

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. During 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 are 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 provide immunization services to patients. Expanding immunization services is beneficial to: patients since pharmacist/pharmacies are the most accessible health care provider; and to the public health since as more individuals are immunized, more will be protected against the occurrence of these diseases. 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. In 2015, the Texas Legislature passed H.B. 1550 that amended the Texas Pharmacy Act to allow pharmacists, in an emergency, to administer epinephrine to a patient using an auto-injector device.

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, and 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. In January 2016, Surescripts reported that the number of prescriptions transmitted electronically is approximately 6.5 billion. This number is expected to increase greatly with more and more practitioners adopting electronic prescribing. Although electronic prescribing may reduce dispensing errors caused by illegible handwriting, there are other types of errors that may occur (e.g., selecting the wrong drug from a drop-down list).

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 the use of technology and keep the Board's rules current 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 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 efficiency 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 schools.
- Pharmacy to provide remote prescription services to 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 tele-pharmacy systems become more accepted, there will be pressure to expand the types of sites that may use tele-pharmacy. 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 workload out of the community pharmacy and places it in a very efficient automated pharmacy. In November 2002, the Board adopted rules to allow 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.

6. Physician Owned Pharmacies and Physician Dispensing

- Physician Owned Pharmacies: Beginning in 2013, a number of individuals have engaged in promoting pharmacy ownership to physicians and other prescribers. These promotions, some by pharmacists, encourage physicians to invest in the ownership of pharmacies that will dispense the physicians' prescriptions to their patients. One of the schemes specifically promotes the ownership of pharmacies that compound prescriptions and even certain types of products such as pain creams. It appears that these promotional offerings are carefully structured to comply with both federal and state laws that regulate physician ownership of entities to which the physician may refer patients. These promotions are seemingly becoming more numerous and aggressive. In April 2014, the House Public Health Committee held a public hearing that discussed these types of arrangements and expressed concern about the growth of these pharmacy ownership promotions to physicians.

The Board of Pharmacy has no provisions to limit the ownership of pharmacies; however, the Board does have a rule that prohibits a pharmacist from "*sharing or offering to share with practitioner compensation received from an individual provided pharmacy services by a pharmacist.*" Even though the Board has a rule prohibiting the sharing of compensation with physicians, investigation of these types of cases was extremely hampered since the Board was prohibited from inspecting financial, sales and pricing data records in a pharmacy, without the pharmacy's specific authorization to do so. However, during the 2015 Legislative Session, the Legislature passed S.B. 460 that allows the Board authority to inspect financial records "only in the course" of the investigation of a specific complaint. This new authority will allow the Board to investigate complaints that allege "*sharing or offering to share with practitioner compensation received from an individual provided pharmacy services by a pharmacist.*"

- Physician Dispensing: In each of the last two sessions of the Texas Legislature, bills have been introduced that would allow physicians to dispense certain "*aesthetic pharmaceuticals*" such as Bimatoprost (Latisse), Hydroquinone (Lustra, Claripel), and Tretinoin (Retin A). During the 2013 session, a bill passed both the Senate and the House and was sent to the Governor for signature. However, Governor Perry vetoed this bill and recognized in his veto proclamation the important role of the pharmacist and the Board of Pharmacy by stating the following:

“SB 227 would circumvent existing safeguards for the dispensing of certain prescription cosmetic drugs by allowing physicians and optometrist to sell these medications directly. It is the role of the pharmacists – who are trained specifically in drug interactions, side effects and allergies – to dispense the medications. Additionally, the State Board of Pharmacy has the authority to inspect pharmacies to ensure drugs are stored securely and at safe temperatures.”

During the 2015 session several other bills were introduced that would have allowed physicians to dispense. Even though none of these bills passed, it should be noted that some of these bills expanded the number of drugs a physician could dispense well beyond those drugs listed in previous bills and one completely eliminated the prohibition against physicians dispensing prescription drugs to their patients and charging for those drugs. The Board and the profession may need to review the issue to see if there might be a way to allow a limited dispensing in physician’s office provided oversight of the dispensing by a pharmacist is provided and important patient protection is provided through regulatory review of this practice by the Board of Pharmacy.

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 more than 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.

- **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’ 2014 report estimates employment for pharmacy technicians will increase 9% from 2014 to 2024, faster than the average for all occupations. 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 to perform certain duties without the direct supervision of pharmacists in rural hospitals. H.B. 1924 defined a rural hospital as a hospital of 75 beds or less located in a county with a population of 50,000 or less, or had been designated by the Centers for Medicare and Medicaid Services as a critical access hospital, rural referral center, or sole community hospital. HB1924 allowed 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.
- 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 American Society of Health-System Pharmacists (ASHP) accredited training program prior to taking the PTCB examination by 2020. In early 2013, 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 and training 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.

A Pharmacy Technician Task Force was convened by TSBP in November 2013. The Task Force was charged to:

- review the current laws and rules relating to pharmacy technicians in Texas;
- review literature and studies regarding the changing roles and duties of pharmacists and how these changes may impact the role of pharmacy technicians; and
- make recommendations to the Board for any changes to the current pharmacy technician laws and rules to allow pharmacy technicians to assist pharmacists in providing safe and quality pharmaceutical care to the citizens of Texas.

More specifically, the Task Force was asked to review minimum education requirements, duties of pharmacy technicians, and ratio of pharmacy technicians to pharmacists. The Task Force held two meetings and presented its report to the Board at the May 6, 2014, meeting. Included in this report were several suggestions for the expansion of duties that could be performed by pharmacy technicians in both community and hospital pharmacies. The Board and the profession will review these suggestions and consider making changes to the Pharmacy Act and rules to implement these suggestions.

(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.

Consumers and pharmacists 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.

In May 2013, the Board proposed rules to set the ratio of pharmacists to pharmacy technicians at 1 to 4. However, in August 2013, the Board voted to withdraw the proposed rules and to propose rules to eliminate the ratio of pharmacists to pharmacy technicians. At the November 2013 meeting, the Board held a public hearing on the proposed rules to eliminate the ratio of pharmacist to pharmacy technicians. The Board received more than 200 written comments on the rules and numerous oral comments at the hearing. After a review of the comments that indicated the comments were split almost equally between those favoring no ratio to those favoring maintaining a ratio, the Board voted to withdraw the rules. After the vote to withdraw the rules, the Board then voted at the November 2013 meeting to re-propose rules that increased the pharmacist-to-technician ratio from 1:3 to 1:4 and increased the pharmacist-to-technician ratio in a call center setting where prescription drugs are neither stored nor dispensed from of 1:6 to 1:8. The Board adopted these proposed rules at the February 2014 meeting and the rules setting the ratio in a community pharmacy to 1:4 and in a call center pharmacy to 1:8.

At the November 2013 meeting, the Board also voted to establish a Task force to review issues related to pharmacy technicians, including the pharmacist to pharmacy technician ratio. This Task Force made its recommendations to the Board at the May 6, 2014 meeting. Included in these recommendations is statement that the Pharmacy Technician Task Force supports elimination of the pharmacist to technician ratio.

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 arrest and conviction of 19 individuals in 2005-2007, including one pharmacist. These expanded partnerships with other law enforcement agencies 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."*

A July 2014 article in the Center for Disease Control and Prevention publication "VitalSigns" presented the following information concerning abuse of opioid painkillers:

- Each day, 46 people die from an overdose of prescription painkillers* in the US.

- Health care providers wrote 259 million prescriptions for painkillers in 2012, enough for every American adult to have a bottle of pills.

The article presented the following suggestions for states to combat abuse of prescription painkillers. States can:

- Consider ways to increase use of prescription drug monitoring programs, which are state-run databases that track prescriptions for painkillers and can help find problems in overprescribing. Use of these programs is greater when they make data available in real-time, are universal (used by all prescribers for all controlled substances), and are actively managed (for example, send alerts to prescribers when problems are identified).
- Consider policy options (including laws and regulation) relating to pain clinics (facilities that specialize in pain treatment) to reduce prescribing practices that are risky to patients.

(4) Transfer of Programs to the Agency.

S.B. 195 passed by the 2015 Texas Legislature, amended the Texas Controlled Substances Act to Transfer the Texas Prescription Monitoring Program and the rulemaking authority for controlled substances from the Texas Department of Public Safety (DPS) to the Texas State Board of Pharmacy (Board). S.B. 195 specified that:

Effective on or after 6/20/2015 the Board has the authority to:

- Adopt rules to implement the Prescription Monitoring Program (PMP) and certain other provisions related to prescriptions in the Controlled Substances Act (Sections 481.003(a), 481.075, 481.076(c), 481.0761(a) and (g), Sections 481.073 (Communication of Prescriptions by Agent), 481.074 (Prescriptions) and 481.352;
- Sign a contract with a vendor to operate the PMP; and
- Call a meeting of the Prescription Monitoring Work Group as established in the Controlled Substances Act.

Effective 9/1/2016 the following become effective:

- The PMP is transferred from DPS to TSBP;
- The Board shall establish a program to fund the PMP through a surcharge on the licenses of persons authorized to access the PMP; and
- The Controlled Substance Registration program is abolished.

The Board has reviewed the existing system used by the DPS for the prescription monitoring system and has determined that this system is inadequate to provide pharmacists and prescribers with the information they need to make informed decisions regarding the prescribing and dispensing of controlled substance prescriptions. The Board has awarded a contract to Apriss to be the vendor for the new prescription monitoring program for Texas.

The Board believes that the move of the prescription monitoring program to the new platform provided by Apriss will increase the tools that pharmacists and physicians may use to make better decisions when dispensing controlled substances.

(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. In FY2003, the fiscal year prior to the registration of pharmacy technicians, the agency received 1,893 jurisdictional complaints, closed 1,850 jurisdictional complaints, and entered 213 disciplinary orders. In FY2014, the agency received 5,561 complaints, closed 5,606 complaints, and entered 604 disciplinary orders. It has been extremely challenging for the agency to handle this phenomenal growth during the past 12 years: 194% increase in the number of complaints received; 203% increase in the number of complaints closed; and 184% increase in the number of disciplinary orders entered.

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 (Note: Only two individuals in Texas received the product and neither patient had serious adverse effects).

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 licensing, inspection and enforcement of these rules. During the 2013 Texas Legislative Session, State Senator and Pharmacist Leticia Van de Putte 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;
- not renew the license of a pharmacy that compounds sterile products 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;
 - the sterile compounding pharmacy provides to the board any requested documentation related to the inspection; and
 - requires a pharmacy that compounds a sterile preparation to notify the Board immediately of any adverse effects reported to the pharmacy or that are known by the pharmacy to be potentially attributable to a sterile preparation compounded by the pharmacy and not later than 24 hours after the pharmacy issues a recall for a sterile preparation compounded by the pharmacy.

In addition, TSBP was successful in obtaining the authority and the funding to hire five new compliance officers/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.

On November 27, 2013, the U.S. Drug Quality and Security Act was signed into law by President Obama. This law removes the advertising provisions of Section 503A of the Food, Drug, and Cosmetic Act (FD&C Act) that were declared unconstitutional in 2002. With these provisions removed, this portion of the FD&C Act passed in 1997 will now become effective. Section 503A exempts pharmacy compounding from compliance three specific sections of the FD&C Act that manufacturers are required to meet (FDA approval of products prior to marketing; Compliance with Current Good Manufacturing Practices and labeling with adequate directions for use). This act makes compounding pursuant to a prescription by pharmacists legal under the FD&C Act.

The law also adds a new section 503B to the FD&C Act. Section 503B 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. An outsourcing facility will also qualify for exemptions from certain provisions of the FD&C Act including those requiring FDA approval of products and the requirement to label products with adequate directions for use. However, these entities will not be exempt from complying with Current Good Manufacturing Practices.

In early April 2014, TSBP staff met with staff of the Texas Department of State Health Services to discuss the regulation of Outsourcing Facilities in Texas and changes that may be necessary in the Texas Pharmacy and Texas Food, Drug, and Cosmetics Acts to implement the provisions of the federal Drug Quality and Security Act. TSBP must continue these discussions and expand them to include the compounding community so that appropriate modifications in Texas laws and rules can be made to protect the safety of the citizens of Texas.

(7) Consolidation of Health Licensing Agencies

In both the 2009 and 2011 legislative sessions 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 (other than TSBP) 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 to have 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. The Sunset Commission developed recommendations for the administration of the State's self-directed semi-independent (SDSI) process; however, the 84th Legislature did not pass the Sunset bill containing these recommendations. TSBP should continue to monitor legislative activity regarding self-directed/semi-independent status for agencies.

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 eight 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**

A. **Brief Description of Issue**

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.

B. **Discussion**

The Texas State Board of Pharmacy (TSBP) should pursue authorization to function as a self-directed/semi-independent (SDSI) 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. 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.

SDSI status would allow the agency to respond to crises in a timelier manner. For example, in September 2012, a multistate outbreak of fungal meningitis and other infections occurred among patients who received contaminated preservative-free methyl prednisone steroid injections from the New England Compounding Center in Framingham, Massachusetts. A total 754 patients were infected in 20-states and 64 patients died because of the infection. Texas had two patients who were infected with fungal meningitis, but these patients were treated and recovered. In order to assure that Texas patients were receiving safe products from pharmacies licensed by TSBP, the agency put a priority for inspection on sterile compounding pharmacies. However, without additional staff, we could not do these inspections as quickly. During the 2013 Texas Legislative Session, the Legislature funded the agency for an additional five compliance inspectors. If the agency had SDSI status, we could respond to situations like this in a much more timely matter and without having to wait for a Legislative Session.

During the 76th (2005) Legislative Session, S.B. 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 services rendered. The 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.

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 to have 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.

In July 2015, the Sunset Advisory Commission issued a report titled “Self-Directed Semi-Independent Status of State Agencies.” This report determined “that the State has an undefined and inconsistent approach to managing the SDSI process, which exposes the State to unnecessary risk. No single entity is responsible for administering and overseeing the SDSI process. Therefore, a comprehensive process with clearly-defined requirements for obtaining and retaining SDSI status does not exist.”

C. Possible Solutions and Impact

If the legislature considers SDSI status for agencies and if TSBP is 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:
 - 99 employees will be removed from the state payroll; and
 - More than a \$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 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 a number of 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. Brief Description of Issue

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.

B. Discussion

The presence of these “Pill-Mill” Pharmacies in Houston and other Texas cities is having a dramatic and deadly effect on the citizens of Texas. In 2013, the CDC called prescription drug abuse a “growing epidemic.” Nearly three of four 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.

While there has been a marked decrease in the use of some illegal drugs like cocaine, data from the National Survey on Drug Use and Health (show that nearly one-third of people aged 12 and over whom used drugs for the first time in 2009 began by using a prescription drug non-medically. Some individuals who misuse prescription drugs, particularly teens, believe these substances are safer than illicit drugs because they are prescribed by a healthcare professional and dispensed by a pharmacist.

Due to the huge number of prescribers and pharmacies involved in this type of activity, in the Houston area, TSBP signed a contract with the Drug Enforcement Administration in 2012 for one field investigator to work full-time with a Drug Enforcement Administration Task Force in the Houston area. This contract ended in October 2014. Unfortunately, at the end of this two-year period, DEA determined not to seek prosecution of any of the pharmacies investigated by the Task Force. 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.

C. Possible Solutions and Impact

Since these cases are very difficult to investigate, prepare the case for hearing and prosecute the case, the agency must have additional funds and personnel to pursue the prosecution of pharmacies and pharmacists who are willfully ignoring the law and dispensing prescriptions that are not issued for a valid medical use.

3. Underutilization of the Clinical Knowledge and Skills of Pharmacists in the Current Health Care System**A. Brief Description of Issue**

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.

B. Discussion

The positive outcome for patients and cost savings to the healthcare system 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.

C. Possible Solutions and Impact

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**A. Brief Description of Issue**

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.

B. Discussion

Since 1982, the Board has following a “preventative” approach to enforcement based upon the belief that 95% 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. This successful educational program must expand and continue.

C. Possible Solutions and Impact

In developing this educational program, the Board should use all of the tools available to educate licensee including written information with the TSBP Newsletter, the TSBP website, social media such as Facebook, Twitter, YouTube, etc., presentations in person and on the Web, and compliance inspections.

5. Retirement of the Current Executive Director**A. Brief Description of Issue**

The current executive director has indicated that she will retire in August 2017. The Board will 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 \$171,688 per year. However, the legislature has specified that the executive director’s salary be set at \$127,280 for FY2016-2017.

B. Discussion

The current salary for the position results in the executive director position being very difficult to fill, since this salary is less than that paid to some beginning pharmacists and certainly less than that paid to pharmacy managers. A 2014 survey of pharmacist’s salary conducted by “Drug Topics” reported the annual base salary for staff pharmacists is between \$116,000 and \$140,000 a year (Note: this salary is for staff pharmacist, not managers. Salary.Com reports that pharmacist managers make a median salary of \$137,836).

A survey of the salaries of the Executive Director of Oklahoma, Arkansas, and Louisiana show that the average salary for these individuals is \$140,000 or \$13,000 less than that of the Executive Director in Texas. It should be noted that Texas licenses 52% more pharmacies, 55% more pharmacists, and 136% more pharmacy technicians than OK, LA, and OK combined.

C. Possible Solutions and Impact

If the salary for the Executive Director position is not increased to be competitive, the agency will have a very difficult time hiring a person with the management, strategic thinking, and planning skills necessary to manage the agency.

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' manager salaries and one that recognizes the qualifications necessary for the executive director.

6. Maintaining Agency's Leadership Position in Pharmacy Practice Regulation through Adequate Staffing and Adequate Compensation of Highly Qualified Agency Personnel

A. Brief Description of Issue

The Board of Pharmacy needs to continue its partnership with the public and profession to aggressively promote the highest level of pharmacy services possible. In addition, opportunities exist for the Board to continue its national leadership role in progressive regulation. While being "out-front" is never comfortable, the pharmacy profession in Texas has come to expect the Board to act in a key leadership position while addressing public needs. However, given the growth in both size and complexity of pharmacy practice and healthcare, multiplied by the continued increase in demand for services, the agency's ability to accomplish its mission is severely challenged. The agency must aggressively pursue activities to retain and increase the number of highly qualified personnel employed by the agency.

B. Discussion

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 and stay focused on enhanced patient outcomes, with continued examination of those issues that are truly important, embracing current technology and acting aggressively and fairly to hold pharmacists accountable for the patient care they provide. In order to protect the public health, safety and welfare, the agency must be adequately staffed. TSBP regulates a total population of 98,763 entities (as of year-end FY14) with a smaller number of FTEs than other regulatory agencies who are regulating the same or a smaller number of entities. Moreover, the agency's population is growing. In addition, the salaries of key positions are way below not only market, but other state agencies. Key positions that are currently underpaid contribute to turnover. If the agency experiences high turnover in these areas, it will certainly cripple the agency's ability to function efficiently and effectively. During the 2015 Legislative Session, the agency requested funding to reclassify key positions but this funding was not granted.

C. Possible Solutions and Impact

The Board should continue to work with stakeholders to strike the appropriate balance in achieving its public protection mandate, yet be flexible enough to develop regulations to facilitate pharmacy practice changes. The Board should continue to seek increased funding from the Texas Legislature to hire an adequate number of staff to meet the increasing demand for licensing and enforcement services. In addition, the Board should continue to seek increased funding from the Texas Legislature to adequately compensate key positions.

7. Physician Owned Pharmacies and Physician Dispensing

A. Brief Description of Issue

In 1981, Attorney General Mark White issued A.G. Opinion 410 regarding the dispensing of prescriptions by a physician (practitioner). This opinion stated:

A practitioner may not practice pharmacy unless he is also licensed as a pharmacist under this act. No licensed pharmacy may legally operate unless there is a pharmacist-in-charge who is a licensed pharmacist. A practitioner who undertakes to fill a prescription of another practitioner engages in the practice of pharmacy, which he may not do unless licensed as a pharmacist. A practitioner who dispenses drugs to his own patients from his office, and charges a separate fee therefor, is engaged in the practice of pharmacy, which he may not do unless licensed as a pharmacist.

In each of the last three sessions, the Texas Legislature has considered bills that would change the law and allow physicians to dispense prescriptions from their office.

B. Discussion

The bills that have been introduced during the 2013, 2014, and 2015 sessions, have generally limited the dispensing in physician's offices to certain "aesthetic pharmaceuticals" such as Bimatoprost (Latisse), Hydroquinone (Lustra, Claripel), and Tretinoin (Retin A).

None of these bills has become law. However, during the 2013 session, a bill did pass the Legislature. Governor Perry vetoed this bill and recognized in his veto proclamation the important role of the pharmacist and the Board of Pharmacy by stating the following: "SB 227 would circumvent existing safeguards for the dispensing of certain prescription cosmetic drugs by allowing physicians and optometrist to sell these medications directly. It is the role of the pharmacists – who are trained specifically in drug interactions, side effects and allergies – to dispense the medications. Additionally, the State Board of Pharmacy has the authority to inspect pharmacies to ensure drugs are stored securely and at safe temperatures."

It is expected another bill that would allow limited dispensing by physicians will be introduced during the 2017 session.

C. Possible Solutions and Impact

The Board and the profession may need to review the issue to see if there might be a way to allow some limited, dispensing in physician's office provided oversight of the dispensing by a pharmacist is provided. As Governor Perry indicated in his "Veto Proclamation" in 2013, "It is the role of the pharmacists – who are trained specifically in drug interactions, side effects and allergies – to dispense the medications. Any changes to this law need to recognize this important role of the physician in diagnosing and prescribing prescription drugs and the important role of the pharmacist in conducting a drug utilization review of all medications taken by a patient and dispensing the prescription."

8. Dual Standards for Pharmacy Practice in Small and Large Hospitals

A. Brief Description of Issue

Currently, Texas has different requirements in the Pharmacy Act for pharmacy services in large hospitals (101 beds or more) and small hospitals (100 beds or less).

B. Discussion

The Pharmacy Act in Section 562.1011 (Operation of Class C Pharmacy in Certain Rural Hospitals) sets up a different standard of practice in rural hospitals with 75 beds or fewer, if the hospital is 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. This section allows pharmacy technicians to be supervised by nurses rather than pharmacists.

C. Possible Solutions and Impact

The Board believes that recent advancements in technology will allow pharmacist to supervise the work of pharmacy technician's in a more cost effective manner. This will allow increased protection of patients' health and to the elimination of the dual standard.

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

A. Brief Description of Issue

The Texas Pharmacy Act contains provisions that authorize the agency to fund a Peer Assistance Program for pharmacists impaired by chemical abuse or mental or physical illness. However, there is not such program for pharmacy technicians.

B. Discussion

Since 1983, the Texas Pharmacy Act (Act) has authorized 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. In FY2015, the one-year completion rate for pharmacists and students in the program was 74%. In addition, 66% of these individuals who completed one year of sobriety in FY2012, completed an additional 3 years of sobriety in FY2015 [i.e., the recidivism rate (relapse) was 34% in FY2015]. These numbers are much higher than those achieved in other recovery programs.

C. Possible Solutions and Impact

The Texas Pharmacy Act should be amended to allow pharmacy technicians to participate in the program.

INTERNAL ISSUES

The following three 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. Appropriate Level of Training and Supervision for Pharmacy Technicians

A. Brief Description of Issue

The practice of pharmacy is evolving and pharmacists are now required to perform more: cognitive services such as review of patient's prescriptions to assure that drugs do not interact with others taken by the patient; and professional services such as administration of immunizations and vaccines to patients. This evolution of the pharmacist's role is placing more time demands on the pharmacists and a corresponding desire to delegate more functions to pharmacy technicians.

B. Discussion

Currently, the Texas Pharmacy Act specifies that a pharmacy technician is individual employed by a pharmacy "whose responsibility is to provide technical services that do not require professional judgment regarding preparing and distributing drugs and who works under the direct supervision of and is responsible to a pharmacist." The Act also specifies that a pharmacy technician must have:

- a high school diploma or a high school equivalency certificate or be working to achieve an equivalent diploma or certificate; and
- passed a board-approved pharmacy technician certification examination.

Because pharmacists are spending more and more time conducting "cognitive services" such as drug use review and counseling patients on how to use their prescription drugs, the demand to expand the duties of pharmacy technicians is growing.

As the demand for expanding the duties of pharmacy technicians grows, the discussion regarding the appropriate level of training and education of pharmacy technicians also grows. Most believe that it is imperative to "raise" the level of practice of pharmacy technicians and to this, the pharmacy technician must be better educated.

In 2013, the Pharmacy Technician Certification Board (PTCB) announced changes to their certification program that will require individuals to have completed an American Society of Health-System Pharmacists (ASHP) accredited training program prior to taking the PTCB examination by 2020. This decision will affect the TSBP since pharmacy technicians must have taken and passed the PTCB examination in order to become a pharmacy technician in Texas.

C. Possible Solutions and Impact

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 held two meetings and presented its report to the Board at its meeting on May 6, 2014. Included in this report were several suggestions for the expansion of duties that could be performed by pharmacy technicians in both community and hospital pharmacies. As of August 2015, the Board has not taking action on the suggestions from the Task Force.

The Board will continue to study the duties and education of pharmacy technicians in Texas and will make recommendations for changes to the Pharmacy Act when a consensus is reached.