Outstanding 2013 Legislative Session for TPA and Pharmacy

Building on relationships established during the 2012 election cycle, the Texas Pharmacy Association and its members succeeded in passing – and defeating – critical legislation that has a far-reaching effect on the practice of pharmacy in Texas. As the advocate for all Texas pharmacists, TPA worked to pass legislation that improves the pharmacy workplace, protects patients and recognizes the professional expertise of pharmacists in delivering health care services.

On almost all issues, the pharmacy profession was united and various advocacy groups cooperated and worked together. This synergy resulted in large part from weekly informational and strategy meetings of the Pharmacy Advocacy Group (PAG) which TPA coordinated and led. Members of the PAG included representatives from the TPA, the Texas Society of Hospital Pharmacists (TSHP), the Texas Pharmacy Business Council (TPBC), the Alliance for Independent Pharmacists (AIP), the Texas Independent Pharmacy Association (TIPA), the National Association of Community Drug Stores (NACDS), HEB, Walgreens, United, Brookshire Brothers, Brookshire Grocery, and TrueCare. Together, pharmacy advocates were able to share knowledge, direct resources, build relationships with legislators and advance legislation that will benefit all practicing pharmacists and patients.

Below are TPA’s highlights of the Good, the Bad and the Dead pharmacy-related key issues that were considered during the regular session of the Texas Legislature, starting with pharmacy’s show of power – convincing the governor to use his VETO stamp.

**Pharmacists Secure Veto of Bill Allowing Physicians to Dispense**

TPA was an integral player in the effort to persuade the governor to veto Senate Bill 227 by Sen. Tommy Williams (R-The Woodlands). The bill would have allowed physicians and optometrists to prescribe AND dispense certain aesthetic drugs. During the session, TPA and other pharmacy advocates were successful in reducing the number of drugs that a physician would have been allowed to dispense from five to three: bimatoprost, hydroquinone and tretinoin. TPA also ensured that both the Texas State Board of Pharmacy and the Texas Medical Board would write the rules implementing the legislation. TPA urged the governor to veto the legislation in part because of patient safety concerns. Physicians’ offices do not have standards for drug storage and are not regulated. The legislation also presented a clear conflict-of-interest for physicians/optometrists who prescribe and dispense medications, and set a dangerous precedent for the state.

And thousands of pharmacists weighed-in.

In this case, the Bad became the Dead. Congratulations to the pharmacists and pharmacy technicians in Texas for stopping a precedent from even starting!
Legislative (continued)

**Bill Standardizes Prior Authorization Form**

*Senate Bill 644* by Sen. Joan Huffman (R-Houston) requires the Commissioner of Insurance to develop a single standard form for requesting prior authorization of prescription drugs and other benefits. The bill creates an advisory committee of stakeholders to assist in development of the form. It must make recommendations about the number of days the insurer has to respond to a request for prior authorization, and whether non-response in a timely manner provides deemed authorization. The advisory committee must make recommendations by Jan. 1, 2015, and the form must be implemented by Sept. 1, 2015. This bill will reduce the administrative burden for pharmacists and enable them to deliver care more efficiently to patients.

**Expansion of Pharmacy Board**

*Senate Bill 500* by Sen. Leticia Van de Putte (D-San Antonio) adds another pharmacist and a pharmacy technician to the TSBP. This is the first time a pharmacy tech has been a member of the board, and TPA advocated strongly for bringing representation of pharmacy technicians, a vital part of the profession, to the TSBP. The TPA Board will consider nominees to submit to the governor’s office for consideration for appointment to the new positions.

**Due Process Requirements Extended to Pharmacists**

*Senate Bill 404* by Sen. Charles Schwertner (R-Georgetown) establishes due process requirements when complaints are filed with the Texas State Board of Pharmacy. The legislation requires the TSBP to obtain and record the identity of the complainant. The bill creates a seven-year statute-of-limitations period, requires the TSBP to give at least a 45-day notice of an informal hearing, and to inform the license holder of the nature of the complaint and the information the board plans to use at the hearing, which must be recorded. Only the licensee may obtain the recording. The TSBP is allowed to create a remedial plan for certain violations. This bill creates a more consistent and fair due process for any licensee facing a complaint.

**Pharmacists Must Monitor Schedule II Prescriptions**

*Senate Bill 1643* by Sen. Tommy Williams (R-The Woodlands) requires pharmacists who dispense Schedule II prescriptions to report the method of payment for the medication to the Texas Prescription Monitoring Program. It also allows technicians, directed by a pharmacist, to access information from the PMP as long as certain precautions are taken to insure privacy and confidentiality. The bill also requires the creation of an interagency work group that will evaluate and work to improve the PMP system in Texas. TPA expressed concerns with the administrative burden the bill places on pharmacists.

**Opioid Study/Tamper Resistant Packing Passes**

*Senate Bill 316* by Sen. Carlos Uresti (D-Corpus Christi) requires the Senate Health and Human Services Committee to conduct an interim study about opioid drug abuse and the use of tamper resistant technology to deliver opioid drugs. The bill also authorizes the TSPB to establish a continuing education program on opioid drug abuse and the “delivery, dispensing and provision” of tamper-resistant opioid drugs. The board may require its licensees to complete a specified number of CE hours on this topic.
Parameters Set for PBM Audit Practices
House Bill 1358 by Rep. Todd Hunter (R-Corpus Christi) establishes parameters for audits conducted by pharmacy benefit managers. The bill requires:

- PBM to give notice of at least 14 days of an audit and identify the claims subject to audit (unless fraud is suspected);
- PBM to allow pharmacists to request rescheduling within seven days of receiving the audit request and to set a mutually convenient time;
- PBM contracts to detail the procedures for audits and notify pharmacies of any changes within 60 days;
- The PBM to report all findings of audits to the pharmacy and allow for a response;
- The auditors to submit a preliminary report within 60 days, followed by a 30-day period where a pharmacy may challenge the report; and
- The finalized report to be submitted, including the amount of claims to be recouped, to the pharmacy within 120 days.

The bill also has many provisions to protect pharmacies from practices deemed unfair, including:

- Preventing unintentional clerical errors from being used by PBMs as evidence of fraud and not allowing the recoupment of payments unless actual financial harm was done to the patient or health plan;
- Prohibiting auditors from entering the pharmacy area unless authorized by the pharmacy;
- Prohibiting auditors from “extrapolating” a sample of claims to represent trends in a larger group, either in contracts or payments;
- Prohibiting auditors from being paid based on the amount of claims recovered through audits;
- Requiring PBMs to consult with a licensed pharmacist to evaluate claims using professional judgment;
- Limiting random samples, if used, to 300 claims;
- Establishing one year as the time period PBMs have to complete a claim’s audit;
- Allowing pharmacies to use prescriptions and delivery records as evidence; and
- Providing pharmacies at least 20 days to submit requested documents to auditors.

Many pharmacists have expressed frustration over complying with unfair audit practices, and many have called for reforms to address these critical issues. The passage of these reforms will help pharmacists better manage their pharmacies and serve their patients more effectively.
Transparency for Maximum Allowable Costs

**Senate Bill 1106** by Sen. Charles Schwertner (R-Georgetown) establishes transparency and consistency in how maximum allowable costs are determined and changed under a Medicaid managed care pharmacy benefit plan. PBMs are required to cover drugs rated “A” or “B” in the Food & Drug Administration’s Approved Drug Products (Orange Book), or use an equivalent nationally recognized resource. These drugs also must be available from national or regional wholesalers. The bill requires pharmacy benefit managers to disclose how MACs are set, including how the plan determines which drugs will be reimbursed using a MAC formula, what the price will be, when the price will change and what factors are used to determine MAC prices or price changes. PBMs are required to update MAC prices at least every seven days. PBMs must establish procedures for evaluating, modifying and eliminating products from MAC lists; these procedures must include means for network pharmacies to challenge listed MAC prices. If a challenge to a MAC price is successful, the corrected price applies to all similar pharmacies in the network. PBMs are required to allow pharmacies easy access to their specific MAC list. All price challenges that are denied must be reported to the Texas Health and Human Services Commission every 90 days.

These reforms will help pharmacists across the state in many different practice settings who have been burdened by unfair or non-transparent use of maximum allowable costs pricing lists when dealing with reimbursement from pharmacy benefit managers.

Tax Bill Helps Pharmacies

**House Bill 500** by Rep. Harvey Hilderbran (R-Kerrville) will provide tax relief to many independent pharmacies. The omnibus franchise tax reform bill provides for a $1 million deduction and a 2.5 percent franchise tax reduction for all businesses. If the comptroller certifies that funds are available, it will provide a 5 percent across-the-board franchise tax reduction in the second year of the biennium. TPA helped secure a provision allowing health care providers to deduct vaccine costs from their franchise tax liability. This will allow more pharmacies to stock and administer important vaccinations to patients.

Out-of-State Compounding Pharmacies Regulated

**Senate Bill 1100** by Sen. Leticia Van de Putte (D-San Antonio) requires an out-of-state pharmacy that compounds sterile prescription drugs for delivery in Texas to be inspected by the TSBP before it can obtain a Class E pharmacy license. The TSBP is authorized to establish appropriate fees to cover the costs of travel and other expenses to conduct inspections. The board may make both random and scheduled inspections of these pharmacies to ensure compliance with the board’s rules and safety requirements. The legislation also tightens the requirements for all compounding pharmacies to immediately notify the board of any adverse events potentially attributed to their products and within 24 hours of any product recalls. This legislation is expected to contribute to increased patient safety throughout the state.
**Legislative (continued)**

**Vendor Drug Program Continued; Medicaid Fraud Addressed**

*House Bill 595 by Rep. Lois Kolkhorst (R-Brenham) (right)* repeals the expiration date for key provisions of the Medicaid Vendor Drug Program and makes patient protections permanent. The bill requires managed care organizations to use the state’s formulary and preferred drug list and follow prior authorization requirements. Similar language also is included in *Senate Bill 8*, an omnibus Medicaid bill, by Sen. Jane Nelson (R-Flower Mound). S.B. 8 establishes a separate division within the Texas Health and Human Services Commission to use analytical and statistical methods to improve contract management and identify possible fraud, waste or abuse, and these efforts include pharmacy. Maintaining the Vendor Drug Program protects patients’ access to care.

**New Pharmacy School Approved**

*Senate Bill 566 by Sen. Kevin Eltife (R-Tyler)* authorizes The University of Texas at Tyler to create a new school of pharmacy to be built without use of any state funds; donations and tuition will fund operations. TPA expressed concerns about the new school due to its impact on the quality/availability of faculty, students, training sites and preceptors. TPA also noted that an additional school will exacerbate the oversupply of pharmacy graduates, which will increase from 600 per year to at least 725 when the state’s seventh pharmacy school opens this fall.
Clarification of TSBP Requirements and the Regulation of Technician Trainees

Sen. Leticia Van De Putte (D-San Antonio) passed a clean-up bill, Senate Bill 869, to clarify certain rules and regulations for the Texas State Board of Pharmacy.

Requirements

- The board may not renew any license for a pharmacist whose license has been suspended, revoked, canceled or is otherwise prohibited from practicing in another state. Such out of state applicant must submit proof that his/her license is not currently subject to these actions in another state.

- The requirement that a pharmacist notify a practitioner before dispensing a drug dosage that is different than the one prescribed is removed.

- All prescriptions for controlled substances must be issued for a legitimate medical purpose by a practitioner who is acting in the usual course of practice. The responsibility for proper prescribing and dispensing rests on the prescriber and the pharmacist.

- The requirement to display the licenses of all pharmacists employed at a class A or class C pharmacy is modified to requiring only the license of the pharmacist-in-charge be displayed. However, the pharmacy must have proof of the licenses of all pharmacists, pharmacist-interns, pharmacy technicians and pharmacy technician trainees and make them available to the public upon request.

- The grounds for which a licensee can be disciplined expanded to include an incapacity that could prevent the practice of pharmacy, failing to properly supervise technician trainees, being disciplined by a pharmacy or health regulatory board of this state or another, or being convicted or adjudicated for a criminal offense that would require one to register as a sex offender.

- The board is authorized to disclose information or materials gathered in an investigation to another jurisdiction that regulates pharmacy.

- The board is authorized to take disciplinary action against a student-intern in the same manner it would against a license hold, when necessary.

Technicians and Trainees

- The board is authorized to take disciplinary action against pharmacy technicians and trainees under certain conditions.

- The bill amends the Texas Occupation Code to require all technician trainees to register with the TSBP and to have at least a high school diploma (or equivalent) or be in the process of obtaining one. The bill authorizes the TSBP to regulate the training qualifications and employment of pharmacy technician trainees. Rules that govern technicians, such as ratio requirements, disciplinary actions and procedures, and other regulations now include pharmacy technician trainees.

- Technicians and pharmacy technician trainees are required to register with the board, but no longer are required to renew their registration every two years. Technicians will remain registered as long as the person meets the qualifications established.

- Technicians and technician trainees are required to notify the board in writing of any change in address or change in employment within 10 days of the change.

These changes strengthen the oversight of technicians and trainees, and enhance quality and patient safety.
Legislative (continued)

The Dead!

Immunization Bills Die
Legislation to allow pharmacists to administer immunizations and vaccinations to patients age seven and older without a physician referral died. House Bill 2938 by Rep. Jodie Laubenberger (R-Parker) and Senate Bill 1013 by Sen. Larry Taylor (R-Friendswood) were heard in their respective committees but did not progress. Although the Texas Medical Association opposed the bills, the group did agree to meet with TPA following the session to discuss how Texas could improve its immunization rates. TPA and TMA also will discuss how pharmacists could be used as physician extenders and fit into the medical home model.

Biosimilars Legislation Allowed to Die
Senate Bill 190 by Sen. Joan Huffman (R-Houston) would have allowed the substitution of brand name drugs with a biosimilar biological product deemed to be interchangeable. The substitution would have offered patients lower cost alternatives. The bill also would have required a pharmacist making a substitution to notify the physician by written or electronic means within three days, creating a burden for pharmacists, especially if the physician’s office did not use electronic communication.

The FDA still is evaluating its stance on biosimilars and how this new category of medication will be regulated. TPA strongly encouraged lawmakers to hold off on legislation regarding the use of biosimilars until after the FDA determines its course of action regarding this class of pharmaceuticals. The House committee ultimately decided to let the bill die.

‘Any Willing Provider’ Legislation Fails
House Bill 3455 by Rep. Craig Eiland (D-Galveston) would have required health plans to include any pharmacy that was willing to accept the administrative, financial and professional conditions presented. The bill would have prohibited certain contractual requirements used by health benefit plans to limit or incentivize patients to use certain pharmacies over others. The bill died in the House Calendars Committee.

Next Steps
The Texas State Board of Pharmacy and other state agencies now will begin drafting regulations to implement the various laws that have been passed. TPA will follow the rulemaking process and offer input and feedback on proposed regulations. In addition, TPA will offer educational programs to help pharmacists implement the new requirements.

TPA Thanks All Advocates
TPA thanks Texas pharmacists, student pharmacists and pharmacy technicians who contacted their legislators, visited their offices, called their staff, and voiced opinions on all the topics that affected pharmacists, patients and pharmacies. TPA also recognizes and applauds the collaboration that was achieved by the various pharmacy groups. Working together, pharmacists and pharmacy owners spoke with a common voice which proved strong and powerful.

And finally, a heartfelt thanks to three key individuals: TPA’s external lobbyist, David Marwitz, for his tireless and outstanding contributions to our legislative efforts; to TPA’s long time general counsel, Dean Davis, for his expert guidance; and to Kim Roberson, R.Ph., for his unexcelled pharmacy knowledge which was much-needed in the trenches. TPA had a knowledgeable and influential four-person advocacy team with more than 135 years of experience in the public policy arena.
Regulatory

Coordination of Regulatory Efforts

With the conclusion of the 2013 regular legislative session, the focus now shifts to the regulatory front. And as was the case during the session, TPA will coordinate strategy sessions with the Pharmacy Advocacy Group in an effort to coordinate, monitor and influence regulatory activities that implement the laws enacted during the session.

In addition, the PAG will participate in interim studies and monitor the activities of the workgroup that will make recommendations in the development of the standard prior authorization form and its use.

TPA already has submitted recommendations to the governor’s office for appointments to the two new positions on the Texas State Board of Pharmacy. The board is being expanded with the addition of another pharmacist and the first-ever pharmacy technician.

TPA will closely monitor the rulemaking process to implement legislation addressing:
- Audits by PBMs
- MAC pricing transparency
- Technician Training - education / certification
- Dosage Substitution – form / tamper resistant
- Standard prior authorization form
- Changes to requirements on compounding
- Due process for pharmacists when complaints are filed with TSBP
- Medicaid formulary, claims processing
- Medicaid fraud
- Tamper-resistant opioid
- Prescription drug monitoring program changes

Pharmacy Regulations

In addition to frequent, private meetings with TSBP executive director, Gay Dodson, R.Ph., the Association attended all meetings of the Board during the past year.

Regarding the special TSBP task force on sterile compounding, TPA successfully recommended Dee Downing, R.Ph., from Longview and Richie Ray, R.Ph., from Conroe as appointees to the task force. Association staff also attended all meetings of the task force.

TPA also provided testimony regarding the supervision ratio of pharmacy technicians to pharmacists and encouraged a more thoughtful approach in determining the appropriate ratio and in changing any educational requirements for techs.

Although legislation related to the Medicaid Medication Therapy Management program did not pass, the Texas Health and Human Services Commission has initiated discussions with TPA and the UT College of Pharmacy to continue and expand the program to include asthma and COPD.