

Legislative Update and Recent Enforcement Actions

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Agenda

1. Fraud and Abuse Law Refresher
2. Qui Tams and Recent Enforcement Activity
3. Recent Legislation



The Stark Law: Refresher

- If a physician, or a member of the physician's immediate family, has a financial relationship with an entity, then the physician is prohibited from making a referral to the entity for the provision of a designated health service paid for by Medicare, and the entity is prohibited from billing for such service, unless an exception is satisfied
- **Penalties:**
 - Denial of payment
 - Civil monetary penalties of up to \$15,000 for *each* offense
 - False Claims Act prosecution, and
 - Exclusion from Medicare and Medicaid programs
- Strict liability statute = No intent requirement
- Stark is all about ***EXCEPTIONS***.



Anti-Kickback Statute: Refresher

- It is a FELONY to knowingly and willfully offer, pay, solicit, or receive any "remuneration" in order to induce referrals of items or services reimbursable by any Federal or State health care programs.
- Intent Based Statute: just One Purpose is to induce referrals = Anti-Kickback Statute violation
- Penalties
 - Criminal: Fine of up to \$25,000 per violation and/or Imprisonment for up to 5 years
 - Civil: Civil fines in the amount of \$50,000 per violation
 - Plus damages of not more than 3 times the total amount of remuneration offered, paid, solicited or received
 - Exclusion From Federal/State Programs
 - False Claim Actions
- Safe Harbors



False Claims Act: Refresher

- The False Claims Act establishes liability for **any person who KNOWINGLY presents false or fraudulent claims to the US government for payment.**
- FCA Obligation: Established duty arising from an express or implied contractual relationship or statute or regulation to disgorge of any overpayments
 - Expressly includes retention of overpayment
- Forms the basis of a “**qui tam**” action (relators can receive 15-30%).
- Penalties
 - Monetary penalties of not less than \$5,500 and not more than \$11,000 per claim. Plus damages of not more than 3 times the total amount of remuneration offered, paid, solicited or received

100 improper claims that each paid on average \$200 could result in:
Amount paid (\$20,000) x 3 = \$60,000 + Fines (100 x 11,000) = \$1,160,000

- Exclusion From Federal/State Programs



QUI TAM AND RECENT ENFORCEMENT ACTIONS



Qui Tam/Enforcement Actions

- FCA awards 15-30% of the recovery to whistleblowers.
- Medicare Incentive Reward Program:
 - CMS can pay whistleblowers an additional 10%.
 - Proposed Rule would expand the amount to 15% up to the first \$66 million received (potential \$9.9 million recovery for whistleblower). The proposed rule has yet to be finalized.



Qui Tam/Enforcement Actions

- 62 healthcare qui tam actions filed from 1987 to 1992.
- In 2011 alone, there were 417.
- In 2012, there were 412.
- 752 new *qui tam* matters filed in 2013.



Qui Tam/Enforcement Actions 2013 and 2014

- Total federal health care recoveries under the FCA exceeded \$2.5 billion in 2013 and \$2.3 billion in 2014
- 2014 was the 5th consecutive year FCA recoveries from health care fraud exceeded \$2 billion.
- Total rewards paid to *qui tam* relators in health care cases was \$345 million in 2013 and \$435 million in 2014.



Recent OIG Statistics

OIG Action	FY09	FY10	FY11	FY12	FY13	FY14	Total
Criminal Actions	671	647	723	778	960	971	4,750
Civil Actions	394	378	382	367	472	533	2,526
Exclusions	2,556	3,340	2,662	3,131	3,214	4,017	18,920
HHS Investigative Receivables	\$3.0 Billion	\$3.2 Billion	\$3.6 Billion	\$4.3 Billion	\$4.0 Billion	\$3.0 Billion	\$21.2 Billion
Non-HHS Investigative Receivables	\$1.0 Billion	\$576.9 Million	\$952.8 Million	\$1.7 Billion	\$1.03 Billion	\$1.1 Billion	\$6.3 Billion
Total Investigative Receivables	\$4.0 Billion	\$3.8 Billion	\$4.6 Billion	\$6.0 Billion	\$5.0 Billion	\$4.1 Billion	\$27.6 Billion

Statistics are for cases in which there was a settlement with or judgment for the United States, and in which the OIG's Office of Investigations was involved.



HEAT Strike Force Activity

The Health Care Fraud Prevention and Enforcement Action Team (HEAT) was started in 2009 by HHS and DOJ to strengthen programs and invest in new resources and technologies to prevent and combat health care fraud, waste, and abuse. Hallmarks include data-driven analyses and interagency collaboration.

Location	Criminal Actions	Indictments	Money*
Miami	622	796	\$881,561,175
Los Angeles	60	135	\$48,295,354
Detroit	111	217	\$60,515,775
Houston	56	99	\$20,529,564
New York	31	84	\$112,298,203
Baton Rouge	43	83	\$39,166,607
Tampa	30	42	\$56,056,891
Dallas	17	57	\$30,277,662
Chicago	9	53	\$4,825,501
Total	979	1,566	\$1,203,526,733

Statistics are for cases in which there was a settlement with or judgment for the United States, and in which the OIG's Office of Investigations was involved between 2009 and 2013.



Qui Tam/Enforcement Actions

- Most relators are employees (more than 75% according to most recent surveys).
- Some are employed or affiliated with competitors.
- According to the HHS' Health Care Fraud and Abuse Program Annual Report released in February 2014, for every dollar spent on health care-related fraud and abuse in the last three years, the government recovered \$8.10.



Qui Tam/Enforcement Actions

- In September 2014, an Assistant US Attorney for the DOJ's Criminal Division, announced that the DOJ will be stepping up its review of False Claims Act (FCA) qui tam complaints.
- All new qui tam complaints are shared by the Civil Division with the Criminal Division as soon as the cases are filed for immediate review.
- The Criminal Division will use criminal investigative tools (e.g., search warrants, wire taps, undercover operations and confidential informants) that it will be able to contribute to FCA cases.
- "Cases involving fraud by executives at health care providers, such as hospitals, are a high priority"



Enforcement Activity

North Broward Hospital District (September 15, 2015)

- Qui Tam filed by physician medical staff member alleging violations of Stark, AKS and FCA.
- Employed orthopedic surgeons, cardiologists, primary care and oncologists were compensated at above FMV salaries that were not commercially reasonable and based on volume or value of referrals.
- Not commercially reasonable because substantial losses were projected.
- Compensation exceeded 90th percentile of physicians in region and compensation to collections ratio exceeded 1:1.
- NBHD internally tracked contribution margin from the employed physicians' referrals.
- Requirement to refer internally, despite quality concerns
- \$69.5 million settlement, 5 year Corporate Integrity Agreement which requires an intense process for entering into and monitoring arrangements and requires NBHD to hire outside third party to monitor compliance.



Enforcement Activity

South Shore Physician Hospital Organization (SSPHO) (January 2015)

- SSPHO and its member organizations, South Shore Hospital, Inc. and Physicians Organization of the South Shore, Inc. paid kickbacks in the form of cash grants to doctors who agreed to make referrals to SSPHO providers.
- From 2001 to 2010, SSPHO approved 103 separate recruitment grants to 33 different physician groups. The recruitment grant program requested that grant recipients refer patients to participating providers, which included the South Shore Hospital.
- \$1.775 million settlement
- Additional Information: <http://www.justice.gov/usao-ma/pr/south-shore-physicians-hospital-organization-pay-1775-million-alleged-kickbacks-patient>



Enforcement Activity

Nason Medical (January 2015)

- Nason Medical, out of Charleston, South Carolina, and two of its owners, Dr. Baron S. Nason and Robert T. Hamilton allegedly:
 - Submitted claims to Medicare and TRICARE for services that were provided by physician assistants, as though the services were provided by physicians. Both Medicare and TRICARE pay 85% of the physician fee schedules for services provided by mid-level providers like physician assistants;
 - Submitted claims for testing that was not medically indicated including laboratory tests and potentially harmful CT scans;
 - Submitted claims for radiological services provided by a radiology technician who did not hold a current South Carolina license; and
 - Submitted claims for Tetanus Immunoglobulin when Tetanus Toxoid was given which is considerably less expensive;
- \$1.021 million settlement
- Qui Tam
- Additional Information: <http://www.justice.gov/usao/sc/news/1.14.15.nason.html>



Enforcement Activity

Hollywood Pavilion (November 2014)

- Former chief operating officer of a Miami-area hospital pled guilty for role in a mental health care fraud scheme that resulted in the submission of more than \$67 million in fraudulent claims to Medicare by a psychiatric hospital.
- Claims were for treatment that was not medically necessary or not provided to patients. COO supervised HP's staff at both its inpatient and outpatient facilities, where Medicare beneficiaries were admitted to HP regardless of whether they qualified for mental health treatment, and were often admitted before seeing a doctor.
- HP obtained Medicare beneficiaries from across the country by paying bribes and kickbacks to various patient brokers. The COO instructed the patient brokers to falsify invoices and marketing reports in an effort to hide, and cover up the true nature of the bribes and kickbacks they were receiving from HP. 4 colleagues have already been sentenced to prison terms ranging from 6-25 years for the same offenses.
- Additional Information: <http://www.justice.gov/opa/pr/miami-area-hospital-chief-operating-officer-pleads-guilty-67-million-mental-health-care-fraud>



Enforcement Activity

Shelby Regional Medical Center-Tyler, Texas (November 2014)

- Former CFO of Shelby Regional Medical Center in Tyler oversaw the implementation of electronic health records for the hospital and was responsible for attesting to the meaningful use of electronic health records in order to qualify to receive incentive payments under Medicare's Electronic Health Record (EHR) Incentive Program.
- On Nov. 20, 2012, White knowingly made a false statement to Medicare falsely representing that the hospital was a meaningful user of electronic health records, when the hospital did not meet the meaningful use requirements. As a result, Shelby Regional Medical Center received \$785,655.00 from Medicare.
- Faces up to 5 years in prison.
- Additional Information: <http://www.justice.gov/usao/txe/News/2014/edtx-hcf-white-111314.html>



Enforcement Activity

Riverside General Hospital -Houston, Texas (October 2014)

- Hospital President and colleagues operated a scheme to defraud Medicare from 2005-June 2012. Defendants caused the submission of false and fraudulent claims for partial hospitalization program (PHP) services to Medicare through the hospital. A PHP is a form of intensive outpatient treatment for severe mental illness.
- Evidence demonstrated that the Medicare beneficiaries for whom Riverside (and satellite locations) billed Medicare for PHP services did not qualify for or need PHP services. Additionally, the Medicare beneficiaries rarely saw a psychiatrist and did not receive intensive psychiatric treatment. In fact, some of the Medicare beneficiaries were suffering from Alzheimer's and could not actively participate in any treatment even if they actually qualified to receive PHP services.
- Kickbacks were paid to patient recruiters and to owners and operators of group care homes in exchange for those individuals delivering ineligible Medicare beneficiaries to the hospital's PHPs.
- Former hospital president sentenced to 45 years in prison following his conviction in the \$158 million Medicare fraud scheme. Other parties involved were sentenced to 20 years and 12 years. Collectively, the parties were ordered to pay approximately \$100 million in restitution. One party remains to be sentenced.
- Additional Information: <http://www.justice.gov/opa/pr/president-houston-hospital-and-three-others-convicted-158-million-medicare-fraud-scheme>



U.S. ex rel. Drakeford v. Tuomey

2013

- Surgeons begin development of an ASC and Tuomey Health System was concerned about losing volume.
- Hospital hires surgeons as employees
 - Part-time employment during surgical procedures; surgeons maintained office practice separately
 - Compensation to physicians: fixed salary, plus 80% of collections, plus quality incentives
 - DOJ alleged that compensation exceeded 100% of actual collections (and was up to 140% of collections)
- Hospital internal documents projected losses on all employment agreements



U.S. ex rel. Drakeford v. Tuomey

- DOJ argues that compensation is not FMV because “the hospital’s motivation in entering into these part-time agreements was to avoid losing the referrals”
 - While Stark Law is strict liability, the DOJ looked at motivation of parties
- Hospital obtained multiple valuation analyses
- During the trial, the hospital argued reliance on advice of counsel.
- Jury found Tuomey submitted a total of 21,730 Medicare claims that were illegal due to the compensation arrangements
- Result: Jury awarded \$237 million for false claims. Affirmed by 4th Circuit (July 2015)



Somewhat Recent Cases

Halifax - March 2014

- Background: a Compliance Officer at Halifax Health Medical Center filed a Qui Tam action alleging that the Hospital gave prohibited bonuses to least 6 doctors under employment agreements. It is alleged the amount of the bonuses increased when the doctors referred more patients to the Hospital.
- A Federal Court has ruled the case can proceed even though some of the claims were submitted to Medicaid and not Medicare.
- Government has intervened in the case and the parties reached a \$85 million settlement on March 3, 2014.



Enforcement Activity

“Largest National Medicare Takedown in History” (June 2015)

- **North Texas** (7 indicted)
 - Primarily charged with upcoding for home health services, and for providing medically unnecessary home health services. 6 of these 7 were related to a house call company which submitted nearly \$43 million in billings under the name of a single doctor.
 - Additional Information: <http://www.justice.gov/usao-ndtx/pr/seven-charged-north-texas-part-largest-national-medicare-fraud-takedown-history>
- **South Texas** (16 indicted)
 - Brownsville: charges include submitting false claims for children’s therapy services that were not provided and billing for more therapy than was provided. Alleged false claims: \$773, 345
 - Laredo: charges include fraudulent billing for personal assistance services (cleaning, bathing, meal prep, etc.) that were never provided and an illegal referral relationship. \$3 million in claims allegedly result of kickbacks
 - McAllen: In separate cases, charges include: soliciting and receiving cash in exchange for referrals to home health agencies, fraudulent billing for DME that was either not provided or authorized, submitting claims as if services were provided by a medical professional when they were not
 - Additional Information: <http://www.justice.gov/usao-sdtx/pr/16-charged-south-texas-part-largest-national-medicare-fraud-takedown-history>
- Similar “takedowns” in Miami, Houston, LA, Detroit, Tampa, Brooklyn, New Orleans



Enforcement Activity

Joseph Megwa, M.D. (Arlington, Texas) (May 2014)

- Convicted of a \$3 million Medicare fraud conspiracy and 3 counts of health care fraud.
- Billed for medically unnecessary home health services from 2006 to 2011. Falsified medical records.
- In exchange for cash payments, Dr. Megwa certified medical necessity.
- Sentenced to 10 years prison in December 2014.



Enforcement Activity

Dallas Attorney Tshombe Anderson (August 2015)

Currently Pending – Only Allegations

- Indicted for allegedly submitting fraudulent DME claims to the United States Department of Labor
- DOL = Federal Healthcare Program
- Innocent until proven guilty.
- Additional Information: <http://www.justice.gov/usao-ndtx/pr/dallas-attorney-and-family-members-federal-custody-allegedly-committing-health-care>



Enforcement Activity

Jacques Roy, MD, et. al. - Dallas, Texas (February 2012)

- Dr. Roy, office manager, and five owners of home health agency indicted for alleged participation in a nearly \$375 million health care fraud scheme.
- According to the indictment, Dr. Roy owned/operated an association of health care providers that primarily provided home health certifications and performed patient home visits. Dr. Roy allegedly certified or directed the certification of more than 11,000 individual patients from more than 500 HHAs for home health services during the past five years.
- The Medicare Fraud Strike Force used “sophisticated data analysis...[to] target suspicious billing spikes.” This analysis showed that in 2010, while 99% of physicians who certified patients for home health signed off on 104 or fewer people – Dr. Roy certified more than 5,000.
- Additional Information: <http://www.justice.gov/sites/default/files/criminal-fraud/legacy/2015/03/06/roy-press-release.pdf>



Enforcement Activity

Pat Akamnonu – Medically Unnecessary Home Health Services (June 2015)

- Pleaded guilty for submitting claims for medically unnecessary home health services.
- Conspiracy Involved Dr. Jacques Roy of Medistat Group Associates and Others
- Husband was sentenced to 10 years in prison, ordered to pay \$25 million in restitution
- Additional Information: <http://www.justice.gov/usao-ndtx/pr/registered-nurse-co-owner-ultimate-care-home-health-services-inc-pleads-guilty-role>



Enforcement Activity

Team Work Ready – Health Care Fraud and Money Laundering (July 2015

Currently Pending – Only Allegations)

- Owners and persons associated with Team Work Ready (TWR) charged with conspiracy to submit false claims for health care benefits to the Federal Employees Compensation Act through the Department of Labor Office of Worker's Compensation (OWCP)
- Among other charges, parties allegedly submitted claims for one-on-one physical therapy when patients were: playing Nintendo Wii, sitting in a massage chair, independently using treadmills and bicycles, playing water volleyball, and watching TV.
- Further alleges that between January 2011 and June 2015, TWR submitted over \$6.5 million in false and fraudulent claims to the OWCP and received over \$5.5 million as payment for the claims
- Additional Information:
http://www.yourhoustonnews.com/fort_bend/news/owners-chiropractor-indicted-in-alleged-nationwide-worker-s-comp-fraud/article_2095cc6f-01e2-



Enforcement Activity

Richard Toussaint, M.D. (Forest Park Medical Center) – Dallas, TX (May 2015)

Currently Pending – Only Allegations

- Dr. Toussaint, an anesthesiologist, was indicted on 17 counts of healthcare fraud for, among others, falsely claiming that he was present for and personally participating in procedures, inflating time of procedures, and signing off on procedures before they occurred.
- Alleged that over an 18 month period, Toussaint charged \$8 million to various payors, \$5 million of which was fraudulent.
- Additional Information:
<http://healthcare.dmagazine.com/2015/05/20/feds-indict-founding-physician-of-forest-park-medical-center-on-17-counts-of-healthcare-fraud/>



Enforcement Activity: Across the Country

A Few of the Biggest of 2015

- Oklahoma: Owner of Prairie View Hospice will pay **\$2.5 million** in restitution and serve **three years** in prison after a jury convicted her of Medicare fraud. From 2010-2013, Paula Kluding concealed the true medical condition of patients in order to "pass" a Medicare audit and to fraudulently obtain money from Medicare.
- Macon, GA: Medical Center-Navicent Health has agreed to pay **\$20 million** to settle allegations that from 2004-2008 it billed Medicare for short-stay inpatient visits that should have been submitted as outpatient stays, which come with lower reimbursements.



Enforcement Activity: Across the Country

A Few of the Biggest of 2015

- New Mexico: Community Health Systems and three of its hospitals agreed to pay a **\$75 million** settlement over a whistleblower suit that claimed it illegally donated money from 2000-2011 to New Mexico counties in return for higher Medicaid payments to cover the costs of indigent care.
 - The suit claimed CHS and the three facilities received higher payments from the New Mexico Sole Community Provider Fund, a matching funds program between the state and Medicaid.
 - The money in the fund was meant to help cover costs for unpaid medical bills. The activity was uncovered by whistleblower Robert Baker, a former revenue manager at Community Health Systems Professional Services Corp



Enforcement Activity: Across the Country

A Few of the Biggest of 2015

Georgia: Columbus Regional Hospital System (CRHS) has settled for **\$25 million, and up to another \$10 million** in contingency payments, to resolve allegations that it overbilled Medicare and paid kickbacks to a medical director for referrals.

- Settlement resolves allegations that CRHS submitted claims for evaluation and management (E/M) services billed at higher levels than supported by documentation, billing separately for E/M services that should have been bundled, for radiation therapy that did not qualify as such, and for claims submitted in violation of rules prohibiting payment in return for the referral of Medicaid patients (doctors compensated on per RVU basis that encouraged upcoding)
- Medical Director Allegations: paid for duplicative services that were not commercially reasonable and in excess of FMV, payment for services not performed by physician
- CRHS agreed to enter into a 5 year Corporate Integrity Agreement with HHS-OIG requiring fraud and abuse policy training and intense processes for entering into, tracking, monitoring, and reviewing each arrangement that could implicate Stark and Anti-Kickback requirements.
- Qui Tam action was filed by CRHS Cancer Center's former administrative director



LEGISLATIVE UPDATE



2015 Texas Legislature: Hospitals

S.B. 373 – Effective 9/1/15

Relating to increased oversight by the DSHS of hospitals that commit certain violations

If the DSHS finds that a hospital has committed a violation that resulted in a potentially preventable adverse event (PPE) which is reportable under Chapter 98 of the TX Health & Safety Code, the DSHS shall require the hospital to develop and implement a plan for approval by the DSHS to address the deficiencies that may have contributed to the PPE. The plan shall include:

- Staff training and education;
- Supervision requirements for certain staff;
- Increased staffing requirements;
- Increased reporting to the DSHS; and
- A review and amendment of hospital policies

Chapter 98 “Preventable Adverse Event”

- A health care-associated adverse condition or event for which the Medicare program will not provide additional payment to the facility under a policy adopted by the federal Centers for Medicare and Medicaid Services; or
- An event included in the list of adverse events identified by the National Quality Forum that is not included above



2015 Texas Legislature: Hospitals

S.B. 1670 – Effective 9/1/15

Relating to the possession and removal of a placenta from a hospital or birthing center

A hospital shall allow a woman to take possession of and remove from the facility the delivered placenta if:

1. The woman tests negative for infectious diseases;
2. The person taking the placenta signs a form acknowledging that (A) the person has received information concerning the spread of blood-borne diseases and (B) the placenta is for personal use.

The form should be retained by the hospital in the patient's medical records.

A person may not sell the placenta.



2015 Texas Legislature: Hospitals

H.B. 2574 – Effective 9/1/15

Relating to increasing awareness of the danger of heatstroke for a child left unattended in a motor vehicle

Requires hospitals and other health care providers who provide prenatal care during pregnancy or at delivery to include information on the dangers of heatstroke of a child left unattended in a motor vehicle in the resource pamphlets distributed to new parents at time of discharge.

Compliance Date: January 1, 2016



2015 Texas Legislature: Hospitals

H.B. 635 – Effective 9/1/15

Relating to the disposition of fetal remains

- Requires hospitals to release the remains of an unintended, intrauterine fetal death on the request of a parent of the unborn child in a manner appropriate under law and the hospital's policy for disposition of a human body
- If the fetal remains weigh less than 350 grams, a hospital must still release the remains on the request of the parent, in a manner that is appropriate under law and consistent with hospital policy
 - This provision is intended to counteract some hospital policies that consider the remains of a fetus as human waste before a certain gestational period and dispose of the remains as such.



2015 Texas Legislature: Hospitals

S.B. 1753 – Effective 9/1/15

Relating to the identification requirements of certain health care providers associated with a hospital

- The identification badge of a health care provider licensed under Title 3, Occupations, must clearly state when the practitioner is licensed under the applicable subtitle:
 - Physician, chiropractor, podiatrist, midwife, physician assistant, acupuncturist, surgical assistant, dentist, dental hygienist, licensed vocational nurse, registered nurse, nurse practitioner, nurse midwife, nurse anesthetist, clinical nurse specialist, optometrist, therapeutic optometrist, speech-language pathologist, audiologist, physical therapist, occupational therapist, massage therapist, medical radiologic technologist, medical physicist, perfusionist, respiratory care practitioner, orthotist, prosthetist, dietitian
- Compliance Date: September 1, 2019



2015 Texas Legislature: Hospitals

S.B. 2131– Effective 9/1/15

Relating to the designation of centers of excellence to achieve healthy fetal outcomes in this state

- The DSHS shall designate 1 or more centers of excellence for fetal diagnosis and therapy
- Priority Considerations for Center Designations
 - Offers fetal diagnosis and therapy through a multi-specialty clinical program that is affiliated with a medical school in this state and an associated hospital that provides advanced maternal and neonatal care
 - Demonstrates a significant commitment to research in fetal diagnosis and therapy
 - Offers advanced training in fetal diagnosis and therapy
 - Integrated an advanced fetal care program with a program that provides long-term monitoring and follow-up care



2015 Texas Legislature: Hospitals

S.B. 2131– Effective 9/1/15

Relating to the designation of centers of excellence to achieve healthy fetal outcomes in this state

- Qualifications for Designation: The rules adopted for designation of centers of excellence must ensure that a health care entity or program that receives such designation:
 1. Provides or is affiliated with a hospital that provides advanced maternal and neonatal care in accordance with its level of care designation;
 2. Implements and maintains a multidisciplinary health care team, including: maternal fetal medicine specialists, pediatric and surgical specialists, neonatologists, nurses with specialized maternal and neonatal training, and other ancillary support staff to provider maternal, fetal, and neonatal services
 3. Establishes minimum criteria for medical staff, nursing staff, and ancillary support staff;
 4. Measures short-term and long-term patient diagnostic and therapeutic outcomes; and
 5. Provides to DSHS annual reports containing aggregate data on short and long-term diagnostic and therapeutic outcomes as requests or required by DSHS and makes those reports available to the public



Texas Legislature: Graduate Medical Education

S.B. 18 – Effective 9/1/15

Relating to measures to support or enhance graduate medical education in Texas

- Creates a Trust Fund to support graduate medical education
- A hospital may partner with an existing graduate medical education program to plan a new graduate medical education program



Texas Legislature: Freestanding Emergency Medical Care Facilities

S.B. 425 – Effective on 9/1/15

Relating to health care information provided by and notice of facility fees charged by freestanding emergency medical care facilities

A FER shall post a notice that states the following:

- That the FER is a FER;
- That the FER charges rates comparable to a hospital ER;
- That the FER and its physicians may not be participating providers in the patient's health plan; and
- That the FER's physicians may bill separately from the FER.



Texas Legislature: Freestanding Emergency Medical Care Facilities

S.B. 425 – Effective on 9/1/15

Relating to health care information provided by and notice of facility fees charged by freestanding emergency medical care facilities

- The notice must be posted prominently and conspicuously at the FER's
 - Primary entrance
 - Each patient treatment room; and
 - At each location at which a person pays for health care services.
 - On the facility's website



Texas Legislature: Emergency Medical Services

S.B. 1899 – Effective 9/1/15

Relating to the regulation of emergency medical services

A person who:

- Is certified under Chapter 773 of the Health and Safety Code as an emergency medical technician-paramedic or licensed paramedic,
- Is acting under the delegation and direct supervision of a licensed physician, and
- Is authorized to provide advanced life support by a health care facility

may, in accordance with department rules, provide advanced life support in a facility's emergency or urgent care clinical setting, including a hospital emergency room and a freestanding emergency medical care facility.



Texas Legislature: Abortion Facilities

H.B. 416 – Effective 9/1/15

Relating to requiring personnel of abortion facilities and certain other facilities performing abortions to complete training on human trafficking

- Applies to individuals who are employed by, volunteers at, or performs services under contract with: (1) an abortion facility or (2) an ambulatory surgical center that performs more than 50 abortions a year and the individual has direct contact with patients.
- Individuals described shall be required to complete within a reasonable time after beginning work at the facility a training program to identify and assist victims of human trafficking



Texas Legislature: Abortion Facilities

H.B. 3994 – Effective 9/1/15

Relating to notice of and consent to an abortion for a minor and associated requirements

- A physician must use due diligence to determine that any woman on which the physician performs an abortion has in fact reached the age of majority or has had the disabilities of minority removed
- If a woman is unable to obtain proof of identity and age and the physician chooses to perform the abortion, the physician must document that proof of identity and age was not obtained and report this to the DSHS.
- If the physician who is to perform an abortion concludes that a medical emergency exists and there is insufficient time to provide notice or to obtain consent, then the physician must make a reasonable effort to inform (in person or by telephone) the parent, managing conservator, or guardian of the unemancipated minor of the performance of the abortion and the basis of the physicians determination that a medical emergency existed
 - Within 24 hours
- The physician who performs an abortion in a medical emergency (as described above) must also send written notice that a medical emergency occurred and that the parent, managing conservator, or guardian may contact the physician for more information and medical records.
 - Within 48 hours



Texas Legislature: Nursing and Assisted Living Facilities

H.B. 2588– Effective 9/1/15

Relating to disclosures by nursing facilities and assisted living facilities regarding certification or classification to provide specialized care, treatment, or personal care services to residents with Alzheimer’s disease or related disorders

- The Executive Commissioner of the Health and Human Services Commission shall require each assisted living facility to include in the facility’s consumer disclosure statement whether the facility holds a license, classified under Section 247.029 of the Health and Safety Code, for the provision of personal care services to residents with Alzheimer’s disease or related disorders.



Texas Legislature: Medicaid Fraud or Abuse

S.B. 207 – Effective 9/1/15

Relating to the authority and duties of the office of inspector general of the Health and Human Services Commission

- The office shall complete a full investigation of a complaint or allegation of Medicaid fraud or abuse against a provider not later than the 180th day after the date the full investigation begins, unless the office determines that more time is needed.
- If the office determines that more time is needed, the office shall provide notice to the provider who is the subject of the investigation, stating that the investigation will exceed 180 days and specifying the reasons why the office is unable to complete the investigation within the 180-day period.
- The office is not required to provide notice to the provider if the office determines that providing notice would jeopardize the investigation.
- Definition of Fraud: now expressly excepts “unintentional, technical, clerical, or administrative errors” (mistakes in billing)



2015 Texas Legislature: Health Care Providers

S.B. 481 – Effective 9/1/15

Relating to consumer information concerning facility-based physicians and notice and availability of mediation for balance billing by a facility-based physician

- Applies to “facility-based physicians”: radiologist, anesthesiologist, pathologist, emergency department physician, neonatologist, assistant surgeon
- When billing out of network patients, facility-based physicians must include on the bill “a conspicuous, plain-language explanation of mandatory mediation available” under the Insurance Code if the amount remaining after copayments, deductibles, etc. is greater than \$500.



2015 Texas Legislature: Health Care Providers

H.B. 2641– Effective 9/1/15

Relating to the exchange of health information in this state

Unless the health care provider acts with malice or gross negligence, a health care provider who provides patient information to a health information exchange is not liable for any damages, penalties, or other relief related to the obtainment, use, or disclosure of that information in violation of federal or state privacy laws by a health information exchange, another health care provider, or any other person



2015 Texas Legislature: Health Care Providers

H.B. 1945– Effective 9/1/15

Relating to the provision of direct primary care

- A physician providing direct primary care is not an insurer or HMO, and the physician is not subject to regulation of the TX Dept. of Insurance for the direct primary care.
- A medical service agreement is not health or accident insurance or coverage under Title 8 of the Insurance Code, and is not subject to regulation by the TX Dept. of Insurance
 - A physician may not bill an insurer or HMO for direct primary care that is paid under a medical service agreement.
- A physician providing direct primary care must provide written or electronic notice to the patient that a medical service agreement for direct primary care is not insurance, prior to entering into the agreement



2015 Texas Legislature: Health Care Providers

H.B. 1945– Effective 9/1/15

Relating to the provision of direct primary care

- Direct Fee: a fee charged by a physician to a patient (or patient’s designee) for primary medical care services provided by, or to be provided by, the physician to the patient.
 - The term includes a fee in any form, including: (1) monthly retainer; (2) membership fee; (3) subscription fee; (4) fee paid under a medical service agreement; or (5) fee for a service, visit, or episode of care.
- Direct Primary Care: primary medical care service provided by a physician to a patient in return for payment in accordance with a direct fee (not limited to just family physicians, it may include many specialists)
 - Primary medical care service means a routine or general health care services of the type provided at the time a patient seeks preventative care or first seeks health care services and includes [many services] providing a broad spectrum of preventative and curative health care over a period of time
- Medical Service Agreement: signed written agreement under which a physician agrees to provide direct primary care services for a patient in exchange for a direct fee for a period of time that is entered into by the physician and:
 - The patient; or
 - The patient’s legal representative, guardian, or employer on behalf of the patient; or
 - The patient’s legal representative or guardian’s employer on behalf of the patient



2015 Texas Legislature: Health Care Providers

H.B. 21 (the “Right to Try Act”) – Effective Immediately

Relating to authorizing patients with certain terminal illnesses to access certain investigational drugs, biological products, and devices that are in clinical trials

- A patient is eligible to access/use an investigational drug/device/biologic product if:
 1. Patient has a terminal illness; and
 - Advanced stage of disease with unfavorable prognosis; without life-sustaining procedures patient will soon die or become permanently unconscious
 2. Patient’s physician:
 - has considered all other options approved by the FDA and determined that those options are unavailable or unlikely to prolong the patient’s life; and
 - has recommended/prescribed in writing the use of an investigational drug/device/biologic
- Before receiving the drug/device/biologic, patient (or parent, legal guardian) must provide written informed consent
- Manufacturer *may* (not mandatory) provide the investigational drug/device/biologic to eligible patients. The manufacturer may not charge for the product



2015 Texas Legislature: Health Care Providers

H.B. 21 (the “Right to Try Act”) – Effective Immediately

Relating to authorizing patients with certain terminal illnesses to access certain investigational drugs, biological products, and devices that are in clinical trials

- No Case of Action Created: Act does not create a cause of action against:
 - (1) a manufacturer of the investigational drug/device/biologic;
 - (2) any other person or entity involved in the care the eligible patient for any harm resulting from use of the investigational drug/device/biologic
- No Interference: An official, employee, or agent of the state may not block or attempt to block an eligible patient’s access
- Physician License: TX Medical Board may not revoke, fail to renew, or suspend a physician's license based *solely* on the physician’s recommendation to an eligible patient, as long as the recommendations meet the medical standard of care



Texas Legislature: Pharmacists and Pharmacies

S.B. 460 – Effective 9/1/15

Relating to the licensing and regulation of pharmacists and pharmacies

- The board may discipline an applicant for or the holder of a pharmacy license, if the board finds that the applicant or license holder has waived, discounted, or reduced, or offered to waive, discount, or reduce, a patient copayment or deductible for a compound drug in the absence of:
 - A legitimate, documented financial hardship of the patient; or
 - Evidence of a good faith effort to collect the copayment or deductible from the patient.



Texas Legislature: Telehealth

S.B. 3519 – Effective 9/1/15

Relating to reimbursement for home telemonitoring services under Medicaid

The commission may not reimburse providers under Medicaid for the provision of home telemonitoring services on or after September 1, 2019

“Home Telemonitoring Service” means a health service that requires scheduled remote monitoring of data related to a patient’s health and transmission of the data to a licensed home and community support services agency or a hospital. Tex. Gov't Code Ann. § 531.001 (Vernon)



Texas Legislature: Telehealth

H.B. 1878 – Effective 9/1/15

Relating to the provision of telemedicine medical services in a school-based setting, including the reimbursement of providers under Medicaid

- Medicaid reimbursement shall be provided to a physician for telemedicine services, even if the physician is not the patient's primary care physician if: (1) the physician is an authorized health care provider under Medicaid; (2) the patient is a child who receives the services in a primary or secondary school setting; (3) the parent or legal guardian of the patient provides consent before the service is provided; and (4) a health professional is present during the treatment
- If the patient has a primary care physician and consents, or the parent or legal guardian consents, to the notification, the Commission requires that the primary care physician be notified of the telemedicine service for the purpose of sharing medical information. If the service is provided to a child in a school-based setting, then the notification must include a summary of the service, including exam findings, prescribed or administered medications, and patient instructions
- If the patient does not have a primary care physician, the commission shall require that the patient's parents or legal guardian receive the notification and a list of primary care physicians from which the patient may select the patient's primary care physician.



Texas Legislature: Out-of-Network Legislation

S.B. 574 – Effective on 9/1/15

Relating to Operations of Managed Care Plans with Respect to Providers

- An insurer may not terminate participation of a provider solely because the provider informs an enrollee of the full range of providers available to the enrollee, including OON providers.
- An insurer may not terminate, or threaten to terminate, an insured's participation in a plan solely because the insured uses an OON provider.
- An insurer may not prohibit, penalize, terminate or otherwise restrict a preferred provider from communicating with an insured about the availability of OON providers.
- An insurer's contract with a preferred provider may require that before an OON referral is made, the provider inform the insured that (1) the insured may choose an OON provider; (2) the insured may have a higher out-of-pocket expense with an OON provider and (3) whether the provider has a financial interest in the OON provider.



Texas Legislature: Out-of-Network Legislation

S.B. 574 – Effective on 9/1/15

Relating to Operations of Managed Care Plans with Respect to Providers

- An insurer may not condition payment on a physician providing a notification stating that the physician is an OON provider to a current, prospective or former patient, if the form contains additional information that is intended or required to be presented in a manner that is intended to intimidate the patient.
- On request, an insurer shall provide to a practitioner whose participation in a preferred provider benefit plan is being terminated all information on which the insurer wholly or partly based the termination, including the economic profile of the preferred provider, the standards by which the provider is measured, and the statistics underlying the profile and standards.



Texas Legislature: Population Health

H.B. 3781 – Effective 9/1/15

Relating to the creation of the Texas Health Improvement Network

- The Texas Health Improvement Network is established to address urgent health care challenges and improve the health care system in this state and the nation and to develop, based on population health research, health care initiatives, policies, and best practices.
- The network shall:
 - Function as an incubator and evaluator of health improvement practices; and
 - Support local communities in this state by offering leadership training, data analytics, community health assessments, and grant writing support to local communities.



Texas Legislature: Compassionate-Use Act

S.B. 339 – Effective Immediately

Relating to the medical use of low-THC cannabis and the regulation of related organizations and individuals

- Gives authority to physicians who meet certain criteria to prescribe low-THC cannabis to physicians who treat patients with intractable epilepsy
- Creation of an online registry that contains prescriber information, patient information, dosage prescribed, means of administration ordered, total amount required to full prescription, and amount dispensed.
- A license issued by the Dept. of Public Safety is required to operate a dispensing organization. An applicant is eligible if:
 - The Applicant possesses: (1) the ability to cultivate and produce low-THC cannabis; (2) the ability to secure the resources and personal necessary to operate, and premises reasonably located to allow patients on the registry access; (3) the ability to maintain accountability for the materials and finished product to prevent unlawful access; and (4) the financial ability to maintain operations for no less than two years;
 - Each director, manager, or employee of is registered under Subchapter D with the Dept. of Public Safety; and
 - The applicant satisfied any additional criteria determined to be necessary to safely implement this chapter
- Additional requirements for those the organization hires (notice of intent to hire, background check)
- Requirements for verification of prescription before dispensing and recording on registry after dispensing
- Lists individuals who are exempt from criminal offense of acquisition, possession, production, etc.





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Josh and Ashley provide counsel to health care providers on complex operational, transactional and compliance issues. They have experience advising hospitals, ambulatory surgery centers, independent diagnostic testing facilities, laboratories, pharmacies, physicians and other health care providers on various issues, including matters implicating the Federal Anti-Kickback Statute, the Physician Self-Referral ("Stark") Statute, the Texas Illegal Remuneration Statute, The Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), the False Claims Act, and the Emergency Medical Treatment and Active Labor Act ("EMTALA"), among many others. Josh and Ashley also advise clients with respect to reimbursement issues and payor audits. Their transactional experience includes drafting and negotiating a variety of health care contracts, including professional services agreements, physician employment agreements, asset purchase agreements, management and co-management agreements, business associate agreements, operating agreements, and equipment and space leases, among others. Josh and Ashley also assist clients in the formation and syndication of hospitals, ASCs, joint ventures, pharmacies, and laboratories.

Josh and Ashley are both Board Certified in Health Law by the Texas Board of Legal Specialization.

