

Legal Matters

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Top Health Industry Issues of 2019

- Digital therapeutics and connected care
- The Affordable Care Act: Still alive
- Workforce training in emerging technologies
- Effects of tax reform
- Creating the Southwest Airlines of healthcare
- Private equity investment in healthcare

Governance Trends

1. Economic and Regulatory Uncertainty
2. Gender Equity
3. Tech/Data
4. Enforcement/Compliance
5. Radical decision-making - “Have the guts!”
6. Board Quality

Did You Know?....

According to a Gallup Poll:
Healthcare was the #1 issue that voters considered most important in 2018 midterm elections.

- 80% said healthcare was “extremely” or “very” important to their vote
- Next most important issues were the economy and immigration

Source: Gallup News (11/2/18)

Our Bankrupt Future

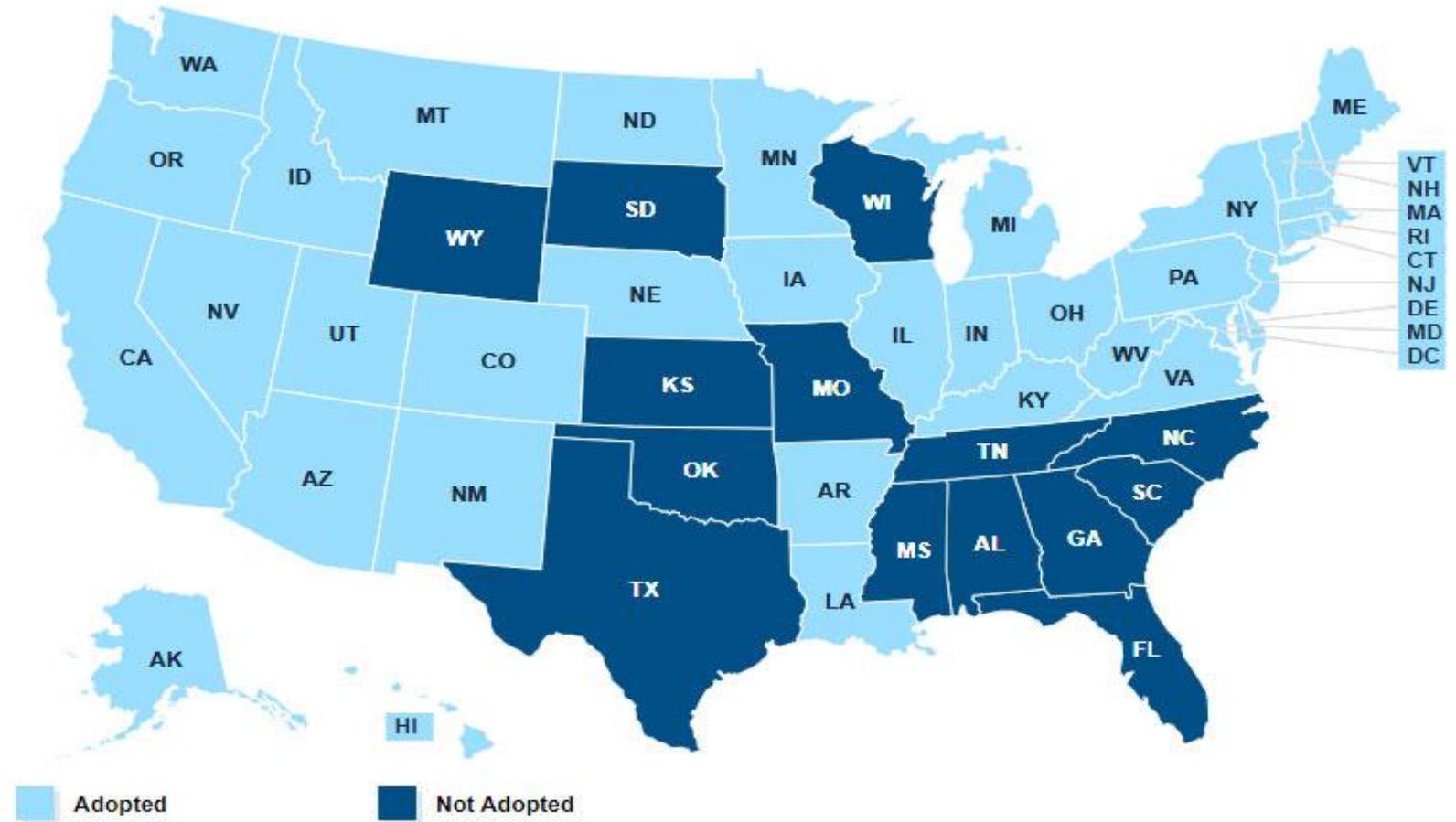
- **Hospitals Shut at 30-a-Year Pace in U.S., with No End in Sight (Bloomberg Law 8/21/18)**
 - Hospitals have been closing at a rate of about 30 a year.
 - Next 18 months should see an increase in shutdowns.
- **A study by Morgan Stanley concluded:**
 - 8% percent of hospitals are at risk of closing
 - Another 10% are considered “weak.”
- **GAO Notes Uptick in Rural Hospital Closures (AHLA Weekly 10/5/18)**
 - More than twice the number of rural hospitals closed between 2013 and 2017 than in the previous five years.
 - 64 closures represent approximately 3% of all rural hospitals
 - Rural hospitals in the South accounted for 77% of the closures.

Source: Rural Hospital Closures: Number and Characteristics of Affected Hospitals and Contributing Factors (GAO-18-634)

Be Careful What You Wish For...

- Kaiser Family Foundation November tracking poll shows many ACA provisions are broadly popular
 - Young adults on their parents' health insurance policies until age 26
 - 82% of the public supports this, including 66% of Republicans
 - Subsidies for lower and moderate income people
 - 81% support this, including 63% of Republicans
 - Closing the "donut hole" so there's no gap in Medicare prescription drug coverage
 - 81% like this, as do 80% of Republicans
 - Eliminating costs for many preventive services
 - 79% support this, as do 68% of Republicans
 - Medicaid expansion
 - 77% like it, as do 55% of Republicans
 - Protection of people with pre-existing conditions
 - 65% support this, as do 58% of Republicans

State Action on Medicaid Expansion as of November 26, 2018



<https://www.kff.org/health-reform/state-indicator/state-activity-around-expanding-medicaid-under-the-affordable-care-act/?activeTab=map¤tTimeframe=0&selectedDistributions=current-status-of-medicaid-expansion-decision&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D>

Indictment of Rural Hospital CEO

Timeline

- USA v. Harris Brooks
 - Filed February 8, 2019; In the United States District Court for the Northern District of Texas – Fort Worth Division
 - Guilty plea entered March 8, 2019
 - Sentencing scheduled for July 5, 2019

Charges

- Conspired to defraud and did defraud Blue Cross and Blue Shield of Texas, CIGNA, United Healthcare and other health insurance providers
 - By submitting claims for laboratory services as though Palo Pinto General Hospital performed the laboratory services
 - Brooks oversaw implementation of billing scheme
 - Billed as though PPGH performed the tests at PPGH

Charges

- Billing Company performed the billing for fraudulent lab claims on behalf of PPGH
- PPGH, however, had an in-house billing department that processed its legitimate lab claims on behalf of PPGH
- Billing Company billed various insurance plans for allergy and genetic testing (September 2017 – June 2018)

Charges

- “These types of tests contrasted significantly with the types of laboratory testing PPGH previously ordered and tested in its laboratory. The reason for the charge was PPGH began the submission of claims for laboratory services for allergy and genetic tests for non-PPGH patients. Moreover, PPGH’s laboratory did not perform the tests, and the physicians ordering the tests had no affiliation with PPGH.”

Charges

- Violation of 18 U.S.C. § 1347 to “devise and execute a scheme and artifice to defraud a healthcare benefit program”
- “... scheme to defraud and conceal PPGH’s role as a pass-through billing entity for out-of-network providers in order to receive significantly higher reimbursements from insurance companies”
- PPGH did not have the equipment on-site to perform the tests for which it submitted claims

Maximum Penalty for Conspiracy to Commit Healthcare Fraud

- 5 years' imprisonment
- Fine up to \$250,000 or twice the pecuniary loss or gain
- Mandatory special assessment of \$100
- Supervised release of up to 3 years
- Restitution
- Costs of incarceration and supervision

Lessons

- More to come
- Pass-through billing
- Advice of counsel
- Board communication and support
- Personal gain

Forest Park Medical Center

Forest Park Medical Center

- 21 executives, physicians, surgeons affiliated with Forest Park Medical Center charged December 1, 2016
- Allegations:
 - From 2009-2013, Forest Park billed insurance plans more than \$500M and collected more than \$200M in paid claims as result of bribes and kickbacks
 - Co-defendants operated shell entities thru which they funneled bribe and kickback payments to surgeons in exchange for referrals
 - Investor PCPs received kickbacks ranging from \$100K to \$7M

Forest Park Medical Center

- Government health care programs affected: Tricare, FECA, FEHBP (federal workers and retirees)
- Charges:
 - Conspiracy to pay and receive health care bribes and kickbacks
 - Violations of federal Travel Act (bars use of U.S. mail and interstate or foreign travel for purpose of engaging in certain criminal acts)
 - Aiding and abetting and conspiracy to commit money laundering

Forest Park Medical Center

- 10 defendants have pleaded guilty, including:
 - Referral coordinator
 - Advertising agency owner
 - Clinic owner
 - Co-founder anesthesiologist (also found guilty by jury on separate charges of health care fraud – false claims for supervision of CRNAs)
 - Hospital manager/co-founder
 - Co-founder bariatric surgeon
 - Referring bariatric surgeon and investor
- Charges dismissed against 1 physician
- Case against worker's comp lawyer separated for trial
- 5 doctors and 4 other hospital officials on trial

Forest Park Medical Center

- Federal trial began February 19, 2019
- Government: Doctors treated patients with private insurance at Forest Park in exchange for payments for services that weren't performed or marketing that wasn't done
- Defendants: Money was spent for co-marketing themselves and the hospital; consulting fees were legitimate payments for services performed; Government using Travel Act to criminalize conduct that is not criminal

Forest Park Medical Center

- Testimony of co-defendants who pleaded guilty:
 - Marketing contracts “papered up” to disguise what they were doing
 - “We didn’t hide expectations”
 - Goal of payments was to get “high revenue-producing surgeries” at hospital
 - Knew payments were illegal
 - Doctors paid by determining how many surgeries they brought in and how much procedures provided in revenue – 10% to surgeons who did operations
 - Payments re-evaluated every 90 days and adjusted up or down depending on number of surgeries referred
 - Didn’t collect co-payments from patients

CMS Preclusion List

CMS Preclusion List

- Providers not eligible to receive payments from Medicare Advantage or Part D plans if on the preclusion list
- Replaces the Medicare Advantage prescriber enrollment requirements
- Initial list precluded as of 1/1/2019, but plans will not begin editing claims until 4/1/2019

CMS Preclusion List

- Who is on the preclusion list?
 - Currently revoked from Medicare and under an active re-enrollment bar; OR
 - Have engaged in behavior for which CMS could have revoked if they had been enrolled in Medicare
 - and CMS has determined underlying conduct is detrimental to best interests of Medicare program
 - Examples: Felony convictions and OIG exclusions

CMS Preclusion List

- Why do we need this?
 - Part D providers and network providers/suppliers that furnish health care items or services to Medicare Advantage participants are no longer required to enroll in Medicare
 - Such providers/suppliers may not show up on the OIG exclusion list because not enrolled in Medicare

CMS Preclusion List

- Can I find out if I'm on the preclusion list?
 - Nope – it isn't being made public
- Then how do I know?
 - When the email or letter shows up from CMS or your MAC

Open Meetings Act and Walking Quorums

Montgomery County Judge Craig Doyal



Timeline

- November 2015: Doyal, two other Commissioners Court members, and a political consultant allegedly “engag[ed] in a verbal exchange concerning . . . the contents of the potential structure of a November 2015 Montgomery County Road Bond” outside confines of a Commissioners Court meeting
- June 2016: Doyal, two Commissioners, and political consultant indicted on misdemeanor charges of violating § 551.143 of TOMA
- April 2017: Trial court rules § 551.143 unconstitutional, dismisses charges
- February 2018: Court of Appeals reverses trial court, reinstates indictments
- December 2018: Doyal’s term as County Judge expires after failed re-election campaign
- February 2019: Texas Court of Criminal Appeals affirms trial court, reverses court of appeals, and dismisses charges
- March 2019: Proposed amendment to § 551.143 filed by Representative Toth (R-The Woodlands)

TOMA, §551.143

CONSPIRACY TO CIRCUMVENT CHAPTER; OFFENSE; PENALTY.

- (a) A member ... of a governmental body commits an offense if the member ... knowingly conspires to circumvent this chapter by meeting in numbers less than a quorum for the purpose of secret deliberations in violation of this chapter.
- (b) An offense ... is a misdemeanor punishable by: (1) a fine of not less than \$100 or more than \$500; (2) confinement in the county jail for not less than one month or more than six months; or (3) both the fine and confinement.

Court of Criminal Appeals Opinion

- “... [I]f it is unclear what it means to circumvent a law, one cannot ‘know’ that he is circumventing the law ... [T]he statute in this case is hopelessly abstract.”
- “[§ 551.143] requires a person to envision actions that are like a violation of TOMA without actually being a violation of TOMA and refrain from engaging in them.”
- “We also conclude that protected speech is likely to be chilled because of the great degree of uncertainty about what communications government officials may engage in.”

Proposed
Amendment
to § 551.143
(filed 3/4/19)

(a) A member of a governmental body commits an offense if the member outside of a meeting knowingly engages directly or indirectly in a series of verbal or written communications with other members of the governmental body without a quorum present regarding a tacit or explicit agreement to act uniformly in sufficient number to constitute a quorum concerning:

- (1) an issue within the jurisdiction of the governmental body; or
- (2) any public business.

(b) An offense ... is a misdemeanor punishable by:
(1) a fine of not less than \$100 or more than \$500;
(2) confinement in the county jail for not less than one month or more than six months; or (3) both the fine and confinement.

Employment Issues

Wage and Hour

- Automatic deductions for lunch break
 - Pros: Administrative ease, employees don't have to remember to clock in/out
 - Cons: If lunch is interrupted by work, can't deduct for lunch break, risk of overtime claims

Wage and Hour

- Regular rate of pay
 - Overtime = 1.5 x regular rate of pay
 - Regular rate of pay is not necessarily the employee's normal hourly rate
 - Have to include all compensation paid to employee
 - Shift differential
 - Perfect attendance bonus
 - Incentive pay

Wage and Hour

- Jane Smith, RN
 - Hourly rate of pay: \$25.00/hour
 - Total hours worked in workweek: 48
 - Shift differential hours: 24
 - Shift differential rate: \$3.00/hour

Wage and Hour

- Straight-time compensation = (total hours worked in workweek x regular rate of pay) + (shift differential hours x shift differential rate)
- Regular rate of pay = straight-time compensation / total hours worked in workweek
- Overtime rate = regular rate of pay x 1.5

Wage and Hour

- Straight-time compensation = $(48 \text{ hours} \times \$25/\text{hour}) + (24 \text{ hours} \times \$3/\text{hour}) = \$1200 + \$72 = \$1272$
- Regular rate of pay = $\$1272 / 48 \text{ hours} = \$26.50/\text{hour}$
- Overtime rate = $\$26.50/\text{hour} \times 1.5 = \39.75
- Straight-time earnings = $\$26.50/\text{hour} \times 40 \text{ hours} = \1060
- Overtime earnings = $\$39.75/\text{hour} \times 8 \text{ hours} = \318
- Total earnings = $\$1378$

Pay Equity

- Gender-based compensation disparities are common
 - Healthcare not immune
 - Surveys and studies
 - Female doctors are paid less than male doctors
 - Pay disparities in female-dominated sectors
- **EEOC v. Denton County, Case No. 4:17-CV-614 (E.D. Tex. 2017)**
 - Male physician paid \$34K more than female for same position

Eliminating Kickbacks in Recovery Act of 2018 (EKRA)

- Part of Substance Use-Disorder Prevention that Promotes Opioid Recovery Treatment for Patients and Communities Act (SUPPORT)
- Prohibits:
 - offering or receiving remuneration
 - for referrals
 - to recovery home, clinical treatment facility, or laboratory
 - for services covered by a health care benefit program

EKRA – What's New

- Applicability
 - Items, services covered by any health care benefit program (public or private)
- Types of services
 - Sober homes, clinical treatment facilities, all laboratory services (whether or not related to addiction treatment)
- Penalties
 - EKRA: \$200,000 fine, 10 years in prison, or both
 - AKS: \$25,000 fine, 5 years in prison, or both
- Exceptions
 - Certain Anti-Kickback Statute safe harbors do not offer protection under EKRA

HIPAA

- DHHS OCR Request for Information – 12/14/2018 (comments closed 2/11/2019)
- Input on modifying HIPAA rules to promote coordinated, value-based healthcare
- Sought comments on
 - Encouraging information-sharing for treatment and care coordination
 - Encouraging providers to share treatment information with parents, loved ones, and caregivers of adults facing health emergencies, particularly opioid
 - How to implement requirement for accounting for disclosures of PHI for TPO
 - Eliminate or modify required to obtain acknowledgement of receipt of Notice of Privacy Practices

HIPAA Enforcement

- Fresenius Medical Care North America (Feb. 2018)
 - \$3.5M for 5 separate breaches over 5 years
- FileFax, Inc. (Feb. 2018)
 - Insolvent company left records unsecured; dumpster diver tried to sell to recycle company; \$100K fine
- OCR v. MD Anderson, # C-17-854 (HHS App.Bd. 6/1/18)
 - ALJ upholds \$4.3M in civil money penalties for 3 breaches of unencrypted data over 2 yrs
- Boston Medical Center, Brigham and Women's Hospital and Massachusetts General Hospital (Sept. 2018)
 - \$999,000 for unauthorized disclosure of PHI during ABC television filming

HIPAA Enforcement

- US v. Gottesfeld (D. Mass. 1/19/19)
 - Man convicted of cyberattacks on Boston Children's Hospital and another treatment facility, sentenced to over 10 years in prison
 - Claimed attack was protest against state taking custody of 14-year old Justina Pelletier; arrested while trying to flee to Cuba and rescued by a Disney cruise line
- U.S. v. Luthra (D.Mass. 4/30/18)
 - Jury convicted MD of disclosing her patients' private medical information to a drug sales representative
 - Drug company used information to pinpoint customers for its expensive osteoporosis drugs
- U.S. v. Montana (D. Mass. 2/28/18; sentenced 1/14/19)
 - Physician pled guilty to wrongful disclosure of PHI, sentenced to probation
 - Disclosed to Aegerion records of 200 pediatric patients for potential use of an expensive medication approved only to treat an ultra-rare disease that none of them had
 - Gave them hard copies of patient records and his own password to log into his medical records database

Cyber Liability Insurance

- Typically provides assistance in providing the required notices (important when dealing with a significant breach that may involve multiple states)
 - Individual, Media and Substitute (if required)
 - Many states have separate notice requirements in addition to federal requirements
- Assist in responding to investigations and lawsuit (assignment of breach counsel)
- Will assist in responding to inquiries from the public (i.e. call center, FAQs, scripts)

Transparency

- Under the 2019 IPPS final rule, hospitals required to make public a list of their standard charges via the Internet in a machine readable format and to update this information at least annually or more often as appropriate.
- CMS issued two sets of FAQs on the new price transparency requirements.
 - What format is a hospital required to use to make public a list of their standard charges via the Internet?
 - Do the requirements apply to all items and services provided by the hospital?

<https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Downloads/FAQs-Req-Hospital-Public-List-Standard-Charges.pdf>

<https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ProspectivePaymentSystem/Downloads/Additional-Frequently-Asked-Questions-Regarding-Requirements-for-Hospitals-To-Make-Public-a-List-of-Their-Standard-Charges-via-the-Internet.pdf>

Reaction

Hospitals Must Now Post Prices. But It May Take a Brain Surgeon to Decipher Them.

New York Times, January 13, 2019

“Baptist Health in Miami helpfully told consumers that an ‘Embolza Protect 5.5’ would cost them \$9,818 while a ‘Visceral selective angio rad’ runs a mere \$5,538.”

“To 99 percent of the consuming public, these data will be of limited utility — meaningless.”

Kenneth E. Raske, President of the Greater New York Hospital Association.

The Opioid Epidemic

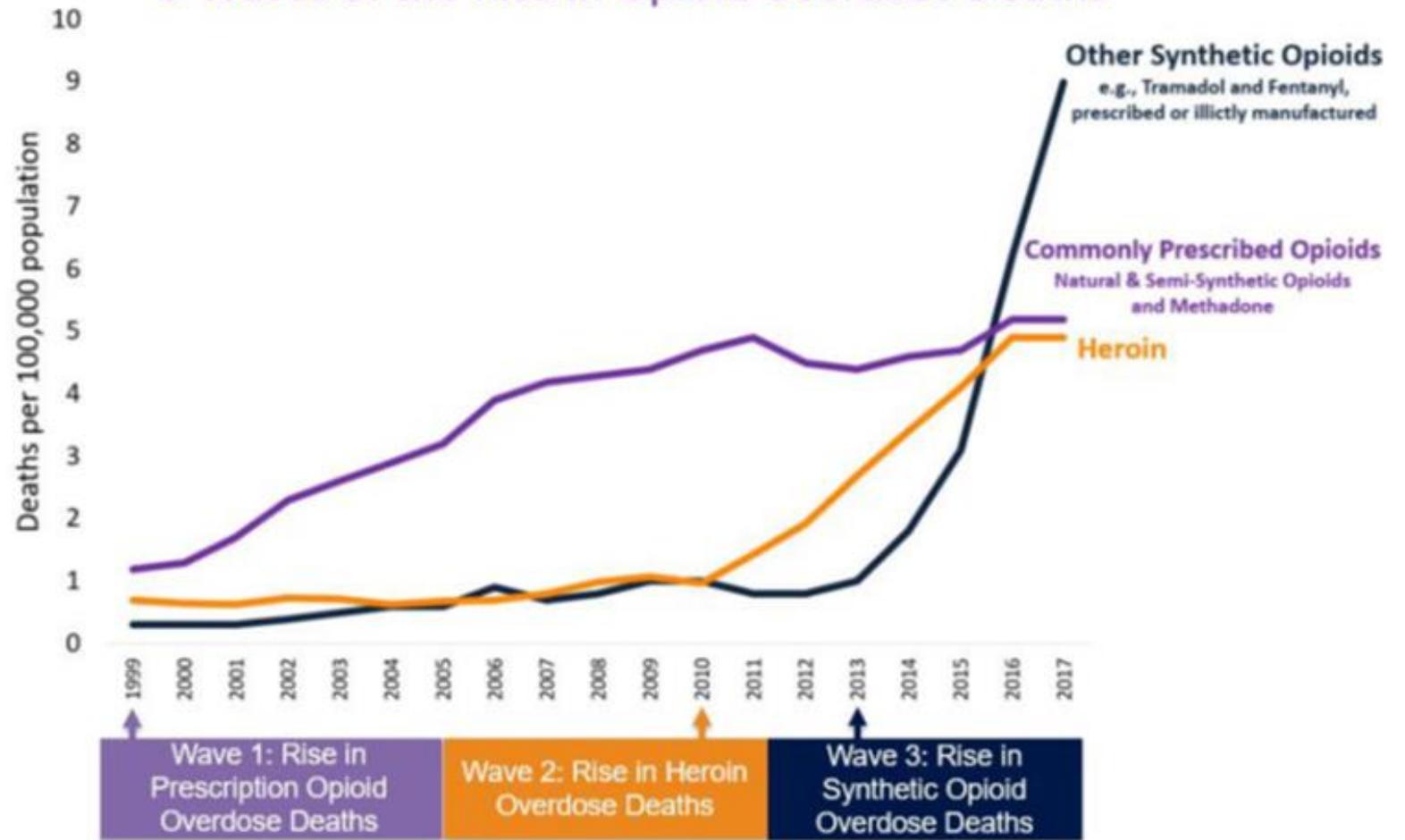
- From 1999-2017, 700,000+ people died from a drug overdose (400,000+ involving opioids).
- 65% of the deaths in 2017 involved an opioid - 6 times higher than in 1999.
- 130 Americans die every day from an opioid overdose.

This data is from the CDC:

<https://www.cdc.gov/drugoverdose/epidemic/index.html>

The Opioid Epidemic

3 Waves of the Rise in Opioid Overdose Deaths



SOURCE: National Vital Statistics System Mortality File.

Federal Efforts in 2018

- \$3+ billion in the 2018 Budget Bill to combat opioid/drug abuse

<https://www.vox.com/policy-and-politics/2018/3/22/17150294/congress-omnibus-bill-opioid-epidemic>

- OCR public education campaign and fact sheets

<https://www.hhs.gov/civil-rights/for-individuals/special-topics/opioids/index.html>

- CDC Second Annual Report of Prescription and Illicit Drug-Related Risks and Outcomes

<https://www.cdc.gov/drugoverdose/data/analysis.html>

Opioid Lawsuits

Fighting Back

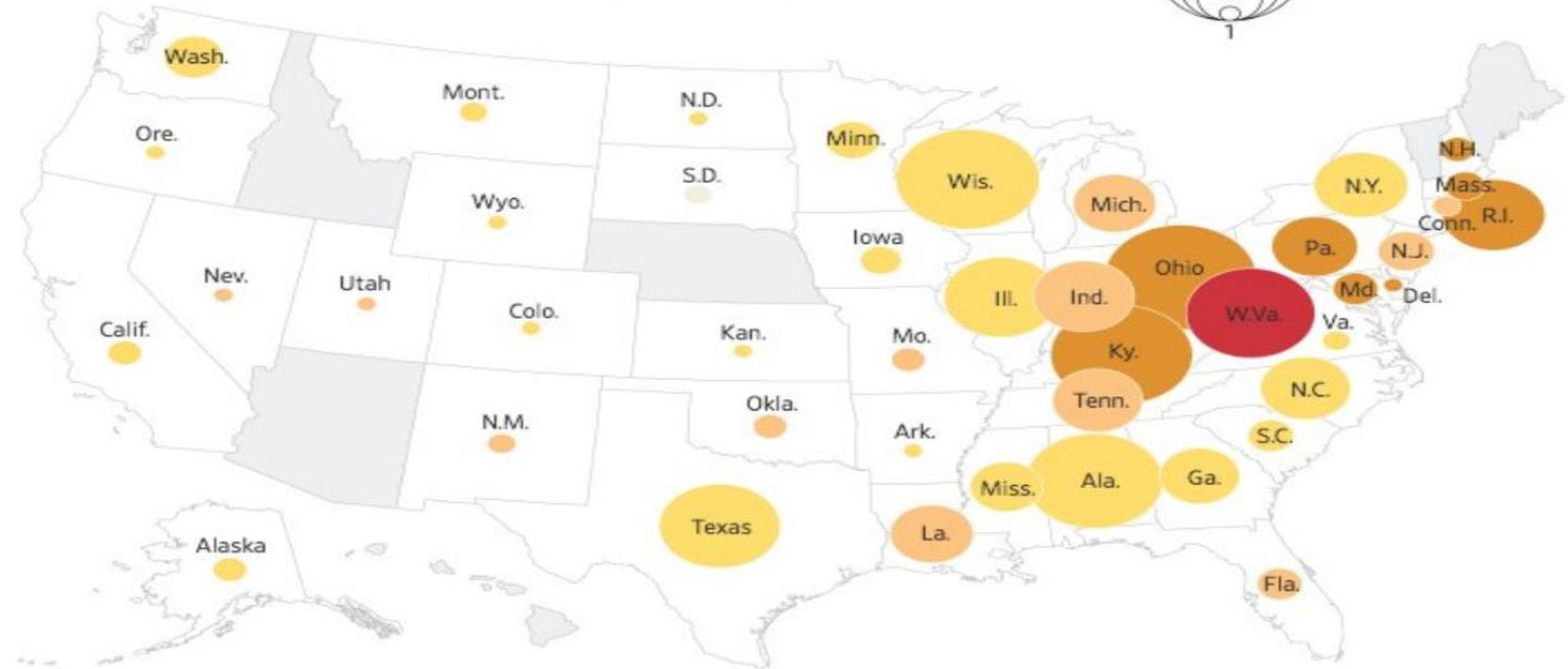
Lawsuits brought by local and state municipalities and Native American tribes over opioids are mounting in places hit hard by the crisis.

Estimated age-adjusted death rates for opioid and other drug poisoning, 2016

By state, per 100,000 population



Number of lawsuits filed in each state



Notes: Lawsuit totals as of April 2. Doesn't include lawsuits solely against Insys Therapeutics.

Sources: Court filings (lawsuits); Centers for Disease Control and Prevention (death rates)

From Wall Street Journal 4/2/18

Opioid MDL: *In re Nat'l Prescription Opiate Litig.*,

No. 1:17-MD-2804 (N.D. Ohio)– see <https://www.ohnd.uscourts.gov/mdl-2804>

An Addiction to Profits?

- *“Sacklers Directed Efforts to Mislead Public About OxyContin, New Documents Indicate”*

(New York Times, 1/15/19)

<https://www.nytimes.com/2019/01/15/health/sacklers-purdue-oxycontin-opioids.html>

- In June 2018, Massachusetts AG sued Purdue Pharma and eight members of the Sackler family (the owners), alleging that they had misled doctors and patients about OxyContin’s risks and had aggressively promoted the drug to big prescribers.



An Addiction to Profits?

“Former Insys CEO pleads guilty to opioid kickback scheme” (Reuters, 1/9/19)

<https://www.reuters.com/article/us-insys-opioids/former-insys-ceopleads-guilty-to-opioid-kickback-scheme-idUSKCN1P312L>

- Michael Babich pleaded guilty to conspiracy and mail fraud charges in connection with a nationwide scheme to bribe doctors to prescribe Subsys, an under-the-tongue fentanyl spray for managing severe pain in cancer patients
- “Prosecutors said Insys paid doctors kickbacks in the form of fees to participate in speaker programs ostensibly meant to educate medical professionals about Subsys that were actually sham events.”
- In August, Insys Therapeutics agreed to pay \$150 million as part of a settlement with the DOJ

EMTALA

Improper Medical Screening

- **McClure v. Parvis, 294 F.Supp.3d 318 (E.D.Penn. 2/6/18)**
 - Because a 4-hour delay in screening may be the functional equivalent of a denial of screening, plaintiff stated an EMTALA claim against hospital
- **Walley v. York Hosp., 2018 WL 3614967 (D.C.Me. 7/27/18)**
 - Negligent screening, as opposed to disparate screening or refusing to screen at all, does not contravene EMTALA
 - Hosp. had no EMTALA stabilization obligation once pt. admitted
- **Elmhirst v. McLaren N. Mich. Hosp., (U.S. 10/9/18)**
 - Denied cert. of 6th Cir. opinion holding pt. must plead hospital acted with an “improper motive”
- **Palmer v. Shawnee Mission Med. Ctr., (D.Kan. 11/8/18)**
 - Misdiagnosed of pt. as false labor not an EMTALA violation
 - Mere de minimis violations of screening protocol not actionable

EMTALA

Failure to Stabilize

- **Gilmore v. Holland, (M.D. Penn. 2/28/18)**
 - Patient admitted for elective surgery; later developed paralysis
 - Claimed paralysis created a “new” emergency medical condition which required stabilization
 - Court dismissed: EMTALA obligations ended when pt. admitted
- **Jones v. Beth Israel Hosp., (S.D.N.Y. 4/12/18)**
 - Patient told ED physician he had suicidal and homicidal tendencies, but received no mental health treatment; later assaulted 3 cops
 - Court refused to dismiss claim for failure to stabilize
- **Dunigan v. Bronson Meth. Hosp., (W.D.Mich. 9/20/18)**
 - Patient discharged but remained in ER waiting room; couldn't stand
 - Moved outside & placed prostrate on ground; died in police custody
 - Summary judgment denied after reviewing security footage & deposition of EMT on emergency medical condition

Book, Blogs and Twitter!

- Book
 - Summary and Analysis of Being Mortal: Medicine and What Matters in the End
Author: Atul Gawande
- Blogs
 - Kaiser Health News: Khn.org
 - Becker's Hospital Review: Beckershospitalreview.com
- Twitter
 - @statnews
 - @beckershr
 - @torchnet
 - @aaronecarroll

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Questions?