

EXTERNAL/INTERNAL ASSESSMENT

IDENTIFICATION OF ISSUES

In developing its Strategic Plan, Board and agency staff sought to identify and analyze those trends and resulting issues expected to have the most significant impact on the profession and regulation of pharmacy over the next five years. As described in the *Description of Agency Planning Process (Appendix A)*, the Board conducted an internal and external assessment, with the following four issues identified and detailed:

POLICY ISSUE #1 – The Changing Focus of Pharmacy Practice

POLICY ISSUE #2 – Increased Use of Technology in the Practice of Pharmacy

POLICY ISSUE #3 – Pharmacy Personnel and Working Conditions

POLICY ISSUE #4 – To Maintain the Agency=s Leadership Position in Pharmacy Practice Regulation and Establish a Key Leadership Position for Addressing Public Needs

POLICY ISSUE #1 – THE CHANGING FOCUS OF PHARMACY PRACTICE

Issue Statement

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 likely to be generated not at the pharmacist-patient level. The savings will be generated at the level of patients' therapeutic successes and the resulting reductions in hospitalizations, surgeries, repeated office visits, nursing home admissions, and prolonged illnesses that result from patients using their medications improperly.

Explanation of Issue

In recent years, the complexity of the healthcare system and the changing ways in which healthcare is delivered similarly changed the way pharmacists practice. Within the next five years the practice of pharmacy will continue to be changed by many factors, such as the aging of Texas' population, increasingly complex and expensive drugs, drug regimens, and diagnostic technologies emerging from the biotechnology industry, and healthcare reform. This will necessitate the viewing of pharmacy by professionals and patients in a way different from our century-old image of the pharmacist *behind the counter* inside the pharmacy.

The Texas Pharmacy Act recognizes this shift to a more patient-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 are currently providing expanded patient care services such as drug therapy management, administration of immunizations, disease state management, disease screening, and health promotion and disease prevention.

Although the Texas Pharmacy Act currently allows pharmacists to perform drug therapy management under written protocol of a physician and to administer immunizations and vaccines, there are limitations to these authorities. In the case of drug therapy management under written protocol of a physician, pharmacists may initiate and modify drug therapy of patients. However, pharmacists cannot sign written prescriptions in the same manner as physician assistants and advanced nurse practitioners are allowed. Likewise, the authority to administer medications is limited to immunizations and vaccines, and the patient must be 14 years of age or older. To more fully use these tools, the Act should be amended to remove these restrictions. In addition, for pharmacists to continue providing these expanded services, the buyers and sellers of healthcare must recognize and understand the pharmacist's value to the patient.

The buyers and sellers of healthcare will continue to scrutinize the system to ensure that care and product are being provided in the most *cost-effective* manner. The role of pharmacists will be viewed in the context of what level of care and services a patient receives. Financiers will be monitoring pharmacy practice in all settings to determine if pharmacists' services are cost-beneficial or if these services could be provided at reduced costs (*e.g.*, could pharmacist services be provided by another health professional?). Policymakers, third-party payers, the public, and pharmacists need to be continually reminded that appropriate drug therapy is generally safer and more cost-effective than other forms of treatment and that the personal and economic consequences of inappropriate drug use are enormous.

If the profession of pharmacy does not move toward a cost-effective, patient-oriented practice, it can expect pharmacy technicians and/or technological advances to replace pharmacists who dedicate themselves solely to the dispensing and sale of medications and other products.

A big step to the recognition that appropriate drug therapy is cost-effective and necessary is the inclusion of medication therapy management programs (MTM) in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA). The passage of this legislation is the first time that Congress recognized in national legislation the importance of pharmacist-provided drug therapy management. In addition, it is the first time that pharmacists will be allowed to bill for Medicare-related patient care services.

Pharmacists were the only healthcare professionals specifically named in MMA to provide medication management services. However neither MMA nor the rules adopted to implement MMA specify that only pharmacists may provide these services.

One problem in the implementation of the MTM provisions was that there was no consensus definition of medication therapy management services. The American Pharmacists Association convened a broad group of national pharmacy organizations and a consensus definition was adopted in July 2004. This consensus definition did not mirror the expectation of MTM as spelled out in the MMA statute.

A big step toward the reimbursement to pharmacists for MTM services occurred in July 2005, when the American Medical Association's official list of procedures added to its chapter on cognitive services, three codes for MTM – initial service, subsequent service, and additional time, each in 15-minute blocks. The Current Procedural Terminology (CPT) manual describes MTM, in part, *as a form of face-to-face assessment or intervention between a pharmacist and a patient or caregiver that is provided to optimize and improve the response to medications and to help avoid potential treatment-related medication interactions or complications.*

The CPT definition also notes that MTM is distinct from information at the point of dispensing and that it involves *a documented review of the patient, history, chief complaint or concern, medication profile (Rx and nonprescription), and any recommendations for improving health outcomes and the level of treatment compliance. These codes are to be used by pharmacists.*

MTM is a tool for pharmacists to use. The data generated from MTM documentation will be used to prove that drug therapy management is effective in improving patient's health. Over the next few years pharmacists will be challenged to provide these services and document their effect on the patient's health. As implementation of MTM moves forward, the Board will need to monitor its implementation and be ready to make modifications in agency rules and or law, if necessary, to allow pharmacists to improve patient care. The greatest need for regulation may be the adoption of minimum requirements for documentation of MTM activities. Thorough documentation is needed for pharmacists to validate their activities and to justify appropriate reimbursement as well as for the agency to monitor all provisions of pharmaceutical care.

In addition to providing drug therapy management and proving the value of their services, pharmacists must also work with other healthcare professionals to assure the safety of the healthcare system. The issue of the safety of the healthcare system has been the focus of numerous reports including a November 1999 report from the Institute of Medicine (IOM). This report titled: *To Err is Human: Building a Safer Health System* states that medical errors kill some 44,000 people in U.S. hospitals each year. The report further states medication errors cause more than 7,000 deaths annually both in and out of hospitals. It is encouraging that the IOM study recognized the value of the pharmacist and stated: *The pharmacist has become an essential resource . . . access to pharmaceutical information must be available all the time.* Additionally, one of the IOM strategies calls for increasing pharmacy participation in medical rounds and in other areas to decrease the potential for error.

In 1999 Texas became the first state to pass legislation establishing pharmacy peer review committees. 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 continuous quality improvement program (CQI) that includes a peer review for the identification and prevention of dispensing errors. The Board has no studies or data to indicate that pharmacies that establish CQI programs make fewer dispensing errors. However, pharmacies that have implemented such programs have indicated that the establishment of such programs has allowed management to identify problem areas and may have reduced the occurrence of serious errors. For example, one pharmacy chain used the data to determine that 80 percent of their errors occurred in 20 percent of the stores. This chain implemented changes in these stores and dramatically reduced errors chain-wide.

During the last four years, the Board has ordered almost 150 pharmacies to implement CQI programs. This number represents less than 3 percent of the pharmacies licensed by TSBP. In most cases, owners of multiple pharmacies have implemented CQI programs in all of the pharmacies, once the Board has ordered one of the pharmacies to implement these 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 a CQI program.

Implementation of CQI programs is crucial for pharmacies to develop a system to prevent medication errors; however, there are other actions that the Board could take to assist in preventing errors. For example, the Board could suggest that the legislature amend the Pharmacy and Medical Practice Act to prohibit physicians from using "as directed" instructions on prescriptions and to strengthen the

requirement for physicians to include an indication for use on the prescription. The use of clear and definitive instructions on prescriptions, including the indication for use, not only helps the patient understand how to take the medication but also allows another check for a pharmacist to verify appropriate therapy. In addition, the Board should encourage the use of electronic systems for the transmission and receipt of prescriptions. These systems reduce the chance of "bad handwriting" causing errors. In addition, the Board should support initiatives by organizations such as the Institute for Safe Medication Practices and the Joint Commission on Accreditation of Healthcare Organizations to eliminate the use of dangerous abbreviations and dose expressions. Symbols and abbreviations are frequently used to save time and effort when writing prescriptions. However, some symbols and abbreviations have the potential for misinterpretation or confusion. Examples of problematic abbreviations include "U" for "units" and "µg" for "micrograms." When "U" is handwritten, it can often look like a zero. Likewise, using the "µg" instead of "mcg" has also been the source of errors because when handwritten, the symbol "µ" can look like an "m."

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

(1) Regulating the Profession

The first issue identified in *Crossing the Quality Chasm: A New Health System for the 21st Century* was *Regulation of the Profession*. Within this issue IOM identified the following two areas:

- (A) Assessment of the competence of a healthcare provider is identified 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.

To assist pharmacists in developing a CPD plan, the National Association of Boards of Pharmacy has developed a Pharmacist Self-Assessment Mechanism (PSAM). PSAM is an evaluation tool intended to assist pharmacists in obtaining objective, non-punitive feedback on their knowledge base. The PSAM is based on a blueprint that is applicable to general pharmacy practitioners in all practice settings. On completion of PSAM the pharmacist will receive a report indicating the percentage of questions answered correctly in each of the five competency areas to allow pharmacists to see areas that may need further study.

The Board should continue to monitor the development of continuing professional development and consider replacing the current mandatory continuing education requirements with a requirement based on a continuing professional development model. A part of the CPD model could be the maintenance of a portfolio of CPD activities by each individual pharmacist.

- (B) With regard to the second area, scope-of-practice acts, the report states the following:

Although scope-of-practice acts are motivated by the desire to establish minimum standards to ensure the safety of patients, they also have implications for the changes to the healthcare system recommended in this report. Since any change can potentially affect scope-of-practice acts, it can be difficult to use alternative approaches to care, such as telemedicine, e-visits, non-physician providers, and multi-disciplinary teams, all of which can help in caring for patients across settings and over time.

Regulatory agencies and professional associations for all of the healthcare professions must work to identify methods to work together to provide the best healthcare to their patients. As the report identifies, healthcare practitioners and regulators must work through these scope-of-practice issues and design a regulatory scheme that both protects the public's interest and supports the ability of healthcare professionals and organizations to innovate and change to meet the needs of their patients.®

(2) Use of Clinical Decision Support Systems (CDSS)

The second issue identified in *Crossing the Quality Chasm: A New Health System for the 21st Century* is use of clinical decision support systems (CDSS). The report defines CDSS as *software that integrates information on the characteristics of individual patients with a computerized knowledge base for the purpose of generating patient-specific assessments of recommendations designed to aid clinicians and/or patients in making clinical decisions*. Pharmacists have been the leader in the healthcare field in using computer support in daily practice. However, to make the best use of the systems, pharmacists must have access to the patients' medical records.

Access to information could be provided through direct contact with the prescriber, a personalized patient ID card (*smart card*), centralized health information and patient profile, or other mechanisms. Concerns regarding intervention into the patient-doctor relationship and confidentiality of patient records will certainly emerge as issues to be addressed.

Medical confidentiality issues were addressed federally through the passage of the Health Insurance Portability and Accountability Act (HIPAA). During the 2001 Session, the Texas Legislature passed a comprehensive medical privacy act that encompasses the provisions of HIPAA and is more stringent than HIPAA in some areas. Both of these pieces of legislation appear to allow the sharing of medical information among healthcare providers, including pharmacists. It is important for pharmacists to monitor the implementing of regulations for these laws to assure that pharmacists may have access to important patient medical information.

Patients respect the information given to them by pharmacists. Pharmacists have consistently been rated as one of the most trusted professionals in the nation. Couple this with the fact that pharmacists are the most accessible healthcare professionals, and it follows that pharmacists are in an excellent position to fulfill an expanded service role to the public. With increased documentation showing that pharmaceutical care will benefit the patient, the expanding role of the pharmacist will be more widely accepted.

However, since non-pharmacists (corporate managers, some managed care officials, insurers, etc.) make many policy decisions about how pharmacy will be practiced, the delivery of true pharmaceutical care will be threatened unless healthcare policymakers and payers determine that pharmaceutical care is cost-effective and establish methods to compensate pharmacists for this service.

Pharmaceutical care will have a positive impact on public health by achieving desired medical outcomes, thereby improving patients' quality of life and reducing healthcare costs and perhaps by demonstrating that pharmaceutical care is indeed cost-effective.

Impact on Agency

The change of the focus of pharmacy practice to one that is more patient-oriented with pharmacists providing an ever-increasing number of expanded/non-traditional services to patients makes it imperative that Board members and staff continually monitor developments in pharmacy practice to be aware of any potential dangers to the public. If the agency is aware of potential dangers, it is better able to recommend laws and rules to assure that pharmacists are able – and willing – to competently provide these expanded services and provide advice and assistance to other health practitioners and to the patient.

Trends indicate that pharmacists do not have control over their pharmacy practice environment. Since corporate control exists in virtually all practice settings, non-pharmacists and non-dispensing pharmacists are making decisions about how pharmacy is to be practiced. Pharmacists should always consider the health of the patient when implementing procedures established by others. In addition, the agency must monitor the practice to assure that pharmacists are able to provide valuable pharmaceutical care

services to patients. If the practice is limited or prohibited by corporate owners, the agency may be required, in the best interest of Texans, to implement rules mandating certain aspects of pharmaceutical care. In addition, the federal government could establish these standards in the absence of appropriate actions by state boards of pharmacy, given the precedent set by OBRA '90 and the recommendations of the Institute of Medicine.

The goals of healthcare reform include greater individual security, improved access to care, more cost-effective care, and maintenance of quality. This reform is an evolving process that will ultimately rewrite all the relationships in healthcare delivery and financing. Healthcare reform will also be occurring at the state level, as well as the federal level. The agency must monitor activities at the state level and provide input into any state legislation, ensuring that pharmaceutical care is incorporated into Texas' overall health plan.

As the role of the pharmacist expands to include shared responsibility for the quality of patient care and patient outcomes, the agency will need to adapt its enforcement efforts to ensure that pharmacists are

being effective. For example, the Board may need to implement measures to ensure that pharmacists are performing (and are competent to provide) such functions as:

- # Drug utilization review;
- # Drug therapy management;
- # Monitoring their patients for drug abuse;
- # Providing effective counseling; and
- # Directly monitoring drug use in certain settings.

Such efforts would represent a departure from the traditional focus of pharmacy regulation, structure, and process to a focus on the results instead of the process. The goal would be not to abandon structure and process, but to link them with the final outcome. The Board is using the concept of *outcome-based regulation* in assessing disciplinary action on pharmacists and pharmacies that have committed dispensing errors. In addition to a sanction on the licensees involved, the Board has required the owner of the pharmacy license to review the dispensing process in the pharmacy and to develop and implement a quality assurance system to detect or anticipate errors, to rectify errors that have occurred, and to reduce the likelihood of future errors. Surely this type of sanction is better for the licensee and the public since it offers the potential for reducing the number of prescription errors.

Hospital pharmacists are currently defining quality of care in terms of outcomes as a result of standards from the Joint Commission on Accreditation of Healthcare Organizations (JCAHO). As community pharmacy practice moves to incorporate the concept of pharmaceutical care, regulatory and enforcement activities must also move to regulate based on quality assurance standards, not just performance of process-oriented tasks. The laws and rules must be structured such that they specify the desired outcome but not detail all of the steps necessary to obtain that outcome. This type of structure will allow pharmacists the flexibility to use innovative practice ideas while protecting the public by specifying positive patient outcomes.

The Texas State Board of Pharmacy's support of the use of outcome-based regulation may require retraining of enforcement personnel for review of quality-related records and procedures. The agency may need to employ *clinical consultants* or retrain pharmacist employees in these areas so they can assess whether clinical services provided by the pharmacist helped or harmed the patient.

Agency Strengths and Opportunities

- (1) The current definition of the *practice of pharmacy* in the Texas Pharmacy Act:
 - (A) Includes *provision of those acts or services necessary to provide pharmaceutical care, drug therapy management, and administration of immunizations and vaccines under the written protocol of a physician*; and

- (B) Is broad enough to include new responsibilities and activities necessary for pharmacists to *dispense/administer* advanced technological drug products and devices in the delivery of pharmaceutical care.
- (2) In May 2001, the Board published *Guidelines for Establishing Pharmacist Peer Review Committees* to assist pharmacists and pharmacy owners in establishing continuous quality improvement programs that include peer review. These programs should allow pharmacists to thoroughly study their dispensing and distribution systems in order to establish a safer system.
- (3) The Texas Dangerous Drug Act gives the agency the authority to regulate prescription drugs and devices regardless of where these drugs are used or delivered.
- (4) A precedent exists for expanded roles for Texas pharmacists, because:
 - (A) The federal government, through the Department of Health and Human Services= Office of the Inspector General, has supported the clinical role of community pharmacists;
 - (B) The Texas Pharmacy Act now recognizes drug therapy management under protocol from a physician in any practice setting and the administration of drugs, under certain conditions, as a role of the pharmacist. In addition, this amendment to the Act was supported by the medical and nursing community; and
 - (C) The federal government, through the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 has recognized the value of pharmacist provision of medication therapy management programs.
- (5) Current Board rules require patient counseling for patients at the pharmacy, Drug Utilization Review (DUR), and provision of written information about prescription medications.
- (6) Current Board rules require patient outcome monitoring in some practice settings.
- (7) The Board of Pharmacy has embraced the concept of *outcome-based regulation* and is using it in imposing disciplinary action by requiring the licensee(s) to develop and implement a continuous quality assurance program to detect errors, to rectify errors that have occurred, and to prevent future errors.
- (8) The pharmacist's credibility with the public in terms of honesty and integrity will help the profession and the agency to move pharmacists toward new or expanded roles.
- (9) The agency has the authority to establish task forces composed of pharmacists and other professionals who have special expertise to advise the Board.
- (10) There is a vast pool of knowledgeable resource persons in Texas' pharmacy educational institutions and in its health professions available to the agency.

Agency Weaknesses and Constraints (Threats)

- (1) In spite of the need for healthcare to be based on a multi-disciplined healthcare delivery system, expanded roles for pharmacists may be perceived as threatening the *turf* of other health professionals such as physicians and nurses. Resolution of problems related to advanced technological drugs, devices, and dosage forms may, in some cases, be thwarted by *turf* battles between the health professions.
- (2) Some pharmacists may perceive that providing *pharmaceutical care* increases their liability. In addition, some pharmacists may be limited in the extent of *pharmaceutical care* services they are able to effectively provide because they don't have access to information in the patient's medical records (*e.g.*, pharmacists may not know the patient's diagnosis or the outcome sought by the physician).
- (3) If pharmacists are not allowed to fully use the assistance of technology and/or pharmacy technicians, but are required to provide *pharmaceutical care*, the cost of pharmacy services could rise significantly.
- (4) Although there is a documented need, the agency has virtually no resources to address the need for consumer education about the use, abuse, and misuse of prescription drugs so critical to positive patient outcomes.
- (5) The current definition of dangerous drugs includes *devices which require a prescription*, but does not include other types of devices.
- (6) Although the current definition of the *practice of pharmacy* in the Texas Pharmacy Act is broad enough to include new responsibilities and activities for pharmacists to *dispense/administer* advanced drug products and devices, the Act may have to be amended to clarify that these activities are included.
- (7) Some of the *corporate* (independent and chain) entities that own pharmacies in Texas talk about their *commitment* to the concept of pharmaceutical care, but the experience of the agency is that the main emphasis of these corporations is on the *bottom-line* or the number of prescriptions dispensed. Therefore, when it becomes apparent that additional resources are necessary to provide pharmaceutical care, these resources may not be readily provided.

Agency Initiatives

- (1) Continue to include outcome-based initiatives in the Board's disciplinary orders.
- (2) Work with the associations and the legislature to amend the Pharmacy Act to give the Board the authority to mandate that all pharmacies implement continuous quality improvement programs that include peer review.

- (3) Develop a compliance inspection process based on the concept of outcome-based regulation.
- (4) Be an active participant with other healthcare providers, legislators, and regulators in establishing initiatives regarding protecting a patient's confidential healthcare information.
- (5) Be an active participant with other healthcare providers, legislators, and regulators in establishing initiatives regarding medication errors, including possibly amending the Pharmacy and Medical Practice Acts to prohibit physicians from using "as directed" instructions and problematic abbreviations on prescriptions and to strengthen the requirement for physicians to include an indication for use on the prescription. The use of clear and definitive instructions on prescriptions, including the indication for use, not only helps the patient understand how to take the medication but also allows another check for a pharmacist to verify appropriate therapy. In addition, the Board should encourage the use of electronic systems for the transmission and receipt of prescriptions. These systems reduce the chance of *bad handwriting* causing errors, as well as increase the breadth of information that is available to the healthcare providers at the time of care.
- (6) Monitor the progress of the profession in establishing continuous quality improvement programs and the effect these programs have on reducing medication errors.
- (7) Monitor the implementation of Medication Therapy Management Programs under the Medicare Part D legislation and be ready to make modifications in agency rules and/or law, if necessary, to allow pharmacists to improve patient care.
- (8) Work in partnership with other state and national pharmacy regulatory organizations and professional associations to ensure that the Act continues to provide the greatest protection for the citizens of Texas while not inhibiting the implementation of new and progressive healthcare and pharmaceutical care systems. It is crucial that the Texas pharmacy regulations not trigger federal preemption requirements in areas such as medication therapy management, electronic prescribing, and electronic medical records.