

POLICY ISSUE #4 – TO MAINTAIN THE AGENCY’S LEADERSHIP POSITION IN PHARMACY PRACTICE REGULATION AND ESTABLISH A KEY LEADERSHIP POSITION FOR ADDRESSING PUBLIC NEEDS

Issue Statement

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.

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 pharmaceutical care, especially in light of new challenges brought about by unexpected bioterrorism events, unplanned natural disasters, growth in prescription drug volume, and pharmacist shortages. 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 challenges facing the agency. Additionally, the agency must aggressively pursue avenues to increase and retain highly qualified personnel while continuing to implement quality management practices. Given the pace of technological advances, the agency must also carefully encourage 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. 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.

Explanation of Issue

Some of the areas identified by the Board in its external assessment include the following observations by board customers.

- (1) The Board should continue to play a public advocacy role as it relates to educating the public about the value of pharmaceutical care.
 - (A) Consumers should be educated on the proliferation of misinformation (e.g., Internet scams, e-mails offering prescription drugs without a prescription, and direct-to-consumer advertising); the dangers of *look alike/sound alike* products; the importance of vaccines; dietary supplements; and prevention of medication errors at home.
 - (B) Consideration must be given to the dramatic increase in the state’s aging population and the associated growth in prescription volume.
 - (C) Consumers, as well as healthcare professionals, are seeking information and advice concerning alternative medicine, including herbal and other nutritional supplements. Alternative drug/herbal therapies are increasingly prescribed by licensed physicians or recommended by other healthcare providers. Efforts should be made to incorporate

complete drug histories into patient charts, including herbal medicines usage. 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) The Board should focus on preparedness for public health emergencies where pharmacist participation is crucial.
 - Recent disaster events have proven that pharmacies and pharmacists will have vital roles in the front-line defense in the event of a public health emergency, such as an act of bioterrorism or natural disaster. Pharmacists are critical to the delivery of pharmaceutical services and direct patient care during such unplanned events. The immediate distribution of emergency refills of critical prescriptions, and assistance with the distribution of vaccines, antidotes, and other pharmaceutical agents are vital to ensure the continued safety of the public citizens.
- (3) 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 more effective enforcement.
 - Examples of these partnerships are two recent cases involving Internet pharmacies, which the Board worked with the Federal Bureau of Investigation, U.S. Food and Drug Administration, and the Drug Enforcement Administration in 2005 and 2006. These cases resulted in indictments against 24 individuals.
- (4) The regulation of all of the entities involved in the drug distribution system in Texas should be consolidated under TSBP.
 - Recent problems with the introduction of counterfeit and adulterated drug products into the nation's drug distribution system have caused a nationwide movement toward more comprehensive regulation of wholesale distributors. Many have suggested that better control could be achieved, if the regulation of all aspects of the drug distribution system (manufacturers, wholesalers, and pharmacies) was centralized under TSBP. The Texas Legislature passed H.B. 164 during the 79th Legislative Session that established new, more stringent requirements for wholesalers that distribute prescription drugs. This bill left the regulation of wholesale distributors in Texas with the Texas Department of Health and Human Services.
- (5) 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.

In 1999, Texas became the first state in the nation to pass legislation to establish peer review committees that may be used to suggest improvements in pharmacy systems to enhance patient

care, assess system failures, and make recommendations for continuous quality improvement processes. The Board should continue this kind of innovation in developing new methods and systems to monitor compliance with existing laws and rules, and/or expand its compliance initiatives around the state.

- (6) In order for the Board to continue to protect the citizens of Texas, it must be adequately funded and staffed. Operation of the agency has been affected by across-the-board budget reductions during FY2003-2005, unfunded mandates in FY2006-2007, and the recent natural disaster events. During this time the agency has experienced budget reductions and the demand for services has increased as the population of licensees and the state population has increased. Further increases in demand will significantly impact the agency's ability to provide quality customer service, information, and protection to the citizens of Texas. In 1999, the Texas Legislature passed S.B. 1438 that transferred three professional and occupational licensing agencies to self-directed, semi-independent status. The self-directed, semi-independent status allows the Boards of these agencies to set and control the budgets for the agencies. Though the agencies are in control of their own budgets, they are still under the oversight of the legislature, governor, state auditor, state comptroller, and other state agencies. The self-directed, semi-independent status has allowed the agencies much more flexibility to react to changes in their respective professions. TSBP should consider seeking self-directed, semi-independent status during the next legislative session.

Impact on Agency

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 function efficiently and effectively in the public interest is challenged. In addition, unexpected and unplanned natural disaster events or bio-terrorism acts have been responsible for unanticipated needs and have placed a strain on agency resources.

Any increase in the current demand for agency services without additional funding, personnel, and updated technology may require a reassessment of the organization. This may require a shift in resources and, consequently, a realignment of agency priorities and initiatives. The net result could be a decrease in the quality and quantity of agency services vital to its mission.

Agency Strengths and Opportunities

- (1) Organizational structure, leadership, and management provide the mechanisms necessary to carry out the agency's mission and to accomplish its strategic and operational objectives.
- (2) The agency's position as an independent agency, along with its statutory authority, gives it the authority and flexibility needed to function as the *lead agency* for pharmacy regulation in Texas.
- (3) The agency generates its own revenue, primarily through licensure fees from pharmacists, pharmacies and pharmacy technicians. The agency does not use general tax revenues and is not directly subject to the problems of fluctuation in state revenue due to economic or political factors.

Further, the regulated community fully supports this method of funding agency operations and would support an increased level of expenditure of the collected funds. While an increase in licensure fees is not needed, the regulated parties expect the agency to spend the money

collected.

- (4) The Board members are dedicated to their role as policymakers, and the staff to its role as implementers of this policy. Through their complementary roles, the Board and staff form an efficient team, achieving consistently high-level agency performance in a customer-service oriented manner.
- (5) The agency has an approved *Strategic Plan for Information Management* that addresses its technology needs for the next five years.
- (6) The agency is serving in a leading role within the Health Professions Council and is in a position to share the agency's successful operational strategies with the other regulatory agencies.
- (7) The agency is highly regarded by its customers, including consumers, legislators, and the regulated profession, as well as local communities throughout Texas. Additionally, the agency, staff, and Board are held in high esteem throughout the country as leaders in the pharmacy profession.

Agency Weaknesses and Constraints (Threats)

Among the challenges facing the agency are those associated with unfunded mandates and poorly funded programs. Examples include:

(1) The provision of significant consumer education

Despite the resounding national and state need for preventive patient care information, the agency continues to be placed in the position of having vital information that would protect or improve the health and safety of the citizens of Texas, but not able to effectively disseminate this information through a comprehensive public information service. Countless agencies have similar efforts, sometimes quite extensive, to disseminate public information about parks, recreation, land usage, environmental issues, immunization concerns for children, and child and adult protective issues.

Medication misuse not only costs the citizens of Texas billions of dollars, it seriously impacts their recovery from illness, their management of chronic illness, their productivity at work, their independent lifestyles, and even their lives. Possibilities exist for receiving grant monies, both private and public, and for forming effective, dynamic coalition-based efforts across Texas; however, the agency's hands are tied due to lack of program and human resource funding. This area is one where a small investment of time and money could grow exponentially and reach the entire state.

(2) The gap between current funding and current and expected needs

One key factor that continues to affect the ability of the agency to serve and protect the public interest is the increased demand for agency services. This demand has been compounded by the budget reductions of FY2003-2005, the unfunded mandates of FY2006-2007, and the recent natural disaster events. Significant reductions have occurred in the areas of travel, salaries, newsletters, registration fees and training, and merit pay. Any new population or increase in the level of services provided by the agency will significantly impact the agency's ability to provide quality customer service, information, and protection to the citizens of Texas.

(3) Proliferation of technology

Proliferation of technological systems allows greater public access to agency information. Improvements in computer-related technology have had a significant impact on agency operations over the past several years, as the agency has modified and initiated new work processes to take advantage of these advances. Future developments will have an even greater impact, but these developments will require quality human resources and funding to implement. The expansion of the agency's web site to provide public education about safety issues, the legal consequences of illegal purchases, guidelines on filing complaints or inquiries, and how to use the Internet wisely to obtain drug products and drug information, are just a few examples of current technology that is available.

Agency Initiatives

- (1) Continue to cultivate working relationships with members of the Texas Legislature, in order to keep them better informed regarding the needs of the agency. Keep professional pharmacy associations and advocates abreast of critical issues to help promote favorable legislative action.
- (2) Continue to access the expertise of pharmacy educational institutions, associations, and related entities through networking and advisory committees on topics of increasing complexity.
- (3) Promote organizational change to meet the challenges of regulating the profession with limited resources.
- (4) Actively seek legislative authority to allow the agency to participate in the Self-Directed Semi-Independent Agency Project Act.
- (5) Remain progressive in initiatives focused on enhanced patient outcomes, with continued examination of those issues that are truly important, embracing current technology, gaining broad-based input, and acting aggressively and fairly to hold pharmacists accountable for the patient care they provide.

- (6) Advocate for key quality enforcement and consumer protection reforms at the state and national levels.
- (7) Participate in national and state-level pilot projects within the Board's areas of expertise.

By taking these initiatives, TSBP hopes to assure continuity of both the quality and quantity of agency services, thereby allowing the agency to move forward in fulfilling its mission.