

October 4, 2013

Ms. Gay Dodson, RPh
Executive Director/Secretary
Texas Board of Pharmacy
333 Guadalupe Street
Suite 3-600
Austin, TX 78701-3943

Dear Ms. Dodson:

The Academy of Managed Care Pharmacy (AMCP) appreciates the opportunity to provide input into the Texas Board of Pharmacy's strategic planning process for fiscal years 2015-2019. As the profession of pharmacy continues to evolve and the role of pharmacists expand from dispensers of medications to direct care providers, so too must board of pharmacy requirements. New requirements must ensure the flexibility to allow for pharmacists to perform services in new and unique settings while continuing to provide the appropriate amount of oversight necessary to protect the public safety. As the Strategic Plan correctly notes, managed care is a growth area in pharmacy and therefore, Board of Pharmacy membership and Board policies must recognize this important sector of pharmacy. As the pharmacy organization with expertise in managed care, AMCP may assist the Texas Board of Pharmacy develop policies to effectively implement managed care practices without implementing unnecessary restrictions to the practice and business model of managed care organizations. After reviewing the Strategic Plan, AMCP supports the Texas Board of Pharmacy's vision to position the profession of pharmacy for its ever-evolving role as direct patient care providers and hopes that our comments and recommendations will enhance that strategic vision.

AMCP is a national professional association of pharmacists and other health care practitioners who serve society by the application of sound medication management principles and strategies to achieve positive patient outcomes. The Academy's nearly 7,000 members across the United States and 298 members in Texas develop and provide a diversified range of clinical, educational and business management services and strategies on behalf of the more than 200 million Americans covered by managed care pharmacy benefits.

Include Managed Care Pharmacists in the Board Structure and Policy-Making

According to the Strategic plan, Texas Board of Pharmacy will continue to be primarily composed of pharmacists who practice in community and institutional pharmacy. AMCP recommends that the Board consider the value to be gained by the addition of at least one managed care pharmacist to provide an appropriate perspective in this important area.

Appointment of one or more managed care pharmacists by the Governor would provide the Board with an understanding of the boundaries surrounding the managed care pharmacy benefit by both federal and state purchasers as well as insurance laws and regulations, thus providing a perspective on how the Board should manage or support policy issues in this area. Furthermore, as evolving models of care, including Accountable Care Organizations and patient centered medical homes grow, pharmacy will be required to provide additional services intended to improve outcomes and manage costs. Managed care pharmacists would provide the Board expertise in utilization of clinical and managed care tools, including step therapy, prior authorization, tiered formularies, and medication therapy management, that balance appropriate access to safe and effective medications while managing costs. For these reasons, AMCP believes that the skill set and perspective of managed care pharmacy would again be a valuable addition to the Board of Pharmacy with the appropriate support of the Governor or legislature.

Ensure that Board Regulation's Encourage Flexibility and Allow for Non-Traditional Pharmacy Practices and Settings

The Strategic Plan correctly identifies the growing role of pharmacists as direct patient care providers and their important contributions to improving health outcomes while reducing costs. AMCP encourages the Board to work with the state legislature to enact laws and consider policies that allow pharmacists to continue to grow in these areas and to not block measures encouraging non-traditional practices. Policies from boards of pharmacy that view the practice of pharmacy as the square footage of a dispensing pharmacy are shortsighted and stop pharmacists from expanding their role in the health care system and also stymie the state job growth for pharmacists in these areas.

The Texas Board of Pharmacy has recognized non-traditional pharmacies with new roles for pharmacists in the past and should continue this tradition. To this end, the Board should resist initiatives to impose stringent procedural and administrative requirements on pharmacists who provide direct patient care services, such as medication therapy management, outside of a traditional pharmacy setting. The Board should also resist proposals where pharmacy services are required to receive a permit as a full-service traditional pharmacy and consider that not all pharmacy settings are traditional pharmacy practices and thus may be arranged differently from a business and practice perspective. As stated above, this approach not only provides pharmacists with new professional opportunities, but could also make the state more attractive to pharmacy companies and practitioners who seek opportunities in non-traditional pharmacy.

Encourage Adoption and Utilization of Technology to Enhance Direct Patient Care Services

The Strategic Plan correctly identifies the expansion of the use of technology in the practice of pharmacy. The Strategic Plan describes in detail its plans for use of technology in traditional pharmacy dispensing and generally describes the need for increased expansion of technology into other areas. Pharmacy must be included into interoperable electronic health records (EHRs) that allow bi-directional communication among health care providers and payers and also ensure pharmacists' access to comprehensive patient medical history. The Texas Board of Pharmacy should partner with other professional boards as well as private entities to encourage adoption of EHR systems that include pharmacists.

Ensure Access to Prescription Drug Monitoring Program by Managed Care Organizations

The Strategic Plan identifies controlled substance misuse and abuse as a public health problem that the Board of Pharmacy along with other entities must work to reduce inappropriate controlled substance utilization. AMCP encourages the Board to work with the Texas Department of Public Safety to allow for managed care organizations to access the prescription drug monitoring system. Partnerships among pharmacies, prescribers, and managed care organizations may help to curb inappropriate controlled substance utilization and one of the

key ways to achieve this outcome is through complete, real-time, online data sharing. Allowing managed care organizations access to the prescription drug monitoring program will allow access to complete prescription information, including controlled substance prescriptions purchased with cash that are not accessible in managed care members' patient records. This access will then allow managed care organizations to partner more closely with community pharmacies and prescribers to implement effective clinical and administrative strategies to reduce inappropriate use of controlled substances. This is yet another reason to include a managed care pharmacist on the Board to provide their unique experience in this area of concern.

Do Not Impose Board Regulatory Restrictions on Pharmacy Benefit Management (PBM) Companies

AMCP opposes statutory and regulatory proposals that impose restrictions on PBMs and diminish the ability of PBMs to assist individuals, health plans, employers, and federal and state governments in accessing safe and appropriate medications at reasonable costs.¹ PBMs with mail order pharmacies domiciled in a state must meet state board requirements for a pharmacy and any pharmacist who is licensed in a state must meet the board's requirements for the provision of dispensing services and patient care services. PBMs must also comply with business licensure requirements and, in some cases, are subject to state insurance commission oversight. Therefore, the imposition of additional regulations is unnecessary. This position is shared by the Federal Trade Commission (FTC) that recommended against implementing 2011 proposed PBM regulations by the Mississippi Board of Pharmacy. The FTC noted that these practices would be anti-competitive and would hinder efforts to negotiate reasonable drug prices that benefit consumers, insurers, and employers.²

Once again, AMCP appreciates the opportunity to provide input on the Texas Board of Pharmacy Strategic Plan. AMCP members continue to work to enhance the value of the pharmacist in the overall health care setting in order to foster quality outcomes for their patients. AMCP is committed to the recognition of the pharmacist as a trained and experienced health care provider. If we can answer any questions or provide additional information, please contact me at (703) 683-8416 x645 or erosato@amcp.org.

Sincerely,



Edith A. Rosato, RPh, IOM
Chief Executive Officer

¹ AMCP Where We Stand on Regulation of PBMs. AMCP Board of Directors; June 2010. <http://www.amcp.org/Tertiary.aspx?id=8746>. Accessed September 26, 2013.

² FTC Staff: Mississippi Bill That Would Give State Pharmacy Board Authority Over PBMs Likely to Increase Prescription Drug Costs and Reduce Competition. March 22, 2011. <http://www.ftc.gov/opa/2011/03/pbm.shtm>. Accessed September 26, 2013.



NATIONAL ASSOCIATION OF
CHAIN DRUG STORES

September 27, 2013

Gay Dodson
Executive Director
Texas State Board of Pharmacy
333 Guadalupe St., Suite 3-600
Austin, TX 78701-3943
Via email: gay.dodson@tsbp.state.tx.us

Dear Ms. Dodson:

RE: Development of the Texas State Board of Pharmacy Strategic Plan for Fiscal Years 2013 through 2017

Dear Ms. Dodson:

On behalf of our members operating approximately 2,798 chain pharmacies in the state of Texas, the National Association of Chain Drug Stores (NACDS) thanks the Texas State Board of Pharmacy ("TSBP") for requesting our input on matters TSBP should consider and/or address when developing the Strategic Plan for Fiscal Years 2015 through 2019. We appreciate the opportunity to present chain pharmacy's perspective on this topic.

The federal healthcare reform laws enacted in 2010 will continue to have significant implications for the delivery of healthcare to Texans in the coming years. Extending health insurance coverage to previously uninsured individuals will continue to yield a corresponding increase in demand for healthcare services. Further, the proliferation of new healthcare delivery models being implemented as a result of healthcare reform will impact all healthcare providers in different ways. For the pharmacy community, we anticipate that the roles of pharmacists will continue to evolve towards pharmacists practicing at the upper limits of their education and training. Related to this, we further anticipate growth in the scope of healthcare services provided in pharmacies. Accordingly, it is critically important that the laws and regulations governing pharmacists and pharmacies enable providers to best provide services to patients in light of these changes. To this end, NACDS urges TSBP to plan for the following statutory and/or regulatory changes that will allow pharmacists and pharmacies to best serve their patients in the newly reformed healthcare delivery system.

Innovative Practices that Enhance the Services Pharmacists Provide to Patients. In years past, NACDS highlighted to TSBP how the current law¹ and rule² allowing TSBP to approve pilot or demonstration research projects for innovative applications in the practice of pharmacy are important towards enabling and supporting innovative practices that could enhance pharmacy services. We continue to encourage TSBP to allow the pharmacy profession to utilize this process as a means to seek out new ways to serve patients and to promote public health in the reformed healthcare system, as these types of practices could be utilized more and more as healthcare providers' roles expand to meet patients' needs.

¹ TX Health & Safety Code §554.011

² 22 TAC 291.23

We also continue to encourage the Board to put a process in place allowing pharmacy providers to obtain waivers to engage in practices that have been proven to be safe and effective through demonstration projects while the Board goes through the process of updating pertinent laws and regulations to permit these beneficial practices in all pharmacies.

Expand Pharmacists Authority to Vaccinate Adolescents. We encourage the Board to support statutory changes to further expand pharmacists' authority to administer a broader portfolio of vaccines to adolescents. Unfortunately, many adolescents in the state of Texas remain unvaccinated and susceptible to vaccine-preventable disease. The current healthcare system has not adequately met the vaccination needs of the adolescent population in the United States over the years; however, overall vaccine rates for adolescents could potentially be increased through improving access to vaccines by making them more broadly available in health care settings such as pharmacies.³ Pharmacists, who are already trusted vaccine providers in the state of Texas, are easily accessible and well-suited to complement the efforts of primary care physicians in providing vaccine services to this population. Making vaccines more accessible to the adolescent population will serve important disease prevention public health goals and help to meet growing demand for healthcare services in the newly reformed healthcare system.

Eliminate Special Requirements that Impede Centralized Prescription Processing Practices. We ask TSBP to revise its rules to allow for greater flexibility with centralized prescription processing practices. For example, out of state pharmacists that engage in centralized prescription processing for a class G Texas-licensed pharmacy, but perform these services from outside of the traditional pharmacy setting, are required to be licensed as Texas-licensed pharmacists. This requirement limits the ability of pharmacies operating in multiple states to fully maximize use of their out-of-state pharmacists to perform centralized prescription processing for their Texas patients. Considering that the limit is a notably different standard than the requirement for Class E Texas-licensed pharmacies, we see no reason for this special licensing requirement for pharmacists in class G pharmacies. Thus, we ask TSBP work to change this requirement and any others that unnecessarily impede pharmacies ability to utilize centralized prescription processing practices.

Work with DPS to Streamline State Regulatory Requirements and Processes that Are Administratively Burdensome. Notably, the current prescription drug monitoring program (PDMP) operated under the purview of the Department of Public Safety ("DPS") could be improved upon by eliminating unnecessary administrative burdens on pharmacies. As we have highlighted to the TSBP in the past, the PDMP data reporting process is burdensome, as some of the program parameters are inconsistent with the PDMP practices in other states (for example the requirement to report the serialized prescription number.) In light of these issues, chain pharmacy supports moving oversight authority for the PDMP from DPS to TSBP, who has a better understanding of pharmacy operations and is better suited to run the program. We would also encourage updating the PDMP requirements that are

³ Schaffer, S., Fontanesi, J., Rickert, D., Grabenstein, J., Rothholz, M., Wang, S., et al. (2008). How Effectively Can Health Care Settings Beyond the Traditional Medical Home Provide Vaccines to Adolescents?, *Pediatrics* (Vol. 121, pp. S35-S45).

inconsistent with other states, as this would serve to facilitate a more efficient reporting process.

Additionally, there are inconsistencies between the TSBP rules and the DPS rules regarding physical security requirements for pharmacies. We ask TSBP to work with DPS to conform the DPS pharmacy physical security requirements to those that are established in the TSBP rule.

Additional Miscellaneous Item. In addition to the above issues, there is one miscellaneous item that we encourage the Board to work to address. We encourage TSBP to update its regulations regarding prescription transfer on pharmacy closing to encompass situations where a pharmacy is closing to regular retail practice but is keeping its Class A license and continuing to operate as a “compounding only” pharmacy. The current regulatory scheme does not accommodate such a scenario. Although in this situation, the compounding pharmacy would need to transfer the traditional (non-compounded) prescriptions to another pharmacy, the compounding pharmacy can still accommodate any compounded prescriptions and should not have to transfer those as well. Additionally, the method of transfer should also be updated, to allow for the transfer the records in bulk by computer (without setting up a joint website), as the transfer involves a large number of prescriptions and the transfer rules are not updated to allow bulk transfer in this situation.

NACDS thanks TSBP for considering our input. We welcome the opportunity to further discuss any of these matters. I can be reached at 817-442-1155; mstaples@nacds.org.

Best regards,

A handwritten signature in black ink that reads "Mary Staples". The signature is written in a cursive, flowing style.

Mary Staples
Regional Director, State Government Affairs

September 27, 2013

Attn: Gay Dodson, R.Ph.
Texas State Board of Pharmacy
333 Guadalupe Street
Suite 3-600
Austin, Texas 78701-3943



Dear Ms. Dodson,

The National Healthcareer Association (“NHA”) is writing in response to the enclosed letter from the Texas State Board of Pharmacy (the “Board”) dated August 27, 2013, requesting NHA to provide comments for the Board’s consideration during its strategic planning process for fiscal years 2015 through 2019.

NHA believes that the Board will face an increase in the dependence on pharmacy technicians, and the commensurate need to ensure the competency and professionalism of these technicians. The pharmacy technician field is projected to grow by 32% between 2010 and 2020, a “much faster than average” rate of growth when compared to all other occupations.¹ With over 57,000 pharmacy technicians holding active licenses², Texas already employs more than 15% of the pharmacy technicians nationwide.³ As the Board noted in its Strategic Plan developed in 2012 for fiscal years 2013-2017, the rapid growth in the number of pharmacy technician trainees through 2011 “had a dramatic effect on the agency’s operations....” Accordingly, over the next few years, the Board will be concerned with the training and credentialing of pharmacy technicians.

NHA offers the Examination for the Certification of Pharmacy Technicians (the “ExCPT”). The ExCPT is a national certification exam accredited by the National Commission for Certifying Agencies (“NCCA”) and, in most states, competes directly with the Pharmacy Technician Certification Examination (the “PTCE”) offered by the Pharmacy Technician Certification Board (“PTCB”).

Although not required to under the Texas Pharmacy Act, the Board has limited pharmacy technicians’ and their employers’ choices for obtaining certification to only one provider, PTCB. NHA believes that this unnecessary restraint on consumer choice will pose a challenge to the Board’s ability to respond to the preferences and needs of the expanding pharmacy technician workforce and their employers. There are many benefits to marketplace competition: innovation; reasonable pricing; customer service

¹ Bureau of Labor Statistics, U.S. Department of Labor, Occupational Outlook Handbook, Pharmacy Technicians, on the Internet at <http://www.bls.gov/ooh/healthcare/pharmacy-technicians.htm> (visited September 26, 2013).

² Pursuant to the “Pharmacy Technicians Lists” for public download available at <http://www.tsbp.state.tx.us/dbsearch/tables.asp> (visited September 26, 2013).

³ Bureau of Labor Statistics, U.S. Department of Labor, Occupational Outlook Handbook, Pharmacy Technicians, on the Internet at <http://www.bls.gov/ooh/healthcare/pharmacy-technicians.htm> (visited September 26, 2013) reported 334,400 pharmacy technicians nationwide in 2010, with a total anticipated growth of 108,300 additional pharmacy technicians between 2010 and 2020 (or approximately 33,000 additional technicians by 2013).

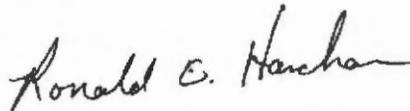
investment; and protection from monopolistic complacency. Texas, however, cannot avail itself of these benefits unless the Board revisits its current policy to approve only one certification program.

For example, PTCB offers 19 test sites in Texas, requiring extensive travel for many prospective pharmacy technician certification candidates. NHA offers more than twice as many test sites. If the Board approved both nationally recognized and accredited exam providers, the number of test sites available to pharmacy technician certification candidates would automatically triple. Moreover, approval of more than one exam will allow the State to respect the preferences of the various constituencies that employ pharmacy technicians. For example, the ExCPT is the preferred exam of some hospitals and major pharmacy chains with a nationwide footprint. By approving the ExCPT, the Board would make it easier for these national organizations to do business in the state of Texas.

NHA believes that accreditation by independent and nationally-recognized accrediting bodies, such as the NCCA (which was selected by both PTCB and NHA for accreditation), serves to provide the Board with assurance of both the psychometric soundness of the examinations and the companies that offer them. Should the Board, however, continue to use the Request for Qualifications process to evaluate potential exam vendors, NHA respectfully recommends that the Board select all vendors that have attained accreditation through a nationally-recognized accrediting body, as opposed to limiting the public's choice to a single vendor.

NHA appreciates the invitation to provide comments for the Board's consideration. If you have any questions, please do not hesitate to contact me.

Sincerely,

A handwritten signature in cursive script that reads "Ronald E. Hanchar". The signature is written in black ink and is positioned above the typed name and title.

Ron Hanchar, MBA
Executive Director, Allied Health Certifications



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October 15, 2013

Gay Dodson, RPh
Texas State Board of Pharmacy
333 Guadalupe Street, #3-600
Austin, Texas 78701

Dear Ms. Dodson,

Thank you for the opportunity to provide input as you develop your 2015 – 2019 Strategic Plan. As a pharmacy technician-centric organization, I would like to focus my comments in that area. We are all aware of the current demands on health care and the need to provide affordable care. Over the past several years, the pharmacy profession has witnessed changes in regulatory oversight, the job market, pharmacy education, pharmacy practice models, automation and technology.

Pharmacists, technicians and patients are all being affected by changes in the broader healthcare system. There are a number of factors that have occurred or are occurring that drive change. Resource constrained budgets, decreasing reimbursements, increasing public demands for access, new pharmacist training and expectations and evolving practice setting are just a few examples. These factors are helping to redefine the roles of pharmacists and technicians. Academia, payers, employers and many state boards of pharmacy recognize that traditional roles are changing requiring them to flex with the times. In light of this, pharmacy technicians are demonstrating the capability and ambition to move beyond traditional roles to support pharmacists and patients. Pharmacy technicians play integral roles in supporting pharmacists in all practice settings. Enhanced responsibilities within traditional dispensing provides time for pharmacists to dedicate to services such as MTM.

Much has been said recently about pharmacist practicing at the top of their license and assuming greater roles in collaborative practices. However, as pharmacists move forward, it is important to recognize that as pharmacists assume greater clinical roles, there must be a work force that is properly empowered and equipped to assume more of the administrative and non-clinical dispensing tasks. PTCB is focused on certification requirements to increase patient safety for the benefit of CPhTs, pharmacists and patients. Therefore as you look towards the future and contemplate how best to remain responsive consider the following:

- Provide a platform to advance pharmacy technicians
- Review or redefine the classic definition of a pharmacy or practice setting
- Define &/or expand the scope of practice for pharmacy technicians

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- Recognize that e-prescribing, automation, robotics, electronic health records, and telepharmacy will alter the order fulfillment process
- Statues &/or legislation must be enabling and flexible enough to address future needs and opportunities
- Technicians must have the education, training and credentials to advance with the pharmacy workforce
- PTCB is elevating our certification requirements in order to meet the demands of the evolving healthcare system. This spring we announced changes to our certification program that will occur over the next seven years to include advanced certification programs and the need to have completed an accredited training program.

No doubt you are facing many challenges within the state and the profession. Taking proactive steps will provide the greatest opportunity to deal with the known and unknown in the immediate and not too distant future. I hope all parties will take this tasking seriously to really discuss the way ahead and how your organization can be a real fulcrum for improving patient care, outcomes and access. Best wishes as you develop your strategic plan.

Sincerely,



Everett B. McAllister, MPA, RPh
CEO/Executive Director



TEXAS DEPARTMENT OF STATE HEALTH SERVICES

DAVID L. LAKEY, M.D.
COMMISSIONER

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October 15, 2013

Gay Dodson, R.Ph., Executive Director and Secretary
Texas State Board of Pharmacy
William P. Hobby Building, Suite 3-600
333 Guadalupe Street
Austin, Texas 78701

Dear Ms. Dodson:

Thank you for your August 27, 2013 letter requesting input from the Department of State Health Services (Department) into the Texas State Board of Pharmacy's (Board's) strategic planning process. We value our working relationship with the Board and our mutual desire to protect the public health of the citizens of Texas.

Drug compounding has evolved over the years from the traditional practice of altering drugs approved by the U.S. Food and Drug Administration for the specific needs of an individual patient to some of today's nontraditional compounding practices designed to produce large quantities of sterile drugs for general use by many patients. These high-volume compounding pharmacies operate within a complex regulatory framework with intersecting jurisdictions from multiple state and federal agencies including both the Board and Department. The challenges presented to us as a result of the 2012 nationwide meningitis outbreak associated with compounded steroidal drugs, and more recently the 2013 bacterial bloodstream infections that occurred in Texas associated with calcium gluconate infusions compounded within our state, underscore the need to study and recommend improvements to the licensing, regulation and monitoring of compounding pharmacies. Of particular concern are the existing requirements for compounding sterile drug products and what changes may be necessary to these requirements in order to prevent future outbreaks involving serious patient adverse effects.

In developing your long-term strategic plan, the Department recommends the Board consider measures to increase the safety of sterile drug products compounded by pharmacies. Additionally, the Department recommends the Board consider opportunities for cross-agency collaboration that build upon our joint efforts to address recent outbreaks, such as: conducting joint inspections where appropriate; assessing areas of overlapping jurisdiction, expanding data-sharing efforts; and developing ongoing forums to discuss issues of common concern.

Gay Dodson, R.Ph.

October 15, 2013

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I look forward to our continued efforts to ensure consumers receive safe and effective drug products. Karen Tannert, R.Ph., M.P.H., with the Drugs and Medical Device Group is available to provide additional information or answer any questions you might have at (512) 834-6755 or via e-mail at Karen.Tannert@dshs.state.tx.us.

Sincerely,

A handwritten signature in black ink, reading "David Lakey MD". The signature is written in a cursive, flowing style.

David L. Lakey, M.D.
Commissioner