included the Board's joint investigation with the US Food and Drug Administration, Drug Enforcement Administration, Federal Bureau of Investigation, Internal Revenue Service, US Department Social Security Administration, US Department of Veteran Affairs, and the Texas Department of State Health Services. This internet fraud case involved more than \$200 million in fraudulently obtained pharmaceuticals and resulted in the guilty pleading of all 19 individuals charged in the indictment. These expanded partnerships will be especially crucial as the trend toward the abuse of prescription drugs continues to grow.

A 2010 study conducted by the Substance Abuse and Mental Health Services Administration (SAMSA) and the Centers for Disease Control and Prevention concluded that "visits to hospital emergency departments involving nonmedical use of prescription narcotic pain relievers more than doubled, rising 111 percent, between 2004 and 2008. The study used data from SAMHSA's Drug Abuse Warning Network (DAWN) emergency department system. It examined emergency department visits for nonmedical use of legal drugs, such as using them without a prescription.

In a June 2010 news release about the study, Office of National Drug Control Policy Director Gil Kerlikowske stated, "The abuse of prescription drugs is our nation's fastest-growing drug problem. And this new study shows it is a problem that affects men and women, people under 21, and those over 21."

(4) Transfer of Programs to the Agency.

A bill passed by the 2009 Texas Legislature directed the TSBP, the Texas Department of Public Safety, and the Texas Medical Board to develop a transition plan for the orderly transfer the regulation of certain records and regulatory functions relating to dispensing controlled substances (Prescription Monitoring Program and the Controlled Substances Registration Program) to TSBP. This study was completed and submitted to the 2011 Texas Legislature, but no action was taken to move either program to TSBP. However, since the end of the session, there have been continued discussions by pharmacy and medical groups regarding the possible move of the two programs to TSBP.

(5) The Board should continue to be a leader in the growth and evolution of the profession

The Board should continue to be a leader in the growth and evolution of the profession by adopting regulations and encouraging legislation that allows pharmacists to use the full scope of their

knowledge, skills, and abilities. Innovation will continue to be necessary in order to improve pharmacy systems to enhance patient care, in developing new methods and systems to monitor compliance with existing laws and rules, and/or expand compliance initiatives around the state. It is important to plan appropriately and address the growing volume of prescriptions and the additional professional services that pharmacy can provide as a key member of the healthcare team.

(6) Protection of the Citizens of Texas

In order for the Board to continue to protect the citizens of Texas, it must have adequate funds and staff. The almost 60,000 pharmacy technicians and trainees licensed by the agency have had a dramatic effect on the agency's operations. Of particular concern to the agency is the growth in the number of disciplinary orders entered by the agency and the continuing growth in the number of complaints received. Since FY2008, the agency has experienced a 5% increase in the number of complaints; a 40% increase in the number of disciplinary orders and a 5% increase in the number of days to resolve a complaint. Each area of growth can be directly attributed to the increase in registrants.

In late 2012, the New England Compounding Center in Massachusetts distributed a compounded sterile preparation that was contaminated with a fungus. This product was distributed to 23 different states, including Texas. More than 751 individuals have become ill and as of January 2014, 64 patients who received injections of this contaminated product have died (only 2 individuals in Texas received the product and neither of these had serious reactions).

After learning of this serious issue in a sterile compounding pharmacy, TSBP conducted an extensive review of the rules related to sterile compounding and the agency's licensing, inspection, and enforcement of these rules. During the 2013 Texas Legislative Session, with the assistance of State Senator and Pharmacist Leticia Van de Putte, the agency was successful in obtaining significant amendments to the Texas Pharmacy Act related to sterile compounding. These amendments give the Board of Pharmacy the authority to:

- inspect an out-of-state sterile compounding pharmacy and require them to pay for the inspection;
- require an inspection prior to opening a sterile compounding pharmacy;
- specify a sterile compounding pharmacy may not renew unless it has been inspected as required by the board and the pharmacy has reimbursed the Board for the costs of the inspection; and
- allow TSBP to accept an inspection report issued by the licensing board in the home state of the pharmacy if:
 - the board determines that the other state has comparable standards and regulations applicable to sterile compounding pharmacies, including standards and regulations related to health and safety; and
 - the sterile compounding pharmacy provides to the board any requested documentation related to the inspection.

In addition, TSBP was successful in obtaining the authority and the funding to hire five new field compliance inspectors and an additional administrative assistant to support these inspectors. These additional five inspectors will bring the total number of inspectors to twelve and will allow TSBP to inspect pharmacies that compound sterile preparations much more frequently to ensure the safety of these facilities. The agency must continue to monitor pharmacies that compound sterile pharmaceuticals closely to ensure that the pharmacies are preparing sterile compounds properly.

In addition, on November 27, 2013, the U.S. Drug Quality and Security Act (Act) was signed into law by President Obama. This law removes the unconstitutional provisions from section 503A of the United States Food, Drug, and Cosmetic Act (FD&C Act) thereby making compounding pursuant to a prescription a part of the FD&C Act. In addition, the law adds a new section 503B to the FD&C Act. This new section allows facilities that are compounding sterile pharmaceuticals not pursuant to individual prescriptions and “outsourcing” these products to other entities to be registered as “outsourcing facilities” rather than as manufacturers. TSBP must monitor the implementation of this act and the effect of the act on the current compounding provisions in the Texas Pharmacy Act.

(7) Consolidation of Health Licensing Agencies

In both the 2009 and 2011, legislative session bills that would consolidate the health licensing agencies into one large agency were introduced. This consolidation will have a dramatic impact on the operation of the agency in that it will likely include less or no control by TSBP in developing and establishing its budget and loss of direct control of some agency functions such as licensing.

A possible alternative to consolidation would be conversion to a self-directed/semi-independent agency. In 1999, 2009, and 2011, the Texas Legislature enacted legislation that transferred several professional and occupational licensing agencies to self-directed/semi-independent status.

The self-directed/semi-independent status allows the Boards of these agencies to set and control the budgets for the agencies. Though the agencies are in control of their own budgets, they are still under the oversight of the legislature, governor, state auditor, state comptroller, and other state agencies. The self-directed, semi-independent status has allowed the agencies much more flexibility to react to changes in their respective professions. A bill was introduced during the 2013 Texas Legislative Session that would have given TSBP, the Texas Medical Board, and the Texas Board of Nursing self-directed/semi-independent status. This bill was not passed by the legislature but the Legislature directed the Texas Sunset Commission to conduct a study of self-directed/semi-independent status for state agencies and to make recommendations to the legislature by December 31, 2014. Depending on the results of this study, TSBP should again consider seeking self-directed/semi-independent status for the agency.

IDENTIFICATION OF ISSUES

In developing its Strategic Plan, the Board and agency staff sought to identify and analyze those trends and resulting issues expected to have the most significant impact on the profession and regulation of pharmacy over the next five years. As described in the *Description of Agency Planning Process (Appendix A)*, the Board sought input from numerous outside individuals and organizations and internal comments from staff and Board members. The agency reviewed all comments and researched current and future trends and issues that will have the most significant impact on the practice and regulation of the practice of pharmacy over the next five years.

EXTERNAL ISSUES

Priority Issues Outside Of TSBP Rulemaking Authority Or Requiring Additional Appropriations

The following seven issues were identified as the most important to the regulation of the practice of pharmacy in the State of Texas. These issues are outside of the Boards' authority or require additional appropriations to implement.

1. **Self-Directed/Semi-Independent Status for the Texas State Board of Pharmacy**

The Texas State Board of Pharmacy (TSBP) should pursue authorization to function as a self-directed/semi-independent agency. The operations of TSBP are supported solely by examination, licensing, and other fees paid by the licensees/registrants. The legislature approves the Board's operating budget each biennium and the agency funds are deposited in the state treasury and each biennium TSBP collects approximately \$2 million more than it is budgeted. These excess funds are returned to the state treasury. Additionally, the Board is required each biennium to fund any new program with new fees rather than the use of any of the current funds it deposits in the treasury.

The rapid changes occurring in pharmacy practice and the changing demands and pressures on the Board's resources has prompted concern by the Board that it may not have the financial resources and the flexibility to meet its responsibilities efficiently and effectively. If TSBP had self-directed/semi-independent status, the agency will have the flexibility to expand and contract resources as needed, thus being more responsive to constituents and the public. This should result in more timely resolution of licensing and disciplinary matters.

During the 76th (2005) Legislative Session, Senate Bill 1438 was passed to allow three state agencies to participate in a self-directed/semi-independent pilot program (Board of Public Accountancy, Board of Professional Engineers, and the Board of Architectural Examiners). The agencies were permitted to move their funds outside the state treasury, pay their own bills, and reimburse the State for all services rendered. The agencies enabling statutes are still under direct control of the legislature and each agency must report certain information to the state regarding accountability of funds, services, and goals. The agencies are also subject to audit by the Office of the State Auditor.

Again, during the 81st (2009) Legislative Session, four additional state agencies were granted self-directed/semi-independent status by House Bill 2774. These included the Texas Finance Commission, the Texas Department of Banking, the Department of Savings and Mortgage Lending, the Office of Consumer Credit Commissioner, and the Credit Union Department.

During the 82nd (2011) Legislative Session, the Real Estate Commission was granted self-directed/semi-independent status by Senate Bill 1000. In addition, during the 82nd Session, House Bill 2092 was introduced that would give the Texas State Board of Pharmacy and the Texas Board of Nursing self-directed/semi-independent status. House Bill 2092 was voted out of the House Public Health Committee during the last few weeks of the session, but it was not heard by the House.

Finally, during the 83rd (2013) Legislative session, a bill was introduced during the 2013 Texas Legislative Session that would have given TSBP, the Texas Medical Board, and the Texas Board of Nursing self-directed/ semi-independent status. This bill was not passed by the legislature but the Legislature directed the Texas Sunset Commission to conduct a study of Self-Directed Semi-independent Status for state agencies and to make recommendations to the legislature by December 31, 2014. Should the results of this study be favorable, TSBP should again seek self-directed/semi-independent status.

If granted self-directed/semi-independent status, TSBP would be removed from the legislative budgeting process and the budget would be adopted and approved by the board members appointed by the Governor. On the first day of each regular legislative session, TSBP would be required to submit a report to the Legislature and the Governor describing all of the agency's activities in the previous biennium. In addition, TSBP would be required to report its two-year expenses and revenue collections by November 1 of each year to the Legislature, the Legislative Budget Board, and the Governor. The TSBP employees would remain members of the Employees Retirement System of Texas under Chapter 812 of the Government Code. The State Auditor would contract with TSBP to conduct financial and performance audits and the Attorney General would collect fees for their legal services. All agency supplies, materials, records, equipment, and facilities would be transferred to TSBP.

The advantages of moving TSBP to self-directed/semi-independent status to the State of Texas are as follows.

- The number of hearings and legislative time spent on agency budgets is reduced;
- The administrative burden of state government will be reduced by approximately:
 - 90 employees will be removed from the state payroll; and
 - \$10,000,000 will be removed from the state budget, thus reducing the biennial state budget.
- State oversight agencies such as the State Auditor, Comptroller of Public Accounts, State Office of Administrative Hearings, and Office of the Attorney General will receive actual reimbursement costs for services.

- The agency will have the flexibility to expand and contract resources as needed, thus being more responsive to constituents and the public. This should result in more timely resolution of licensing and disciplinary matters.
- The number of reports to oversight agencies will be reduced with most reports required annually.
- The governing Board of the agency will be held to a higher level of accountability to their constituents.
- The agency budget will be held to a higher level of scrutiny by licensees and professional associations.
- The Self-Directed/Semi-Independent status will be reviewed in 2017 during the Agency's Sunset process.

The move to self-directed/semi-independent is a major change to how the agency finances are managed. This shift from direct state oversight to an agency driven process is a significant change but has been tested by eight licensing agencies and has proven to be successful and effective. By virtue of past State Auditor, Comptroller, and State Office of Risk Management audits, the Texas State Board of Pharmacy has proven to be an effective, efficient, and well-managed state agency and an excellent candidate for self-directed/semi-independent status.

2. Diversion of Controlled Substances through the Dispensing of Prescriptions without a Valid Medical Need

A limited number of pharmacists and pharmacies are creating a situation that has a critical impact on the public health and safety through the dispensing of controlled substances to patients who do not have a valid medical reason to receive these prescriptions at "Pill Mill" pharmacies. These types of pharmacies dispense controlled substances outside the course of professional practice. The prescribers who issue the prescriptions are not prescribing the controlled substances for a legitimate medical need and the pharmacies are dispensing these invalid prescriptions. The presence of these "Pill-Mills" in Houston is having a dramatic and deadly effect on the citizens of Texas. In 2013, the CDC called prescription drug abuse a "growing epidemic." Nearly 3 of 4 prescription drug overdoses is caused by opioid pain medication, and more people have died in recent years from the abuse of prescription drugs than from heroin and cocaine combined. The Harris County Coroner's Office reported in 2010 that prescription drugs have killed more than 1,200 people in Harris County since 2006.

Due to the huge number of prescribers and pharmacies involved in this type of activity, primarily in the Houston area, TSBP signed a contract with the Drug Enforcement Administration for one field investigator to work full-time with a Drug Enforcement Administration Task Force in the Houston area. This contract ended in October 2013. Unfortunately, at the end of this two-year investigation, DEA determined not to seek prosecution of any of the pharmacies investigated by the Task Force. All of the files were transferred to TSBP, and these files are being reviewed for the possible institution of disciplinary action by TSBP. The Board will continue to pursue cases against

pharmacies and pharmacists for “pill mill” activity in the administrative/licensing system as well as assisting with criminal prosecution of those licensees involved.

3. Underutilization of the Clinical Knowledge and Skills of Pharmacists in the Current Health Care System

Pharmacists have the knowledge and opportunity to help patients achieve better outcomes from drug therapy and, in turn, provide a significant cost savings to Texas' healthcare system. The cost of this pharmaceutical care can very likely be recovered from the savings it generates.

This outcome can be realized only if an environment is created by healthcare reform that recognizes that the savings are not likely to be generated at the pharmacist-patient level. The savings will be generated at the level of patients' therapeutic successes and the resulting reductions in hospitalizations, surgeries, repeated office visits, nursing home admissions, and prolonged illnesses that result from patients using their medications improperly.

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

Because the clinical knowledge and skills of pharmacists is underutilized in the current healthcare system pharmacists must work to expand the scope of collaborative practice agreements. The Board should monitor legislative efforts to expand the scope of collaborative practice agreements.

4. Increase Licensee Compliance with Laws and Rules Relating to the Practice of Pharmacy through Education of Licenses

Because the profession is changing rapidly, the laws and rules relating to the practice of pharmacy are also changing. The Board should re-dedicate its efforts to educate pharmacist about the laws and rules that relate to the practice of pharmacy including the importance of patient counseling.

Since 1982, the Board has following a “*preventative*” approach to enforcement based upon the belief that 98% of its licensees/registrants will obey the laws and rules governing the practice of pharmacy, if the licensees are well informed as to the requirements of the pharmacy laws and rules. A review of prior reports of TSBP performance measure *Percent of Licensees with No Recent Violations* proves that preventive enforcement is working well.

In developing this educational program, the Board should use all of the tools available including written information with the TSBP Newsletter, the TSBP Website, social media such as Facebook, Twitter, YouTube, etc., presentations, and compliance inspections. The Board will ask the legislature for an increase in staffing levels to allow the agency conduct this multi-faceted education program.

5. Retirement of the Current Executive Director

The current executive director has indicated that she will retire in August 2015. The Board should establish a plan for hiring a new executive director. The Texas Pharmacy Act requires that the executive director of TSBP be a pharmacist. One item may make the process of finding a pharmacist to be the executive director of TSBP is the salary paid to this position. Currently the legislature has placed the salary of the executive director in exempt group 4, which has a minimum salary of approximately \$106,500 and a maximum salary of \$167,500 per year. However, the legislature has specified that the executive director's salary is set at 107,565 for FY2014 and \$109,716 for FY2015.

The current salary for the position will make filling the executive director position very difficult since this salary is less than that paid to beginning pharmacists. A 2013 survey of pharmacist's salary conducted by "Drug Topics" reported the annual base salaries for staff pharmacists between \$116,000 and \$140,000 a year. The lower range of these salaries is more than \$6,000 more than the salary of the TSBP executive director.

For the last two legislative sessions, the Board has asked the legislature to give them the authority to set the salary within the Group 4 exempt salary range. With this authority, the Board will be able to pay the person who is the executive director a salary that is competitive to pharmacists' salaries and one that recognizes the experience of the executive director. The Board will ask the 2015 Legislature to give them the authority to set the salary within the Group 4 exempt salary range or raise the salary specified in the Appropriations Act to \$140,000 per year.

6. Education of the Public on the Value of Pharmaceutical Care

The public is not aware of the value of pharmaceutical care and of the positive impact that pharmacists provided care would have on their health. Because of this lack of knowledge of the value of pharmaceutical care, the Board should participate in a public education program to educate the public on the value of pharmaceutical care.

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.

Pharmacists are becoming participating members of the healthcare team and work collaboratively with physicians and other healthcare practitioners to provide total care to the patient. Many Texas pharmacists are providing expanded patient care services such as drug therapy management, administration of immunizations, disease state management, disease screening, and health promotion and disease prevention.

TSBP was given the authority to hire an educational specialist during the 2013 Legislative Session which will allow the agency begin this education program.

7. Program for Pharmacy Technicians Who are Impaired by Chemical Abuse or Mental or Physical Illness

Since 1983, the Texas Pharmacy Act (Act) authorizes the agency to contract with an entity that operates a program established to aid pharmacists or eligible pharmacy students impaired by chemical abuse or mental or physical illness. In addition, the Act authorizes the agency to collect a surcharge on pharmacists' licenses to fund this program.

This program has been very successful in treating and rehabilitating pharmacists and pharmacy students and the success rate has been very high as can be seen by the agency performance measures. The one-year completion rate for pharmacists and students in the program is 90% while the 3-year recidivism rate was 15% in FY 2010 and 19% in FY2012.

Currently the Texas Pharmacy Act does not allow the agency to refer pharmacy technicians who are impaired by chemical abuse or mental or physical illness. The Texas Pharmacy Act must be amended to allow pharmacy technicians to participate in the program

INTERNAL ISSUES

The following four issues were also identified as the most important to the regulation of the practice of pharmacy in the State of Texas. However, the Board is not asking for additional authority or funds to implement action on these issues.

1. Use of Technology in the Practice of Pharmacy

Due to the rapid proliferation of technology, the board must stay abreast with advances in technology that will enhance the practice of pharmacy and patient care, and understand the changes in technology and how that applies to the practice of pharmacy. This rapid proliferation of technology 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 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.

The Board should monitor and study the emerging use of technology in the practice of pharmacy and attempt to adopt regulations that will allow the use of the innovations without endangering the public health.

2. The Current Continuing Education Model May Not Be Adequate to Maintain Pharmacists' Professional Competency

Many recent studies have questioned the value of the current continuing education model used by pharmacy boards. These studies indicate that the current continuing education model may not be adequate to maintain pharmacists' professional competency. The Board should monitor the study of this issue and if that study indicates Continuing Professional Development (CPD) is a better system, the Board should suggest amendments to the Texas Pharmacy Act to replace the current system.

3. Prospective Drug Regimen Review of Medication Orders Prior to Administration of a Drug to a Patient in Small Hospitals

Currently Texas has different requirements for pharmacy services in large hospitals (101 beds or more) and small hospitals (100 beds or less). One of the areas where these standards differ is in the requirements for review of medication orders by pharmacists. Larger hospitals are required to review medication orders and a patient's medical history prior to administration of the drug. Small hospitals are not required to meet this requirement. The Board believes that recent advancements in technology will allow this drug use review to be performed in a more cost effective manner. Therefore, in order to protect patients' health and to eliminate the dual standards between large and small hospitals, the Board should enter in discussions with stakeholders to amend the rules to require drug regimen review prior to administration of any medication in small hospitals.

4. Appropriate Level of Training and Supervision for Pharmacy Technicians

In November 2013, the Board formed a Pharmacy Technician Task force to review pharmacy technician practice in the State of Texas including educational requirements, scope of practice and overall regulation of pharmacy technicians in all pharmacy settings, including hospital and community. The Task Force is scheduled to make recommendations to TSBP in the summer of 2014. Once the Board receives these recommendations, the Board should consider working with the professional associations to incorporate these recommendations into the rules and regulations or Texas Pharmacy Act if appropriate.