



2013 Prescription for Pharmacy Legislation

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There were numerous new laws impacting the practice of pharmacy passed or considered during the 2011 Texas legislative session, but none impacted the “economics of pharmacy” more than the decision to move all Medicaid pharmacy benefits into managed care. That transition began on March 1st, 2012 and the impact on retail pharmacies has been devastating to those located in high Medicaid communities. Dispensing fees as well as drug reimbursement rates have been cut across the board and certain legislators are looking to reopen the issue.

However, time moves quickly and notwithstanding the changes to Medicaid managed care, the impact of federal changes found in the Affordable Care Act will be addressed during the 2013 legislative session. The following is a brief forecast of not only the issues that were left over from the previous legislative session, but also those issues that have been developing in the past year. We can anticipate discussions of the following issues during the 2013 legislative session.

Medicaid Managed Care of Pharmacy Benefits – Carve Out.

The shifting of the Medicaid pharmacy benefit from the state-run Vendor Drug Program to managed care has provided significant savings for the state budget, but has occurred mostly to the detriment of retail pharmacies with high Medicaid patient populations. Legislators representing South Texas and the Rio Grande Valley have indicated their interest in “carving out” pharmacy benefits from the managed care system and returning to a state run reimbursement method. This proposal will carry a large fiscal implication for the state which will make passage difficult.

Medicaid “Split-Reimbursement” – Pitting Pharmacy Against Pharmacy

Those pharmacies located in communities with high Medicaid populations are looking for any solution that will mitigate the significant cuts that managed care has brought to the retail community. One idea that has been discussed has been to adopt a different reimbursement rate for pharmacies that are either located within certain areas of the state or who have a higher Medicaid patient mix than others. This would either require additional state appropriations or would result in a lower reimbursement rate for those pharmacies in other parts of the state.

Regulation of Pharmacy Benefit Managers

With the addition of Medicaid drug benefits to the control of managed care, the role of PBMs in the pharmacy delivery system has become substantial and with no state regulation (other than of the insurance companies that use them) the state has taken notice.

Legislation may be recommended that PBMs in Texas should be licensed, registered or regulated by the Texas State Board of Pharmacy. Provisions regulating the;

- ★ Transparency of financial dealings,
- ★ Audit procedures,
- ★ Any-willing provider exemptions,
- ★ Standardized prior-authorization forms,
- ★ Specialty drugs, and
- ★ Contracting practices,

will provide some assurance of ethical practice in the marketplace.

Texas DPS Prescription Monitoring Program....

The legislature several years ago required that prescriptions filled for all schedule II-V drugs be reported to the Texas Department of Public Safety and gave them the responsibility to maintain a data base of information that could be used to identify both providers and pharmacies that prescribe and fill higher amounts of pain medications. This was a part of the DPS effort to identify and close down “pill mills” and the illegal trafficking of drugs. Now that the data base has been upgraded to a system that will allow real time access to reports, one legislator has indicated that he will file a bill requiring all practitioners and pharmacists check the data base prior to prescribing or filling any prescription.

Oversight of Compounding Pharmacies....

The pharmaceutical compounding industry has come under intense review in recent months due to compounded injectable steroid medicines that lead to meningitis illnesses and deaths across 19 states. The FDA closely regulates manufacturers, requiring regular product testing, but the oversight of compounding pharmacies is assigned to the states. The Texas compounding testing program has diminished over time due to budget constraints and present law does not require a separate registration for pharmacies that engage in compounding. One Texas Senator has already indicated that she will file legislation improving the tracking system in Texas, and the debate may also lead to a discussion of the definition of manufacturing versus compounding.

Generic Drug Substitution....

Each legislative session has seen a variety of bills that attempt to limit a pharmacist’s ability to substitute a generic for a brand name drug. There was an effort this past session to prohibit substitution of any drug that came in a “tamper resistant” form – even though the FDA had not approved any drug dosage form as being tamper resistant. While that bill failed, we anticipate that effort, and others will resurface in 2013.

Doctor & Nurse Dispensing....

There were several bills last session that attempted to allow physicians and advanced nurse practitioners to dispense (sell) drugs directly to their patients. Those bills ranged

from broad bills dealing with all non-schedule drugs to others limited to a specific cosmetic drug designed to grow eye-lashes. None of those bills passed, however we are assured that the effort will continue in 2013.

Immunizations by Pharmacists....

Current law allows a pharmacist to give immunizations to adult patients and an effort was made last session to expand that authority to middle school age children to help meet the rush to meet requirements for students before they enter school in the fall. This effort has been opposed by the pediatricians in Texas and we anticipate that the discussion will continue in 2013.

Interchange of Biosimilars....

A biosimilar is a similar version of a biologic medicine approved by the FDA, but is not an exact copy of the original product. The Patient Protection and Affordable Care Act of 2010 created a formal pathway for the FDA to approve the marketing of biosimilar therapies and interchangeability is a standard considered when determining whether a similar medicine can be substituted for one prescribed. The FDA makes the scientific decision as to whether medicines meet that standard, but state laws determine how the substitution is used in practice. Texas law must be amended to determine if a pharmacist may substitute a biosimilar for a prescribed drug without the physicians consent.

Medication Therapy Management by Pharmacists....

Even though MTM is authorized within some managed care programs legislation might be considered to expand the scope of practice to promote MTM as a way to improve patient care and cost savings.

Pharmacy Technician Training, Certification, and Utilization....

The State Board of Pharmacy has identified the training and utilization of technicians as an issue to monitor during the next legislative session. The board has agreed to review replacing current accreditation of technician training programs with TSBP approved programs. The Board has also indicated that they will study the possible expansion of delegated duties for pharmacy technicians who have additional specific training and voluntary certification. Legislation may also be considered to add a Governor's appointed pharmacy technician to the Texas State Board of Pharmacy.

Pharmacy Peer Review....

Following legislation passed in 1999 the Texas State Board of Pharmacy has had the authority to allow for Pharmacy Peer Review Committees as a tool to assess medication errors and evaluate patient safety. Recently other states have passed legislation that *requires* all pharmacies to participate in quality assurance programs that document and evaluate medication errors. Texas may consider a bill next session that will give the TSBP the authority to require pharmacy peer review when necessary to protect the health and welfare of the citizens of Texas.

Pharmacist's Professional Discretion....

Legislation is being considered that will include within a pharmacist's professional discretion the authority to refuse to fill a prescription if the medication order is not for a legitimate medical purpose or was issued without a valid patient-practitioner relationship.

Substitution of Dosage Form....

The State Board of Pharmacy is recommending the removal of the current requirement that prescribing practitioner be notified when a pharmacist makes a substitution of a dosage form as long as the patient consents and the product substituted contains the identical amount of the drug, is not an enteric-coated or timed release product and does not alter the desired clinical outcome.

Pharmacist Service in Small Hospitals....

The TSBP is considering a recommendation to eliminate the current exemption for small hospitals (100 beds or less) from the standard requiring the services of a full-time pharmacist in non-rural hospitals. They are also looking at redefining "rural hospitals" from the current 75 beds to 50 beds, which have the CMS designation and are located in counties with a population of 50,000 or less. Rural hospitals are currently exempt from the full-time pharmacist requirement.

Pharmacist/Technician Relief Services....

Pharmacist relief services are not currently regulated in Texas and the TSBP has had problems in obtaining information from those services. The TSBP is considering a proposal that would give them the authority to register those services and determine which pharmacists and technicians are working for each service.