



Interim Report

to the 84th Legislature

House Committee on
Public Health



December 2014

**HOUSE COMMITTEE ON PUBLIC HEALTH
TEXAS HOUSE OF REPRESENTATIVES
INTERIM REPORT 2014**

**A REPORT TO THE
HOUSE OF REPRESENTATIVES
84TH TEXAS LEGISLATURE**

**LOIS W. KOLKHORST
CHAIRMAN**

**COMMITTEE CLERK
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Committee On
Public Health

December 30, 2014

Lois W. Kolkhorst
Chairman


P.O. Box 2910
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The Honorable Joe Straus
Speaker, Texas House of Representatives
Members of the Texas House of Representatives
Texas State Capitol, Rm. 2W.13
Austin, Texas 78701


Dear Mr. Speaker and Fellow Members:

The Committee on Public Health of the Eighty-third Legislature hereby submits its interim report including recommendations and drafted legislation for consideration by the Eighty-fourth Legislature.

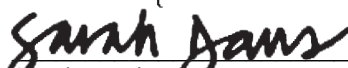
Respectfully submitted,



Lois W. Kolkhorst



Elliott Naishtat, Vice Chair

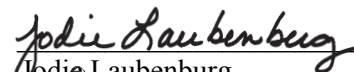

Nicole Collier

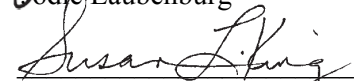

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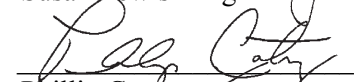

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**PUBLIC HEALTH
HOUSE COMMITTEE ON PUBLIC HEALTH**

INTERIM STUDY CHARGES AND SUBCOMMITTEE ASSIGNMENTS

- 1) Assess the prevalence of nonmedical prescription drug use in the state (including opioid analgesics, stimulants, tranquilizers, and sedatives). Identify adverse health impacts. Recommend strategies to curb emerging substance abuse trends among children, pregnant women, and adults, as well as to reduce health care costs and mortality.
- 2) Study and make recommendations for improvements to the licensing, regulation, and monitoring of compounding pharmacies, including a review of the joint cooperative efforts between the Texas State Board of Pharmacy, Department of State Health Services, and U.S. Food and Drug Administration. Consider the impact of the passage of SB 1100 (83R), additional appropriations made by the 83rd Legislature to strengthen inspections, and any relevant federal legislation.
- 3) Identify strategies to support the efficient exchange of electronic health information with Texas Health and Human Services enterprise agencies. Examine legal and technical issues around the accessibility of information held in registries maintained by state agencies to authorized health care providers. Identify issues related to health information exchange and providers' liability, as well as concerns related to transitioning patient data in cases where a provider selects a new electronic health record vendor.
- 4) Examine the current practice for dispensation of biologic and follow-on biologic (biosimilar) pharmaceutical products in our state. Review any practices for interchangeability of drugs that might pertain to these particular medicines. Review and make recommendations regarding the substitution of biosimilar and biologic medicines.
- 5) Monitor transition of the state's immunization registry to a new system. Determine whether the registry can be better utilized to prevent and/or respond to communicable disease outbreaks, including pertussis. Identify potential factors contributing to the rise in the number of pertussis cases and strategies to prevent future outbreaks.
- 6) Conduct legislative oversight and monitoring of the agencies and programs under the committee's jurisdiction and the implementation of relevant legislation passed by the 83rd Legislature, including HB 15 (83R). In conducting this oversight, the committee should:
 - a) consider any reforms to state agencies to make them more responsive to Texas taxpayers and citizens;
 - b) identify issues regarding the agency or its governance that may be appropriate to investigate, improve, remedy, or eliminate;
 - c) determine whether an agency is operating in a transparent and efficient manner; and
 - d) identify opportunities to streamline programs and services while maintaining the mission of the agency and its programs.

CHARGE #1

Assess the prevalence of nonmedical prescription drug use in the state (including opioid analgesics, stimulants, tranquilizers, and sedatives). Identify adverse health impacts. Recommend strategies to curb emerging substance abuse trends among children, pregnant women, and adults, as well as to reduce health care costs and mortality.

RECOMMENDATIONS

1. Make improvements to the state's prescription drug monitoring program (PDMP) by providing incentives to healthcare providers to use the program without interfering with their ability to administer care according to the accepted standards of their professions, including:
 - a. making prescribing information available in real time;
 - b. developing interoperability with other states;
 - c. implementing an appropriate transition plan of the PDMP from the Department of Public Safety to the Texas State Board of Pharmacy, as described in the report published in December 2010 from the interagency council created by HB 2730 of the 81st Legislature, Regular Session;
 - d. developing a program that identifies suspicious prescriber and patient behavior and alerts prescribers, licensing boards, and law enforcement;
 - e. allowing prescribers to automatically enroll in the PDMP when they renew their license, if not requiring them to;
 - f. creating continuing a medical education program to teach practitioners the benefits of using the PDMP; and
 - g. drafting laws that define a health care provider's liability for handling a patient's medical records through the PDMP.
2. Provide education to pregnant mothers on Medicaid benefits who are prescribed opioids painkillers.
3. Educate the public on the safe storage, use, and disposal of prescription drugs and how to report a pill mill.
4. Facilitate take-back programs like those used by the federal Drug Enforcement Agency; increasing state and local take-back programs.
5. Expansion of medication-assisted treatment for opioid-addicted individuals, such as Opioid Substitution Therapy (OST), with particular emphasis on appropriate treatment for pregnant women and young users.
6. Expand the use of the drug naloxone in a meaningful way that prevents people from overdosing on opiates, and saves lives, including providing the naloxone to first responders or friends and family of addicts.
7. Extend the two-year renewal period currently applied to physicians registered with the Controlled Substances Registration established by HB 1803 from the 83rd Legislature, Regular Session, to all prescribers, including advance practice registered nurses.

BACKGROUND

Prescription drug abuse is not a new issue to the Texas Legislature but it nevertheless continues to grow at an alarming rate. The Centers for Disease Control and Prevention (CDC) reports that, since 2011, drug overdose deaths have become the leading cause of injury deaths in the United States surpassing car wrecks. A recent study by the CDC and the University of Pennsylvania concluded that opioid pain relievers are the most common class of medications consumed in the United States. Additionally, the House Public Health Committee heard testimony stating that hydrocodone is the most frequently prescribed drug in the United States today, with U.S. consuming 99% of the world's supply.

A recent policy paper by the Association of State and Territorial Health Officials cited a study from the National Institute on Drug Abuse that found 210 million prescriptions were filled for opioid pain relievers. In 2010, an amount sufficient for every American receive a typical adult dose of hydrocodone every four hours for an entire month. In 2014, hydrocodone, a schedule II substance by itself, made national news when the Drug Enforcement Administration rescheduled hydrocodone combination products from schedule III to schedule II of the Controlled Substances Act.

Despite many troubling statistics on the proliferation of prescription pain killers, pain management is still a legitimate concern of the medical community. A 2011 report from the National Institute of Medicine estimated that 100 million Americans suffer from chronic pain and 10 million are disabled by it. Pain management became a growing niche in medicine during the mid-1990's, as with the growth of managed care and the return of veterans who required effective treatment for chronic pain. The Veterans Health Administration added pain as the "fifth vital sign" in 1999 when patients describe their discomfort on a scale of 1 to 10. To feed the rising demand, Drug manufacturers developed new forms of opiates like OxyContin that did not have the negative properties of heroin or morphine and were cheaper than non-opioid treatment like physical therapy.

As practitioners' grew indifferent to the prevalence of these legitimate drugs, opiate abuse escalated through the 1990's into the 2000's. The mortality rate for overdoses in Texas between the years 1999 and 2010 increased by 78%. According to the CDC, Texas ranks 44th in the nation for drug overdose death rates in the nation, 33rd for highest opioid pain relief prescribing rates, and 12th for the prescription of nonmedical opioid pain relievers.

Aside from the creation of the state's prescription drug monitoring program in the 1980's and subsequent legislation to enhance it, the Texas Legislature did not address the growing trend in prescription drug abuse until the late 2000's. In the 81st Legislative Session, Sen. Tommy Williams (R-Woodlands) filed several bills to combat the rise of "pill mills" and the practice of shopping doctors to receive massive amounts of prescriptions. Harris County in particular had earned a reputation, coining the term "the Houston Cocktail," a powerful combination usually consisting of hydrocodone (Vicodin), carisoprodol (Soma) and alprazolam (Xanax).

The Legislature passed SB 904 in 2009 which made carisoprodol a schedule IV drug and placed restrictions on refills and instituted stiffer penalties for possessing and distributing the

drug without therapeutic use. During the same Session, SB 911 created licensing and inspection schemes for legitimate pain management clinics through the Texas Medical Board. As of April 2014, the Board had received 816 applications initially granting 455, reviewing 121, denying 26, with 94 currently pending, and 46 expired applications]. Since December 2012, the Board has taken approximately 85 disciplinary actions related to nontherapeutic prescribing. During the last session, the Legislature granted funding for additional staff to conduct biennial inspections of clinics. In oral testimony to the House Public Health Committee, the Board's Executive Director Mari Robinson described particularly bad actors with clinics flush with cash and guns.

Additionally, SB 158 in 2011 created criminal penalties for doctor shopping and enhanced penalties for illicitly distributing prescription drugs including an organized criminal activity statute.

The rise of drug abuse from prescription opiates involves many other illicit activities. Dr. Jane Maxwell from the University of Texas at Austin School of Social Work described in her testimony before The Public Health Committee the compulsion of addicts to ingest opiates, either prescribed or illicit, to fight off the sickness caused by withdrawal. According to Dr. Maxwell, this compulsion to stave off sickness, not the sensation of "getting high," is the nature of addiction.

Because the street value of heroin is much cheaper than the street value of prescription drugs, addicts often turn to street drugs to support their drug habit. A recent publication of the National Governors Association, cited a study by the *International Journal of Drug Policy* that found 86% of heroin users started on prescription opioids. The Association of State and Territorial Health Officials (ASTHO) reports that 82.6% of heroin users had used prescription drugs before heroin. The ASTHO reported that heroin treatment admissions rose from 33,606 in 2000 to 55,598 in 2010. U.S. Attorney General Eric Holder stated in a March 2014 press release that heroin deaths increased 45% from 2006 to 2010.

Experts continue to study the rise in heroin use as policies discouraging prescription drug abuse take root. The increased price and scarcity of prescription opioids along with reductions in supply caused by law enforcement activity and the development of abuse-deterrent drug formulations often causes addicts to resort to street heroin.. One study by Theodore Cicero, a psychiatry professor at Washington University in St. Louis, found that abuse-deterrent technology developed for OxyContin alone caused heroin use to nearly double.

The tie between prescription drug and heroin abuse exists, whether it is a by-product of stricter policy reforms on prescriptions or simply a natural consequence of their similar effects on the body. In the year in a press release from the Justice Department, U.S. Attorney General Eric Holder stated "The transition to – and increase in- heroin abuse is a sad but not unpredictable symptom of the significant increase in prescription drug abuse we've seen over the past decade."

Prescription abuse is not limited to opioid pain killers and heroin. Dr. Maxwell also testified that 87% of deaths from opiates involve benzodiazepines. During testimony, Rep. Garnet Coleman expressed concern that prescription drugs, such as amphetamines, could be used to illicitly trade for opioids and benzodiazepines, particularly with youth.

While much of the information resources submitted to the Public Health Committee focused

on the dangers of prescription painkillers, the prevalence of other prescription drugs should be noted for the purposes of this report. In a recent publication by the Drug Enforcement Agency citing a 2011 study of the National Survey on Drug Use and Health, 2.7% of the U.S. population takes psychotherapeutic drugs taken non-medically, including:

- 5.1 million people using pain relievers;
- 2.2 million people using tranquilizers;
- 1.1 million people using stimulants, and
- .4 million people using sedatives.

However, upon reviewing admissions into state supported prescription abuse treatment in Texas, opioids are the most frequently used substances for Fiscal Years 2011 through 2013. Opioid treatment admissions were more than triple the admissions for the next highest substance, amphetamines. Dr. Jane Maxwell from the University of Texas at Austin School of Social Work testified before the Public Health Committee that statistics showed a greater prevalence of methamphetamines over prescription amphetamines. In 2013, 59 calls were made to poison control centers for prescription amphetamines like Ritalin or Concerta, but 503 calls for methamphetamine. The meth problem is even greater now than in 2006, when large quantities of pseudophedrine were banned. The meth found on the streets today comes from Mexico, where the “P2P” process is used to create a product that is 96% pure.

TEXAS’ PRESCRIPTION DRUG MONITORING PROGRAM

The roots of the modern Texas Prescription Program (“the Program”) date back to 1982, when the State first began monitoring the dispensation of Schedule II controlled substances. The program later expanded in 2008 to include Schedules III through V, classification system of descending categories of controlled substances adopted by the Commissioner of the Health and Human Services Commission based on Federal law. Substances are classified according to medical use and its potential for abuse. For the purposes of this report, Schedule I drugs will not be discussed, as they are essentially deemed to have little or no medical value in relation to their potential for abuse or dependency.

The Texas Controlled Substances Act (TCSA), found in Chapter 481 of the Texas Health and Safety Code governs practitioner and pharmacist behavior in Texas and establishes the Texas Prescription Program. Title 37, Chapter 13 Subchapter D of the Texas Administrative Code, regulates the program at the administrative level. The Program originally required practitioners to use a designated triplicate form to fill Schedule II prescriptions. Since the Program’s expansion in 2008, a provider may use other valid paper forms to prescribe controlled substances in subsequent drug Schedules and, in limited instances, electronic transmittals. Pharmacists were obligated by law to send records of the prescriptions to the Department of Public Safety (DPS), who kept this information searchable for practitioners and pharmacists to inquire about a patient they were treating and for law enforcement professionals investigating abuse. Subdivision 481.075(i)(3) of the Health and Safety Code, pharmacists must submit prescription data to DPS no later than seven days after the prescription was filled.

Until 2012, all requests for a patient’s prescribing history were made in writing and sent by mail to DPS to receive a printout back in the mail. The Program became accessible online in

June of 2012 to all providers and pharmacists who registered an account through a portal called Prescription Access in Texas (PAT). Compiled from the data DPS regularly receives from pharmacists, the PAT provides an electronic spreadsheet file to registrants who seek a prescription history on a particular patient. While the file can be delivered electronically, physicians and pharmacists can request hard copies of a patient's prescription history by mail without PAT account. Healthcare professionals in Texas are not required to register with or use the PAT. Law enforcement may also access PAT but only for violations of the Texas Controlled Substances Act and not to get the location or patient history of a suspect for a crime not covered by the TCSA.

Regardless of whether a provider registers with the PAT, all pharmacists and prescribers renew their registration with the Texas Prescription Program when they renew their medical license. Prescribers have to register with the Program in order to receive the prescription pads necessary to prescribe a patient a Schedule II controlled substance and pharmacies have to send information on the Schedule II prescriptions they fill to the Program within seven days. HB 1803 from the 83rd Regular Session allowed physicians to renew their registration with the Controlled Substance Registration Program every two years instead of annually, and SB 1643 made several changes to prescription monitoring, including:

- keeping records for three years instead of one,
- authorizing access to prescription information through a health information exchange,
- allowing access to licensed registered nurses/licensed vocational nurses and pharmacy technicians,
- allowing prescription information to be kept in medical records, and
- clarifying language regarding pain management certification for applicants under investigation for offenses related to controlled substances.

According to testimony by the Texas Medical Board submitted to the Senate Health and Human Services Committee on August 15, 2014, none of these legislative initiatives from 2013 have been implemented by DPS.

PREGNANT MOTHERS AND OPIOIDS

The Department of State Health Services (DSHS) targets pregnant women as a “high risk” population and oral testimony on the Public Health Committee’s Charge # 1 on April 7, 2014 focused heavily on the trend of pregnant mothers taking opioid painkillers during pregnancy. Echoing the concerns of DSHS staff, an April 2014 article in *The New York Times* cites two different recently published studies in the medical journals *Obstetrics & Gynecology* and *Anesthesiology*. One study published last February focused on privately insured women and found that, from 2005 to 2011, about fourteen percent of women were prescribed opioids at least once during pregnancy. The other study found that the percentage nationally of pregnant women on Medicaid filling opioid prescriptions had grown from 18.5% in 2000 to nearly 23% in 2007. The study shows that nearly one in four pregnant women on Medicaid are prescribed opioids. In a May 2014 presentation, DSHS staff found that drug overdose is the third leading cause of death for women who are pregnant or have given birth within the last year.

Prenatal consumption of opioid affects more than the mother's health. DSHS staff described in committee testimony the rising trend of Neonatal Abstinence Syndrome (NAS), the neonatal withdrawal after exposure to drugs in the womb that abruptly stops at birth. NAS is an acute, temporary condition. Depending on symptom severity, hospitalization may be required for administration of medications. Symptoms can be managed at home once they become less severe. While each baby is different, symptoms usually last about 14 days, though mild symptoms can persist beyond 14 days. There are no prolonged affects associated with NAS and typically by age 2 there are no observable developmental differences between babies born with and without NAS.

NAS is not the only negative effect caused by exposing a fetus to drugs during pregnancy. Recent studies by the CDC and its partners have shown correlations between opioids consumed during pregnancy and neural tube defects and spina bifida. Neural tubes form early and defects may occur before a woman even knows she is pregnant. These early structures develop and close to form a baby's brain, skull, spinal cord, and back bones. Spina bifida is one particular defect of the neural tubes possibly caused by drug abuse, where the backbone protecting the spinal cord does not close properly, resulting in damage to the spinal cord and nerves.

During the House Public Health hearing, Vice-Chair of House Public Health Elliott Naishtat began questioning how many Medicaid births occur where the mother is prescribed opioids during pregnancy. Medicaid covers 45% of births nationally and 54% of births in Texas spending \$2.2 billion. According to data provided by DSHS in later testimony to the Senate Committee on Health and Human Services, recent figures on Medicaid births involving NAS were 854 in 2011, 994 in 2012, and 1009 in 2013. The cost for inpatient services to those NAS births were \$31,822,422 in FY 2011, \$30,334,312 in FY 2012, and \$31,602,668 in FY 2013. In testimony to the House Committee on Public Health, Commissioner Mike Maples with DSHS stated that opioid and heroin abuse was the top.

SUCCESS AT THE WORKERS COMPENSATION DIVISION

The Workers Compensation Division at the Texas Department of Insurance (TWC) also testified before the committee to some decreased prevalence of prescriptions made to its beneficiaries that may have either been too risky or medically unnecessary. TWC covers all governmental employees and 81% of private sector employees, spending \$2 billion in direct written premiums with 270 insurance companies actively writing. Prescription drugs account for about 14% of TWC's medical payments, of which almost a third are opioids.

The Texas Labor Code Section 408.028(b) directs the Commissioner of Workers' Compensation to adopt a closed formulary for pharmaceutical services within TWC. This formulary was developed with TWC and stakeholders, including care providers and insurance carriers, and was adopted by rule in December 2010 for claims with a date of injury on or after Sept. 1, 2011. The closed formulary includes all FDA-approved drugs prescribed and dispensed for outpatient use, but excludes:

- drugs with “N” status identified in the current edition of the Official Disability Guideline (ODG) Treatment in Workers’ Comp/ Appendix A, ODG Workers’ Compensation Drug Formulary and any updates;
- any compounded drugs that contains a drug identified with an “N” status in ODG; and
- investigational or experimental drugs as defined in Texas Labor Code §413.014(a).

The prescribing doctor, the injured employee, or the dispensing pharmacy may request for preauthorization approval to prescribe, receive, or dispense a drug excluded from the closed. If denied, the requestor may submit a request for medical dispute resolution to an independent review organization, as stated in 28 Texas Administrative Code §133.308, and then appeal that decision to a Division contested case hearing. In the event of an unreasonable risk of medical emergency, prescribing doctors or pharmacies may request a medical interlocutory order under §134.550 and an injured employee may request an interlocutory order.

Data from TWC is available only from the years before and after implementation of the closed formulary, but cumulative pharmaceutical claims per injury fell two percent total between 2010 and 2011. Claims for “N” status drugs dropped 65% with total prescriptions written for these drugs decreasing 74% between these two years. Total cost of all drugs dropped 14% as the cost of “N” status drugs tumbled 82% from 2010 to 2011, while the cost of drugs off the “N” list actually increased slightly. Opioid use reduced 10%, and TWC saw better use of generic alternatives to brand name drugs during this time.

According to Commissioner Rod Bordelon, opioid use reduced 10%, and TWC even saw better use of generic alternatives to brand name drugs during this time. While TWC will continue to monitor the apparently effective impact of the closed drug formulary, Commissioner Bordelon reported better treatment coordination between prescribing doctors and insurance carriers on individual workers’ compensation claims and no rise in medical necessity disputes or complaints from injured employees.

The private sector has also embraced the concept of a controlled formulary. In Massachusetts, Blue Cross Blue Shield of Massachusetts, the state’s largest insurer, implemented a prior approval process for prescription narcotic painkillers. For short-acting opioids generally effective for four to six hours, a patient can receive a fifteen-day prescription with a single fifteen-day refill without prior approval from the insurance company. Longer-acting opioids, generally lasting 10 to 12 hours, needed prior authorization even before the reform. Essentially, the insurer must evaluate the patient's risk of addiction in a treatment plan pre-approved by practitioner. Some of the insured are exempted prior authorization like cancer patients or patients with terminal illnesses.

The reform was in response to practitioners’ description of a pattern easy access to these highly addictive frequently overprescribed substances. After the reforms of July 2012, prescription rates for shorter-acting opioids decreased by 20%. Even though the prior authorization process already existed for longer-acting drugs, these prescriptions declined 50% during the 18 month reporting period. The program was designed only to restrict access to these highly addictive substances but to change the attitudes of prescribers. As *The Boston Globe* quoted Dr. Anton Dodek, associate chief medical director for Blue Cross, “We were trained that

way: just write 30-day prescriptions.”

In addition to limiting access to longer- and short-acting drugs, Blue Cross Blue Shield of Massachusetts has been proactive by working with in-network providers to curb their contributions to statewide narcotic supply. The insurer contacts physicians when patients have gotten narcotic prescriptions from three or more prescribers within a six month period, and case managers have been hired to work with practitioners on non-narcotic methods of pain management. Other insurers in Massachusetts have been equally proactive. Tufts Health Plan and Harvard Pilgrim Health Care have developed algorithms to track outlier patients as well as perform periodic audits on physicians and pharmacies. Dr. Ronald Dunlap, president of the Massachusetts Medical Society, praised the efforts in *the Boston Globe* but hoped for a single monitoring system in the future. “You don’t want to go into three different systems,” he was quoted.

Some managed care companies (MCOs) also use a process known as “lock in,” where internal reporting determines whether certain patients meet criteria for potential prescription abuse. The criteria often involve the number of prescribers visited, quantity and types of drugs received, and prior diagnosis of drug or alcohol abuse. After the patients' records are reviewed by the MCO and “lock-in” status is approved, the patient is often restricted to certain practitioners or pharmacies. One MCO, Centene will restrict patients in the “lock in” program to a single pharmacy, not necessarily a single prescriber.

In the fall of 2014, the Pharmaceutical Care Management Association, representing pharmacy benefit managers nationally, urged Congress to implement a “lock in” program in the Medicare Part D prescription program in order to fight fraud and abuse. Their proposal would allow beneficiaries to pick their pharmacy for dispensing controlled substances. In a press release picked up by KXXV in Waco, CEO Mark Merritt was quoted, “This battle must be won at the pharmacy counter.”

OTHER PROGRAMS

The battle lines, however, extend beyond simply the retail pharmacy. A recent survey released by the Substance Abuse and Mental Health Services Administration found that 54% of people abusing prescription drugs received them through friends and family, often from drugs still in the medicine cabinet. Similarly, the Drug Enforcement Administration reported that 70% of seniors in high school receive prescription drugs through a friend or relative.

In 2010, the DEA began the “National Prescription Drug Take-Back Day,” which has led to biannual events every year since the program’s initial inception. Compared to 242,000 pounds collected in 2010, the program took back 780,158 pounds of prescription drugs delivered to local entities authorized by the U.S. Attorney General in April of 2014.

In addition to the success of the national program, cities like Fort Worth have installed permanent drop boxes for turning in unused prescriptions. Online, Fort Worth provides citizens information on proper disposal of their controlled substances, and discourages simply flushing the drugs down the drain to contaminate the water supply. The website suggests seeking take-back programs from public or private entities (some participating pharmacies have their own

programs) and provides instruction on safely throwing the drugs away, such as crushing them in with unpalatable substances like coffee grounds or cat litter. Not only are take-back programs successful for every unnecessary pill taken off the street, but they also raise awareness to citizens of the danger sitting unsecured in their medicine cabinets.

While many programs aim to prevent prescription addiction, substance abuse treatment is also essential to combating prescription abuse in Texas. In a recent publication of the National Governor's Association, the National Institute on Drug Abuse reported that one dollar invested in substance abuse treatment yields between four and seven dollars in reduced costs related to crime and theft. Attitudes are clearly changing toward substance abuse, as it was included as "primary care" under the Affordable Care Act.

Texas received \$116.8 million through the federal Substance Abuse and Treatment Block Grant, so, with appropriations from General Revenue and some other grants, Texas has \$150,976,220 in funding available for FY 2014. About 60% of these funds go to treatment with the remaining 40% going to prevention and intervention programs. Adults in Medicaid are eligible to receive the following substance abuse treatment benefits:

- assessment (once per episode of care);
- outpatient treatment (substance abuse treatment counseling – up to 26 hours of individual counseling, and 135 hours of group counseling)
- ambulatory detoxification (up to 21 days);
- residential detoxification (up to 21 days) Residential treatment (up to 35 days per episode of care); and
- medication-assisted therapy (e.g., methadone or buprenorphine for opiate addiction, etc.) – not limited.

To find state benefits for substance abuse, regional offices with the Department of State Health Services can connect beneficiaries to local programs. Outreach, Screening, Assessment, and Referral (OSAR) is a program funded by DSHS that provides confidential alcohol and drug screenings and assessments, referrals for state-funded inpatient and outpatient drug and alcohol treatment, brief interventions that include motivational counseling, education and support, and case management for clients who need assistance accessing supportive services.

There are 11 OSAR regions throughout the state. All Texas residents who are seeking substance abuse services and information may qualify for the OSAR program. Interested individuals can schedule an appointment with the OSAR in their area to complete a screening and if needed, a drug and alcohol assessment. After the initial appointment, OSAR can provide case management and weekly brief counseling sessions.

For the last three years, nonmedical prescriptions account for between twelve and thirteen percent of admissions to state funded substance abuse programs. Heroin admissions account for another twelve to thirteen percent, which is relevant to the big picture of prescription abuse because opiate addicts typically switch between heroin and its synthetic counterparts.

In the event of an overdose, one form of an immediate treatment is gaining popularity: the drug naloxone. Naloxone is a substance that reverses the effect of opiates on the human body, so it not only ceases the sensation of the drug's "high" but more importantly can restore breathing to someone succumbing to an overdose. Because street heroin and prescription

opiates are so alike in their effect on the body, naloxone is effective for a victim overdosing from either one. In testimony before the Public Health Committee, the analogy was made that naloxone for a drug overdose acted like an epinephrine injection for a severe allergic reaction.

CURRENT ISSUES

Dr. Jane Maxwell states in her publication *Substance Abuse Trends in Texas: June 2013* that prescription abuse in Texas centers on the drugs supplied by “pain clinics, pharmacies, and physicians.” In testimony to the Committee and follow up from stakeholders, one of the most discussed prevention methods dealing specifically with these prescribers was the state’s prescription drug monitoring program (PDMP) with the Department of Public Safety (DPS).

The state’s PDMP has made great strides in the last decade to improving both its law enforcement and monitoring functions, such as covering schedules III through V in 2008 and creating an online portal to request data in 2012. Texas has a long road with many options to becoming of the top monitoring programs in the nation, particularly when compared with other states.

During oral testimony before the Public Health Committee, representatives from the Texas Association of Business, the National Safety Council, and Pharmaceutical Research and Manufacturers of America made several suggestions to Texas PDMP including:

1. moving toward real-time monitoring of prescriptions,
2. requiring prescribers to register with the online portal,
3. improving user friendliness of the portal and its report generated by inquiries,
4. developing training on the state’s PDMP,
5. making Texas’ PDMP interoperable with other states, and
6. implementing a program that tracks outlier patient and prescriber patterns.

In 2009, the Legislature appointed an interagency council through HB 2730 (Kolkhorst) to create a transition plan of the PDMP from DPS to the Texas State Board of Pharmacy (TSBP). Under the agreement between representatives from the TSBP, DPS, and the Texas Medical Board, the plan described the budget for an improved system funded through grants and user fees. The TSBP workforce would increase by 35% to 60%, so office space was the main logistical and financial impediment to the move. Several recommendations from the interagency council report, released in December 2010, have already been implemented, including putting the PDMP online and having pharmacists report data every seven days instead of the 30 to 45 days previously required by statute. Several recommendations have not been implemented, including interoperability of Texas’ PDMP with other states. To date, neither of transition plans created by the interagency report have begun implementation.

According to the National Safety Council, New Mexico, Kentucky, New York, Ohio, and Tennessee all require prescribers to access the PDMP before issuing prescriptions for certain controlled substances including opioids. Furthermore, Oklahoma was the first state to develop a truly real-time PDMP, compared to the seven day turnaround Texas requires from pharmacies filling prescriptions (NGA Article “Six Strategies...”). New Mexico’s PDMP has the capability to report patterns “of interest” to the state’s medical board, such as prescribing an opioid with a benzodiazepine and a muscle relaxer (Governing, “Overdose Nation”).

Other states like Utah and Washington have developed guidelines for appropriate prescription of controlled substances and disseminated them to practitioners. According to testimony of the National Safety Council, these states created best practices by assembling a

spectrum of stakeholders. Touted in a recent publication by the National Governor's Association, these best practices have also been converted to continuing medical education courses for providers. Washington in particular has focused on opioid dosing, and requires a practitioner to ask a compelling first question: would a non-opioid treatment be more appropriate?

These best practices also focus on OB/GYN's in response to the growing trend of providers prescribing opioid painkillers to pregnant women, which, from Dr. Jane Maxwell's testimony, is lacking for OB/GYN's in Texas. Dr. Maxwell described some focus at the federal level, however, as the FDA is now requiring warning labels for pregnant patients that use of the opioid may require treatment of the infant for withdrawal. Data on malformations and risks to neonates is inconsistent and more research on safety of these drugs during pregnancy may need to be funded.

According to a recent publication by the National Conference of State Legislatures, thirty-eight states have pharmacy lock-in programs that a 2009 analysis of the Oklahoma Pharmacy Lock-In program led to decreased "doctor shopping, the use of narcotics and emergency department visits among participants." Per beneficiary, the state saw average savings on narcotics close to \$600 in the first year.

The state of Texas can play a significant role in data reporting as well as implementing the best prescribing practices through the sizeable portion of the state's population served in Medicaid and workers compensation systems. As stated earlier, Medicaid pays for 54% of births in Texas with a total caseload of 3,664,163 as of February 2014 (<http://www.hhsc.state.tx.us/research/MedicaidEnrollment/MedicaidEnrollment.asp>) Medicaid beneficiaries are twice as likely to be prescribed opioid pain relievers than other patients and six times more likely to overdose (National Governors Assn "Six Strategies..."). By implementing closed or restricted drug formularies, opioid abuse can be better controlled; shown by the success of Texas Workers Compensation reforms. In Texas, however, repeating that success in the Medicaid program may be impractical. In a memo between DSHS staff and Public Health Committee staff, the agencies states:

"Federal law (42 U.S. Code § 1396r-8(d)(4)(C)) requires Medicaid formularies to include the covered outpatient drugs of any drug manufacturer that has entered into and complies with a federal rebate agreement. However, Medicaid programs are allowed to exclude or otherwise restrict a drug from the formulary if the use is not for a medically accepted indication, is subject to restrictions pursuant to an agreement with the manufacturer authorized by the federal Department of Health and Human Services Secretary, excluded from coverage under the law, or does not have a therapeutic advantage over other drugs included in the formulary. Opioid drugs have medically accepted indications and cannot be excluded from the Medicaid program. A closed formulary model is therefore not feasible for the Medicaid program."

In the absence of the state's ability to implement a closed formulary, Texas has the ability to change behavior in the medical community through less restrictive means. HB 915 passed during the 83rd Regular Session in response to concerns that psychotropic medications were being overprescribed to children in foster care. The implementation of the bill will be discussed

later in this report under Charge # 6, but the bill's emphasis on informed consent is worth noting in the context of prescription abuse. HB 915 requires patients to receive summaries of their medical care, which have a particular section describing treatment options that did not involve psychotropic medication. The behavior of pregnant women on Medicaid and their health care providers might change with similar requirements for informed consent; particularly with opioid painkillers.

While a closed formulary system may be unavailable to all state health care beneficiaries at this time, programs like the "lock-in" program used by other private and public insurers may still provide helpful lessons for Texas. For instance, the "lock-in" program necessitates criteria for spotting suspicious prescriber or patient behavior. Texas' law enforcement and health care licensing agencies could use such an algorithm to investigate outliers in the current PDMP more closely.

Consider this quote from CDC Director Dr. Thomas Friedman:

"We're saying make explicit your reasoning and set up your protocol, as long as it's evidence-based. What we're basically saying is we need to reduce unwarranted variability. So, come up with an algorithm, come up with a protocol, and then stick to it unless you have a valid and documented reason to depart from it." – Perils of Problematic...

Developing a protocol with the medical community can also lead to the creation of best practices and a standard of care. Proliferating, if not requiring, continuing medical education courses in prescription abuse for health care practitioners based on these best practices could prevent the good actors from unknowingly becoming participants in doctor shopping or simple overprescribing. Any CME on proper pain management should also instruct prescribers on using the state's PDMP, particularly as the program continues to improve and innovate. According to the Texas Association of Business, 16 states have some sort of statute on mandatory use of the state's PDMP.

In addition to prevention strategies, the state should consider effective forms of treatment. According to DSHS testimony before the House Public Health Committee, Neonatal Abstinence Syndrome occurred in 1.2 cases per 1,000 births in the United States, but the rate had nearly tripled to 3.3 cases per 1,000 births by 2009. The number of cases of babies born in the U.S. with NAS grew 475% between 2000 and 2009 from 4,682 to 13,539. In Texas, NAS cases tend to cluster around urban areas, but Bexar County in particular accounts for 30% of the occurrences statewide (DSHS submitted testimony).

To combat the disproportionate incidence of maternal drug use, a partnership formed between the University Hospital System in San Antonio and the Center for Health Care, a DSHS funded substance abuse treatment provider, in 2007 called Project Cariño. The "Mommies Program," as it has been now called since 2013 after the grant from the Substance Abuse and Mental Health Services Administration ran out and the University Hospital System, integrates high quality prenatal care with opioid substitution therapy. Hospital and substance abuse treatment staff collaborate to prepare program participants for the labor and delivery, the NICU experience, and the immediate postpartum period.

The current standard of care for pregnant women with opioid dependence is referral for opioid substitution therapy (OST) with methadone, but emerging evidence suggests that OST with buprenorphine also should be considered. Medically supervised tapered doses of opioids (detoxification) during pregnancy often result in relapse to former use. Abrupt discontinuation of opioids in an opioid-dependent pregnant woman can result in preterm labor, fetal distress, or fetal demise (DSHS memo response).

Programs like “Mommies” in San Antonio treat pregnant women from any type of insurer; public or private. Participants can come from referrals like those from law enforcement or by one’s own self-referral, but all pregnant and parenting women that are admitted into the DSHS funded Opioid Addiction Treatment Services program in Bexar County are automatically referred to the Mommies program upon intake/screening. DSHS testified to an annual decrease in average days spent in the Neonatal Intensive Care Unit for babies identified with opioid exposure in the University Hospital System 38 days in 2011, 23 days in 2012, and 30 days in 2013.

Opioid Substitution therapy is proven to turn lives around, but naloxone can truly save lives in the event of an overdose. The effect of too much of an opiate can often slow breathing down to the point of death, but naloxone can negate the drugs’ effects and restore respiration to an overdosing victim. After New Mexico expanded its “Good Samaritan” laws to eliminate civil and criminal liability for Expanding from a pilot program in 2010 that gave naloxone doses to family members of addicts, first responders in Quincy, Massachusetts and soon all over the state started carrying the life-saving drug, saving 242 lives as of this year (Governing Article – “Overdose Nation”). According to testimony from the National Safety Council, thirteen states have created laws expanding access to naloxone. For every 227 naloxone kits distributed, one death can be prevented (Written testimony, National Safety Council).

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CHARGE #2

Study and make recommendations for improvements to the licensing, regulation, and monitoring of compounding pharmacies, including a review of the joint cooperative efforts between the Texas State Board of Pharmacy, Department of State Health Services, and U.S. Food and Drug Administration. Consider the impact of the passage of SB 1100 (83R), additional appropriations made by the 83rd Legislature to strengthen inspections, and any relevant federal legislation.

RECOMMENDATIONS

The recommendation of the Public Health Committee would be to create more efficient and transparent processes for the use of compounding pharmacies by beneficiaries of public health care.

BACKGROUND

Compounding Pharmacies have recently come under scrutiny and many people believe they may become a public health concern. Compounding drugs is an ancient practice where a pharmacist customizes a medication to a patient's individual needs by combining, mixing, or altering the chemical ingredients. Compounded drugs are not uncommon, reaching millions of people every year. According to the Food and Drug Administration (FDA), about 30 million drugs are compounded annually and constitute an estimated one-to-three percent of all pharmaceutical sales (FDA Video & Health Policy Briefs).

An individual needs compounding pharmacies when an FDA-approved medication cannot treat their diagnosis or if it has specific compounds they cannot ingest. A common example of this is when a patient is allergic to a preservative or dye in the FDA approved drug so the medication is recreated without the allergens. Another common practice is changing the consistency of the prescription. Usually a pill is broken down into a liquid and flavor is added to make it easier for the young, elderly, or domesticated animals to swallow. Compounding pharmacies can also create topical creams and injections for direct application. Other needs for compounding pharmacies include lethal injection combinations, physician office use, and replacements for Emergency Medical Services during shortages.

There are several types of compounding pharmacies: traditional, nontraditional, and anticipatory. As above, traditional compounding involves the customization of a drug to meet an individual's specific medical needs and has existed for centuries. Non-traditional compounding and outsourcing facilities arose during the 1990s when drug compounders began producing larger batches of pharmaceuticals and selling them to doctors' offices and hospitals. These drugs are produced in advance without a prescription and are frequently requested by hospitals and doctors' offices during minor and major procedures like open-heart surgery, bacterial infection treatments or just to stock samples in doctors' supply closets. Similarly, hospitals in some states are allowed to engage in what is known as anticipatory compounding. The process of compounding limited quantities of drugs with the expectation they will be used in the near future by certain individuals. Anticipatory compounding is legal in Texas.

In 1997, as compounding pharmacies began more production, Congress passed an amendment to the Food and Drug Administration Modernization Act in an attempt to federally regulate compounding procedures. Section 503(a) of the Act exempted compounding facilities from some FDA guidelines, such as requiring direction labels on medicines, or following the FDA's Current Good Manufacturing Practices (cGMP). Also, compounding facilities do not have to engage in the FDA's New Drug Application Process (NDA) so long as they do not advertise, market, or solicit their prescriptions in an attempt to solicit business or deter large-scale manufactures from behaving like traditional drug producers This amendment caused severe backlash from compounding pharmacies soon after its release. The pharmacies claimed section 503(a) violated their First Amendment right to freedom of speech (Health Policy Briefs). In, *Thompson v. Western States Medical Center*, filed in the spring 2002, the US Court of Appeals for the Ninth Circuit ruled that the provisions were unconstitutional restrictions on commercial speech (Health Policy Briefs & Case released in memo by USSC). Another ruling took place in 2006, by the United States Court of Appeals for the Fifth Circuit. The Fifth Circuit agreed the advertising restrictions were unconstitutional but believed the rest of 503(a) should remain in

place (Health Policy Briefs). Due to the confusion surrounding the release of 503(a), several Circuit courts made their own rulings, resulting in various interpretations of the federal law.

To address this turmoil, the FDA issued a Compliance Policy Guide, delegating responsibility over compounding pharmacy regulations to the State Pharmacy Boards. In their opinion, the FDA stated that they believed it was best for the FDA to focus on large-scale issues associated with drug manufacturing, while State Pharmacy Boards should focus on minor violations at native compounding pharmacies. The FDA faced resistance against their attempts at inspection. According to a 2013 Governmental Accountability Office Report, between 2002-2012 the FDA had to obtain at least eleven warrants to gain access to drug compounders who challenged their authority (Health Policy Briefs).

Although compounding pharmacies have aided people when FDA manufactured drugs could not treat their diagnosis, many are concerned that the virtual lack of regulations over compounding pharmacies may result in the production of drugs of questionable condition and reliability. Both fungal and bacterial outbreaks affecting hundreds of people in the past several years exacerbated the problem. The most famous case is the 2012 fungal meningitis outbreak that killed 64 people (2 in Texas) and left over 751 individuals sick in at least 20 states. The syringes associated with the outbreak were traced back to The New England Compounding Center in Framingham, Massachusetts that shipped more than 17,600 steroid injectables across the country. An FDA investigation found about one-quarter of the syringes contained a foreign greenish-black substance. Amid all of the lawsuits, NECC filed for bankruptcy and closed down before agreeing to establish a compensation fund worth more than \$100 million (CBS Dallas; Health Policy Briefs).

Texas has also experience issues with compounding pharmacies. In Portland, Washington three people died from taking gout medication in 2007. The FDA investigated these cases and traced the medications back to a Dallas compounding pharmacy called Apothécure who pled guilty to shipping mislabeled medications that were 640 percent stronger than prescribed (WFAA 8 ABC NEWS). In August 2013, the FDA also recalled all of the products from Specialty Compounding, LLC based in Cedar Park, Texas after at least 15 patients who received calcium injections developed a bacterial infection and two patients had died in a Corpus Christi hospital (CBS news). Though, the connection between the calcium injections and these deaths are still inconclusive. More recently, in July 2014, Unique Pharmaceuticals, Ltd. announced a voluntary nationwide recall after an FDA inspection found a lack of sterility (FDA recall press release).

These outbreaks represent the worst-case scenario for many health organizations and since they have become more common, state regulators are calling for change. Many leaders hope to examine several issues associated with compounding pharmacies. First and foremost, it is difficult to access the quality, safety, and efficacy of compounded drugs because of the lack of FDA supervision, the lack of proper equipment and controls, and the fact that changing the chemical compounds of drugs are often unpredictable, especially without safety testing. Calculation errors have also become an issue with some pharmacists are making the doses stronger than prescribed. Additionally, many states state agencies who have been in charge of compounding pharmacies are now calling on the FDA to help them regulate companies that are beginning to act like large-scale manufacturers and are shipping across state lines.

After the NECC outbreak, Congress gave more enforcement authority to the FDA and attempted to strengthen communication between federal authorities and state health officials. As a result, the FDA and other state authorities began copious inspections of sterile compounding pharmacies across the country. After some investigations, the FDA issued a report stating they found “objectionable conditions at more than sixty facilities and issued several warning letters, while more than twenty compounders made voluntary recalls.” (Health Policy Briefs). Not surprisingly, health officials demanded more to regulate compounding pharmacies to ensure their reliability and safety.

In November 27, 2013, Congress signed HR 3204, the Drug Quality and Security Act into law, intending to rejuvenate the previous Food and Drug Administration Modernization Act of 1997. The purpose of this law was to bridge the gap between the state legal authorities and the federal government. The law included updates from previous court cases and added regulations on compounding pharmacies. The act was split into two sections: Title One, the Compounding Quality Act, contained two sections: 503(a) and 503(b). Section 503(a) officially removed the solicitation and advertising provisions struck down by the Supreme Court, making the previous 1997 law effective with some major differences. Pharmacy compounders are now required to use mainly FDA-approved drugs when compounding, they must comply with the FDA’s Current Good Manufacturing Practices, and now they must include direction labels on their products. Current Good Manufacturing Practices are USFDA enforced regulations and precautions that ensure the proper monitoring and control of manufacturing processes in facilities. Through guideline adherence, pharmacies can effectively know the “identity, quality, strength, and purity” of the drug products during manufacturing (FDA facts on cGMP). In addition, compounding pharmacies are required to obtain a license native to their state, and undergo a thorough inspection before receiving and renewing their license from the State Pharmacy Boards. Lastly, licensees can compound prescriptions from individual clients and can produce small quantities of anticipatory supply, depending on their state laws.

Under Title Two 503(b), a national drug database will be set up to quickly and conveniently “track and trace” prescription drugs across the country. Additionally, section 503(b) made it clear that outsourcing facilities can qualify for exemptions from FDA approval requirements and direction labels but are no longer exempt from Current Good Manufacturing Practices (cGMP). An outsourcing facility engages in compounding drugs that are not necessarily patient-specific; but are compounded at the request of a health care provider or facility. An outsourcing facility will qualify from FDA drug approval requirements and labeling products but they are not exempt from cGMP (Dodson slides). Compounding pharmacies with manufacturing characteristics are encouraged to voluntarily register with the FDA as an outsourcing facility without penalty. The FDA now regulates outsourcing facilities and will soon inspect all facilities nationwide according to a risk-based schedule. Other criteria that must be met are reporting adverse effects and providing the FDA with information about the compounded products (Dodson slides). There are currently seven outsourcing facilities in Texas, according the registration files with the FDA (FDA).

In 2013, during the 83rd Texas Legislative Session, the Texas Legislature amended the Texas Pharmacy Act with SB 1100. After the bill’s passage, new pharmacies that compound sterile compounds will not be licensed by the Texas State Board of Pharmacy until the board

inspects the pharmacy to ensure all laws and requirements are met and the Board is reimbursed for all inspection costs. The same rules apply to pharmacies out of state. As for the current existing licensees, they will be unable to renew registration until the pharmacy has been thoroughly inspected to ensure compliance and the State Board of Pharmacy is reimbursed for their inspection. Compounding pharmacies are required to meet regulatory provisions enacted by the Board regarding compounding sterile and nonsterile constructions. The Board also adopted minimum standards for processing, quality control, testing, packaging, and labeling compounded drugs. Additionally, outsourcing facilities are required to obtain licenses native to their state, as well as Texas if they plan on shipping across state lines. Pharmacies regulated by the TSBP must notify the board immediately of any adverse effects attributable to a sterile product released from the company and no later than twenty-four hours after recall. The Legislature appropriated the Texas State Board of Pharmacy funds to hire an inspection team and additional funding to test all sterile products made by compounding pharmacies. These laws went into effect on December 10, 2013. Currently TSBP is on schedule hiring the new team and all additional training will be completed by the end of September, 2014.

CURRENT ISSUES

The Texas House of Representatives Public Health Committee held a hearing on April 14, 2014 in which Gay Dodson, the Executive Director of the Texas State Board of Pharmacy, led the panel on the compounding pharmacy discussion. The Texas State Board of Pharmacy is the regulating body that investigates the practice, operation, and distribution of pharmacies in Texas (TSBP website). Recently, the Board has been determining which facilities produce compounded drugs, are investigating priority inspections, and accessing low, medium, and high-risk facilities. Dodson, however, expressed concerns over the TSBP's lack of authority to subpoena a pharmacy's financial records. Because TSBP oversees all compounding pharmacies in the state, they argue that their inability to audit financial records hinders thorough investigations, especially when they receive complaints about compounding pharmacies overcharging for medications. An example mentioned would be a topical medication costing about \$1,000 to create but the pharmacy charging the patient \$11,000. Dodson suggested that the Board receive the ability to survey licensees' financial records in order to validate claims of extortion and enforce penalties if needed, such as charging fines or removing licenses. In light of this, the Texas State Board of Pharmacy has been collaborating with the Texas Medical Board and the Department of State Health Services.

Mari Robinson, Executive Director of The Texas Medical Board also spoke on the panel. The Texas Medical Board's mission is to protect public health and safety through discipline, education, and licensure. Unlike TSBP, the Texas Medical Board can subpoena a pharmacy's financial records during an investigation but Robinson testified to the Public Health Committee her concerns about the regulation of referrals by physicians. Issues arise when a doctor refers a patient to a compounding pharmacy in which the doctor has an ownership interest due to the potential for them to make a return profit from the sale. It is difficult to ensure that doctors have been accurately disclosing financial gains from referrals to their compounding pharmacy. Patients are rarely offered options for another pharmacy and no law is in place requiring written consent of a patient before visiting a compounding pharmacy that his or her treating physician has ownership. Patients are often unaware of their rights to get a prescription filled wherever they please and are unaware the doctor must provide disclosure.

These arrangements violate both the Federal Anti-Kickback Statute, Texas Solicitation of Patients Act, and The Federal Physician Self-Referral Law. The Federal Anti-Kickback Statute is an intent-based statute requiring the accused party to knowingly and willingly engage in a prohibited act, in which a physician receives a reward of any value from a referral of business with a patient on a federal healthcare program. The Federal Anti-Kickback Statute was enacted in the early 1970s to protect patients and federal health care systems from fraud and abuse. Similar to the Federal Anti-Kickback Statutes, the Texas Solicitation of Patients Act prohibits financial gain of an entity from patient referrals, but is broader in its application. Lastly, The Federal Physician Self-Referral Law commonly known as "Stark Law" is a strict liability statute, that does not require proof of intent to establish that an entity is in violation of the law. Stark Laws "prohibit physicians from referring patients to receive designated health services" paid for by Medicare or Medicaid from entities with which the physician or immediate family member has a financial relationship. Financial relationships could include ownership, investment interests, and compensation arrangements. It is also possible for a physician to violate Stark Law, if the patient is covered under private health insurance, not just those on federal health insurance.

Regulators want to caution physicians when pharmacies solicit profitable deals from referrals and to make sure there are legitimate clinical benefits. Most people do not know compounding drugs are not FDA approved. They are also not familiar with Stark Laws and no law specifically states the patient must consent to purchasing the compounded medication from the physician's pharmacy in writing after reviewing other options. This is a problem because the Texas Medical Board's investigation of breaking Stark Laws can only commence once a complaint is filed, and cases are generally overlooked if a patient is not on Medicare or Medicaid. According to the TSBP and TMB, there are currently no records indicating which doctors have investments in compounding pharmacies in the state of Texas.

CompPharma and The Employment Retirement System of Texas echoed similar concerns about the costs of compounding pharmacies. Joseph Paduda, President of CompPharma, states that compounded medications have increased five-fold within the past five years. CompPharma, LLC, is a conglomerate of pharmacy benefit management (PBM) firms that provide services for the workers' compensation marketplace. Using their own research, compounded pharmacies seem to seek out injured workers by claiming that topical creams will help with their pain management, but the creams often include formulas that exceed the FDA-approved amount for topical formulations. They are concerned with the safety, quality, and efficacy of the products being prescribed at "astronomical costs" and they believe it is important to "require preauthorization for all compounded medications to assure patient safety and medical necessity." This will require documentation, allow for patient consent, provide for the disclosure of medicinal ingredients and procedures, and ensure that the pharmacy is properly licensed.

The Employers Retirement System of Texas also believes the costs of compounded medications have increased in the last five years. An investigation showed the rising costs is due to the use of bulk chemicals or additional ingredients, unrelated to the treatment of the illness for which drugs are prescribed. In a letter from ERS government relations to the Legislature, evidence is asserted that compounding pharmacies are inflating their prices. For example, the letter states that a prescription for the compound, Itraconazole usually comes in pill form but can also be used in an oral solution or injectable to treat fungal infections, fever, and low white blood cell counts. A doctor prescribed Itraconazole to a patient at 360 ML for a 30 day supply to be filled by Health Scripts Specialty Pharmacy. ERS calculated the cost of this medication at \$18,516.24 but the pharmacy submitted the cost to them at \$22,003.68 (Nail Email). For individuals on Medicare, Part D specifically covers all prescription drug plans, can help lower drug costs, and can apply in conjunction with other coverage providers such as employer or union health coverage (medicare.gov). Based off their results, the ERS believes their best approach on the overcharging of compounding medications is to utilize the CMS method under Medicare Part D because it will not pay for medications with bulk ingredients. On July 1, 2004 medications costing over \$300 required pre-authorization. In addition, ERS will cover costs and compounding of only FDA-approved drugs, but the patient will cover bulk ingredient expenses. Furthermore, ERS believes that requiring pre-approval prior to filling the prescription will help reduce the costs of compounding drugs and encourage a more affordable asking price.

Compounding pharmacies provide medications to a significant percentage of the population with specific medical needs. Although there is potential for health scares, they are of great benefit to the public and are high in demand. As more companies manufacture

compounded drugs, it is important to have procedures that ensure the safety and quality of these products. It is the aim of many health officials to be able to track and trace products being produced as quickly and as efficiently as possible in the event of a public health scare. The recommendation of the Public Health Committee would be to create more efficient and transparent processes for the use of compounding pharmacies by beneficiaries of public health care.

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CHARGE #3

Identify strategies to support the efficient exchange of electronic health information with Texas Health and Human Services enterprise agencies. Examine legal and technical issues around the accessibility of information held in registries maintained by state agencies to authorized health care providers. Identify issues related to health information exchange and providers' liability, as well as concerns related to transitioning patient data in cases where a provider selects a new electronic health record vendor.

RECOMMENDATIONS

1. The Legislature should clarify its intent in statute on the interoperability of state registries with health information exchanges (HIE's).
2. The Legislature should update liability standards for handling health records that contemplates the electronic sharing of records between providers, electronic records platform vendors, and health information exchanges.
3. Strengthen and clarify notification requirements for patients regarding their protected health information (PHI) created, retained, or disclosed by the state, including PHI to state public health registries. Provide clear and consistent guidance to agencies and providers on the means of obtaining authorization by patients if this data will be created or disclosed for particular purposes described in Chapter 181 of the Health and Safety Code added by HB 300 (82nd Session).
4. The state should seek to alleviate the administrative burden for health care providers who access the state's public health registries. If one online portal is created to access registries, the Legislature should contemplate and provide guidance on the possibility for providers to receive health information from the registry via the portal.

BACKGROUND

As part of the American Recovery and Reinvestment Act of 2009, Congress enacted the Health Information Technology for Economic and Clinical Health (HITECH) Act to encourage the proliferation of health information technology among the states. HITECH authorized the U.S. Department of State Health Services to create a State Health Information Exchange (HIE) Cooperative Agreement Program to promote the creation of HIE's via formula funding. Over the program's four years, Texas received \$28.81 million (Gilman oral: all funds now expended, the program ended in March 2014), with the Health and Human Services Commission (HHSC) acting as the fiscal agent, initially for planning the networks, receiving applicants for health exchange vendors, and then establishing the exchanges (THSA Self Evaluation to Sunset).

In 2007, the Legislature created the Texas Health Services Authority (TSHA) as an advisory board in the Office of the Governor, but with the enactment of the HITECH Act its role switched from advising to promoting and setting up health information exchanges in the state. At the time, electronic records were already being shared between member hospitals in the same corporate system, but Chapter 182 of the Health and Safety Code currently establishes the TSHA as a non-profit corporation via a public-private partnership. Though the TSHA does not receive any state appropriations, the entity is obligated to operate under the Texas Open Meetings Act, Public Information Act, and Sunset Act, and the Governor of Texas appoints the eleven member Board of Directors with the advice and consent of the Senate. The statute authorizes the agency to fund itself from general revenue, grants, user fees and "other ways consistent with its statutory purpose." The TSHA, until recently, has been receiving installments of \$28.81 million in federal money under the authorization of the HITECH Act by contracting with the HHSC to promulgate electronic records, but the four year program ended in March of 2014 and all money in it expended setting up a statewide and multiple local HIE's (HHSC Sunset Report).

As input came in from stakeholders during the planning process, the Texas system was designed based upon multiple regional exchanges, as opposed to one statewide exchange, in order to better serve the needs of Texas' diverse population. As Texas Health Services Authority CEO Tony Gilman testified before the House Public Health Committee, it is a "network of networks model." Gilman compared the Dallas area exchange, which supports a centralized data repository, to the Houston area health information exchange, which maintains a more local or "federated" model where the data is only used only for transitions of care (Gilman oral testimony 9/24/2014). The TSHA mainly functions to connect local HIE's with their provider members to allow them to share health records electronically. The Authority also acts like a hub to connect the local networks to each other, other states, and national HIE's (HHSC Sunset).

With the federal money, the HHSC and THSA developed a statewide HIE plan and then contracted with providers to start local networks. The program initially had 16 local exchanges, eventually whittled down to ten through mergers or vendors going out of business. Local HIEs must provide minimum service, including supporting the delivery of lab results and allowing providers to exchange patient clinical summaries. Some even offer population health analytic services or portals for patients to access their records (THSA Sunset self-evaluation).

Despite federal funds for electronic health records being exhausted primarily in the form of grants for local network development, the THSA currently receives no state appropriations,

although \$5 million was distributed during the last budget cycle from the Texas Health Insurance Pool in fiscal year 2014 to continue THSA operations through 2017. Statute demands that HHSC and THSA work together to continue HIE promulgation in Texas when more federal funds become available (HHSC Sunset Report 2014). The HITECH Act also authorized \$17.2 billion to incentive Medicare and Medicaid payments to doctors and hospitals to become “meaningful users” of electronic health record technology. THSA provides support to providers to achieve the federal requirements for meaningful use to earn subsequent incentive payments (THSA sunset self-evaluation).

In 2011, during the 82nd Legislature, HB 300 by Public Health Chair Lois Kolkhorst expanded the role of the THSA beyond simply setting up the state’s networks and required the THSA to develop privacy and security standards for electronic sharing of electronic health records. With the development of standards, the THSA created a process to apply for certification of an entity’s compliance with these standards, which is, at this point, voluntary. THSA's accreditation program ensures HIE's maintain these standards and model best practices to ensure optimum connectivity and interoperability within the state's system (THSA sunset self-evaluation). If a vendor can become certified under the relatively new THSA certification program, the certificate under current statute can act as a mitigating factor against liability for breaches of privacy or other types of mishandling medical records. The certification program alone may make THSA financially self-sufficient by levying one-time implementation, annual, and user fees (THSA sunset staff recs).

HB 300 (2011) not only instructed the THSA to develop model practices for sharing EHR's but also explicitly stated the requirements to inform patients when their medical records are shared with for databases maintained by the state. In oral testimony before the Committee, THSA CEO Tony Gilman summarized HB 300's requirements for patient notification and potential patient authorization. For the purposes of treatment, payment, operations, or general healthcare administration, consent from the patient is required to disclose his or her medical records, but authorization is needed for other purposes like selling electronic health records. In the same hearing, Kalunde Wambua, Director for the Centers for Program Coordination and Health Policy at DSHS, stated that the requirements for notification versus authorization with respect to information retained in state registries mostly depends on the enabling statute for that program, and she estimated about two hundred individual programs and registries were created in statute. Mr. Gilman then gave the example of one registry, ImmTrac, the state's repository for child and adult vaccines. Participation in the program is voluntary by the patient, who must consciously authorize the state to maintain their immunization history in ImmTrac. However, from the standpoint of the provider, the immunization record is required to be submitted to the state without exception, and the record is destroyed if authorization cannot be clearly ascertained by the patient. In comparison, Gilman went on to state that consent and notification requirements are significantly different for information collected for mental health and substance abuse registries than ImmTrac.

Patricia Vojack, Deputy Executive Commissioner at HHSC, stated that HHSC has made successful strides with Medicaid patients and notification of the use of their medical records according to HB 300 requirements. In a follow-up memorandum from HHSC, every household in the Supplemental Nutrition Assistance Program, Temporary Assistance for Needy Families program, Medicaid, the Children’s Health Insurance Program, or other state funded health care

coverage receives an initial notice of their health privacy rights, and, if still seeking assistance, a follow up every three years.

In addition to the complex distinction between patient notification and a patient authorizing the state to use their medical records, providers are often frustrated by the administrative burden associated with communicating with the state's nearly 200 health information repositories. For every state program a provider communicates health data with, the provider must go through a corresponding number of registrations; costing significant time and money. The HHSC is currently partnering with THSA to develop the infrastructure of one "Gateway" that will act as one universal portal for providers to the public registries. According to Director Wambua's oral testimony before the Committee, the Gateway will need statutory authorization to begin operating, but the information will be able to flow to and from the registries for providers as "two-way street"; an idea strongly encouraged by the testimony of Dr. Joe Schneider with the Texas Medical Association.

Another obstacle providers face when converting to electronic health records is the specter of significant liability stemming from physicians' role as the sole custodians of a patient's medical records. According to Mari Robinson, Executive Director of the Texas Medical Board, the statutes governing a physician's responsibility have not been updated to contemplate the switch to electronic records, and, while patients have rights established to access information in their records, their doctor is the sole custodian bearing liability in the context of malpractice or other actions before the Medical Board. In testimony, Tony Gilman with THSA described provider hesitancy to embrace EHR's, as the lack of legal precedent spreading liability to other entities involved with maintaining medical records. Mrs. Robinson continued to say that, without a change to the law, the Texas Medical Board will continue to enforce the current custodial obligations under the law that simply require the records be maintained for seven years and remain silent on the liability of anyone else but the doctor; a remnant of the paper records era.

Robinson went on to describe frequent scenarios where a doctor would certainly but perhaps unjustly, be liable under the law. One situation arises where providers change their EHR vendor perhaps due to that entity merging with another or simply going out of business. The storage of electronic health data may vary from vendor to vendor, and the transfer of this data can lead to loss of a record itself or the burying of information potentially vital to a patient's treatment, like a food or drug allergy, because the new vendor's different coding or manner of presenting a the summary of a patient's treatment history. Particularly in the cases of the vendor ceasing or transferring its business functions, a doctor may not always have a choice in the matter, but he or she will still be liable to the Medical Board if an incomplete medical record results from a lack of interoperability between vendors. Not only is the integrity of medical records a concern with transferring records, but it raises the question of a new standard of care to have a physician comb through every line of available data. Even before the proliferation of electronic records, stated Tony Gilman, doctors exchanged summaries of patient treatment histories.

Dr. Joe Schneider in his testimony representing the Texas Medical Association stated that he supported vendors developing interoperability, but Nora Belcher with Texas e-Health Alliance, a trade group for EHR vendors countered that developing simple billing or encoding frameworks did not currently exist and would be costly. Dr. Schneider agreed that rural

hospitals might prefer to spend limited funds on staff salaries instead of converting their electronic records to the latest version of encryption software. To illustrate the danger, Mrs. Belcher described the typical use of medical information by identity thieves, who use someone's personal data to collect tax returns on people who would normally receive them for participation in the state's Medicaid program.

CURRENT ISSUES

On June 25th, 2014, Executive Director of HHSC, Dr. Kyle Janek, issued HHS Circular C-044 titled “Enterprise Health Information Exchange Policy.” Circular 44 asks all HHS agencies to develop an electronic health information exchange system and to make HHS agencies interoperable with each other as well as external information technology systems. In the policy paper, Dr. Janek instructs all HHS agencies in Texas, if and when legally permissible, to participate in the health exchange networks and to develop interoperability between agencies and outside stakeholders that provide or use information in the state’s registries.

Circular 44 started a larger conversation about moving all of Texas’ HHS toward better technology integration. The policy paper echoes much of the commentary heard by the House Public Health Committee on this charge. As pointed out by Tony Gilman of the THSA and Kalunde Wambua with DSHS, statute does not explicitly allow the registries maintained by the state to send and share data with HIE’s, and would need to be amended in the face of a project like the one-stop “Gateway” that allows providers to register once for their contributions and receipt of data across nearly 200 registries. Dr. Joe Schneider with the Texas Medical Association estimated that each registry’s individual interface could cost a practice around \$15,000 over the lifetime of that relationship. In addition to saving money for providers, the patient records can potentially withstand some completeness issues with less administrative burden communicating with state agencies. For example, Dr. Schneider estimated that about 75% of newborn screening data becomes lost over the course of a child’s life moving from physician to physician after the initial newborn screening data was originally entered at the hospital of his or her birth (oral testimonies).

An amendment to SB 7 during the 2013 session that, would allow HIE access to state registries was drafted but the amendment was preemptively ruled not germane to the bill and was never offered. The amendment was endorsed by provider trade groups as well as trade groups for electronic vendors (Tony Gilman written testimony). According to Tony Gilman, DSHS and THSA are testing connectivity using the statewide network, HIETexas, for a DSHS Public Health Gateway. However, a lack of statutory clarity on whether registries and use HIE’s remains an impediment to this level of interoperability.

Similarly, the same coalition of providers and EHR vendors another amendment to SB 7, again ruled not germane by the House parliamentarian, that would have given a safe harbor to HIE’s and participating providers. The amendment would have protected providers who, unless acting with gross negligence, fail to obtain a complete and accurate record on a patient from a HIE. Alternatively, the amendment protected HIE’s from damages related to having obtained inaccurate or incomplete medical records, unless, again, the HIE was acting with gross negligence (Tony Gilman written testimony).

Another potential avenue for “safe harbor” was suggested by THSA CEO Tony Gilman, whose organization created privacy standards according to HB 300 from 2011 and is currently developing a certification process under those standards for entities covered by the Texas Medical Records Privacy Act. Mr. Gilman testified that, at this stage, THSA has contracted with a third party vendor to implement the voluntary certification process, but only one organization is certified as of fall 2014. While other programs are pursuing certification, according to Mr.

Gilman, he suggested that many more organizations would justify the cost to meet the requirements if certification offered more than just a mitigating factor for matters before the Office of the Attorney General, state agencies, or courts. Instead of merely taking some of the sting off damages awarded or penalties accrued, he proposed that reaching the THSA certification could provide an organization a safe harbor from liability if the program's standards were truly followed (Tony Gilman oral testimony).

Members of the House Public Health Committee also took notice of another essential function of the THSA: the Texas White Space Program. The "white space" refers to a large swath of Texas on a map that covers a mostly contiguous rural area in West Texas that currently has no access to the electronic exchange of records on the HIE. Through grant money provided by the THSA, certain vendors called "health information service providers" can provide HIE "lite" services by a "push"-based query of a patient's medical records. Push-based queries allow providers to actively send clinical information to other providers, but pull-based queries, like the service offered in areas covered by exchange networks, are more like a search engine that can query all sources available in the network for a patient. When asked about the "white space" by Committee Member Susan King from Abilene, Mr. Gilman explained that the areas in these underserved areas did not respond to the outreach during the planning process to define regions for HIE's undertaken several years ago by the HHSC and THSA.

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CHARGE #4

Examine the current practice for dispensation of biologic and follow-on biologic (biosimilar) pharmaceutical products in our state. Review any practices for interchangeability of drugs that might pertain to these particular medicines. Review and make recommendations regarding the substitution of biosimilar and biologic medicines.

RECOMMENDATIONS

The Food & Drug Administration (FDA) has not yet released a definition of interchangeability of biologics and biosimilars, but a bill should be in place when the FDA announces their decision. This bill would adopt the federal definitions of a biological product, a biosimilar product, an interchangeable product, and a reference product. A proactive bill should be enacted that ensures safety and affordability for the patient. If the price of an interchangeable biosimilar is lower than a patient's copayment, the patient should be allowed the option of paying for the cheaper alternative. Before dispensing an interchangeable biosimilar, the pharmacist would have to notify the patient an alternative product was available and allow the patient to choose between that product and the prescribed brand. If a substitution does occur, an update of the patient's electronic medical records by the pharmacist would complete their medical record and could suffice as a notification as long as the practitioner also has access to these records. These records must be updated within one to two weeks of the substitution. A practitioner does have the option to write "as prescribed only" on the prescription which would not allow for a substitution to occur. Likewise, the pharmacist who selected an interchangeable biosimilar product would assume the same responsibility as when filling a prescription for a biological product. A pharmacist could select an interchangeable biosimilar product only if it was less expensive than the prescribed product. A pharmacist could not charge a higher fee for dispensing interchangeable products than for brand name products. A two year sunset clause for the notification process is not necessary.

BACKGROUND

Biological medications are not new to the medical community, however, they have become a new health issue for many policymakers as production of new medications that are biologically similar to brand name biologics begin to enter the market in the United States at a more affordable rate. Although biological medications have been around for about 30 years, the patents on these medications will soon expire, causing other manufacturers to reverse engineer these medications and sell them at an affordable rate to enhance competition. Manufacturing these drugs is a complicated process in comparison to traditional tablet drugs and their generic versions. As a result, the current policies at the federal level are focused on defining and perfecting the safe interchangeability of these products (FDA). To promote a biosimilar market, legislators and health officials are creating “licensure pathways for biological products” by inventing a standard of interchangeability that states can adopt into laws allowing for substitution or notification of substitution at the pharmacy. Despite the current debate over biosimilars, many European countries and some states in the U.S. have already begun drafting legislation. But the main disagreement in the United States surrounds physician notification. Currently in Texas, the central disagreement between stakeholders is fixated on notification of substitution.

A biological medication, or biologic, is derived from living tissue in animals or humans then is transformed into a therapeutic drug and prescribed in the treatment of ailments (Amgen Handout). Most biologics are used for the treatment of various cancers, immune system disorders, neurologic disorders, and hematologic conditions (Amgen handout). Biologic medications originate from a range of materials such as viruses, serums, toxins, antitoxins, vaccines, blood and blood components, recombinant proteins, and monoclonal antibodies (Amgen Handout). Biologics can be produced synthetically, through biotechnology, and can be derived from natural sources. Biologics have a large complex molecular structure and the manufacturing process is intricate but for good reason. They must be “carefully engineered, refined, and re-grown until they’ve reached their desired effect” (Abbvie Handout). This is because biologics are designed to target the root cause of a disease, not treating the symptoms and side effects. Through fabrication, scientists reprogram the living cells of an organism to generate proteins that effectively confront a disease at its source (Abbvie Handout).

It is important to note that in order to distribute or sell a biologic, manufacturers must file a biologics license application with the United States Secretary and must meet regulation requirements and inspections before approval (FDA: regulatory information). In more recent years, there has been a push to create a generic version of biologics because of their high costs. According to Elizabeth Richardson, Research Associate of the Urban Institute in her Health Policy Brief on Biosimilars, biologics are the most expensive drugs on the market, averaging twenty-two times that of non-biologic drugs (Brianna Clark & Health Policy Briefs). During her testimony, she stated that in 2010, costs of the top seven biologics represented almost half of Medicare Part B’s total drug budget (Health Policy Briefs). Ultimately, biologics are such complicated molecules and the expenses associated with their development, manufacture, monitoring, and extensive clinical testing requirements contribute to their high cost. As a result, there is interest in promoting a market competition through an accelerated biosimilar approval pathway (Health Policy Briefs). However, producing biologic material is complicated because it comes from living cells, presenting several manufacturing challenges. Just the smallest changes in the manufacturing process can produce a variety of final products, which can affect the safety,

and potency of the biologic (Health Policy Briefs). Over time, there could be changes in the product's profile, or in the immune response, or effects of the biologic could be rare or not occur for several months (Amgen handout).

In light of these issues, manufacturers are generating a new version of biologics, called biosimilars, in an attempt to solve some of those concerns. A biosimilar is an artificial replica of a U.S.-licensed biologic. The Food and Drug Administration and the Public Health Service Act define a biosimilar as "a biological product that is highly similar to the reference product notwithstanding minor differences in clinically inactive components and there are no clinically meaningful differences between the biological product and the reference product in terms of the safety, purity, and potency of the product" (Amgen & FDA: information for consumers, biosimilars). Its function is to treat the same disease for which biologics are dispensed. Although biosimilars can be used in place of the biologic it mimics, it is imperative to clarify biosimilars are not generic versions of biologics (Abbvie Handout). Through the creation of biosimilars, physicians have another treatment plan and patients have a more affordable option for treatment. The purpose of biosimilars is not to replace biologics but to provide a cheaper alternative for treatment to the patient.

In order to understand the difference between biologics and biosimilars, it is pertinent to examine the paralleled analogies of brand name and generic medications. Generic versions of brand name medicines are exact copies because they are made with the same processes, the same ingredients, and the same recipes. Generic drugs can be produced in exactly the same way as its brand name counterpart because patents for the brand name product expire eventually leading to the introduction of generics that are exactly the same. Simply put, the reproduction process is easier for generic versions of name brand drugs because their smaller molecules make them easier to replicate. They have the same chemical formulas and shared procedures. Biological products are the opposite because they originate from natural organic materials. This means that the process can only be repeated once for that organism. In contrast, it is impossible for biosimilars to be an exact copy of an existing biologic based on current science because biological products originate from rDNA of a living cell. Because no two biological molecules are the same down to the last atom, it is impossible to replicate biological products completely. These factors contribute to the controversy over biosimilars because biosimilars are not generic biological products. According to Dr. Gabriel Hortobagyi, Medical Oncologist and Professor of Medicine at the University of Texas MD Anderson Cancer Center, who testified during the biosimilar hearing, stated "during production, cell lines are specifically selected preventing other people from repeating this same cell line and production." This is because biosimilars are manufactured by using different cells and different processes than biologic drugs (Abbvie Handout). As a result, there are concerns regarding the long-term safety and efficacy of these drugs and which drugs, if any, could be substituted for biologics. In order to fully understand the current controversies of biologics and biosimilars, it is critical to examine the history of biologic medications.

The Drug Price Competition and Patent Term Restoration Act of 1984 (also known as the Hatch-Waxman Act) laid out regulations for generic drugs entering the market but failed to mention biologics. This law did establish the foundation of the modern system of governing generic drugs in the United States. Under this Act, generic drugs, if already approved under the Food, Drug, and Cosmetic Act, can undergo accelerated review by filing an Abbreviated New

Drug Application. If manufacturers can prove their generic is “bioequivalent” to the original drug, established on the basis of pharmacodynamic testing, then no additional trials are needed, ultimately reducing the cost of the drug (Health Policy Briefs, FDA: Hatch-Waxman). This law created incentives for drug manufacturers to encourage generic drug competition after brand-name drug patents expired (Health Policy Briefs). Additionally, the same has been expected for biosimilar competition after the brand name biologic patents are expiring but there was a lack of legislation regarding how these biosimilars can enter the market.

Although the PHS Act of 1999 approved most biologics, it did not create an abbreviated pathway for the approval of biosimilars. It was not until the Biologics Price Competition and Innovation Act (BPCIA), a provision of the Affordable Care Act of 2010, that the market was designed to encourage competition of biologic drugs. The ACA amended PHS Act to include the abbreviated licensure pathway for biological products demonstrated to be “biosimilar” and “interchangeable” to already approved products. The law provided incentives to innovative product developers, giving them twelve years of market exclusivity and an additional six months of drugs designed for pediatric use. It also granted a year of exclusivity to first product considered interchangeable with its reference product, which prevents the FDA from doing a second approval of the product. Although this law approves most biologics, the PHS Act did not create an abbreviated pathway for generic approval of biologics (Koeller handout).

The BPCIA also prevents patent holders from prolonging market exclusivity, and create patent dispute resolutions. The most significant change of the BPCIA authorizes the Food and Drug Administration to establish two levels of biosimilarity. At the first level, the products must be “highly similar” so that there are no “clinically meaningful differences between the biological product and the reference product in terms of safety, purity, and potency and requires analytical data, animal testing data, and clinical study data. The second and more stringent level is that the two biologics are judged to be similar enough to be considered interchangeable, to the extent that the biosimilar may be automatically substituted without the intervention of the prescriber” (FDA & Health Policy Briefs). Furthermore, the FDA will begin approving biosimilars on a case-by-case basis and each product submission will require a one-off evaluation between the FDA and the sponsor (Koeller handout).

The real task that lies ahead is getting to the point where biologics and biosimilars are truly interchangeable. Interchangeability is a long process. Making biologics and biosimilars interchangeable will first require “switching” studies (Koeller Handout). For a drug to be considered “interchangeable” a product must have been approved as a biosimilar and have the same expectation of the same clinical result in any given patient. Also, any product that is administered more than once must present no additional risk of safety or efficacy as a result of switching or alternating medicines (Amgen Handout). This indicates that a product will have to be ‘on the market’ first as a biosimilar prior to being approved as interchangeable. In addition to have scientific and manufacturing capabilities, a company will also have to invest in significant marketing of the product as a biosimilar despite not having immediate interchangeability. Lastly, there is a chance the federal definition of substitution will differ from the state pharmacy laws dealing with substitution (Koeller Handout).

The United States is not the first to attempt biologics and biosimilars, but is the first to encourage the automatic substitution of these medications. The European Medicines Agency

(EMA) was the first governing body to approve of biosimilars in 2006, when they issued regulatory framework. The European Commission approved two human growth hormones named Omnitrope and Valtropin (Amgen Handout). But the EMA does not have the authority to evaluate or designate products as interchangeable. In fact, substitution is a country-level decision and many European countries prohibit biologic substitution. So far no one has tried implementing automatic substitution as the U.S. plans to do (Amgen & Koeller Handout).

In the United States, the FDA and the states have different responsibilities regarding biosimilar policies. Legislation has currently been at a standstill waiting on the FDA to determine the criteria for interchangeability (Amgen Handout). Once the FDA has determined interchangeability, states will most likely begin establishing substitution requirements. The FDA approval standards do not determine substitution requirements and they acknowledge the states' authority over drug substitution practices (Amgen Handout).

There are currently five principles that are the focus of biologic substitution laws and proposals. The first is that substitution is based on an FDA determination. Second, the prescribing physician should be able to specify 'dispense as written' (Amgen Handout). This means a physician reserves the right to not have a medication he prescribed automatically substituted if he made a note on the script that it the prescription needed to be specifically what he wrote. Third, the patient should be informed of the substitution. Fourth, the pharmacy should maintain all records of what was prescribed and substituted. This would include which medications were exchanged for another. Lastly, after-the-fact, the prescribing physician should also be informed of the exchange in medications after the product was dispensed and recorded (Amgen Handout).

There is no apparent resistance to the first four principles, but there is nationwide disagreement among officials regarding physician communication after the pharmacist dispensed the medication. In 2013 and 2014, several states have passed legislation on biologic substitution laws. Five states have passed all five principles, four out of the five include sunset provisions applicable to only pharmacist-physician communication. These states include Florida, Indiana, North Dakota, Oregon, Utah, Virginia (Amgen Handout). Other states who have considered this legislation or have legislation pending are Delaware, Georgia, Illinois, Massachusetts, Mississippi, New Jersey, Pennsylvania, Texas, Vermont, and Washington (Amgen Handout).

CURRENT ISSUES

In 2013, the Texas Senate filed SB 190 relating to the prescription and pharmaceutical substitution of biological products led by Senators Huffman, Davis, Thompson and Representative Bonnen. Senate Bill 190 would “allow interchangeable biosimilar biological products to be substituted for brand-name biological products under certain circumstances, with the intent of saving money for consumers” (SB 190 House Research Bill Analysis). The bill would make the pharmacist let the patient choose their option of paying for a lower-priced alternative if a biosimilar cost less than their copayment. It gave physicians the right to have script-specific prescriptions filled. But if there wasn’t a particular brand specified, a pharmacist could dispense an interchangeable biosimilar (SB 190 House Research Bill Analysis). In addition, SB 190 had a sunset provision, expiring December 31, 2015 that required a pharmacist to notify the prescribing physician within three days if the pharmacist dispensed an interchangeable biosimilar drug. They also had to notify the patient of the switch before dispensing the new medication and ask for their consent (SB 190 House Research Bill Analysis). The bill would also adopt all federal definitions of biological product, biosimilar, interchangeable, and reference product.

This bill would have taken effect September 1, 2013, but after passing the Senate it failed on the House floor. Supporters of SB 190 believed this was a forward-thinking law that provided Texans with access to the newest advances in medicine and at an affordable cost. These products have previously been effective at treating serious and chronic health conditions and since biosimilars will soon become available, this bill would allow the framework to update state pharmaceutical laws to include biosimilars (SB 190 House Research Bill Analysis). Opponents of the bill claim this legislation is premature since the FDA has not released names of biosimilars they approve of. They believe it is important to wait for guidance from the FDA until they have fully researched the safety of these medications before making them available to Texans. This bill was also seen as an improper advancement of the commercial interests of large biopharmaceutical groups. Lastly, opponents believe SB 190 would create an unnecessary burden notification system on a heavily regulated industry (pharmaceuticals) and could prompt pharmacies to want to limit the availability of biosimilars (SB 190 House Research Bill Analysis).

At the Texas House of Representatives Public Health Committee Hearing April 14, 2014, several health officials spoke on the subject of biologics and biosimilars. The panel of health officials included Gay Dodson, Executive Director of the Texas State Board of Pharmacy, Dr. Gabriel Hortobagyi, Medical Oncologist and Professor of Medicine at the University of Texas MD Anderson Cancer Center, Dr. Tomas Felix, R&D Policy Director at Amgen’s Global Regulatory Affairs and Safety Organization, Dr. Jim McKay, Director of Clinical Development and Medical Affairs for Sandoz Biopharmaceuticals, and Brynna Clark, Senior Director of State Affairs for the Generic Pharmaceutical Association. Dr. Felix informed the committee biosimilars are on the cusp of market release and a law with extreme clarity should be in place for when biosimilars are released. He also reiterated the anticipation of the FDA’s approval of biosimilars, guidance on labeling, and definition of interchangeability. Dr. McKay emphasized the importance of manufacturers tracking prescriptions and being accountable for their medicines long term. He also voiced his concern on SB 190 because the bill would create unfair treatment of biosimilars since it only had a notification requirement for biosimilar substitution and no

notification for the use of biologics. Dr. McKay supports the use of electronic health records to enhance communication of physicians and pharmacists. Dr. Hortobagyi stressed how this bill would only apply to a small percentage of biologics and biosimilars given in retail settings.

The next panel consisted of Audra Conwell, CEO Alliance of Independent Pharmacists of Texas, David Gonzales, Executive Director of Texas Association of Health Plans, and Dr. Joshua Stolo, advocating for patients, the American Alliance for Patient Access, and the Coalition of State Rheumatology Organizations. The main topic of this discussion was the notification requirement and process. Audra Conwell stated the notification requirement is not necessary because the FDA will have approved biosimilars at that point so biosimilars should be treated as generics. David Gonzales stressed there be no barriers to access cheaper biosimilars. He also raised the point of doctors working with certain biological product manufacturers so no notification should be required. If a doctor believes there should be no substitution, he can write 'brand medically necessary' so no substitution occurs. Dr. Stolo emphasized the importance of the doctor-patient relationship and the trust between the two. He believes notification should be required to ensure this continuing relationship. His main concerns were the balance between cost effectiveness, safety, and confidentiality.

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CHARGE #5

Monitor transition of the state's immunization registry to a new system. Determine whether the registry can be better utilized to prevent and/or respond to communicable disease outbreaks, including pertussis. Identify potential factors contributing to the rise in the number of pertussis cases and strategies to prevent future outbreaks.

RECOMMENDATIONS

1. Ensure that Texas maintains a robust vaccine registry that can direct better resources during adverse events as well as ensure that citizens are neither over- nor under vaccinated.
2. Alleviate administrative deterrents to health care providers using ImmTrac, the state's vaccine registry.
3. Evaluate the ease by which immunization exemptions are received by school age children and track exemption data to use in the event of possible outbreaks.
4. Improve outreach to children reaching the age of consent, before their records are purged from ImmTrac on their 18th birthday.
5. Improve public education on the potential benefits and harms from vaccines with a particular emphasis on vulnerable populations like pregnant women or unvaccinated adults living in a household with infants too young to be inoculated for diseases like pertussis.
6. Expand best practices available to physicians such as post exposure prophylaxis antibiotics for those in contact with infected individuals that will not require them to visit the treating physician.

BACKGROUND

Next year, ImmTrac, the state's repository for immunization data, will turn 18 years old. As with most milestone birthdays, we reflect on the past as well as where we are headed. ImmTrac was created in 1997 by the 75th Legislature passing HB 3054. Originally, the database collected data on immunizations for children 17 years old and younger only with parental consent. In 2009, the 81st Legislature enhanced the program by changing it from solely a children's registry to a lifetime registry but, again, only if the adult actively consents. To satisfy legislative mandate, ImmTrac set out to promote awareness among adults of the registry starting in 2011. At any age, they can opt into the system and then, unless they opt out, participate for the rest of their lives. However, without a proactive communication to the Department of State Health Services that an adult wants to remain in the system, the ImmTrac records will be purged by his or her 18th birthday (DSHS website).

After researching the impact and procuring a vendor to build a statewide immunization registry starting in 1993, ImmTrac was originally created as an "opt out" system, but change in administrative rules in 1999 changed the database to an "opt in" system. Whereas the opt out system needed an affirmative communication from parents to remove their child's records from ImmTrac, the program now only keeps the records from children whose parents affirm participation. In 2003, the 78th Legislature passed HB 1921 to clarify what constitutes parental consent, protect the privacy of the database, increase participation by both providers and patients, and make the data in the registry more useful. The bill required every provider to report the records of vaccines administered to children 17 and under, but without an affirmation from the parents to maintain the record, the records are destroyed. Parents, however, are allowed to submit their child's records for safekeeping in the registry as well (DSHS website).

In 2007, the Legislature passed SB 11 to increase the scope of the program to first responders and their families as well as the records of medicines administered to combat or prevent a disaster or epidemic. Parental consent was also further streamlined, as providers were allowed to submit an affirmation to the custodian of the registry at the Department of State Health Services (DSHS), that consent was given by the parent instead of the provider submitting the actual consent form. Still, according to testimony from DSHS, if the record does not clearly reflect the consent, it will not be entered into ImmTrac (DSHS website).

Furthermore, the most recent indication of parental consent trumps all others before it. Accordingly, about 92.8% of parents' consent to their newborn being in the ImmTrac database, but this number drops to 82% of the first year of life as parents still receive prompts to consent to their child's inclusion in ImmTrac (DSHS document).

According to testimony before the House Public Health Committee, the registry currently contains about 120 million immunization records of 7 million children and 270,000 adults with almost 13,000 authorized providers using the system. Separate from ImmTrac, Texas participates in the Electronic Vaccine Inventory (EVI), which supports the data collection and accountability for two federal vaccine programs: The Texas Vaccines for Children for underinsured children and the Adult Safety Net program for uninsured adults.

As an 18th birthday gift from the Centers for Disease Control and Prevention (CDC), ImmTrac will get an upgrade to integrate with the EVI, so providers are only entering in the information once. The CDC will cover all costs, estimated to be \$4 million, to convert ImmTrac to the Wisconsin Immunization Registry (WIR) system, an open source software program that the CDC developed with the State of Wisconsin to be free of charge for states. WIR is normally an “opt out” system, so developers are customizing it for the state’s “opt in” system.

The data migration will have a progressive roll out starting in the Fall of 2014 to be completed in the Spring of 2015. DSHS staff testified that the customization contractor, Hewlett-Packard, already has servers installed and the WIR application uploaded. As the software customization continues, the rollout will still require data migration from ImmTrac and EVI into the new system, training, and retirement of the legacy systems after rollout is complete. One new feature from the merger of ImmTrac with EVI will be the use of EVI’s accountability function that notifies parents that their children are due for a vaccine. This feature helps keep children on track for their needed immunizations but also ensures that they are not over vaccinated either (DSHS testimony).

Regardless of the new system, ImmTrac will continue serve several key functions: keeping Texans current for their vaccines, spreading information to providers and parents, tracking outbreaks and the gaps in immunizations that may have led to them, ensuring children receive critical vaccines, and avoiding over vaccination or duplicative vaccines for Texans (DSHS testimony).

Texas, like all other states, requires a child’s immunization before he or she can be enrolled in school, but, except for Mississippi and West Virginia, parents are allowed to claim exemptions from the mandate.¹⁹ states including Texas have exemptions for parents claiming “philosophical” reasons, which some speculate could be exploited by parents too lazy to follow through with their children’s shots in light of an easy way out. Most objectors, however, feel a legitimate danger comes from vaccines, and the decision to spare their children from immunizations is their right as parents. A recent Time Magazine article from October 2014 tracked the trends of most clusters of unvaccinated children. With little surprise, exemptions have higher concentrations in states that have more relaxed exemption policies, but the clusters tended to huddle around left leaning, affluent, and highly educated communities; like the recent mumps outbreak in Columbus, Ohio just outside of Ohio State University.

Not everyone can be immunized regardless of religious or philosophical objection, because they are too young or their immune systems are too fragile. Still, the overall “herd immunity” of a community can be preserved if immunization rates reach between 90 to 95% of the population. Consider some of these statewide numbers from the Centers for Disease Control highlighted in TIME Magazine:

- Louisiana has rate of 96.6% of school age children receiving the measles, mumps, and rubella (MMR) vaccine and 98.3% for diphtheria, tetanus, and pertussis (DTaP).
- Mississippi, the national leader for immunization rates, has a rate of 99.9% for both vaccines.
- In contrast, California has 92.7% and 92.5% respectively for these vaccines.
- Even worse, Colorado comes in at 85.7% and 82.9%.

- Looking at a more local trend, public schools in New York City have an immunization rate of 98%, but half of the private schools in the city come in at less than 90%.

In the overwhelming majority of states such as Texas, simply complying with the law requiring immunizations before enrolling in school does not mean that a child was vaccinated. All states allow for medical exemptions to vaccines, and all but two have exemptions for religious and philosophical reasons (TIME magazine). In oral testimony, Dr. Donald Murphy urged committee members that exemptions should not be more convenient to obtain than the vaccines themselves, and perhaps the process to vet them should be more rigorous.

Consider that 93% of Colorado's parents claiming an exemption did so based on personal beliefs. Washington and California both have laws requiring a doctor's signature before a personal exemption can be claimed. Oregon requires a doctor's signature or that the parents receive an online course on immunization. Such a measure was rejected in Colorado, as enraged parents and medical professionals railed against the measure for harassing citizens or labeling them "intellectually or morally inferior" (EDUCATION WEEK).

Some states approach their low vaccination rates through data collection and empowering parents through that information. This year, Colorado's General Assembly passed House Bill 1288, which directs schools to provide parents with the vaccination rates at their campus. Just like the rationale behind exemption laws that provide parents with a choice for their child's health, this measure is coupled with a pre-existing law allowing parents to choose which public schools they attend.

Colorado took another approach to deal with its permissive exemption laws. In 2012 and 2013, students were forced to stay home from school during long intervals due to pertussis outbreaks that doubled and tripled 2011 rates. Last April, local officials in Ohio told parents that unvaccinated students may have to stay home from school, as the region was suffering from an outbreak of the mumps (EDUCATION WEEK). A June 2014 decision of the Eastern District of New York, *Phillips v. City of New York* dismissed federal and state claims from parents in support of state law that barred attendance from unvaccinated students if another student reported a case of a "vaccine preventable disease" (University of Houston Law Center – Update on Health – July 2014).

Last Session, the Legislature considered several measures to improve the state's immunization policies. Several became effective last year, including SB 62 by Sen. Jane Nelson, chair of the Senate Health and Human Services Committee, which reduced the maximum age required for meningitis vaccines to enter into institutions of higher education and clarified that the Department of State Health Services has exclusive control over such exemptions with a special online portal for community college students. This bill was sponsored by House Public Health Committee member Rep. Jodie Laubenberg. SB 63, also by Chair Nelson, broadened the list of individuals who can consent immunizations to now encompass pregnant minors or minors with children. This bill was sponsored in the House by Public Health Committee member Rep. J.D. Sheffield. Finally, Nelson's SB 64 instructs childcare facilities, where children are not required by law to get vaccinated before enrolling, to develop staff immunization policies, including exemptions, to protect children from vaccine-preventable diseases.

Some measures, however, made it out of committee and came close to passing but ran out of time at the end of Session. HB 772 by Rep. Donna Howard would have changed ImmTrac to an opt-out system, but like a similar measure, SB 40 by Sen. Judith Zaffirini, it did not get a hearing in the Senate Committee on Health and Human Services. House Public Health Committee Member Rep. Phillip Cortez also filed HB 2709, which directed the Department of State Health Services to create and prevention and treatment plan for bacterial pneumonia.

Other bills did not make it out of the legislative committee to which they were originally referred. HB 771 by Rep. Donna Howard would have instructed ImmTrac to retain records past the child's 18th birthday without needing the affirmative consent of that child to hold onto the records. Also, SB 1013 by Sen. Larry Taylor, HB 2938 by Public Health Committee member Rep. Jodie Laubenberg, and HB 2222 by Rep. Gene Wu would have allowed pharmacists to administer vaccines to all children older than seven (Immunization Partnership 83rd Session wrap up).

The 84th Legislature will have a new challenge to address related to immunizations as 2013 had the highest incidence of pertussis cases in the last 50 years according to the Department of State Health Services. Pertussis, known as "whooping cough" because of the signature wheeze following a fit of coughing, first presents as a cold with a possible mild cough or fever, but then a severe cough can begin after a week or two that lasts for several weeks on its own. It is highly contagious, as the virus spreads from the cough or sneeze of the infected person. Unfortunately, infants, who are too young for immunization, are particularly susceptible to the disease, but immunization is the most effective protection from the disease. Unfortunately, a baby usually catches it from parents, older siblings, or other caretakers, who are often unaware they are spreading it (Austin American-Statesman).

According to the CDC, pertussis took the lives of 9,000 children annually but that number plummeted to less than 20 a year as a vaccine became available in 1933. With a resurgence of the disease, however, Texas is now experiencing 54-year high of child mortality (TMA website and TIME magazine).

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CHARGE #6

Conduct legislative oversight and monitoring of the agencies and programs under the committee's jurisdiction and the implementation of relevant legislation passed by the 83rd Legislature, including HB 15 (83R). In conducting this oversight, the committee should:

- a) consider any reforms to state agencies to make them more responsive to Texas taxpayers and citizens;
- b) identify issues regarding the agency or its governance that may be appropriate to investigate, improve, remedy, or eliminate;
- c) determine whether an agency is operating in a transparent and efficient manner; and
- d) identify opportunities to streamline programs and services while maintaining the mission of the agency and its programs.

HOUSE BILL 15

Since the implementation of H.B. 15 on September 1, 2013, several advancements have been made possible with regards to establishing levels of prenatal and maternal care at every hospital in the state, establishing more education on these levels of care, anonymity and confidentiality of the data provided from these hospitals, and a Perinatal Advisory Council.

H.B. 15 amended the Health and Safety Code relating to designating levels of care to hospitals providing maternal and prenatal services. H.B. 15 continues the work of the Neonatal Intensive Care Unit (NICU) Council created by HB 2636 from the 82nd Legislature, which expired on August 31, 2013. Under HB 15, the executive commissioner of the Health and Human Services Commission (HHSC) in consultation with the Department of State Health Services (DSHS) will assign levels of care designations to hospitals and will prescribe the process and criteria for these designations no later than March 1, 2017. Other duties of the HHSC will be to divide the state into neonatal and maternal care regions, facilitating transfer agreements, require payment regardless of the hospital designation, prohibit the denial of a level of care designation that meets the minimum requirements, require hospitals to regularly submit outcomes and data, and the requires to obtain each level of care must be posted on the department's website. In addition, the HHSC will study transfers that are not medically necessary but cost-effective with potential to adopt regulations surrounding these transfers.

Of other importance, the bill provided confidentiality of all information the hospitals submit to the DSHS regarding the level of care designations and the request from hospitals if they seek to change their designation, ensuring summaries provided by DSHS does not release any identifying information. Hospitals who do not meet minimum requirements of any level of care designation might not be eligible to receive reimbursements from Medicaid in certain scenarios.

Lastly, H.B. 15 established the Perinatal Advisory Council. The Council and its 17 members (made up of physicians, nurses, and hospital representatives) will help the executive commissioner develop designation criteria and processes and will make recommendations to the executive commissioner regarding improving neonatal and maternal outcomes and level of care designations. At the Texas House of Representatives Public Health Committee Hearing on September 24, 2014, Patricia Vojack Deputy Executive Commissioner of Health Policy and Clinical Services of HHSC gave the Public Health Committee updates regarding the Perinatal Advisory Committee and their next steps. Vojack said so far this year the Council has met six times to focus on the NICU designation process, and Neonatal design, outcomes, and definitions have been completed. The Council's recommendations for newborn levels of care are currently being incorporated into administrative rules, including DSHS Regulatory and HHSC reimbursement rules for Medicaid. The next steps for the council include concentrating on obstetrical levels of care designation process and quality reporting. Furthermore, the Council must submit a report with its recommendations to HHSC and DSHS by September 1, 2015. The newborn standards of Medicaid reimbursement are effective September 1, 2017. This is an important measure because, as reported by Vojak, over half of the births in Texas are on Medicaid. Lastly, the obstetrical standards tied to Medicaid reimbursement are effective September 1, 2019.

The House of Representatives Committee on Public Health, chaired by the Honorable Lois Kolkhorst, hosted a hearing on September 24, 2014 to receive updates from stakeholders about the impact of H.B. 15. Also through H.B. 15, the HHSC is trying to create or improve the current neonatal care units at existing hospitals.

Chris Daskevich, Senior Vice President of Women's Services at Texas Children's Hospital (TCH) spoke on behalf of the Texas Hospital Association. Daskevich stated that TCH is the largest newborn center in the country. Since H.B. 15, TCH has been partnering with community hospitals and supporting deliveries in those facilities. Daskevich said they are training neonatal nurses in addition to emphasizing collaboration and simulation training.

Daskevich also recommended how important it was to begin implementing the American Academy of Pediatric Guidelines when determining care level designations for newborn babies. There was also a small discussion regarding educating patients who choose to back transfer, and how rural hospitals have a lack of volume and resources. Daskevich mentioned a drawback of HB 15 is "back transfer". This is the transportation of a child to a specialized care unit. An example of back transport would be when a child needs to be born or taken to specialized care at a larger institution for specialized care, and then once they are stable the family wants to transport them to a more local facility out of convenience. However, the transport of a child to various hospitals is an expensive process that Medicaid does not pay for. As a result, back transfers are an item to consider moving forward.

In conclusion, the efforts made by the Perinatal Council have made a positive impact on hospitals by advancing levels of care. Lastly, the Public Health Committee will continue oversight of HB 15.

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Obtained from handouts and witness testimony from:

Committee on Public Health. September 24, 2014 at 9:00am.
Testimony from: Patricia Vojak, Cris Daskevich

Email correspondence between Texas Department of Family and Protective Services

HOUSE BILL 915

Before HB 915, in 2011, judges were concerned with foster care children being over-prescribed psychotropic medications (Amberboy handouts). Health leaders feared these prescribing physicians had a lack of accountability to ensure they were taking appropriate measures to find a treatment that accurately fit the needs of that particular individual. About a year later, the House of Representatives Public Health Committee hosted a hearing regarding the update on the bill since its implementation. Health officials stated in their invited testimony this bill has had success in bringing more attention and awareness to this issue and attributed the success of this bill to enhancing collaboration among Texas stakeholders. The Texas Department of Family and Protective Services believe an important step had been harnessing a cooperative team who gave additional oversight ensuring the appropriate treatments are given to children especially if they are prescribed psychotropic medications.

Once House Bill 915 was filed by Representative Lois Kolkhorst, many stakeholders such as the Children's Commission and the Department of Family and Protective Services not only worked together on the final language of the bill but also on how the bill's implementation. Since HB 915 was passed, the Texas Children's Commission worked with Commissioner Judge John Specia and DFPS to organize discussions about how to put the bill into effect. They created an Implementation Committee that identified existing practices and policies already supporting HB 915. The actions by the Implementation Committee included making new recommendations regarding new policies to support the ongoing implementation of the bill, and identified the training needs required to support new practices while bringing in stakeholders to communicate their support regarding the implementation. The workgroup met in June, July and August 2013 to prepare for the bill's effective date on September 3, 2013. Topics discussed in the final months leading up to the effective date included informed consent, what it means to be a medical consenter, creating medical consent training, establishing a medical consent form, developing further advocacy and oversight of the judges, attorneys, and CASA volunteers, in addition to monitoring the use of medications (Amberboy Handouts).

So far, noticeable features of HB 915 have been implemented with regard to medical consenters, strengthened informed consent, non-pharmacological interventions, increased frequency of health care provider visits, enhanced judicial review of medical care, and foster care transition planning in an attempt to boost comprehension and education of psychotropic medications (DFPS handouts).

Since filing, a large focus of the Texas Department of Family and Protective Services has been to provide statewide medical consent training. There have been several actions with to medical consent and informed consent practices. According to DFPS, Medical Consent and Psychotropic Medication trainings were updated to include new items targeting psychotropic medications, trauma informed care, and non-pharmacological interventions. They also emphasized that all new and existing medical personnel are required to attend training annually and sign a certificate after finishing the course. Additionally, Child Protective Services staff who are medical consenters must be present at every psychotropic medication appointment at Residential Treatment Centers and other facilities. Medical consenters must attend appointments in person, and will complete the "Psychotropic Medication Consent Form" for every new medication. Lastly, another way to boost education regarding medical decisions of prescribing

psychotropic medications has been distributed to all Child Protective Services staff and residential providers, and posted on the DFPS websites.

Another category of medical consenters includes the foster youth themselves. Attorneys and Guardian Ad Litem are responsible for ensuring children over 16 know of their right to medically consent to their health plans in court. Youth who can medically consent on their behalf are now required to complete online medical consent training, in addition to caregivers who are also responsible for medical consent of the child. The Youth Transition Plan of HB 915 had several strategies in place to assist youth when their medical decision making. The DFPS released policies which authorized children aging out of the foster care system or those who can now legally consent in their medical decisions to complete online Medical Consent Training, and even the Residential Contract was amended to require contractors to ensure youth completed their online training.

Another focus of HB 915 was to investigate non-pharmacological interventions or therapies. The bill has encouraged additional non-pharmacological therapies as an alternative to psychotropic medications, and these therapies are increasing over time. Data from STAR Health shows that in the fiscal year of 2014, there were increases in children receiving behavioral health therapy prior to being prescribed medication, enhanced therapy in conjunction with medication, and more children are maintaining their visits with their prescribers every 90 days. Caseworkers are helping residential contractors and CPS staff with treatment plans addressing behavioral strategies and psychosocial therapy to help children cope with stress and heal from trauma. In addition, STAR Health is currently working on building clinical therapist staff that focus on trauma-informed, evidence-based psychosocial therapies. Residential contractors are required to ensure foster parents and direct caregivers complete online Trauma Informed Care Training. Judge John Specia commented to the Public Health Committee hearing, Sept. 24, 2014 on the need for children psychologists in rural areas specializing in trauma informed care.

The Texas Department of Family and Protective Services has established policies to enhance judicial review of medical care with direction from HB 915. This includes considering alternative therapies before a prescription is administered, the expected timeframe and benefits of any psychotropic medication the child is taking, documenting the dates of the appointments, and that youth aged 16 and older are notified about their right to consent on their medical care during court hearings (DFPS Handouts). Also, judges must review the summary of the medical care provided to the child at the most recent hearing and ensure the child has expressed their opinion on their medical care. For children who are on psychotropic medication, the judge must determine whether or not the child has received appropriate psychosocial therapies, behavioral strategies, or other non-pharmacological interventions, has been routinely seeing their prescribing physician every 90 days. In July, attorneys were trained on their new Attorney Ad-Litem duties. Attorneys and CASA volunteers are required to also review the medical care provided to the child, elicit the child's opinion on their medical care, and they must advise all clients who are at least 16 years old of their right to request the court to authorize the child's consent on all their medical decisions (Amberboy Handouts).

Texas CASA commented on how the implementation of HB 915 was making a positive impact in these children's lives specifically by physicians taking more time for an appropriate medical diagnosis and treatment plan. Stephanie LeBleu, Public Policy Coordinator at Texas

CASA believes that although HB 915 has made a positive impact, not every area has seen positive improvements from the bill. She believes it is important for all stakeholders to continue working together to educate workers and networks about the provisions of HB 915 (hearing material).

Lastly, another important objective of House Bill 915, is putting together an effective strategy for youth transitioning out of the foster care system who are still reliant on medications. According to the provisions of HB 915, the Youth Transition Plan was revised to include resources to youth addressing their physical and mental health care with regards to medical decision making. Texas Department of Family and Protective Services have released new policies when it comes to informing youth. They are requiring youth who are authorized to give medical consent to their own care or who are aging out of the foster care system to complete online Medical Consent Training. Furthermore, residential contractors are legally required to ensure youth complete the online trainings.

At age 16, children in foster care are given the option to be in charge of giving themselves their own medication. They are instructed to fill out the Youth Transition Plan packet with the guidance of a caseworker and caregiver during a Circle of Support or Transition Plan Meeting. Once completed, the adolescent keeps this packet and makes updates when needed. Caseworkers then report the status of transition planning to the court via a court report. The Youth Transition Plan packet allows for the adolescent to strategically plan out his/her future, so the adolescent will be properly prepared for adulthood. Information provided in the Youth Transition Plan includes but is not limited to personal information, future goals, strengths, fears and concerns, education, job information, life skills, housing, and citizenship. Aging-Out Seminars are offered once or twice a year to adolescents, but attendance is not required at the functions.

Since the implementation of HB 915, we have seen children attend doctors' visits more regularly, in addition to the increase of behavioral therapies prior to prescription, or supplementing prescriptions. The increases have been attributed to implementing more health checkpoints for those on psychotropic medications, increasing education on psychotropic medical decisions, and educating health professionals and youth on medical consent. Although it is unfortunate that children under age 16 don't have legal consent, they are encouraged to and have been asking more questions at their routine doctors' appointments concerning their medication and the medical decisions their physicians made. Overall Commissioner Judge John Specia felt as though this is an important bill and has been heading in the right direction.

REFERENCES

Obtained from handouts and witness testimony from:

Committee on Public Health. September 24, 2014 at 9:00am.
Testimony from: Judge John Specia, Tina Amberboy, Stephanie LeBleu, and Diane Black

Email correspondence between Texas Department of Family and Protective Services

HOUSE BILL 3201

Prior to the passage of H.B. 3201 in the 83rd Session, the Texas State Board of Dental Examiners (TSBDE) struggled in its investigative and enforcement capacity, leading to less efficiency in resolving complaints in a timely manner. This was mainly due to a lack of funding, staff, and enforcement authority. H.B. 3201 set out to address these problems in multiple ways. First, the TSBDE now receives an additional \$55 surcharge for dental license issuance and renewal fees, which is then used to fund the board's review and resolution program. Second, the respondent—license holder—is now required to be informed of the specific allegations against her. Third, H.B. 3201 required the TSBDE to collect certain information from dentists seeking licenses or renewals with regard to their involvement with dental service organizations (DSOs). Under H.B. 3201, DSOs are also required to provide certain information to the board on request. Fourth, the TSBDE is now authorized to establish a preliminary complaint investigation to determine if a full investigation/proceeding is warranted. H.B. 3201 set a deadline of 60 days for the completion of a preliminary investigation. Fifth, in order to assist the board members with investigations, the Board has been required to provide for expert panels and procedures for the review of complaints regarding professional competency. Sixth, the bill authorized parents of children under the age of 18 to be present in the treatment room, except in certain situations. Finally, H.B. 3201 established the Board's right to issue and establish terms of a remedial plan to resolve the investigation of a complaint. While these are the pertinent aspects of the bill for the interim report's purposes, this list is by no means exhaustive.

Julie Hildebrand, the Executive Director for the TSBDE, was the sole panelist regarding this issue on September 24, 2014. According to her, H.B. 3201 has greatly improved the Board's complaint review and resolution process, thus increasing the Board's overall efficiency. While the bill has proven to increase the efficiency of the Board, given the Board greater authority to regulate dentists' professional conduct and non-dentists ownership of dental practices and influence on a dentist's professional judgment, some concerns have been expressed along with possible solutions. The problems arise from the board's limited authority over the actions of non-dentists, including DSOs that affect the practice of dentistry. As will be discussed below, the Board has suggested holding dentists accountable for any disciplinary issues arising from the action/inaction of a non-dentist with whom the dentist has a contract. According to the TSBDE, this will solve the problem of not being able to hold DSOs accountable for any aspect, except for the practice of dentistry, of the Dental Practice Act (DPA). The TSBDE has proposed rule changes that will be considered on October 1, 2014 that will address this problem. However, these proposed changes do not go without opposition. Some stakeholders have expressed concerns that these proposed changes would greatly affect a dentists' ability to contract with DSOs, render DSOs obsolete, and does nothing to protect or benefit the patient. In fact, these stakeholders say that no other state has attempted to restrict a dentist's ability to contract with a DSO like the TSBDE has proposed to do. The report will address how H.B. 3201 has been implemented by the TSBDE, what TSBDE says the problem is with not having the authority to take action against DSOs, and how they plan to address this problem.

H.B. 3201's authorization to collect a \$55 surcharge for dental licenses and renewal fees has allowed the TSBDE to combat the lack of staff problem. Ms. Hildebrand said the TSBDE is in fact collecting this fee. This additional revenue has provided a way for the board to hire more full-time employees (FTEs) to assist in enforcement. The results of this increase in FTEs is that

the Board has seen the average age of open cases dropping significantly, and, as opposed to before H.B. 3201, the TSBDE is closing more cases than receiving. According to information provided by the TSBDE, the total number of open complaints in January of 2014 was 1,316. This number has dropped to 1,085 open complaints as of the date of the hearing.

Another important result of the TSBDE's increased revenue from the \$55 surcharge coupled with the bill's requirement for establishing expert panels to assist with investigations and complaints has been that the Board has approved about 100 expert reviewers. The implementation of the expert panel/reviewers went into effect on January 1, 2014. Chairwoman Kolkhorst asked Ms. Hildebrand how helpful the establishment of these panels has been to the Board. Ms. Hildebrand responded with background on how the Board used to handle complaints pre-H.B. 3201. According to her, there were eight Board members that were dentists and they would review about 500-600 cases per year. Two Board members had to review every case. Once reviewed, the reviewing members would provide an expert opinion. However, because of the intense case load and the reviewing members' own practice obligations, these opinions were low quality.

The backlog forced many complaints/cases to settle for way less than they should have, according to Ms. Hildebrand. However, the TSBDE now has over 100 reviewing dentists. With the increased support staff, the TSBDE is now asking 14 days on easy cases, 30 days on difficult ones, and sometimes more based on the complexity of the case. Ms. Hildebrand stated that while there is no average time for resolution of cases as of now, the TSBDE will begin keeping track of the days to close a case at the start of the new fiscal year. Additionally, the TSBDE has seen a notable increase in the quality of expert opinions as a result of the expert panels. Ms. Hildebrand explained that a complaint gets two full expert reviewers, but if these two don't agree, a third expert review is required. Overall, the quality and efficiency of the complaint review and resolution process has greatly increased because of H.B. 3201.

Before H.B. 3201, the average time for dismissal of a complaint was about 500 days. The number is now below 300 and continually dropping. This number is not a true number, however, because of the extensive backlog pre-H.B. 3201. Thus, the number of days to close a complaint is expected to drop.

Another critical part of the TSBDE's increased efficiency is the institution of processes to conduct preliminary inquiries on complaints. Dentists on staff now review standard of care cases, while non-standard of care cases are being reviewed by an attorney. These both have decreased the amount of time investigations take and allow rapid closing of complaints that would normally be added to the backlog. Previously, a complaint would have to go through the entire reviewing process and investigation before a lawyer could even review it. The new process has allowed cases that should have no action taken to be quickly resolved without a full investigation. To demonstrate the effectiveness of this process, "standard of care cases that were received between January 1, 2013 and August 13, 2013, 6 cases were closed within that period. In contrast, between January 1, 2014 and August 13, 2014, 86 standard of care cases, received during that period, were closed during that period."

On a different note, first, Ms. Hildebrand reported to the committee that as required by H.B. 3201, the TSBDE has in fact implemented rules to effectuate the requirement that all

investigative files be kept confidential, except as to inform respondents of complaints of the specific allegations against them. Second, the TSBDE now has another efficiency-increasing tool in its repertoire post-H.B. 3201 in the availability of non-disciplinary remedial plans. Ms. Hildebrand reported the TSBDE has in fact put rules in place to effectuate this option for the Board to resolve less severe complaints more quickly. And third, the section of H.B. 3201 regarding parents being able to be in room except in certain circumstances has already been put into place. Ms. Hildebrand said this was put into rule at the December 2013 Board meeting. Almost immediately the TSBDE began seeing dentists establishing policies banning parents from entering treatment rooms in those limited circumstances. However, the TSBDE wanted to make the rule even more specific. The TSBDE has now added that in each case where a parent is banned from entering the treatment room, a reason must be documented and provided. The Board wanted to avoid a blanket prohibition on parents being in the treatment room.

During the Public Health committee hearing, the question was brought up about who owns the dental records of a patient. According to the TSBDE, the dentists are the custodians of dental records. However, there have been instances where a DSO has prohibited a dentist from accessing the records. Ms. Hildebrand stated that, generally, records stay with owners of the practice, which must be a dentist according to the DPA. A patient may, however, obtain a copy of her records when moving to another dental practice. The problem, though, is that DSOs have held on to the records and would not allow a patient access to her own records. Dentists are the only ones who have filed complaints related to this issue so far. As the laws and rules are now, with regards to disciplinary action, the TSBDE could not take action against the DSO in situations like this. The TSBDE could only take action against the dentist.

Now, to more of the meat of H.B. 3201 the attention turns to the TSBDE collecting information related to DSOs from dentists and DSOs alike. Per H.B. 3201, the Board is required to collect information described in §254.019 of the DPA in conjunction with the issuance and renewal of each dental license. On September 1, 2013 the TSBDE began the process of collecting the relevant information as provided by H.B. 3201. Questions included inquiries regarding ownership of clinics and DSOs the dentists work with, DSOs that employ the dentists, etc. Simultaneously, the board is compiling a list of DSOs associated with each dentist. The board will then send them a letter asking the questions the TSBDE is allowed to ask under H.B. 3201. For example, which dental practice offices are they working with, whom are they employing, and where are they located. The goal in all of this is to report back to the legislature its findings to see if additional action needs to be taken to increase oversight of DSOs by the TSBDE.

An additional tidbit to note is that, according to Ms. Hildebrand, during the investigations, if a DSO is thought to have been a part of why a complaint was filed in the first place, the TSBDE will follow up with that DSO and will ask them for the contract between them and the relevant dentist. This is to see the effect the DSO may have on the complaint. Because many DSOs work behind the scenes of a dental practice, the concern is that the complaints filed will only address the alleged wrongdoing of the dentist and not the actual reason for the complaint if the DSOs were in fact the actual catalyst to the issue. Since September 1, 2013, the TSBDE has received information from about 98% of renewing dentists and plans on providing a report to the legislature on November 1, 2014. Noncompliance with reporting will result in a fine.

The real issue here is what the TSBDE can do about non-dentists—i.e. DSOs—that violate an aspect of the DPA. According to Ms. Hildebrand, the TSBDE has very limited authority over the actions of non-dentists that affect the practice of dentistry. The board cannot regulate a DSO under any aspect of the DPA, except for unauthorized practice of dentistry. One of the only things the TSBDE can do if a DSO violates something in the DPA is to send the DSO a cease and desist order. There is no issue with DSOs running book keeping and other administrative aspects of a dental practice, but the problems arise when DSOs go beyond that. According to the DPA, DSOs may be hired to run billing, and other “back-office” aspects, but they can in no way dictate to a dentist how to run her practice. For example, a DSO cannot tell the dentist how many patients she must see in a week. DSOs can be investors in a practice, but must never own a practice.

Ms. Hildebrand provided an example of how the limited authority over the actions of non-dentists affects the practice and regulation of dentistry. To illustrate the Board’s limited authority through an example, if a non-dentist contracts with a dentist where the non-dentist is allowed to own, maintain, or operate a dental practice or have control over a professional/clinical aspect of the dental practice, the Board can issue a cease and desist order against the non-dentist and take disciplinary action against the dentist. However, the board cannot institute disciplinary action against the non-dentist.

To address the problem of DSOs lacking accountability under the DPA, according to the TSDBE, the Board has suggested amending its current rules to provide clear and unequivocal notice to dentists and non-dentists of an owner dentist’s responsibility for the dental practice in general and in contracting with a non-dentist for support. Again, the TSBDE is to hold a hearing on potential changes October 1, 2014. In effect, the suggested changes would mean that the TSDBE would hold the dentist responsible, not only for what she does, but also for anything the non-dentist/DSO does. This would be stated in the contracts between dentists and non-dentists as provided by the TSDBE. The TSBDE wants to clarify the rules in order to give clear notice of what an illegal contract looks like. As stated by Ms. Hildebrand, one of the goals in all of this is to educate young dentists on the process and how the DPA affects them.

Ms. Hildebrand admitted that stakeholders have landed on both sides of the proposed changes. As mentioned earlier, several stakeholders, specifically Delta Dental and Texas Association of Business, have said the proposed rule changes would effectively shut down DSOs in Texas, which is something that has not been attempted in any other state. These stakeholders further say that there are plenty of avenues to enforce laws against DSOs practicing, owning, or influencing a dental practice.

It seems that the laws are already in place within the DPA to hold dentists accountable for any wrongdoings by them or DSOs, or other non-dentists, so it may just be a matter of enforcement rather than needing more rules/laws.

This wasn't talked about in the hearing, but it was provided for in a handout from TSBDE in June of 2014 that “recommended that the leg amend the DPA to allow for a shorter time period for a dentist to provide dental records requested by the board. Because of the 60 day period to comply with preliminary inquiry, a 15 day period to provide dental records requested

would allow the board to be more efficient in reviewing standard of care cases. In fact, the Texas Medical Board allows for a 15 day response period in §159.006 of its Act.

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UNACCOMPANIED CHILDREN AND BORDER HEALTH UPDATE

Representative Lois Kolkhorst, Chair of the Public Health Committee, invited testimony regarding the surge of unaccompanied children on the Texas-Mexico border from Dave Gruber, Assistant Commissioner for Regional and Local Health Services with DSHS and Steve McCraw, Director of DPS. Gruber spoke regarding the attempts DSHS has made to improve communication and partnerships with CDC, Border Patrol agents, and HHS regarding the influx of unaccompanied children. Three objectives they have is to protect the health of Texans, Border Patrol agents, and children in sheltering facilities, while supporting local health departments involved in these issues, and anticipating any future events. Dr. Lakey, Commissioner of DSHS has been working tirelessly with agents to improve sheltering sanitation conditions and the possibility of outbreak in holding facilities. Significant progress has been made with regards to communication and cooperation of various state and federal departments since assigning a DSHS staff member in the Rio Grande Valley at the Customs and Border Patrol Operation Center.

Gruber emphasized unaccompanied children (UAC) overall are in great health. They have seen minimal cases of Tuberculosis, H1N1, Pheumococcal and chickenpox. It was more common for agents to come across scabies, rashes, abrasions, lice, and dehydration. Gruber mentioned, if unaccompanied children have any health issues they will receive immediate treatment and the actions will be documented before they will be released. In fact, unaccompanied children are not a public health concern because they come across the most health checkpoints before integration into the general public. The majority of the children come from countries who have high vaccination standards at the same level of the U.S. and even higher. Once unaccompanied children are done with their health screenings, they are either released to a close relative or parent who was already here, or a family friend the parents can vouch for eventually entering the public school system. At this point they will have to provide vaccination records and if they can't provide them they will be administered shots again. Furthermore, unaccompanied children have not had a negative impact on public health of schools, according to Gruber.

On the other hand, individuals entering as a family unit, have limited, if any health checkpoints. They get a 'permiso' from the federal government to travel by bus to their desired location and have a temporary pass into the U.S. until their immigration hearing begins. However, the assurance of them attending their trial is very low. Another drawback is the fact that family units do not have to prove their age, or if they are legal guardians of the children that are with them. Chair Kolkhorst, committee members, DSHS and DPS all addressed their concerns with this. Lastly, another major concern is the lack of federal tracking of these family units after they enter the country and communicating their whereabouts to state officials. The state of Texas has no control over this issue of visibility because it is a federal process family units go through to enter.

As far as the total percentage of traffic across the border, only 17-20% are unaccompanied children and family units; the rest being undocumented aliens, gangs, or drug traffickers. The amount of people attempting to cross the border has been increasing, as a result Texas has been spending significant energy and resources along the border. The current hot-spot of all crossings occur the Rio Grande Valley because of proximity to Mexico, easier terrain to navigate, and tolerant weather conditions. For the fiscal year of 2014 to date, the foot traffic in

the Rio Grande Valley accounts for 54% of the total nation's migration. Border Patrol's apprehension rates have also increased due to additional efforts. The total apprehension rates in 2011 were 125,821 and steadily increased over the next 3 years to 323,664 people, according to DPS. They strongly believe the reason why the number of people crossing the border has decreased is due to the Texas Legislature putting substantial resources and energy at the border, thereby weakening the cartels and protecting the local communities.

In conclusion, the Public Health Committee recommends strengthening communication between state and federal agencies to enhance strategies regarding the tracking of family units.

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EBOLA UPDATE

The Texas Department of State Health Services (DSHS) and the Centers for Disease Control (CDC) confirmed the United States' first case of the Ebola virus on September 30, 2014, when native Liberian Thomas Duncan walked in the Emergency Room at Dallas Presbyterian Hospital. He became symptomatic upon his arrival to Texas from West Africa (DSHS Handouts). Duncan's case evoked alarm because he was not immediately diagnosed with Ebola. His condition and travel history were originally overlooked which could have led to a potential outbreak. Days after he was sent home with antibiotics, he returned to the ER, where he was quarantined and his blood work confirmed he had Ebola.

Although Duncan lost his life, his case became valuable at educating local, state, and national health officials on emergency preparedness. From this case, government officials have learned the importance of accurate diagnosis, proficient hospital protocols, and constant communication and collaboration among all health agencies (Sloan, Shaw at County Affairs hearing). All government officials have emphasized effective protocols and procedures hospitals must follow when coming in contact with a contagious patient. In fact, all health clinics are training staff to identify patients with the Ebola virus in addition to stocking up on proper equipment such as air ventilators and protective gowns.

There is a current chain of action that occurs if a patient walks into a health clinic unexpectedly. They will be asked if they have traveled to Liberia, Sierra Leone, or Guinea in the past three weeks, if they have come into contact with the bodily fluids someone who has traveled to these African countries, or if they are becoming symptomatic. If someone has met these criteria they are immediately isolated. The protocol for health officials would then be to contact their local health department and identify the risks of the situation. They will discuss if testing should take place and obtain approval from the CDC to conduct laboratory testing. Moreover, there is probability that the virus might not be visible right away, so it might be necessary to retest within the next 72 hours. If a case is confirmed, the patient may need to be transferred to another facility to provide 'long-term' care (Gonzales - county affairs hearing).

Hospitals across the nation are on high alert and making necessary adjustments in protocol from lessons learned from others. (Ressmann). Hospitals preparing for another situation similar to the one seen at Dallas Presbyterian is great for emergency preparedness but some view it as inefficient. (Ressmann). Because of the health infrastructure of the United States and the low probability of contraction, the chances that all health clinics and large institutions will receive Ebola walk-ins is highly unlikely at this point. As a result, there have been active discussions surrounding designating specific hospitals to give long term treatment or supportive care to patients diagnosed with Ebola. (Alsip). Larger institutions would feel more comfortable containing an Ebola patient because they would have better protocols and more equipment to handle such a contagion (like air containment quarantined rooms in the likelihood a contagion is airborne).

Currently, the main public health-oriented goal is to interrupt and prevent the transmission of Ebola in the United States. (Shaw). As of now, the focus of government and health officials are the facilitation of resources, educating the public, testing of clinical equipment, and spreading health care messages through networks. (Shaw, Sloan, Cole, Shah,

Alsip, Ressmann). In sum, the lessons learned from Dallas Presbyterian are both practical, crucial and are continually evolving.¹

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