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

Issue Statement

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

The Board must find ways to support the increased use of technologies that enable pharmacists to better serve the public health, safety, and welfare. This includes finding ways to balance productivity with safety, automation with accountability, and pharmacy service with patient confidentiality. Additionally, the National Association of Boards of Pharmacy (NABP) and the Food and Drug Administration (FDA) are both working on rule language to facilitate the use of electronic transmission of prescription data. TSBP should work with these agencies to enhance the tools available to prescribers and pharmacists.

Explanation of Issue

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

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

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

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

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

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

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

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

The profession will continue to seek ways to automate the prescription transmission process between practitioners and pharmacies. Besides written and verbally communicated prescriptions, the Board has, for many years, allowed prescriptions to be electronically transmitted between practitioners and pharmacies. Electronic prescribing may be one of the most effective methods to reduce dispensing errors due to illegible handwriting. However, the Board must be aware of the potential for other types of errors to occur when using electronic prescribing. Entrepreneurs have been monitoring this type of prescription transmission and are seeking ways to facilitate the process. This includes use of the Internet, e-mail, personal digital assistants (PDAs), fax-to-fax or fax-to-computer, prescription depositories, as well as direct computer-to-computer links between practitioners and pharmacies.

This raises the concern of unauthorized access to the confidential healthcare information contained in these prescriptions. To ensure patients' confidentiality, prescribers should be required to produce an *audit trail* for prescriptions electronically submitted to pharmacies.

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

(2) Storage of Prescription Information

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

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

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

(3) Delivery of Pharmacy Services

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

(A) Prescription Drug Products

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

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

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

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

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

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

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

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

(B) Drug Information Services

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

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

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

(4) Accountability for Pharmacy Services

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

(5) Patient Confidentiality

Patient confidentiality, as viewed by a healthcare professional, may not be the same as that expected by a patient in the healthcare system. Whereas a healthcare professional may consider sharing confidential information with another healthcare professional caring for a patient as being in the best interest of that patient, the patient may have a much stricter interpretation of confidentiality where only those entities specifically noted by the patient may receive confidential information. The issue of patient confidentiality is a hot topic at both the state and federal levels, as demonstrated by the Health Insurance Portability and Accountability Act (HIPAA), followed by Texas law (passed by the 78th Texas Legislature), and will be an evolving issue during the next five years.

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

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

(6) Internet Pharmacies

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

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

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

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

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

- Provisions that require the Board to maintain a list of all licensed pharmacies that maintain an Internet web site including the pharmacy's name, license number and state in which it is located. In addition, the bill requires all pharmacies that maintain a web site to post information on how a consumer may file a complaint regarding the pharmacy with the Board.

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

- A provision that required the Texas State Board of Pharmacy to inspect and authorize Canadian pharmacies to sell prescription medications to patients in the State of Texas. The law required the Board to designate from one to ten Canadian pharmacies as having passed inspection, and thus allow the pharmacies to ship prescription drugs into Texas. The Board was also mandated to provide information on these pharmacies on its web site to facilitate ordering of drugs by Texas

residents. Because the Board had received a letter from the Federal Food and Drug Administration stating that this portion of S.B. 410 was in conflict with federal law, the Board asked the Texas Attorney General for an opinion on whether the law was, in fact, in conflict with federal law. On December 21, 2005, Attorney General Greg Abbott issued Opinion #GA-0384 in response to the Board's request. The opinion states that designating certain Canadian pharmacies, promoting them on the Board's web site, and permitting Texas consumers to import prescription drugs from Canada would violate federal law.

Impact on Agency

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

The marketplace will increasingly demand *less regulation* in order to provide less costly services to the healthcare consumer. Therefore, as the use of technology expands, the agency will be tasked to determine the critical functions that must be controlled, supervised, or performed exclusively by pharmacists in order to promote, preserve, and protect the public health.

Agency Strengths and Opportunities

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

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

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

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

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

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

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

Agency Weaknesses and Constraints (Threats)

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

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

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

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

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

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

Agency Initiatives

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

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

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

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

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

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

- The legal use of technology in pharmacy practice; and
- Patient confidentiality.