The 2015 Legislative session was a challenge for the pharmacy profession. The profession needed to defend our Practice Act from numerous attacks from insurance and the medical profession while attempting to pass an ambitious number of bills advancing the practice of pharmacy. The pharmacy community was looking to expand ways to better provide quality care to patients and to enhance the ability of pharmacists to utilize new technologies and advancements in their professional capabilities. That task was made more complicated due to the fact that the last election sent an unprecedented number of new legislators to Austin and that the expanded number of groups representing pharmacy was learning to work as a team. There was no shortage in the number of bills impacting the practice of pharmacy and the following is a brief recap of what passed and what didn’t

### 2015 PHARMACY LEGISLATION THAT PASSED

(Unless otherwise noted, all laws go into effect on September 1st, 2015)

#### TRANSFER OF THE PRESCRIPTION MONITORING PROGRAM TO TSBP.

The Texas Prescription Program collects prescription data on all Schedule II, III, IV, and V controlled substances dispensed by a pharmacy in Texas. The program is currently administered by the Department of Public Safety and is used to monitor and prevent the diversion of prescription drugs. Access to the database is statutorily restricted, and only certain individuals are authorized to access the information to inquire about patients, verify prescription records, and collect useful information about prescription trends. Pharmacy representatives contended that the operation of and certain requirements relating to the program were in need of updating and would be better administered by the Pharmacy Board.

SB 195 by Sen. Schwertner repeals the provisions regarding the requirement that a person register with the Department of Public Safety to dispense a controlled substance and provides for the transfer of the regulation of the official prescription from the Department of Public Safety (DPS) to the Texas State Board of Pharmacy not later than March 1, 2016. The bill also removes the current requirement for a specific DPS identifier number.

#### ADMINISTRATION OF EPINEPHRINE BY PHARMACISTS IN EMERGENCY SITUATIONS.

HB 1550 by Rep. Zerwas expands a pharmacist’s authority to administer an epinephrine auto-injector to any individual in an emergency. Current law only extends only to a patient who is having an allergic reaction as a result of a vaccination or immunization and not to an individual who enters the pharmacy experiencing anaphylactic shock or goes into anaphylactic shock while in the pharmacy. The Pharmacy representatives argued that this limitation created an unnecessary public safety issue, particularly when the pharmacist had a life-saving device readily available.

HB 1550 required the TSBP to adopt rules that provide a pharmacist with the authority to administer epinephrine through an auto-injector device to a patient in an emergency situation and to report the use to the patient’s primary care physician, as identified by the patient.
PUBLIC SCHOOL ADMINISTRATION OF EPINEPHRINE AUTO-INJECTORS.

Anaphylaxis is a severe allergic reaction that is rapid and unpredictable. Alarmingly, some anaphylactic reactions occur in schools among students with food allergies. Primary treatment of anaphylaxis consists of administration of epinephrine as soon as the reaction is identified. Failure to treat anaphylaxis with epinephrine within minutes is a major risk factor for fatality from anaphylaxis.

Public school representatives have expressed concern that public schools are not currently required to have the necessary epinephrine auto-injectors available to treat individuals suffering from anaphylaxis. S.B. 66 by Sen. Hinojosa requires each school district and open-enrollment charter school to adopt and implement a policy requiring the maintenance, administration, and disposal of epinephrine auto-injectors at each campus in the district or school. S.B. 66 also authorizes a physician to prescribe epinephrine auto-injectors in the name of a school district or open-enrollment charter school and requires the physician to provide the school district or open-enrollment charter school with a standing order for the administration of an epinephrine auto-injector to a person reasonably believed to be experiencing anaphylaxis. **The bill authorizes a pharmacist to dispense an epinephrine auto-injector to a school district or open-enrollment charter school without requiring the name or any other identifying information relating to the user.**

PBM TRANSACTION FEES PROHIBITED

The Texas Department of Insurance noted that pharmacy benefit managers were not subject to the same prohibition on charging a transaction fee for electronically submitted claims that health benefit plans are subject to. Pharmacy representatives contended that pharmacy benefit managers are charging unnecessary fees to pharmacists and pharmacies for electronically submitted transactions as a consequence of this disparity resulting in millions of dollars lost in reduced claims payments.

S.B. 94 by Sen. Hinojosa amends the Insurance Code to **prohibit a health benefit plan issuer or a pharmacy benefit manager from directly or indirectly charging or holding a pharmacist or pharmacy responsible for a fee for any component or mechanism related to the pharmacy benefit claim adjudication process.**

MAC PRICING FOR GENERIC DRUGS

Pharmacies note that pharmacy benefit managers each use their own formula based on maximum allowable cost (MAC) to reimburse pharmacies for dispensing generic medications. However, pharmacies explain, there is no transparency in the method by which a pharmacy benefit manager determines which drugs will be reimbursed using a MAC formula, what the price will be, when the price will change, and what sources are used to determine MAC prices. Pharmacies contend that this lack of transparency creates major challenges for pharmacies and note that recent legislation enhancing the transparency of MAC pricing in Medicaid managed care should be extended to the commercial insurance market.

S.B. 332 by Sen. Schwertner amends the Insurance Code to **prohibit a health benefit plan issuer or pharmacy benefit manager from including a drug on a maximum allowable cost list unless the following conditions apply: the drug is not obsolete, the drug is generally available for purchase by pharmacists and pharmacies in Texas from a national or regional wholesaler, and the drug has an “A” or “B” rating in the most recent version of the U.S. Food and Drug Administration’s (FDA) Orange Book, or is rated “NR” or “NA” or has a similar rating by a nationally recognized reference. SB 332 implements numerous other transparency improvements relating to MAC pricing practices by PBMs.**

REGULATION OF PHARMACY DISCOUNT CARDS

Discount health care programs can be a useful tool for consumers to lower the cost of pharmaceutical drugs. However, concerns have been raised regarding whether these discounts are being offered without the consent or knowledge of the pharmacy dispensing the drugs. It has also been suggested that a pharmacy may be required to participate in certain discount health care programs as a condition of accessing certain provider networks.

H.B. 3028 by Rep. John Frullo amends current law to **regulate the conduct of discount health care program operators and requires a separate contract with each pharmacy prohibits payments to healthcare providers to promote the use of discount cards and prohibits misleading information to be printed on the discount cards.**

POSSESSION OF OPIOID ANTAGONISTS FOR THE TREATMENT OF OPIOID OVERDOSES.

Healthcare providers contend that drug overdose is one of the leading causes of accidental death in the United States, with opioid painkillers accounting for a large majority of these cases. Prioritizing access to anti-overdose medications by making such medications more available by prescription is a critical element of reducing opioid overdose deaths.

S.B 1462 by Sen. West amends the Health and Safety Code to **authorize a prescriber to prescribe an opioid antagonist to a person at risk of experiencing an opioid-related drug overdose or to a family member, friend, or other person in a position to assist such a person. SB 1462 authorizes a pharmacist to dispense an opioid antagonist under a valid prescription to a person at risk of experiencing an opioid-related drug overdose or to a family member, friend, or other person in a position to assist such a person.**
MEDICAID MANAGED CARE REFORMS

The vast majority of individuals enrolled in the Texas Medicaid program are served through contracts with managed care organizations. Providing access to care through adequate provider networks is one of the most important functions of these state contractors. S.B. 760 by Sen. Schwertner seeks to provide the Health and Human Services Commission the tools necessary to adequately monitor these contracts and ensure that managed care organizations are being held accountable for having adequate provider networks to deliver the care for which the state is paying.

S.B. 760 requires the Health and Human Services Commission (HHSC) to establish minimum provider access standards for the provider network of a managed care organization that contracts to provide health care services to Medicaid managed care recipients. S.B. 760 also requires a managed care organization that contracts with HHSC to:

- Establish and implement an expedited credentialing process that would allow applicant providers to provide services to Medicaid recipients on a provisional basis and requires HHSC to identify the types of providers for which the expedited credentialing process must be established and implemented,
- Prohibits a PBM from collecting rebates on Vendor Drug Formulary products,
- Prohibits a PBM from limiting a patient's selection of a pharmacy through different copayments,
- Prohibits PBM exclusive contracts with specialty pharmacies owned by a PBM,
- Prohibits a PBM from excluding a pharmacy's participation as a provider if they agree to the terms and conditions of the contract, and
- Prohibits a PBM from requiring a patient's selection of a mail order pharmacy.

INTERCHANGE OF BIOSIMILARS FOR BIOLOGICS

The development and use of biologics has led to advancements in the treatment of difficult-to-manage diseases and disorders such as cancer, multiple sclerosis, rheumatoid arthritis, heart disease, HIV and AIDS. A biosimilar, or follow-on biologic have similar properties to existing biological products but are not identical. Federal law provides for the approval of biosimilars, but a formal regulatory process is still being established by the United States Food and Drug Administration (FDA).

H.B. 751 by Rep. Zerwas updates the Texas Pharmacy Practice Act by allowing Texas pharmacists to substitute an FDA approved interchangeable biosimilar for a prescribed brand name biologic. H.B. 751 would update current substitution laws to include a similar process to ensure safe biologic substitution. Physicians will retain the authority to use Dispense as Written and ensures that physicians will be notified of the substitution. That notification requirement will allow pharmacies to use their existing pharmacist benefit management system to communicate with physicians.

CANNABIS OIL FOR TREATING EPILEPSY.

According to estimates of the Epilepsy Foundation of Texas, intractable epilepsy afflicts almost 150,000 people in this state. Concerned parties explain that patients with intractable epilepsy can suffer dozens or more severe seizures each week and that these individuals are at a higher risk for disability, injury, and even death. S.B. 339 by Eltife seeks to regulate the growth and dispensation of low-THC cannabis for use in treating certain Texas residents diagnosed with intractable epilepsy.

The bill amends the Occupations Code to authorize a qualified physician to prescribe low-THC cannabis to a patient with intractable epilepsy, defined by the bill as a seizure disorder in which the patient's seizures have been treated by two or more appropriately chosen and maximally titrated antiepileptic drugs that have failed to control the seizures.

S.B. 339 requires a dispensing organization to obtain a license issued by DPS; sets out eligibility and application requirements for such a license; provides for the issuance, renewal, or denial of a license; and establishes provisions relating to the suspension or revocation of a license. The bill also exempts from the Texas Pharmacy Act a dispensing organization that cultivates, processes, and dispenses low-THC cannabis.

PHARMACY BOARD CLEAN-UP BILL

Each legislative session the Texas Pharmacy Board recommends updates to the Texas Pharmacy Act to close loopholes and keep pace with changing technologies. S.B. 460 by Sen Schwertner seeks to amend the law in order to increase the efficiency of the Texas State Board of Pharmacy and hold bad actors accountable.

S.B. 460 amends the Pharmacy Practice Act to:

- authorize a pharmacist, in the event of a natural or manmade disaster, to dispense not more than a 30-day supply of a dangerous drug without the authorization of the prescribing practitioner,
• authorize the Board to allow required notices within a pharmacy to be posted on an electronic messaging system,
• authorize a board representative to enter and inspect a facility relative to financial records relating to the facility’s operation but restricts the board’s inspection of those records to an inspection in the course of the investigation of a specific complaint,
• require a pharmacist to provide to the board records of the pharmacist’s practice that occurs outside of a pharmacy,
• increase from two to four the maximum number of times an applicant for a license to practice pharmacy may retake the licensing examination,
• reduce from one year to 91 days the minimum amount of time that a pharmacy’s license can be expired before

2015 PHARMACY LEGISLATION THAT DID NOT PASS

PHYSICIAN DISPENSING OF CERTAIN AESTHETIC DRUGS
HB 1483 by Rep. Zerwas would have amended the Occupations Code to authorize a physician to dispense to patients an aesthetic pharmaceutical in excess of the patient’s immediate needs without obtaining a license to practice pharmacy and authorizes the physician to charge a fee for dispensing the pharmaceutical.

IMMUNIZATIONS ADMINISTERED BY A PHARMACIST
SB 480 by Sen. Perry would have authorized a pharmacist to administer vaccinations and immunizations to children age seven years or older. The pharmacist would have been able to charge a fee and would be responsible for notifying the physician of record.

SMOKING CESSATION DRUGS DISPENSED BY A PHARMACIST
HB 3246 by Crownover would have allowed a pharmacist to dispense and deliver smoking cessation drugs without a prescription.

SYNCHRONIZATION OF PRESCRIPTION DRUGS
HB 3025 by Rep. Farney would have allowed a pharmacist to work with patients to synchronize their refill dates so that prescriptions could be refilled on the same day each month.

REIMBURSEMENT FOR EARLY REFILLS
HB 185 by Rep. Zedler would have required a health benefit plan to provide benefits for a refill, regardless of whether the refill was early if the prescription would have been covered if dispensed on time.

REGULATION OF PHARMACY BENEFIT MANAGERS BY TDI
HB 2618 by Rep. Munoz would have provided a definition of a PBM and would have required them to be regulated by the Texas Department of Insurance. Certain contracting and marketing practices would have specifically prohibited.

AUTHORITY OF PHARMACY SERVICE ADMINISTRATIVE ORGANIZATIONS
HB 2479 by Rep. Guerra would have authorized PSAOs to engage in contract negotiations with PBMs on behalf of individual pharmacies.

REGULATION OF THE SALE OF DEXTROMETHORPHAN TO MINORS
HB 3066 by Rep. Coleman would have amended the Health and Safety Code to prohibit a business establishment from selling dextromethorphan to a customer under 18 years of age without a prescription.

TRANSFER OF UNUSED DRUGS FROM HOSPITALS
HB 1008 by Rep. Davis would have allowed a health facility to transfer unused Medicaid medications to the Texas Department of HHS to be used in state health facilities.

PILOT PROGRAM FOR DONATION OF UNUSED PRESCRIPTION MEDICATIONS
HB 2271 by Rep. Sheffield would have required the Department of State Health Services (DSHS) to establish a pilot program that would have authorized a licensed convalescent or nursing facility, licensed hospice, hospital, physician, pharmacy, or a pharmaceutical seller or manufacturer to donate certain unused prescription drugs to DSHS for the pilot program.

LIMITATION ON PAIN MEDICATION REFILLS
HB 3200 by Rep. Capriglioni would have prohibited a pharmacist from dispensing more than a 10-day supply of an opioid pain medication for that patient in a 60-day period unless the pharmacist receives a form from the prescribing physician stating that the physician intended that the patient be treated for pain for a period longer than 10 days.