

## **Leg IX. Major Issues**

### **ISSUE #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.

## **ISSUE #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.

## **ISSUE #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.

#### **ISSUE #4: INCREASE LICENSEE COMPLIANCE WITH LAWS AND RULES RELATING TO THE PRACTICE OF PHARMACY THROUGH EDUCATION OF LICENSEES**

##### **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.

#### **ISSUE #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.

## **ISSUE #6: 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.

## **ISSUE #7: 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. 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 Act to eliminate the dual standard established in the Pharmacy Act and to require pharmacy technicians to be supervised by a pharmacist.

## **ISSUE #8: 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.

## **ISSUE #9: 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.

## **ISSUE #10: 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 facility pharmacy practice changes. The Board should continue to seek increased funding from the Texas Legislature to hire and 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.