

Legal Arguments, Advice and Analysis for Rural Hospitals

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Top Health Industry Issues of 2018

- Healthcare industry tackles the opioid crisis
- Social determinants come to the forefront
- Price transparency moves to the statehouse
- Natural disasters create devastation that lasts long after the event passes

Top Health Industry Issues of 2018

- Medicare Advantage swells in 2018
- Health reform isn't over – it's just more complicated
- Securing the internet of things
- Patient experience as a priority and not just a portal

Top Health Industry Issues of 2018

- Meet your new coworker – artificial intelligence
- Healthcare’s endangered middlemen – pharmacy benefit managers and wholesalers
- Real-world evidence is a growing challenge for pharma
- Tax reform moves forward

Affordable Care Act

Where are we now?

The Opioid Crisis

- Opioids are the leading cause of death for US adults younger than 50
 - 64,000 overdose deaths in 2016
 - Almost half involved a prescription opioid
- Up to a quarter of patients prescribed opioids become dependent on them
- 2010-2015: Deaths involving fentanyl and similar synthetic opioids increase 200+% nationwide

The Opioid Crisis in Texas

- Experts believe Texas undercounts overdoses
 - Only 13 of 254 counties use a medical examiner
 - No legal requirements for autopsy or toxicology report to fill out death certificate
- Sharp rise in maternal mortality may be connected to drug overdoses

The Opioid Crisis - Challenges

- Reimbursement link to patient satisfaction with pain relief
- Large size of some prescriptions
 - People taking opioid for longer than truly needed
 - Extra pills in medicine cabinet → recreational use by someone else
- Crackdowns on prescription abuses have led to a shift to heroin and illicitly manufactured opioids

The Opioid Crisis – Taking Action

- 2015 Texas law allows pharmacists to dispense naloxone OTC pursuant to physician standing order
- Texas Targeted Opioid Response
 - Increase licensed providers of methadone for medication-assisted treatment
 - Drug takeback programs
 - Carbon pouches
 - Physician education regarding appropriate prescribing guidelines
 - Texas Prescription Monitoring Program

The Opioid Crisis – Taking Action

- CDC Guideline for Prescribing Opioids for Chronic Pain
 - Lower dosage recommendations
 - Assessing risks and harms for all patients, not just “high risk patients”
 - Use of state prescription drug monitoring programs
 - Monitoring and discontinuing opioids when risks and harms outweigh benefits

<https://www.cdc.gov/drugoverdose/prescribing/guideline.html>

The Opioid Crisis – Taking Action

- DOJ Opioid Unit
 - Using data analytics to identify prescriber targets
 - 12 dedicated AUSAs
- Criminal convictions of physicians and pharmacists
- Fraud cases
- Proposed Part D rules to impose over-prescribing safeguards

Top HR Issues

- Fighting harassment and improving inclusion
 - Do your workers feel safe and supported by company leadership while at work?
 - Does your leadership reflect the gender and ethnic makeup of your workforce?
- Sexual orientation protections
 - Courts are split

Top HR Issues

- Evolving workforce and workforce planning
 - Changing social demographics
- Cyber breaches
 - Employee training is vital
- Technology and social media
 - What are your employees posting?
- Workplace violence

Cyberliability – 2017 OCR Settlements

- St. Luke's-Roosevelt (Mount Sinai-NY): \$387,000 for disclosure of patient's HIV status to patient's employer
- Memorial Hermann (Houston) - \$2.4M for release of name of patient who had presented allegedly fraudulent ID card
- CardioNet (Penn.) - \$2.5M for stolen laptop
 - No policies for electronic safeguards
 - Insufficient risk analysis/risk management

Cyberliability – 2017 OCR Settlements

- Metro Community Provider Network (Denver) - \$400,000 for phishing incident resulting in hacker access of 3,200 individuals' ePHI
 - No security risk analysis
- Memorial Health System (Florida) - \$5.5M for impermissible access of PHI by employees and impermissible disclosure to physician office staff
 - Lack of procedures regarding user right of access
 - Failure to follow through on risk analyses

Cyberliability – 2017 OCR Settlements

- Children’s Medical Center of Dallas - \$3.2M for loss of mobile device and theft of laptop
 - No encryption; not password-protected
 - Didn’t implement risk management plan
- 21st Century Oncology - \$2.3M for hacker accessing ePHI of 2.2M patients
 - No risk assessment
 - No adequate security measures

Cybersecurity

- OCR Guidance 2017
 - Covered entities should monitor US-CERT website or US-CERT email alerts for current threats
 - Monitoring is evidence of meeting administrative safeguard obligations under HIPAA Security Rule
 - Compliance programs should address threats raised by US-CERT
 - Failure to identify and mitigate a threat when identified by US-CERT may be evidence of inadequate risk management plan under HIPAA Security Rule

New Regulations/ Guidance

- Do Not Resuscitate (DNR) orders for inpatients
 - Effective April 1
 - Regulates issuance of DNR orders for inpatients in hospital and other healthcare facilities
- Anti-trafficking signs
 - Effective January 1, 2018
 - Emergency department of hospital to display signs regarding human trafficking and forced abortions as required for abortion facilities

Texting of Orders

- The Joint Commission in 2011:
 - Safety and security concerns bar providers from texting orders for patient care, treatment or services
- The Joint Commission in May 2016 :
 - Texting allowed so long as it includes a secure sign-on process, message encryption, delivery and read receipts, date and time stamps, customized message retention time frames, and specified contact lists for individuals authorized to receive and record orders

Texting of Orders

- The Joint Commission in July 2016:
 - Places a hold on May 2016 decision
- The Joint Commission and CMS in December 2016 Position:
 - TJC reverses course and again bans the use of secure text orders

Texting of Orders

- TJC and CMS recommendations:
 - All health care organizations should have policies prohibiting the use of unsecured text messaging—that is, short message service (“SMS”) text messaging from a personal mobile device—for communicating PHI.
 - Computerized provider order entry (“CPOE”) should be the preferred method for submitting orders as it allows providers to directly enter orders into the electronic health record.
 - In the event that a CPOE or written order cannot be submitted, a verbal order is acceptable.
 - The use of secure text orders is not permitted at this time.

Texting of Patient Information

- CMS Survey & Certification Letter (12/28/2017) regarding texting patient information
 - Texting patient orders is prohibited
 - Messages among clinicians permissible so long as everyone uses a secure platform
 - Secure = encrypted and mechanisms in place to prevent unauthorized access to PHI if mobile device left unattended or stolen
 - Your phone's built-in messaging services is probably not HIPAA-compliant

Texting Concerns

- Orders conveyed via text message cannot be entered into patients' medical records in real time
- Text orders lead to an increased burden on providers to manually transcribe text orders or talk to the ordering clinician

Physician Covenants not to Compete

- Sec. 15.50, Texas Business and Commerce Code
 - Part of otherwise enforceable agreement
 - Reasonable limitations as to time, geography and scope of activity
 - No greater restraint than to protect business interest of party seeking enforcement
 - Public policy

Physician Covenants not to Compete

- Sec. 15.50(b) – Physicians
 - List of patients treated within one year of termination
 - Access to medical record (in same format)
 - Buy-out at a reasonable price
 - Continuation of care for acute illness

Public Funds Investment Act

- At least quarterly, investment officer shall submit to Board a written report of investment transactions for all public funds for preceding reporting period
 - Describe in detail investment position of entity on date of report
 - Be signed by investment officer(s)
 - Contain summary statement of each pooled fund group
 - State book value and market value of each separately invested asset by type of asset and fund type invested
 - State maturity date of each separately invested asset that has maturity date
 - State account or fund or pooled group fund for which each individual investment was acquired
 - State compliance with investment policy and Ch. 2256, Gov. Code

Debt Reporting – Ch. 140, Local Government Code

- Political subdivision must annually report debt obligation information:
 - The amount of all authorized debt obligations;
 - The principal of all outstanding debt obligations;
 - The principal of each outstanding debt obligation;
 - The combined principal and interest required to pay all outstanding debt obligations;
 - The combined principal and interest required to pay each outstanding debt obligation;
 - The amounts required by Paragraphs (A)-(E) secured by ad valorem taxation, expressed as a total amount; and
 - The following for each debt obligation:
 - the issued and unissued amount
 - the spent and unspent amount
 - the maturity date
 - the stated purpose for which the debt obligation was authorized

Debt Reporting – Ch. 140, Local Government Code

- Annual report must be made available for in person inspection and be posted on the Internet
- Posting Options:
 - Post the annual debt obligation report on local government's website
 - Post on the local government's website a direct link to the location of the separately posted information
 - Provide the information to the Texas Comptroller, who shall post the information on the Comptroller's website
 - Local government must provide link on its website to the location of the information on the Comptroller's website

EMTALA

- Hospital should have a comprehensive policy addressing EMTALA obligations and patient transfers
- Requirement: Provide an **appropriate medical screening examination** to each patient who **comes to the emergency department** seeking treatment for an emergency medical condition without regard for the patient's ability to pay AND provide necessary stabilization or treatment within **capability and capacity** of Hospital or an **appropriate transfer** of the unstabilized patient

EMTALA

- Triage by a nurse is NOT a medical screening examination
 - Triage is clinical assessment of signs and symptoms in order to prioritize when individual will be seen by physician or QMP
- MSE must be conducted by a physician or qualified medical professional designated in document approved by Hospital's Board
 - MSE can involve wide spectrum of actions, from H&P to ancillary procedures
 - Full MSE may not be within an RN's scope of practice

EMTALA

- “Emergency department” is more than just your ED
 - A person “comes to the emergency department” if he/she is on Hospital property requesting exam or treatment for a medical condition
 - Ground or air ambulances owned and operated by the hospital constitute Hospital property

EMTALA

- Do you have capability and capacity to assess and stabilize a patient presenting with acute psychiatric illness?
 - Still have to perform MSE and provide stabilization of any medical issue
 - Maintain safe setting until can be transferred if needed

EMTALA

- Make sure your physicians, nurses and registration staff have been trained on EMTALA obligations
- Transfers are physician-to-physician and hospital-to-hospital
- Make sure your paperwork is in order
 - ED log
 - Memorandum of Transfer

Lab Management Agreements

- Agreement to provide lab management services
- Multiple variations
 - Lab done in-house or outsourced
 - Sample goes to hospital
 - Never
 - Sometimes
 - In part
 - Lab draw by employed phlebotomist
 - MSO or no MSO

Lab Management Agreements

- MSO
 - Secondary agreement
 - Identified services to hospital
 - Referring doctors are owners
 - Doctors paid based on ownership share
- Payors
 - No federal reimbursement
- Issues
 - FMV
 - Anti-kickback
 - Pass-through billing / payor agreements

DACA

- Deferred Action Childhood Arrival
 - Implemented in 2012
 - ~800,000 persons affected
 - September 2017: President Trump - “winding down” DACA
 - On expiration of DACA deferral, employment must terminate
 - Check eligibility status – when does employee’s current deferral expire?
- Post-employment health benefits (COBRA)?
- Accrued PTO and/or other benefits?

Books, Blogs and Twitter!

- Book
 - [Life 3.0: Being Human in the Age of Artificial Intelligence](#) by Max Tegmark
- Blogs
 - www.kevinmd.com
 - www.healthcaresuccess.com/blog
- Twitter
 - @torchnet
 - @statnews
 - @texashospitals
 - @aaronecarroll
 - @TexasTrustees
 - @HarvardHealth
 - @BeckersHR

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Questions?