Welcome to the 23rd Annual Health Law Conference

July 25, 2019

GRAY PLANT MOOTY

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2019 Health Law Seminar

Where We've Been and Where We're Going:

The Health Regulatory Year in Review

Jesse A. Berg

Agenda

- Trends in 2019-2020
- What's happening with the Affordable Care Act?
- Federal and State Legislation
- Medicare & Medicaid Programs
- Fraud and Abuse
- HIPAA
- Public Health
- SCOTUS

Trends

Health Technology

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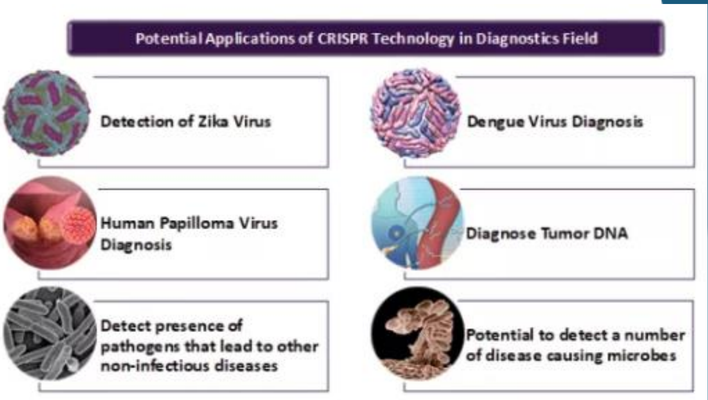
- GlaxoSmithKline entered into a four-year collaboration with 23andMe to work on drug discovery through human genetics.
- CRISPR-based diagnostic platforms are being increasingly used to detect diseases and are expected to grow with the discovery of more biomarkers.
- Recalls by medical device manufacturers grew, raising concerns about the increased complexity and inter-connectivity between medical devices as technologies advance.



Health Technology

- FDA clears Apple to sell heart rhythm-sensing Apple Watch.
  - Capable of taking EKGs, detecting atrial fibrillation, and sharing the data in PDFs with physicians.
  - Also capable of detecting falls and making automatic emergency phone calls.
- Siemens develops smartphone-based urine testing.
  - Creates an app that can scan a patient’s urine and send the results to the patient’s doctor for assessment.

Artificial Intelligence

- AI algorithms that predict clinical outcomes are already being used by some payers and providers.
  - Blue Cross/Blue Shield of North Carolina and University of Pittsburgh Medical Center announced they are using or testing AI to predict hospital readmissions.
- Sample sizes and accuracy varies widely amongst studies of the effectiveness of algorithms aimed at predicting clinical outcomes.
- Current reports are not validated in real-world clinical settings. A model's accuracy doesn't guarantee it will work in a clinical setting or improve outcomes

Crowdfunding Medical Bills

- Popular crowdfunding site GoFundMe CEO confirmed that **one-third** of all donations on the fundraising site go toward health care costs.
- According to the company's website, about 250,000 campaigns have raised $650 million in contributions for health care costs alone since its founding in 2010.

Growing Issues of Video Surveillance

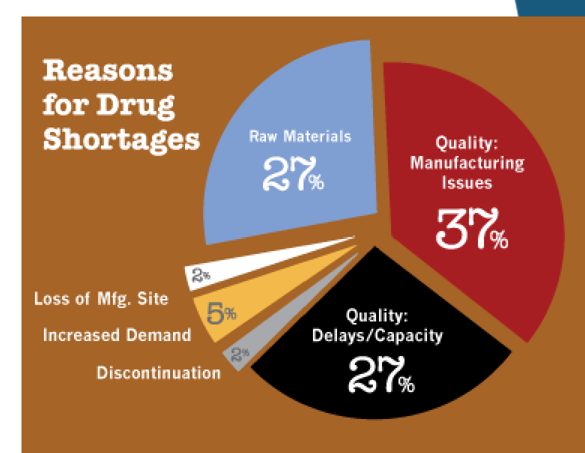
- Sharp Grossmont Hospital placed hidden cameras in its OR in an attempt to catch drug thieves.
- Recorded caesarean births, hysterectomies, dilation and curettage.
- 81 female patients have sued.
- Other issues include police bodycam HIPAA risks for hospitals and "Granny Cams" in SNFs.
- Boston Medical Center, Brigham and Women's Hospital, and Mass General settle suit for $999,000 for unauthorized disclosure of patient information during ABC television filming.

Other Privacy Issues in Healthcare

- US Chamber of Commerce, California tech giants, and the GAO call for a new comprehensive federal data privacy law.
- Senate Commerce Committee has begun hearings on the issue.
- HHS proposed rules on information blocking, interoperability and patient access.
  - Focus is on ensuring patient access to data, data exchange, and care coordination.

Drug Shortages

- A new study has found that drug shortages cost providers nearly $360 million a year in labor expenses.
- Current trade disputes with China are growing fears of potential drug shortages.
  - More than 80% of the active ingredients in prescription drugs sold in America are manufactured abroad. The majority of those are made in China.
  - Pharmaceuticals are on the tariff exemptions list, but worries remain that they may be taken off or that China will retaliate by blocking exports.



Affordable Care Act Developments

Current State of the ACA

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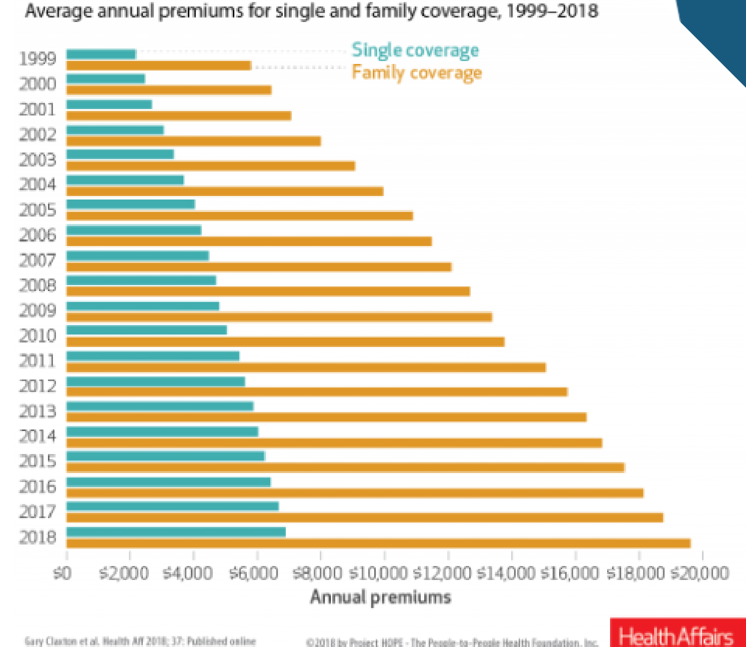
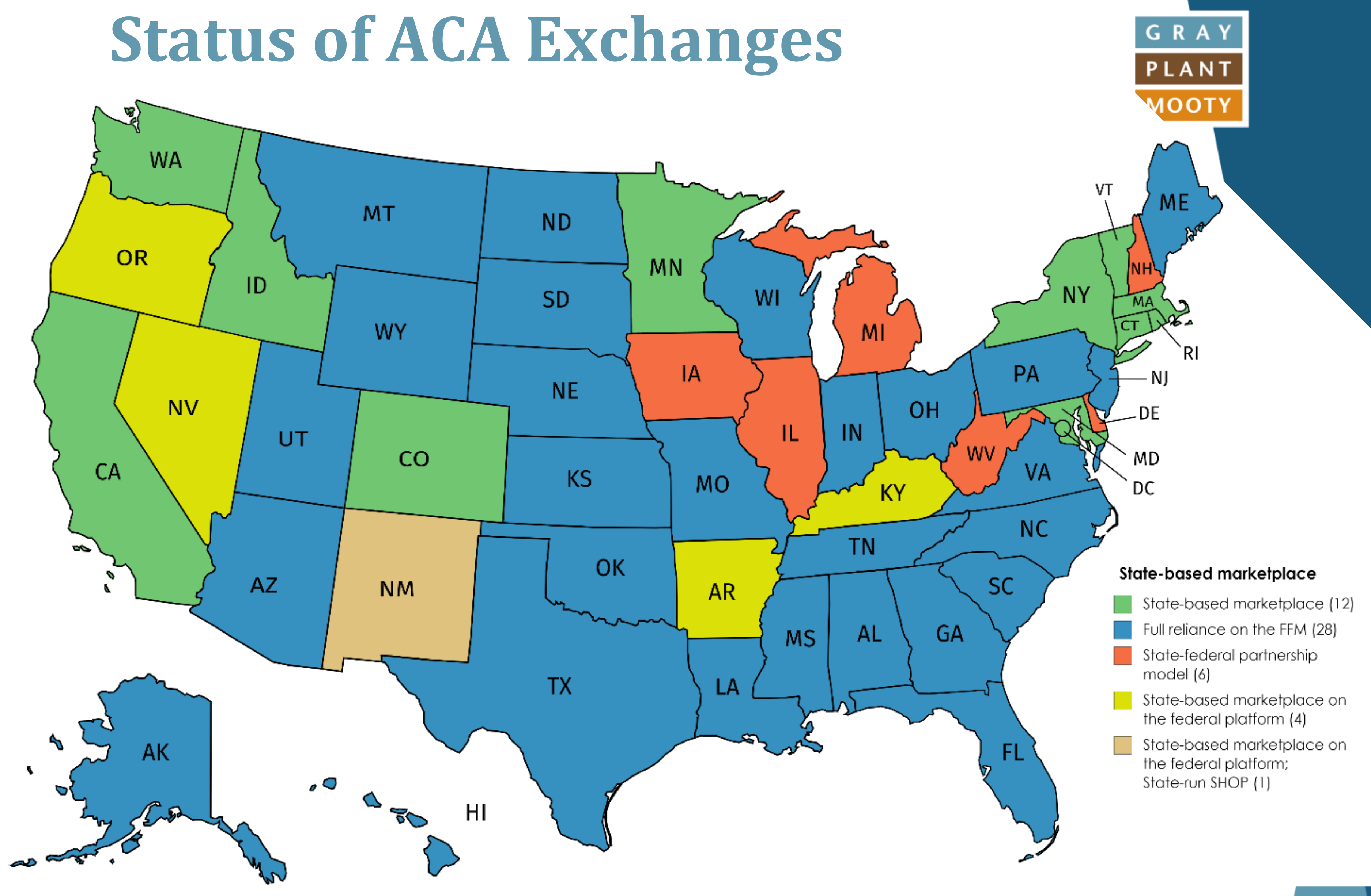
- The repeal of the ACA individual mandate penalty went into effect on Jan. 1, 2019.
- Uninsured rate increased from 27.5 million in 2016 to 30 million in 2019.
- Decrease in average cost of coverage for the lowest cost plan on the HealthCare.gov platform:
  - 2018: $291 per month
  - 2019: $288 per month
- Average annual premiums for employer-based healthcare continued to rise.



New ACA Guidelines

- Trump Administration gives states more flexibility to offer plans that include options with less coverage.
- Guidance released at the end of last year folds short-term coverage and association health plans into the definition of acceptable coverage.
- Short-term plans will count as coverage, incentivizing states to boost enrollment in those plans and redirect federal subsidy dollars away from ACA-compliant plans.
- Could lead to increased revenue for insurers like UnitedHealth Group, a top seller of short-term plans in 2017, which earned premiums of nearly $42 million on limited plans.

Status of ACA Exchanges



Medicaid Expansion

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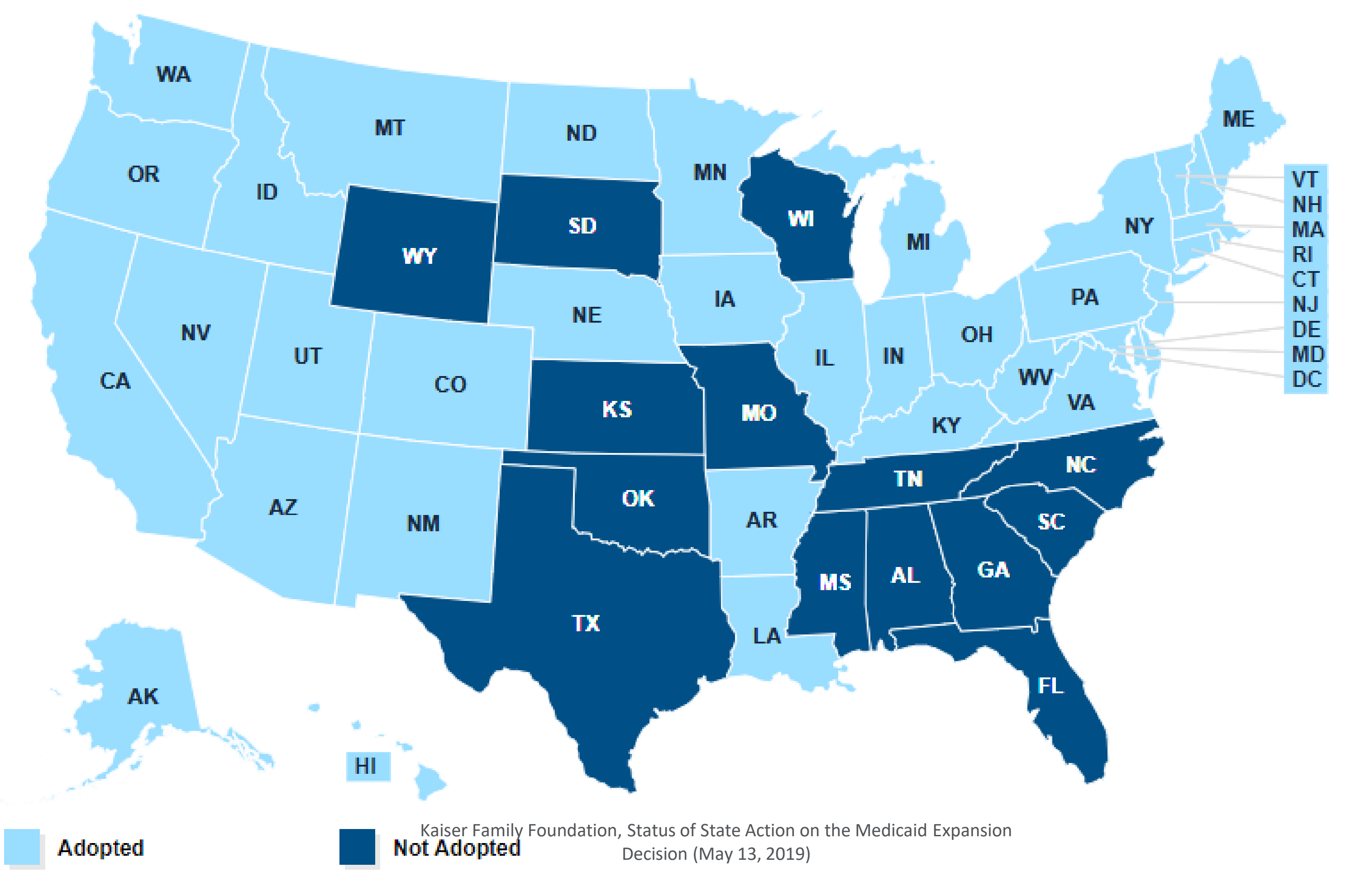
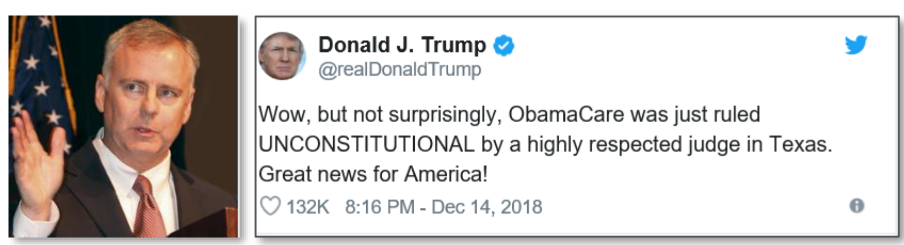
- 36 states have expanded Medicaid (7 states with Section 1115 Waivers).



Kaiser Family Foundation, Status of State Action on the Medicaid Expansion Decision (May 13, 2019)

Efforts to Repeal the ACA

- *Texas v. United States* – In April 2018, Texas and 19 other states filed a complaint in the Northern District of Texas saying that the individual mandate is unconstitutional and, since the rest of the law is inseverable from that provision, the ACA must also fall.
  - In December the District Court agreed. The 5th Circuit heard oral arguments on the appeal in early July.
- *Maryland v. United States* – Maryland seeks declaratory relief regarding ACA constitutionality. District Court judge held that the state failed to establish substantial or impending risk that the government would no longer enforce the ACA, no injury-in-fact to the state and the case is dismissed.



Administrative Efforts to Repeal the ACA

- *New York vs. Department of Labor* – Final rule permitted employers to offer coverage through Association Health Plans that didn't have to comply with the ACA.
  - 11 states and DC sued and the District Court invalidated the rule.
- *Association for Community Affiliated Plans v. Department of the Treasury* – Final rule allowed short-term, limited-duration insurance coverage that doesn't comply with the ACA, summary judgment pending.
- Final rule announced allowing the use of HRAs to pay for health plans, effective 1/1/20.
- Insurers sued HHS for $2.3B in unpaid cost-sharing reduction payments. 3 cases are currently on appeal to the Federal Circuit.

ACA Waivers

- State Relief and Empowerment waivers “encourage states to move away from the Federal Marketplace and create innovative new healthcare programs and state-based marketplaces.”
  - Expands definition of “coverage” to include short-term plans, removes focus from targeting specific populations to focus on all residents, and lowers the bar for states to meet the legislative authority requirement.
- Work Requirements
  - Approved in: AZ, AR, IN, KY, MI, NH, WI
  - Pending in: MS, OH, OK, SD, TN, UT, VA, AL
  - Approved work waiver examples:
    - Indiana and New Hampshire – 100 hours per month of community engagement
    - Arkansas – 4000 people lost coverage because of noncompliance
    - Alabama – 35 hours per week requirement

CMS Initiatives – Waivers cont'd

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- Approved waivers:
  - Healthy Behavior Incentives condition eligibility on completing health risk assessment and creating a premium surcharge for smokers
  - Copays above statutory limits
  - Fees for missed appointments
  - Exclusion of psych and substance abuse treatment
- Waivers Not Approved:
  - Closed prescription drug formulary
  - Lifetime limits on Medicaid benefit
  - Eligibility conditioned on drug screening
- Pending:
  - Freedom of choice for family planning (SC, TX, TN)
  - Evaluation of the community engagement requirements
  - Changing political directions (Maine)

2020 and the ACA

- Healthcare was the #1 issue that voters considered most important in last fall's midterm elections.
  - 80% said healthcare was "extremely" or "very" important to their vote, according to the Gallup poll.
- Kaiser Family Foundation April 2019 poll shows 50% of Americans support the ACA and 38% oppose it.
- Looking to 2020 – Medicare for All?
  - A variety of 2020 Democratic candidate proposals reflect different points along the single-payer spectrum.

Bank Robber Commits Crime in WI for Better Healthcare

- William Gallagher heard that healthcare in Wisconsin prisons was better than other institutions and superior to the care offered through the US Department of Veterans Affairs.
- He went to a bank in Wisconsin and, after robbing it, waited to be arrested.
- Instead of giving him his requested 10 year prison sentence, the Judge ordered a presentence investigation.

Legislative Developments

Federal Developments

- Drug pricing – a longstanding bipartisan concern
  - Jan 2019 – Sen. Grassley sponsored the Safe and Affordable Drugs from Canada Act of 2019 to amend the Food, Drug, and Cosmetic Act to allow for personal importation of more affordable drugs from Canada.
  - This summer a bipartisan group of health committee leaders in the House have drafted reforms to Medicare Part D in a move to cap out-of-pocket spending and lower costs.
  - Jul. 11: Sens. Grassley & Wyden plan "to advance a bipartisan deal to lower drug prices, 'very soon'".
- Surprise medical bills have also prompted bipartisan concern.
  - 2018 saw proposals for bills to eliminate the practice.
  - In a January round table, Trump directed HHS Secretary to focus on surprise medical bills.

Federal Developments Cont'd

- Rural Healthcare
  - Sen. Grassley (Chair, Senate Finance Committee) indicates rural healthcare a significant objective.
  - Bipartisan bills in the House and Senate have been introduced but have gone nowhere.
    - Save Rural Hospitals Act
    - Rural Emergency Medical Center Act
- New legislation proposed during the last session of Congress would require greater Sunshine Act reporting.
  - Fighting the Opioid Epidemic with Sunshine Act of 2018
  - Patient Advocacy Transparency Act of 2018

Medicaid Bill Passed in the House

- HR 3253, passed in June 2019 371 to 46, extends Medicaid-related health programs by increasing manufacturer Medicaid drug rebate obligations.
- Authorizes state Medicaid fraud control units to review complaints of abuse in non-institutional or other settings.
- Extends spousal impoverishment protections for recipients of home- and community-based services.
- Increases funding for the Medicaid Improvement Fund.

State Developments

- Colorado, Florida, and Vermont are exploring plans to import drugs from Canada in the face of soaring drug costs.
  - President Trump has offered his support of the solution, giving momentum to the idea of Canadian prescription drug importation.
  - It is unclear whether the plans could gain federal approval and withstand court challenges.
- California Consumer Privacy Act 2018
  - Similar to GDPR, gives rights to notice of data collection, access and portability of personal data, ability to have personal data deleted.
  - Gives a private right of action after a data breach.
  - Indicates potential push for federal privacy act.

MN Legislative Updates

- HF 90 establishes assisted living licensure and resident protections:
  - Prohibits deceptive marketing and business practices,
  - Establishes licensure requirements:
    - Creates 2 tiers: (1) Assisted Living; (2) Assisted Living + Dementia
    - Takes effect Aug. 1, 2021
  - Rulemaking process to fill out many of the details
  - Creates retaliation protection and appeal process for termination of housing/services
  - Creates penalties for violations of these new regulations.

MN Legislative Updates cont'd

- HF 400 requires drug makers and distributors to pay $20.9 million in fees which will then be used to combat the opioid crisis through county governments.
  - $12 million from manufacturers
    - Fee assessed by the Board of Pharmacy annually.
    - 2,000,000 or more opiate units costs $250,000 in fees.
  - $8 million from wholesalers
    - $5,000 fee
    - Big three: McKesson, Cardinal Health, AmerisourceBergen
  - Creates prescribing limitations
    - 7 days for adults and 5 days for under 18, though physicians may prescribe for longer based on professional clinical judgment.
    - No prescription can be filled 30 days after written.
    - Mandatory checking of the prescription drug monitoring program, but with many exceptions.

MN Legislative Updates cont'd

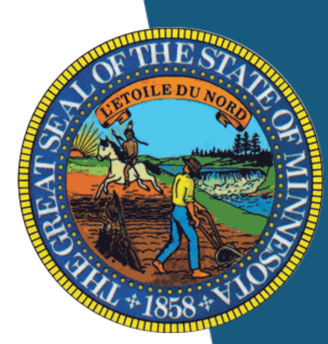
- Pharmaceutical benefit manager licensure and regulation.
- New documentation requirements for certain providers/suppliers (HCBS, Adult Day, Transportation):
  - E.g., for services reimbursed at daily rate HCBS providers required to maintain documentation showing for each service provided:
    - Date documentation occurred
    - Day, month, year that services were provided
    - Service name, description of services provided
    - Name, signature and title of individual providing services

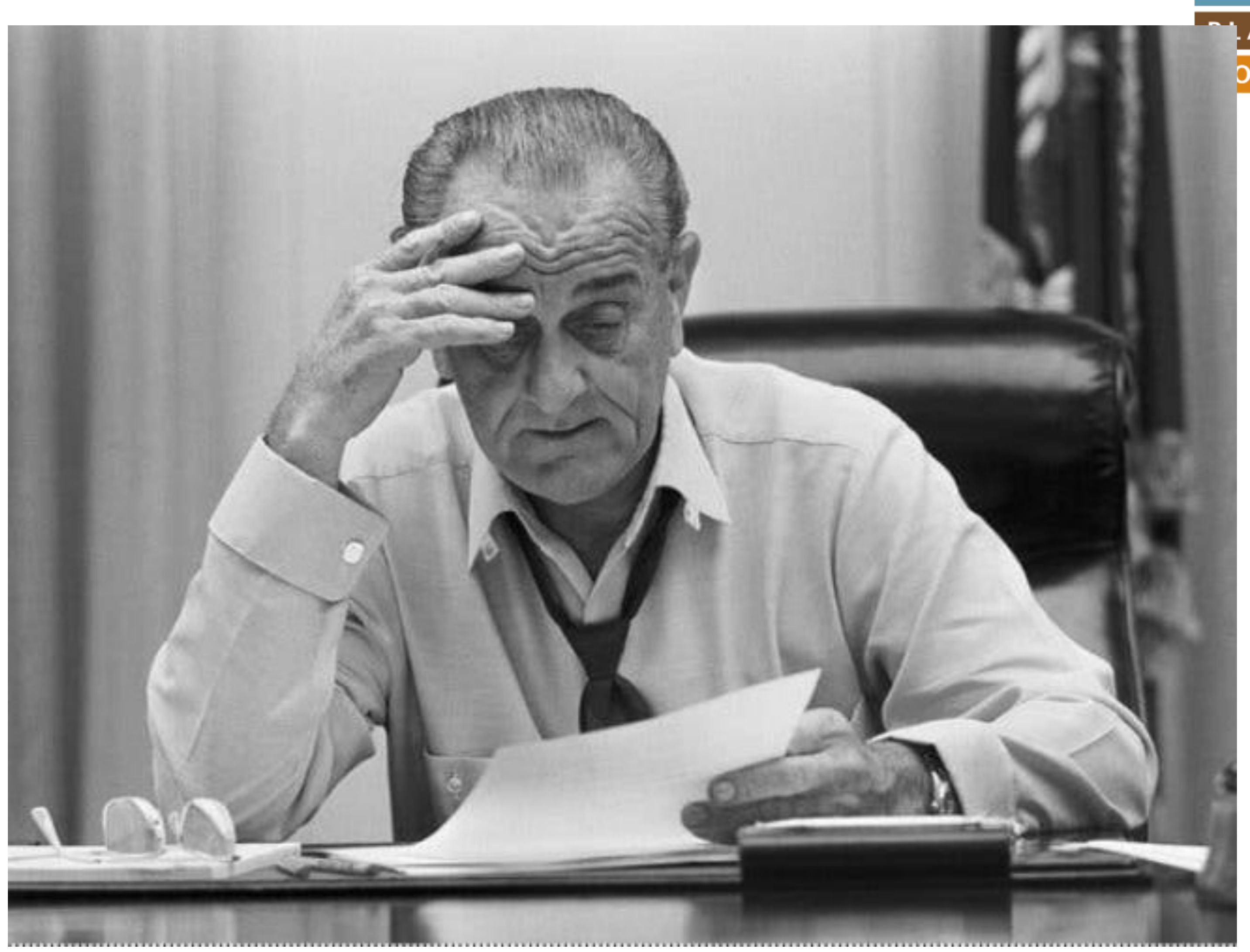
MN Legislative Updates cont’d

- Starting Aug. 1, vendors are statutorily obligated to conduct monthly Medicaid exclusion checks to ensure payments are not being made to excluded individuals or entities.
  - Minn. Stat. 256B.064, subd. 3
- Must keep log of the date and time the exclusion list was checked and the name of the person conducting the exclusion checks.
- New refund obligation if vendors pay excluded parties.
- Vendors caught making payments to excluded entities could face fines of up to $25,000.

MN Legislative Updates cont'd

- Other major areas of focus:
  - Blue Ribbon Commission created to improve efficiency and effectiveness of the HHS system.
  - Proposed $68M cuts to nursing facilities was defeated.
  - Provider tax will remain indefinitely at a lowered 1.8%.
  - Reinsurance program extended for another 3 years.
  - New Minn. Stat. 144.6502 outlines circumstances in which "granny cams" can be used.

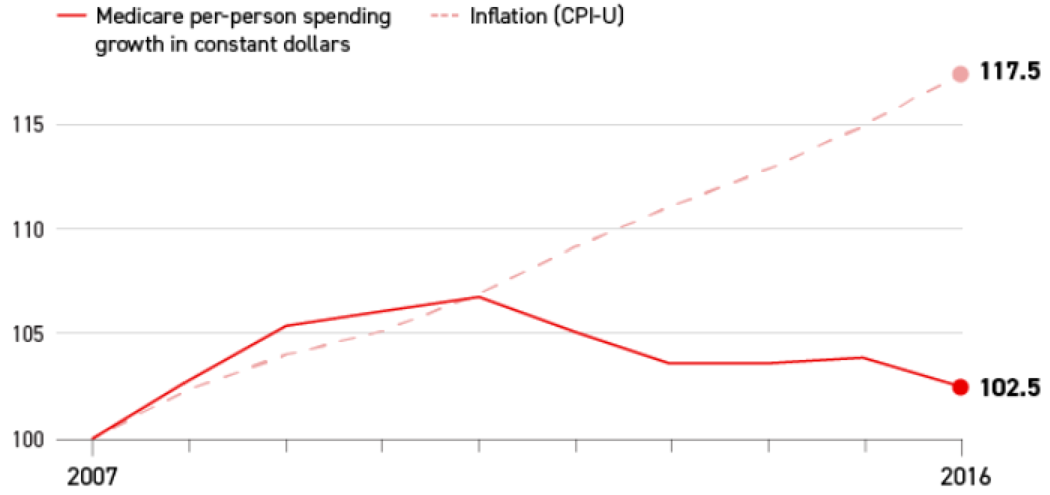




Medicare & Medicaid

Medicare Spending Going Down

- Overall spending increased, but per capita spending rose only 1%/year, less than inflation, compared to a 7.1% increase between 2000-2010.



Tucker Doherty/POLITICO

ACA Program Integrity Update

- Provider/Supplier Enrollment Moratoria:
  - As of Jan. 2019, CMS confirms there are no active Medicare Provider Enrollment Moratoria in any state or U.S. territory.
  - Last moratorium, the provider enrollment moratorium of Home Health Agencies and ground ambulance suppliers, was allowed to expire in Jan. 2019.
- OIG Report: *Problems Remain for Ensuring that All High Risk Medicaid Providers Undergo Criminal Background Checks (July 2019)*

ACA Program Integrity Update

- Status of Proposed Enrollment Rule
  - Proposed Rule (Mar. 1, 2016)
  - Deadline extended to Mar. 1, 2010 (84 Fed. Reg. 6740, Feb. 29, 2019)
  - E.g., proposes to extend reenrollment bar from 1-3 years to 10 years!
- Payment Suspensions
  - 551 active in 2017 (252 new that year)
- Integrated Data Repository
- One Program Integrity Data Analysis
- 2018 HHS and VA announced partnership to address F&A between programs

ACA Program Integrity Update

- Deactivation of billing privileges because—
  - Incorrect email address results in physician not receiving revalidation request
- Revocation of billing privileges because—
  - Billed for locum tenens physicians who did not yet have billing number
  - Physician unable to submit complete medical records and documents to support claimed home health certification
  - Clinic billed for physician services without valid reassignment
  - IDTF failed to notify CMS of updates to supervising physician

ACA Program Integrity Update

- 2018 BBA doubled the amounts of many CMPs
  - 42 USC 1320a-7a amounts increased from $10,000-$20,000; $15,000-$30,000; and $50,000-$100,000)
- OIG Exclusions:
  - Cindy Scott (APRN)-excluded for 10 years for prescribing controlled substances substantially in excess of patients' needs
  - First Initiative, Ms. Amin and Ms. Greenough—(behavioral health provider and owners) excluded for 50 years for billing individual therapy (when group therapy provided) and billing under wrong NPIs.
  - Labib Riachi—physician excluded for 20 years for billing for pelvic floor therapy services that he did not perform or directly supervise.

Off-Campus Provider-Based Departments

- Historically, same services resulted in higher reimbursement when provided in hospital depts.
- Hospital outpatient services provided after Nov. 2, 2015 in new, off-campus PBDs no longer covered under OPPS but billable by hospitals under MPFS.
- Certain off-campus PBDs were “grandfathered”.
- 2019 Final Rule:
  - Payments to excepted OCBPDs reduced to the MPFS rate (which is 40% less than the OPPS rate)
  - No finalization of “clinical family of services” proposal
  - Includes reduction for 340B drugs
  - CMS says new rule will save Medicare $480 million (2019) and result in beneficiaries paying less out of pocket
  - Lawsuit pending

Hospital Co-Location

- In May 2019, CMS released draft guidance for Medicare hospital co-location with other hospitals or healthcare facilities.
  - Notice and comment ended on July 2.
- Hospital must:
  - meet the definition of a hospital at all times.
  - have defined and distinct spaces of operation for which it maintains control at all times.
  - Travel between separate entities utilizing a path through clinical spaces of a hospital by another entity co-located in the same building would not be considered acceptable as it could create patient privacy, security and infection control concerns.
  - Clinical space is any non-public space in which patient care occurs.
- Shared public spaces such as public paths of travel need clear guidelines and both entities would be individually responsible for regulatory compliance in those spaces.
- Limitations on ability to “float” certain staff with co-located entities.
- Surveyors directed to review floorplans.

Clinical Lab Co-Location

- In August 2018, CMS issued letter to State Survey Agency Directors "clarifying the operation of multiple laboratories at the same location".
- Outlines situations where multiple labs can operate out of the same physical location.
- Restrictions on labs operating out of the same location and sharing "the same testing personnel and equipment".
- Supported by CLIA?

CMS Initiatives – "Patients Over Paperwork"

- Announced in 2017 by CMS Administrator Seema Verma – branded as allowing "doctors to focus on care instead of paperwork."
- Estimated to save $5.4 billion and 40 million hours of paperwork burden through 2021.
- Collected comments from over 2000 clinicians and beneficiaries.
- Established the Patient Driven Payment Model to reduce paperwork in skilled nursing facilities.

New Approach to Local Coverage Determinations

- CMS announces revisions to the Medicare Program Integrity Manual and revamping the Local Coverage Determination (“LCD”) process.
- LCD process allows providers to request that certain items and services be covered that are not already clearly covered under existing rules.
- Confusion and inconsistency prior to CMS announcement.
- Manual now has road map of step by step instructions for LCD process.

Physician Fee Schedule Payments and Coding

- Reduce documentation burden, shift focus back to the patient.
- Offer flexibility for small and rural practices, increase access to virtual care.
- Meaningful Measures Initiative created to streamline quality reporting.
- Estimated to save providers $87M in admin costs in 2019.
- Home visits no longer require documentation of medical necessity.
- Effective 2019: Policies meant to avoid redundant data recording in office and outpatient visits.
  - New or established patients: Physician/NPP does not have to re-enter chief complaint or history recorded by ancillary staff or patients and may simply indicate they reviewed and verified the information.
  - Established patients only: Physician/NPP can focus on changes since last visit and does not need to re-record all elements of history and exam.

Teaching Physicians, Residents, and Students

- Teaching physicians can now verify student documentation of components of E/M services instead of re-documenting the work.
  - Must still perform the physical exam and medical decision-making activities.
- Effective 2021:
  - Single rates for new/established office/outpatient visits levels 2, 3, and 4.
  - Add-on codes for additional resources inherent in visits for primary care and certain specialized medical care for E/M office/outpatient levels 2 to 4.
  - Flexibility in documentation for E/M levels 2-5 based on current framework, medical decision making, or time.

Quality Payment Program: MIPS

- 2019 adjustments smaller than the maximum +/- 5% permitted under program
  - Based on 2017 data
- Providers receiving the maximum MIPS score received 1.88% increase in 2019
- Current scoring
  - Quality (45%)
  - Promoting interoperability (25%)
  - Clinical practice improvement (15%)
  - Resource use/cost (15%)

Quality Payment Program: MIPS

- Bipartisan Budget Act of 2018 extends transition rule for setting performance thresholds through 2021 instead of setting the threshold at the 2019 average.
- Adds a number of eligible providers including PT, OT, speech pathologists, audiologists, and nurse midwives.
- Expands low-volume exclusion threshold through August 2019.
- MIPS payment adjustments based on MIPS composite performance score: clinicians could receive up to +/- 7% payment adjustment for 2020.
- MIPS scoring adds emphasis to cost and use of resources.

Quality Payment Program: APMs

- Participants bear more financial risk but those who qualify get a 5% lump sum bonus in 2019-2024.
  - Payments linked to quality, must use CEHRT, exempt from MIPS.
- Common APM structures:
  - CMS establishes quality and cost targets, participants contract with CMS, beneficiaries continue to choose their providers and CMS analyzes various factors like utilization, cost, and quality to determine whether providers met the target.
- APMs include:
  - Comprehensive ESRD Two-Sided Risk
  - Comprehensive Primary Care Plus
  - Medicare Shared Savings Program with Two-Sided Risk
  - Oncology Care Model Two-Sided Risk
  - Comprehensive Care for Joint Replacement Payment Model
  - Bundled Payments for Care Improvement

Bundled Payments for Care Improvement (BPCI)

- BPCI-Advanced 2019 Changes:
  - CMS engages with physicians and shares knowledge as a way to gain feedback from participants.
  - New participants can apply this year for 2020, current participants can withdraw retroactively if they contacted CMS by 3/1/19, current participants are given an optional one-time opportunity to amend participation agreements.
  - BPCI Advanced—single bundled payment and risk track for defined clinical episodes (admission through 90 days after discharge).
  - 29 inpatient clinical episodes and 3 outpatient clinical episodes
  - Second waive of BPCI Advanced applications were due on Jun. 24 for Jan. 1, 2020 start date
  - Optional one-time opportunity for participants to amend certain parts of BPCI Participation Agreement

Medicare Shared Savings Program

- 2018 “Pathways to Success” changes to ACOs
- Accelerated timeframe by which providers need to assume risk under MSSP
  - More coverage for telehealth (including home based care)
  - 2 application cycles
- 10.9 million Medicare beneficiaries getting care
  - Up from 10.5 million year before
- 48% of ACOs assuming at least 2% (of revenue) risk for spending above cost target
- New waivers:
  - SNF coverage without a 3-day inpatient hospital stay (ACO must have agreement with SNF and communication plan for care coordination)
  - SNF must have at least 3 of 5 stars in CMS rating system

Telemedicine

- Medicare coverage remains relatively limited, but has been slowly expanding since 2000.
- Bipartisan Budget Act of 2018 expanded telehealth allowing for more extensive coverage of telehealth services, including telehealth in Medicare Advantage basic benefits.
- CMS added two new codes for 2019 for prolonged preventative services in the office or other outpatient setting requiring direct patient contact.
- OIG report found that 31% of telehealth claims did not meet conditions for payment, creating anticipation of more billing audits of telehealth services in the future.

Center for Medicare & Medicaid Innovation

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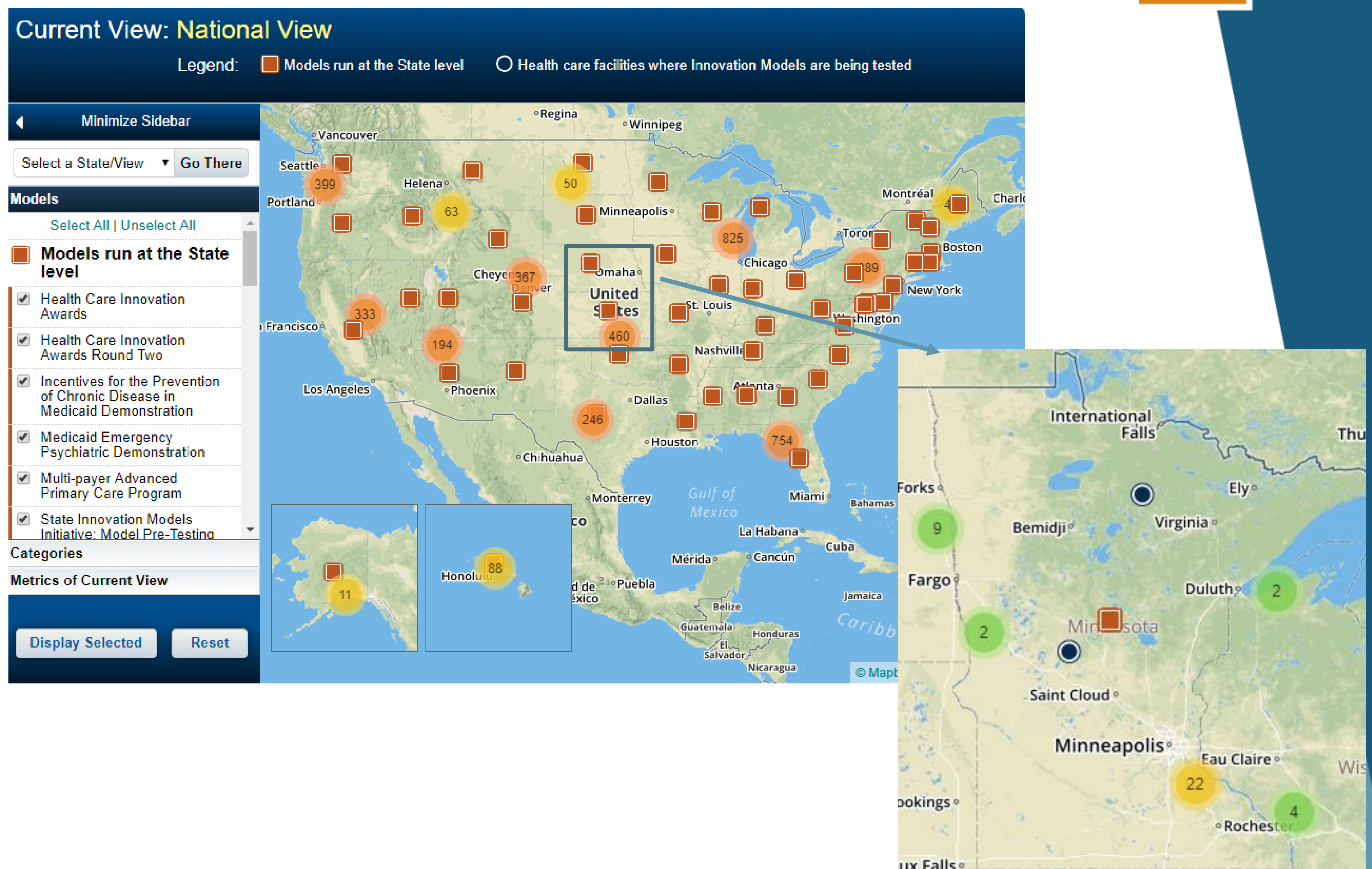


CMMI in MN

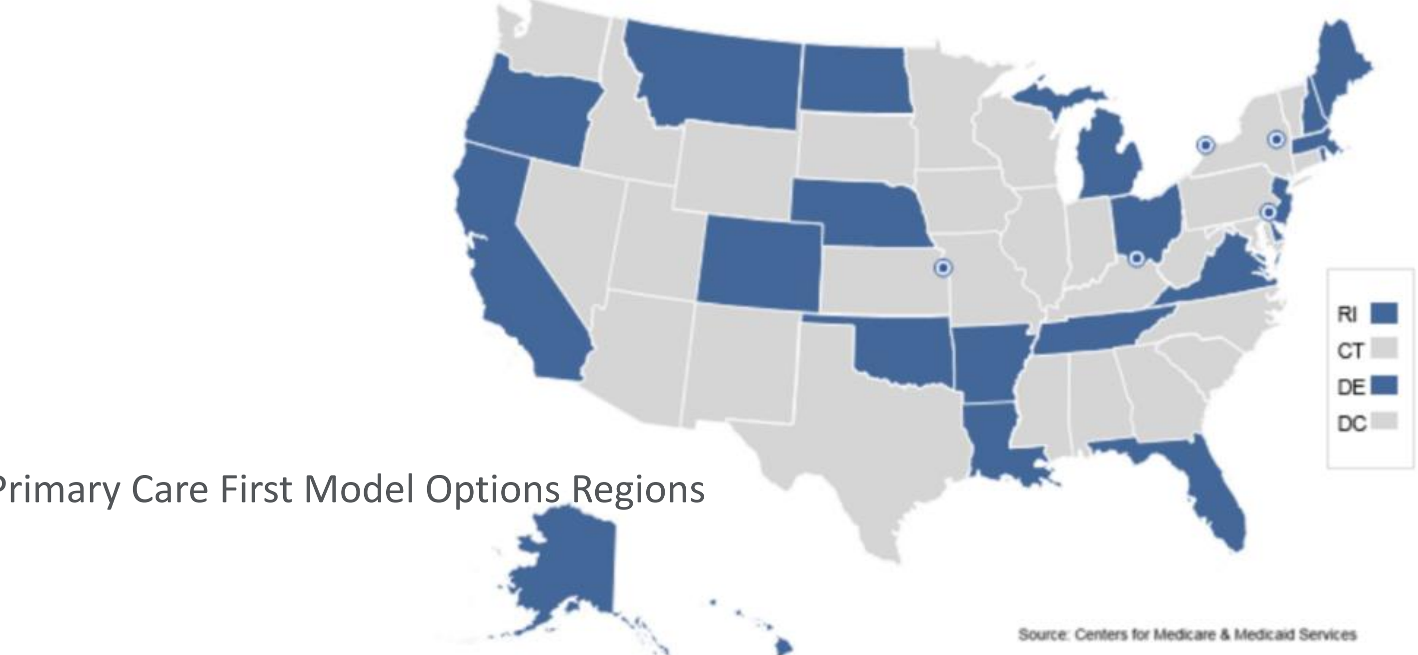
- 14 State Level Innovation Awards:
  - Allina, Mayo Clinic, Institute for Clinical Systems Improvement, Trustees of Dartmouth College, YMCA of the USA, Sanford Health, Care Choice Cooperative, Avera Health, National Health Care for the Homeless Council, Community Health Center Association of Connecticut and State of MN have all received at least one.
- 26 facilities in MN with CMMI models in use:
  - Accountable Health Communities, ACO, BPCI Advanced, BPCI Initiative Model 3, Comprehensive ESRD, FQHC Advanced Primary Care, Innovation Advisors, Medicare Care Choices, Million Hearts CV Disease Risk Reduction Model, Next Generation ACO, Part D Enhanced Medication Therapy Model, Pioneer ACO and Strong Start for Mothers and Newborns.

New CMMI Payment Models

- CMS announces a call for entry in June for innovative AI solutions to predicting health outcomes such as unplanned hospital and skilled nursing facility admissions and adverse events
  - Focus on deep learning and neural networks
  - 1 grand prize winner will receive $1 million
  - Shows a clear priority of shifting care towards AI
- Emergency Triage, Treat, and Transport (ET3) Model begins Jan. 2020 (applications this summer) to solicit Medicare-enrolled ambulance suppliers:
  - Voluntary, five-year payment model.
  - Aims to improve quality and lower costs by reducing avoidable transports and unnecessary hospitalizations after these transports.
  - Voluntary 5-year model pays suppliers to transport to ED, transport to PCP and provide on-scene or telehealth treatment

New CMMI Payment Models

- Primary Care First Model Options - voluntary five-year payment options offering an innovative payment structure to support delivery of advanced primary care.
  - Based on the underlying principles of the existing CPC+ model design: prioritizing the doctor-patient relationship; enhancing care for patients with complex chronic needs and high need, seriously ill patients, reducing administrative burden, and focusing financial rewards on improved health outcomes
  - 5 separate programs available



Primary Care First Model Options Regions

Recent HHS Rulemakings

- Proposed Rule: Update to e-prescribing standards to reduce provider burden and expedite access to needed medications.
- PACE Final Rule – first update and modernization of the PACE program since 2006.
- Final Rule: Medicare Advantage and Part D drug pricing.
  - Ensures greater transparency into the cost of prescription drugs in Part D.
- Final Rule: New Limits on Medicaid Reassignment.
  - Removes state's ability to permit reassignment of Medicaid reimbursement to certain third parties (primarily on behalf of independent in-home personal care workers).
- Proposed Rule: Require greater transparency when ownership changes occur at Accrediting Organizations by establishing specific processes AOs must follow in the event of a sale, transfer, or purchase.
- Proposed Rule: Update Medicare payment policies for hospitals under the IPPS and LTCH Prospective Payment System for FY 2020.

Recent HHS Rulemakings

- "Conscience Rule" – Providers can refuse to provide treatment that conflicts with their religious and moral beliefs.
  - Extends to services like abortion, sterilization, assisted suicide, advance directives, and HIV/AIDS.
- "Discrimination Rule"
  - Obama administration issues final rule interpreting the ACA to ban discrimination based on "gender identity."
  - *Franciscan Alliance v. Burwell* – Texas court grants preliminary injunction against the rule.
  - 2019 – HHS has issued a proposed rule removing references to "gender identity" and "termination of pregnancy."
- Waste management – final rule imposes sewer ban effective 8/21/19 stating no disposal of Rx drugs down the drain; requires employee training on proper waste disposal at health care facilities

Recent HHS Rulemakings

- Transparency in Hospital pricing
  - 2019 IPPS obligates hospitals to publish a list of their standard charges on the internet and update at least annually
  - Vanderbilt University Medical Center listed a charge of $42,569 for a cardiology procedure described as “HC PTC CLOS PAT DUCT ART”
  - Kaiser Health News—”Fanciful, Inflated, Difficult To Decode And Inconsistent”

Recent HHS Developments

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- CMS proposes that Medicare will start paying for acupuncture
  - Limited coverage initially
- CMS revises Medicare State Operations Manual (App. Q) process and guidelines for determining "immediate jeopardy"
  - Noncompliance that "creates a likelihood (reasonable expectation) that serious injury/harm/impairment or death will occur
  - Requires IJ determination as opposed to automatic IJ situations
  - Applies to most provider/supplier categories (lab, under CLIA, has its own rules)

Recent HHS Developments

- May 10, 2019 Final Rule (42 CFR 403) requires direct to consumer television ads for prescription drugs/biologics (eligible for Medicare/Medicaid) have to disclose wholesale acquisition cost (WAC) for 30-day course of treatment
- A group of drug manufacturers sued in June, arguing that the rule could mislead consumers, was beyond the authority of HHS, and could undermine the advertisers' First Amendment protections.
- On July 9, the day before the rule was to take effect, the US District Court for the District of Columbia held that the rule could not stand and was beyond the authority of the HHS, saying that the authority to act lies with Congress.

- CMS is expanding 340B by extending the payment change to additional off-campus provider-based hospital outpatient departments paid under the physician fee schedule.
  - Hospitals saved $320 million in out-of-pocket payments in 2018 due to a 340B change that lowed the cost of outpatient drugs.
  - Member hospitals have reported negative impacts on the quality of patient care from the 2018 cuts.
- Implications:
  - Providers subject to this payment adjustment were required to use modifier JG to identify 340B acquired drugs, with hospitals exempt from this payment reduction cut using a different modifier TB.
  - In conjunction, CMS increased OPPS reimbursement by 3.2% for all hospitals, resulting in a windfall to non-340B hospitals.

340B Program Update:
American Hospital Assoc. et al. v. HHS

GRAY PLANT MOOTY

- Federal lawsuit challenging payment cuts to 340B program
- In late 2017, AHA, AAMC among other sued HHS following publication of 2018 OPPS Rule.
- Suit alleges cuts violated Administrative Procedures Act and exceeded HHS authority.
- Suit refiled in late 2018. Court granted permanent injunction in plaintiff's favor, finding that HHS exceeded its authority by cutting Medicare reimbursement for 340B drugs by almost 30%.

340B Program Update: *American Hospital Assoc. et al. v. HHS*

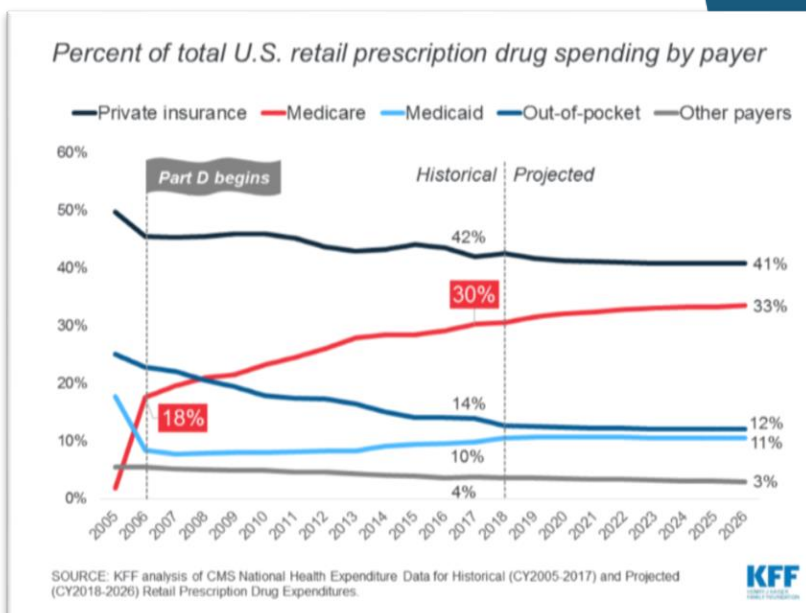
- Highlights from the decision:
  - The Court found that the exhaustion of administrative remedies was waived, saying it would be futile in this case.
  - HHS exceeded authority to adjust the statutorily-mandated benchmark rate of ASP plus 6%, meaning the ability of HHS to adjust rates is not without limit. The magnitude of the adjustment was significant to the court.
  - The court ultimately entered a permanent injunction in favor of the plaintiffs.
- May 2019 – The Court entered a decision concluding that HHS's 2019 340B reimbursement rate is unlawful but instead of vacating the 2018 and 2019 rules, it is remanding the rules to HHS so it can have the "first crack at crafting appropriate remedial measures."
  - The Court ordered a status report from the agency by August 5, 2019.

Medicare Advantage Updates

- Communication and Marketing
  - Marketing prohibited in locations where care is delivered – this does not include educating the beneficiary about the MA program, but does include brochure distribution. Updates provide clear guidelines on where marketing can be located.
- CMS reinterpreted the rules on uniformity of benefits to improve flexibility.
  - Bipartisan Budget Act of 2018 amends SSA section 1853 to allow waiver of the uniformity requirement beginning in 2020 for certain MA plans.
  - Flexibility allows for greater tailoring for patients, though still requires objective and measurable medical criteria to determine eligibility.
- CMS eliminated mandatory compliance and fraud, waste, and abuse training.

Medicare Prescription Drug Spending

- Medicare's share of the nation's retail prescription drug spending has increased from 18% in 2006 to 30% in 2017.
- Prescription drugs account for every $1 in $5 of Medicare spending.
- In May 2018, President Trump announced proposed changes to Medicare Part D, specifically suggesting allowing Medicare Part D plans to limit access to high cost drugs that did not provide Part D plans with rebates or fixed prices.
- In June 2019, CMS announced it would **not** allow Part D sponsors to exclude protected class drugs when the price of the drug exceeds a certain threshold, rejecting President Trump's suggestion.



CMS Initiatives – Lowering Drug Prices

- Medicare spent $109 billion on prescription drugs in 2012. This number increased to $185 billion by 2017.
- Part D Payment Modernization Model – begins in 2020 with initiatives to incentivize lower drug spending.
  - Open to eligible standalone Prescription Drug Plans and Medicare Advantage-Prescription Drug Plans that are approved for participation.
  - Voluntary, 5-year model.
  - Includes a Part D Rewards and Incentives program to promote enrollee understanding of their Part D benefits.

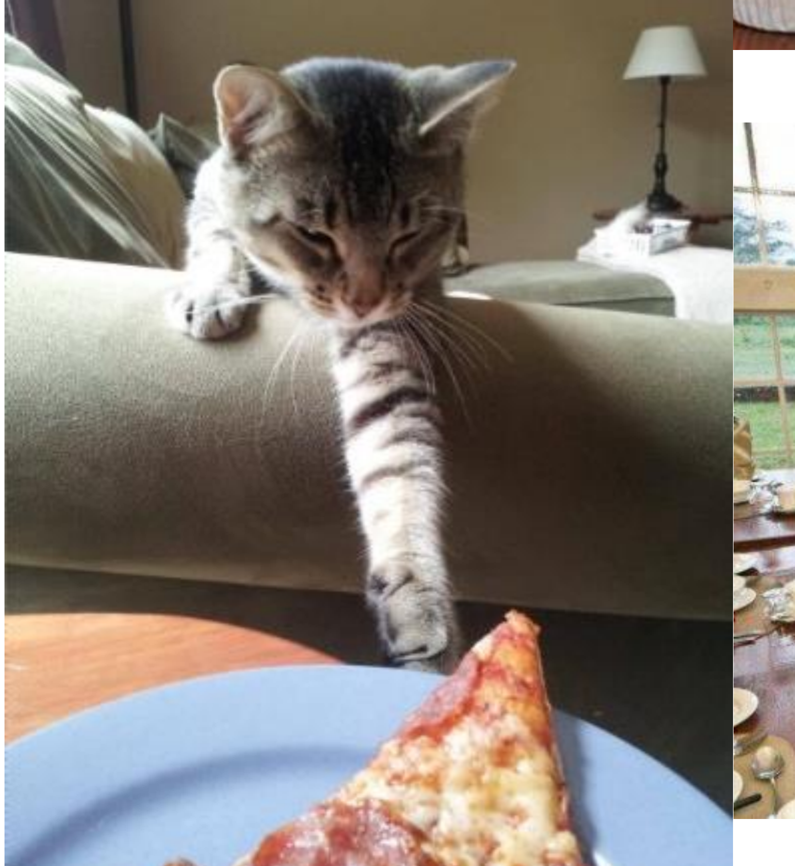
So Much for One Idea to Address High Drug Prices

President Trump Withdraws Plan To End Drug Rebates

The Washington Post (7/11, A1, Abutaleb, Goldstein, Parker) reports the Trump Administration withdrew "one of its key proposals to lower drug prices by eliminating industry rebates in Medicare." The article points out that "the rule is the second major drug pricing effort to collapse this week, revealing the internal conflicts surrounding the question of how to lower prescription drug costs." The article adds that Secretary of Health and Human Services Alex Azar and several "top White House policy advisers...disagreed over the merits of the rule."

The New York Times (7/11, A1, Thomas) reports Judd Deere, a White House spokesman, said, "Based on careful analysis and thorough consideration, the president has decided to withdraw the rebate rule."

Fraud & Abuse



False Claims Act

The False Claims Act: Recovery ($B)

$7
6
5
4
3
2
1
0

Non-Qui Tam
Qui Tam (U.S. Declined)
Qui Tam (U.S. Intervened)

2007 2008 2009 2010 2011 2012 2013 2014 2015 2016 2017

Source: Department of Justice Data

Bloomberg Law

False Claims Act

- The US recovered $2.8 billion under the False Claims Act in 2018.
  - More than $2.5 billion from health care (87%)
  - $1.9 billion of the $2.5 billion health care resulted from *qui tam* actions (2018).
  - Relators recovered $301 million.
  - Down from 2017's $3.4 billion in recoveries. Down from $4.7 billion in 2016.
- 645 new *qui tam* cases were filed in 2018, down from 680 in 2017.
- 9th consecutive year with health care fraud FCA cases bringing in more than $2 billion.

But Watch out for this Person

- The “experienced” whistleblower US recovered $2.8 billion under the False Claims Act in 2018.
  - Cecelia Guardiola, RN (worked in clinical documentation and case management)
    - Successful 3-time relator
      - Christus Spohn Health System (2012, $5 million)
      - Renown Health (2016, $9.5 million)
      - Banner Health (2018, $18 million)
- Quote from Ms. Guardiola’s attorney—”she’s really unemployable at this point in her career”.

Granston Memo

GRAY PLANT MOOTY

- January 2018 Granston Memo outlines 7 factors that DOJ attorneys should use to determine whether to seek dismissal in declined *qui tam* cases.
  - Meritless
  - Parasitic, duplicative, opportunistic
  - Preserve govt. resources, etc.
- 2018 saw a significant increase in number of motions to dismiss filed by DOJ on non-intervened qui tam cases (16 total motions).
- But 11 of the 16 cases involved the same realtor filing what appeared to be copycat *qui tam* suits.
- Lasting impact of the Memo remains unclear.

Interesting FCA Cases

- Private Equity
  - Patient Care America and its private equity fund owner announced in July that they are close to a settlement with the government over an alleged $70 million kickback scheme. A federal judge in Florida agreed to stay the case pending settlement.
    - According to the government, over the course of 8 months, from 2014-2015, the pharmacy racked up $70 million in bogus charges.
    - The case marks the first time that the government has named a private equity owner in an FCA complaint-in-intervention alongside the portfolio company accused of making false claims.
  - Follows on the health of US ex rel. Medrano v. Diabetic Care Rx, LLC (Feb. 16, 2018)
    - Alleges compounding pharmacy paid kickbacks to marketing firms to induce Tricare referrals

Interesting FCA Cases

- Greenway Health (IT company) paid $57.5 million to settle allegations that its software misled purchasers about meeting HHS certification standards.
- SNFs and affiliated consulting company settled FCA case (alleging medically unnecessary therapy services) with payment of $10 million.
- Clinical lab (Inform Diagnostics) settled FCA case with payment $63.5 million (alleged improper EHR subsidies to referring physicians).
- Walgreen's paid $270 million to settle FCA action alleging failure to disclose discounts to Medicaid and overbilling for insulin.

Continued Challenges with the 60-Day Rule

UnitedHealthcare v. Azar, Sept. 7, 2018

- FCA standard: deliberate indifference or reckless disregard
- 60-Day Rule standard: defines "identified" when "it has determined, or should have determined through the exercise of reasonable diligence, that the MA organization has received an overpayment."
- Court vacated the MA Overpayment Final Rule

Credit Balances

- First Coast Cardiovascular Institute had credit balances of $175,000 owed to federal healthcare programs
- Failed to repay credit balances within 60 days
- Settled for $448,821 to resolve allegations that it violated the False Claims Act

OIG Reports

- The 2018 Annual report of the Board of Trustees estimates that the Trust Fund for Medicare Part A will be depleted by 2026. Spending for Part A will outpace US economy. OIG continues to focus on curbing improper spending. For example:
  - Identified $86 million in improper Medicare payments to skilled nursing facilities for beneficiaries not meeting the "3-day rule."

OIG Reports

- OIG Semiannual Report to Congress highlights enforcement activities, OIG's efforts to harness emerging technologies, ensure cybersecurity, and curb harm experienced by Medicare patients in long-term-care hospitals.
  - OIG found that NIH and FDA control over sensitive data was insufficient, recommended both develop more robust security frameworks.
  - 25% of Medicare patients in LTCHs experience temporary harm events and an additional 21% experience more serious adverse events. More than half were preventable with better care.
- OIG's Active Work Plan items show increased attention to Medicare's role in the opioid epidemic, data security and technology concerns.

At-a-Glance Highlights
October 1, 2018–March 31, 2019

$496.42 Million	Expected Audit Recoveries
$246.93 Million	Questioned Costs
$776.58 Million	Potential Savings
$2.30 Billion	Expected Investigative Recoveries
421	Criminal Actions
1,293	Exclusions
331	Civil Actions
212	New Audit and Evaluation Recommendations
186	Recommendations Implemented by HHS Operating Divisions

Fraud & Abuse: Individual Accountability

- Physician borrowed $300,000 from patient. Diagnosed patient with dementia when patient asked to be paid back.
  - Doctor resigned medical license.
- In June, 2019, opioid manufacturer Insys Therapeutics entered a $225 million settlement for various civil and criminal investigations stemming from mail fraud and violations of the False Claims Act.
  - Insys used “speaker programs” to facilitate bribes and kickbacks to targeted practitioners in exchange for increased Subsys prescriptions to patients.
- In August, 2018, Prime Healthcare paid $62 million in Medicare overbilling. The CEO also paid $3.25 million.
  - 14 Prime Hospitals in CA overbilled via upcoding and drove admissions via ER.

Fraud & Abuse: Individual Accountability

- In June 2018, Mass. AG sued Purdue Pharma and the Sackler family, alleging that the parties had misled doctors and patients about the risks of OxyContin and had aggressively marketed the drug to increase prescriptions.
- Kansas cardiologist will pay $5.8 million to settle allegations that he and his medical group submitted false claims to federal health insurance programs for medically unnecessary stents implanted in patients, the U.S. Justice Department has announced. The agreement is the third False Claims Act settlement the government has reached with this doctor.

Fraud & Abuse: Individual Accountability

FCA Settlements Involving Personal Provider Liability

35
30
25
20
15
10
5
0

5
5
6
8
33
26

2013
2014
2015
2016
2017

Projection through the end of 2017

Settlements as of Oct. 20

The Yates Memo was issued in September 2015.

Bloomberg BNA

Recent Enforcement Actions

United States ex rel. Hammett v. Lexington County Health Services District, Case No. 3:14-cv-03653 (D. S.C.) (2016)

- Alleged system "place[d] golden handcuffs on physicians by incentivizing referrals with employment contracts that use excessive compensation formulas that can only be explained as consideration for the past and future referrals the physician will generate."
- System focused on imaging referrals. Tracked volumes, sent out reports and reminders to referring physicians.
- System settled with DOJ.
  - $17 million and enter into CIA to address Stark issues.

Add Some Context Next Time…

HAMMETT MONTHLY COUNTS

45
40
35
30
25
20
15
10
5
0

38.29
26

2010 MRI
LMC MRI

Recent Enforcement Actions

United States ex rel. Mohatt v. HealthCenter Northwest, LLC, 18-CV-80 (Mont.) (2018)

- Whistleblower was hospital's physician network CFO
- FMV, CR & V/V problems with compensation—
- System tracked physician contribution margins and periodically issued "reminders" regarding same
- $24 million settlement

United States ex rel. David Felten, M.D., Ph.D. v. William Beaumont Hospitals, et al., No. 2:10-cv-13440 (E.D. Mich.) (2018)

- 2009 report on physician contract system concluded the situation was a "serious OIG matter". Identified following problems—
  - Physician compensation did not match productivity standards because "no standard performance evaluation metrics exist."
  - Incentive pay was highly variable and little or no outcome data had been used to evaluate job performance or activities.
  - Cash collection for physician activities was well below that of Beaumont's benchmarked institutions in the region
- System settled the claims in 2018 by agreeing to pay $82.74 million to United States and $1.74 million to the State of Michigan.

Recent Enforcement Actions

United States ex rel. Bruno v. Schaeffer, 328 F. Supp. 3d 550, 558–59 (M.D. La. 2018)

- Lab Swapping
    - Alleged that Defendants offered physicians ownership interests in POLs, which existed in name only, and they received payments from the labs in proportion to the number of specimens the physicians sent to a different lab for urine testing covered by private payors.
    - Incentivized the same doctors to send their urine specimens covered by Medicare and Medicaid to a different lab.
- Indirect Compensation Analysis
    - Denying motion to dismiss Stark Law cause of action because Plaintiff sufficiently showed an “unbroken chain of persons with financial relationships”.
- DOJ declined to intervene in April 2018. The litigation is still ongoing and trial is currently set for September 2020.

Recent Enforcement Actions

Abiomed, Inc. pays $3.1 million to settle qui tam arising out of “lavish free meals”

- Sells heart pumps (cost approx. $20,000)
- Dinners exceeded Abiomed’s $150 per person guideline (up to $450 per person)
- DOJ: “attendees ordered alcohol in an amount inconsistent with legitimate scientific discussion”
- Used receipts with fake names, like “Mike Anesthesia”

Recent Enforcement Actions

United States ex . Riedel v. Boston Heart Diagnostics Corporation, 2018 WL 4354944 at *12 (D.C. Sept. 12, 2018)

- Relator alleged:
  - (1) AKS scheme through waivers of co-pays for commercial payor lab tests as way of inducing gov't business; and
  - (2) Paying "outrageous consulting fees to referring physicians" such that their compensation was not FMV or CR.
- The "outrageous consulting fee" was $200,000 in 2012 and 2013 to a nurse practitioner and a physician who "were among the top referral sources" to defendant, and relator alleged that amount was not proportional to the services they provided.
- The Answer was filed November 2, 2018, and the litigation is ongoing.

Recent Enforcement Actions

Oviatt Hearing and Balance, LLC, et al. (December 2018)

- Offered and provided kickbacks through improper inducements to FHCP beneficiaries to induce them to obtain services at Oviatt. Inducements included:
  - Entering beneficiaries into a contest for a free iPad
  - Free Butterball turkeys
  - $15 Visa gift cards
  - $15 Dunkin Donuts gift cards
  - $30 Omaha Steaks gift cards
- Oviatt also allowed audiology students and other non-licensed individuals to perform audiology exams that were billed as if licensed providers rendered services.

Recent Enforcement Actions

GRAY PLANT MOOTY

Hospital Management Associates agreed to pay over $260 million to resolve false billing and kickback allegations.

- Whistleblower had 30 years health care finance experience.
- 2nd *qui tam* case for relator (his other case settled for $613 million)
- Quotas for inpatient admissions (instead of keeping patients in observation).
- AKS & Stark violations alleged at 8 system hospitals:
  - Contracts with ED group where they received bonuses for inpatients
  - Threatened to terminate contracts unless group hit admission targets
  - Leased space at below market rates to referring physicians

Recent Enforcement Actions

Forest Park Medical Center (Dallas, TX)

- Physician-owned hospital
- Nov. 2016—21 individuals (physicians, non-physicians & management) indicted on charges they paid $40 million in kickbacks between 2009-2013
- Attempted to "avoid" gov't patients by selling accounts to other facilities. Alleges $200 million scheme.
- DOJ alleges hospital billed FHCPs over $93 million (2009-2013) despite plan to avoid gov't programs.
- DOJ used Travel Act to extend reach to private health plans.

EKRA: A New Anti-Kickback Law

- The SUPPORT Act included the Eliminating Kickbacks in Recovery Act of 2018 (EKRA) to address the problem of "patient brokering" in treatment centers.
- EKRA fills in the "holes" left by the Anti-Kickback Statute by creating prohibitions specifically for treatment centers, sober homes, and labs.
- The Act makes referring a patient to any of these places in exchange for remuneration a federal crime.
  - Federal crime (punishable by up to $200,000, imprisonment for up to 10 years).
  - Similar prohibition as AKS ("offer", "pay", "solicit" or "receive" remuneration).

EKRA: A New Anti-Kickback Law

- Exceptions in the Act do not mirror the AKS and will require careful attention, especially as it relates to employed marketers and sales force members.
- Applies to all referrals to treatment facilities, homes, labs, even if referral does not involve addiction treatment or recovery services.
- EKRA applies to all payors (and allows govt. to monitor payment arrangements related to services not reimbursable under FHCPs).
- EKRA applies to specific entities, regardless of volume of substance abuse treatment they provide.

Anti-Kickback Statute Developments

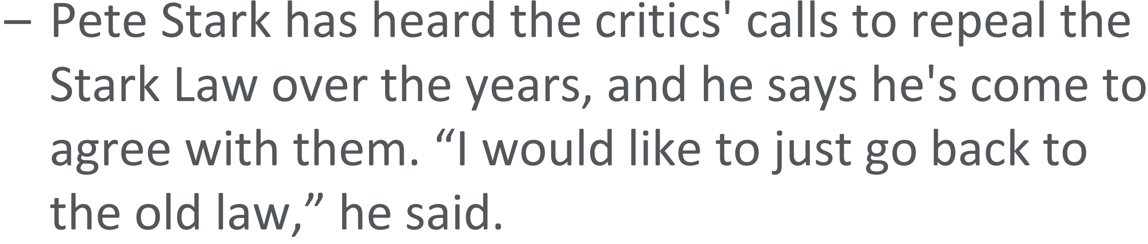
- Inspector General (OIG) Daniel Levinson left office in May
  - Had been IG for 15 years (longest tenure ever)
- New IG: Joanne Chiedi (Acting)
- Proposed safe harbors issued in Feb. 2019 (discount safe harbor)
  - Would remove rebates paid by manufacturers to PBMs under Medicare Part C/D from discount safe harbor
  - Commentary accompanying regulation includes discussion of how OIG views common arrangements
- No new Special Fraud Alerts, Special Advisory Bulletins

OIG Advisory Opinions

- OIG released three advisory opinions (so far) in 2019:
  - 19-03 –program offered by a medical center that provides free, in-home follow-up care to eligible individuals with congestive heart failure.
  - 19-02 –pharmaceutical manufacturer's proposal to loan a limited-functionality smartphone to financially needy patients.
  - 19-01 –charitable pediatric clinic's arrangement under which the clinic waives cost-sharing amounts in certain circumstances.
- Notable 2018 OIG Advisory Opinions:
  - 18-05 –arrangement under which a hospital has established a caregiver center that provides or arranges for free or reduced-cost support services to caregivers in the local community.
  - 18-01 –effect of exclusion from Medicare, Medicaid and all other Federal health care programs.

Stark Law: No Love Lost

From Modern Healthcare:



- Pete Stark has heard the critics' calls to repeal the Stark Law over the years, and he says he's come to agree with them. "I would like to just go back to the old law," he said.

- "Those ***complications were added by high-priced lawyers who tried to build loopholes for their clients***. The original law was pretty simple," Stark said. "Basically it says anyone who takes a bribe or a split or a commission or a kickback in exchange for referring services gets five years or a $50,000 fine."
  - Pete Stark, Aug. 2, 2013

Stark Law Developments

- No advisory opinions in 2018 or 2019
- Self-Referral Disclosure Protocol

Calendar Year	Number of Disclosures Settled	Range of Amounts of Settlements	Aggregate Amount of Settlements
2011	3	$60 - $579,000	$709,060
2012	14	$1,600 - $584,700	$1,236,200
2013	24	$760 - $317,620	$2,468,348
2014	41	$3,322 - $463,473	$5,175,168
2015	49	$5,081 - $815,405	$6,706,458
2016	103	$80-$1,195,763	$6,962,988
2017	47	$83-$575,680	$3,876,588
2018	36	$600-$1,196,188	$3,663,100
Totals	**317**	**$60 - $1,196,188**	**$30,797,910**

Fraud and Abuse Reform

- Jun. 25, 2018, CMS published Stark RFI "Request for Information Regarding the Physician Self-Referral Law" . Aug. 27, 2018, HHS published similar RFI for AKS & CMP
- HHS received 359 comments for AKS and 38 for Stark Law
- Stark Law
  - Establish new payment exception for value-based arrangements
  - More exceptions for "technical" non-compliance
  - Repeal application to compensation arrangements
  - Change advisory opinion process
- AKS and CMP
  - Broader safe harbors/exceptions to cover things like cost-sharing assistance, medical devices, gift cards and technology
  - Revamp OIG Compliance Guidance
  - Replace "one purpose" test with a "balancing test"
  - Make safe harbors applicable to all payor arrangements
  - Formula—if meet CMP exception, deemed compliant for AKS even if not within safe harbor

Changes to Stark in 2019?

- "We are actively working on an update to our Stark regulations ***to be issued later this year***. Some of the changes include clarifying the regulatory definitions of volume or value, commercial reasonableness and fair market value; addressing issues such as lack of signature, incorrect dates or other areas of technical noncompliance; and updating the regulation to address a world in which there are cybersecurity and electronic health records requirements … This will represent the ***most significant changes*** to the Stark law since its inception."

  – Kimberly Brandt, CMS Principal Deputy Administrator

Stark and AKS Reform?

Shared Accountability for Improved Patient Outcomes Act of 2018

- November 13, 2018, H.R. 7122 was introduced to the House of Representatives and referred to the Ways and Means and Energy committees.
- Creates exceptions to AKS and Stark for value-based arrangements.

Stark and AKS Reform?

Medicare Care Coordination Improvement Act of 2017 (HR 4206)

- Provides HHS with identical waiver authority as applies to ACOs under MSSP for entities participating in—
  - Advanced APMs
  - APMs approved by Physician-Focused Payment Model Technical Advisory Committee
  - MIPS APMs
  - Other APMs specified by HHS
  - Must have written arrangement, signed by parties, semi-annual reports to HHS

Stark and AKS Reform?

Medicare Care Coordination Improvement Act of 2017 (HR 4206) (cont.)

- Provides HHS broader authority to create exceptions
  - Changes "risk of program abuse" to "significant risk", including "those that would promote patient care coordination, quality improvement…"
  - CMS prohibited from imposing new regulatory requirements that adversely impact physician care coordination in MIPS or physician participation in APMs
- New statutory (general) exception that removes "volume or value" prohibition
  - For all types of APMs
  - Written arrangement, signed, services identified, semi-annual reports to HHS, tied to APM model and at FMV

Stark and AKS Reform?

Stark Administrative Simplification Act of 2017 (HR 3726)

- Continued emphasis on addressing “technical” violations
- Bipartisan bill, approved unanimously by House Ways & Means (Dec. 21, 2017)
- On June 12, 2018, Senate bill 3054 was introduced to the floor and referred to the Committee on Finance. No action since introduction.
- Creates alternate self-disclosure option and sets penalties at $5000 or $10,000 (depending on timeliness)

HIPAA & Privacy

HIPAA & Privacy Developments

- In Dec. 2018, HHS issued an RFI seeking input on how HIPAA (Privacy Rule) could be modified to promote better coordinated healthcare.
  - RFI requests information on any provisions of the HIPAA Rules that may inhibit information sharing needed for care coordination without endangering patient privacy and security.
  - Seeks comments on specific areas of the HIPAA Privacy Rule like facilitating parental involvement in care and addressing the opioid crisis and serious mental illness.
- OCR continues to publish sub-regulatory guidance and training materials
  - E.g. Jul. 29 and Aug. 15, 2019 free webinar on use of Security Rule Risk Assessment Tool
  - Cybersecurity awareness newsletters
  - Fact sheets and "special topics" documents (e.g., ransomware, mobile devices, mental health, emergency response, de-identification, research, cloud computing, etc.)

HIPAA & Privacy Developments

- Proposed rule on interoperability, information blocking and HIT certification
  - CMS and ONC issued in Feb., 2019
- Focus is on ensuring patient access to data and reducing barriers for data exchange to facilitate care coordination
- OCR set an all-time record in HIPAA recoveries in 2018, totaling $28.7 million.
- Included the largest individual HIPAA settlement in history, totaling $16 million, with Anthem, Inc.

HIPAA Enforcement

GRAY PLANT MOOTY

- *Advanced Care Hospitalists* paid $500,000 for sharing PHI with person who claimed to billing company employee (but no BAA in place).
- *Cottage Health* paid $3M for 2 incidents of server misconfiguration that made PHI available
  on the internet.
- *Pagosa Springs Medical Center* paid $111,400 for failing to remove past employee's remote access to a web-based scheduling calendar.
- *Medical Informatics Engineering* paid $100,000 for incident in which hackers used compromised user ID/password to access PHI (no Risk Analysis at Covered Entity).
- HIPAA obligations continue post-closure (receiver of records agreed to pay $100K to resolve allegations it improperly disposed of records at unsecure shredding facility.
- "OCR is committed to enforcing HIPAA regardless of whether a covered entity is opening its doors or closing them. HIPAA still applies".
  - Roger Severino, OCR Director

2018 Enforcement Actions

Date	Name	Amount
Jan. 2018	Filefax, Inc (settlement)	$ 100,000
Jan. 2018	Fresenius Medical Care North America (settlement)	$ 3,500,000
June 2018	MD Anderson (judgment)	$ 4,348,000
Aug. 2018	Boston Medical Center (settlement)	$ 100,000
Sep. 2018	Brigham and Women's Hospital (settlement)	$ 384,000
Sep. 2018	Massachusetts General Hospital (settlement)	$ 515,000
Sep. 2018	Advanced Care Hospitalists (settlement)	$ 500,000
Oct. 2018	Allergy Associates of Hartford (settlement)	$ 125,000
Oct. 2018	Anthem, Inc (settlement)	$ 16,000,000
Nov. 2018	Pagosa Springs (settlement)	$ 111,400
Dec. 2018	Cottage Health (settlement)	$ 3,000,000
	Total (settlements and judgment)	**$ 28,683,400**

HIPAA Enforcement

- State AG Enforcement – 15 state AGs file data breach lawsuit alleging violation of HIPAA, forcing Medical Informatics Engineering to pay $900,000.
- *U.S. v. Wang* – Chinese nationals indicted on hacking related to Anthem breach.
- *US v. Gottesfeld* – Man convicted of cyberattacks against Boston Children's Hospital, sentenced to over 10 years in prison.
  - Man was arrested while trying to flee to Cuba and rescued by a Disney cruise line.

HIPAA Enforcement: Individual Liability

GRAY PLANT MOOTY

- OCR released a fact-sheet laying out the situations in which a business associate can be held liable for HIPAA privacy violations. Those include:
  - Failure to comply with the requirements of the Security Rule.
  - Failure to provide breach notification to a covered entity or another business associate.
  - Impermissible uses and disclosures of PHI.
- This is part of HHS' push to promote patient security and make liability issues as clear as possible for potential offenders.

HIPAA Breach Highlights

500+ Breaches by Type of Breach
7/1/2015 – 6/30/2019

Improper Disposal 3%
Theft 15%
Loss 4%
Hacking/IT 41%
Unauthorized Access/Disclosure 37%

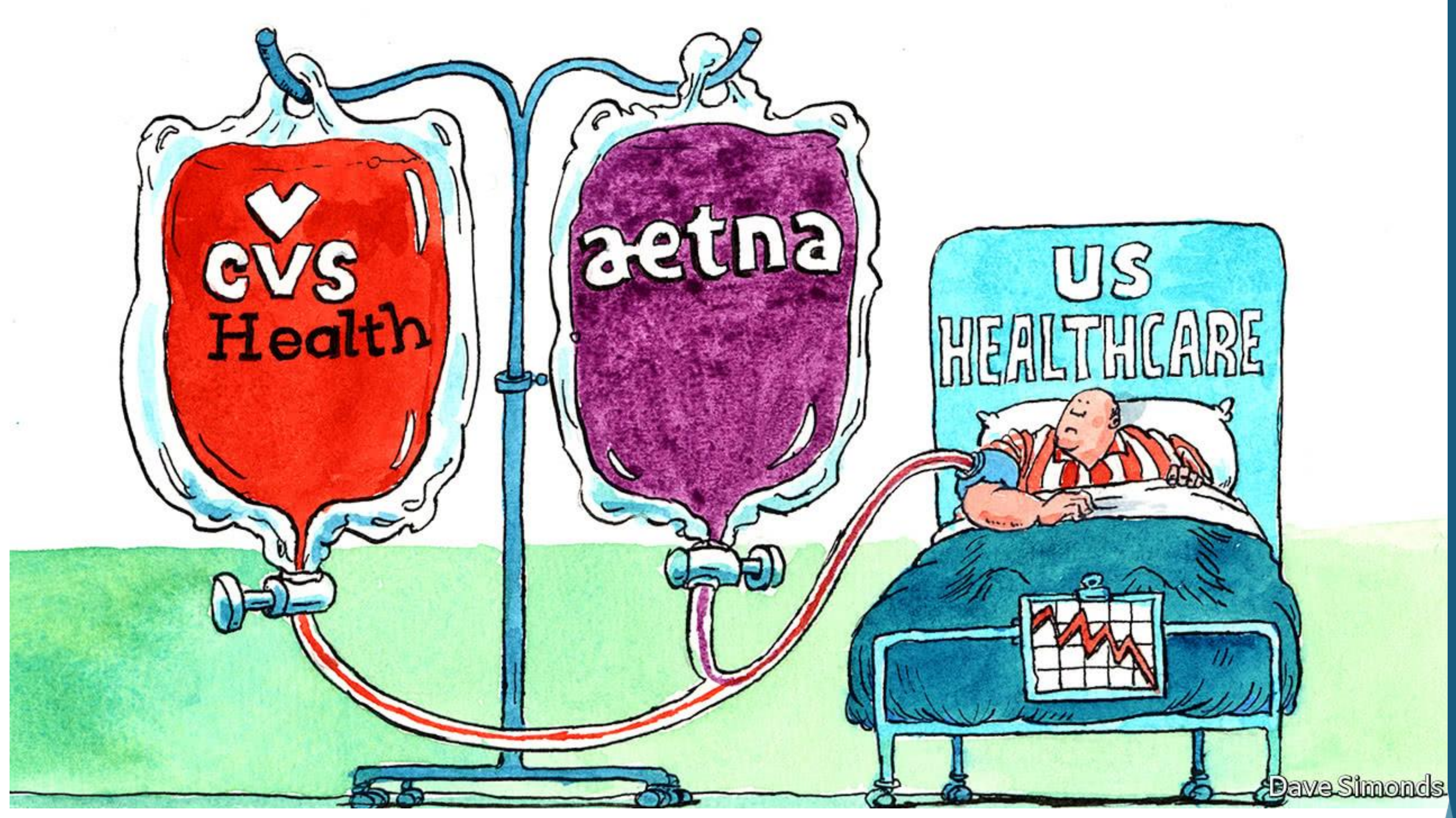
HIPAA Breach Highlights

500+ Breaches by Location of Breach

7/1/2015 – 6/30/2019

Common Rule & Research Update

- "Common rule" revised with a general effective date of 1/21/19.
  - Revisions include an exemption for HIPAA-regulated research and secondary research with broad consent, and requirements for informed consent.
- 21st Century Cures Act to be implemented by the FDA to bring it into alignment with the new Common Rule, specifically regarding informed consent.
- *U.S. v. US Stem Cell Clinic* – FDA is allowed to regulate stem cell clinics that are selling unproven therapies.
- HHS states it would ban research by its scientists on fetal tissue from elective abortions, and would not renew existing grants with outside scientists without additional review.



Antitrust

Antitrust Developments

- Horizontal mergers
  - Aurora & Advocate (closed Apr. 2018)
  - CHI + Dignity = “Common Spirit” (closed Jan. 2019)
  - Baylor + Memorial Hermann (cancelled)
  - Ascension + Providence St. Joseph (cancelled)
- Vertical mergers
  - CVS + Aetna (approved by DOJ in Oct. 2018, under review by court)
  - Cigna + Express Scripts (approved by DOJ in Sep. 2018)
  - Optum + DaVita Medical Group (approved by FTC in Jun. 2019)
    - Optum required to divest HealthCare Partners of Nevada and reach agreement with CO Attorney General

Antitrust Developments

U.S. v. Charlotte-Mecklenburg Hospital Authority (aka Atrium Health)

- CHA has a 50% share in the Charlotte area and its payer contracts prohibit CHA exclusion or listing other hospitals in the same top tier as CHA.
- Sept. 2018 WSJ article exposes the anti-competitive practices.
- Sen. Grassley requests FTC investigation of the hospital’s contracting practices.
- Nov. 2018 – CHA settles case with DOJ by removing existing anti-steering provisions and agreeing not to use them going forward.

Litigation

Medical Staff Privileges

- *Economy v. Sutter East Bay Hospital* – MD suspended from schedule, sued the hospital for lack of notice & hearing, jury awarded $3.8 million
  - District Court affirmed, stating the hearing was required because the hospital had effectively terminated the MD
- *Zamanian v. Jefferson Par. Hosp.* – Court ruled a suspended doctor has a property interest in privileges at public hospital, but in this case the doctor received adequate post-termination review.
- *Peer v. W. Shore Medical Center* – radiologist demoted for substandard care and failing to disclose mental impairment on initial application for privileges, court rules no due process violation.

Disciplinary Action

- *Ndulue v. Fremont-Rideout Health Group* – Physician group suspended an MD who wrote letters implying another MD was incompetent, saying the outrageous language violated the group's Code of Conduct.
- *McGary v. Williamsport Reg'l Med. Ctr.* – surgeon failed to perform at least 100 heart surgeries and 100 lung surgeries within previous year.
- *Gallagher v. Penobscot Community Healthcare* – Disciplinary action after numerous staff and patient complaints of rudeness, bullying, inattentiveness, and other unprofessional behavior.

Updates to NPDB Guidebook

- Guidebook updated October 2018 (new Q & As)
  - Agreement not to exercise privileges during an investigation without actually surrendering the privileges is still reportable.
  - Some requests for additional information during reappointment could be considered the start of an "investigation."
  - Resignation while under a "quality improvement plan" could be considered a resignation while under investigation.
  - A non-renewal of privileges while under investigation is reportable.

Copayment Waivers

- *N. Cypress Medical Center v. Aetna* – Hospital sued plan for underpayment, plan countersues for fraud in misrepresentation of its waiver of copays.
  - Court rules Aetna could not prove it was unaware of hospital's copay waivers and trial court did not abuse its discretion by excluding evidence of hospital's history of kickbacks to physicians; BUT Aetna did not abuse discretion in reducing hospital's payments
- *North Cypress Medical Center v. Cigna* – similar case of the same hospital suing a different insurer for underpayment, court found Cigna did not abuse its discretion in reducing payments.

Other Cases

- Suits based on not providing sign language and foreign language interpreters:
  - *Crane v. Lifemark Hospitals* – Rehab Act and ADA violated when a hospital failed to provide a sign language interpreter to a deaf patient.
  - *Xie v. Memorial Hermann* – first case regarding a failure to provide a foreign language interpreter pending; based on section 1557 of the ACA which allows for liability for unintentional discrimination.
- Increased workplace violence – incidents of violence are 4x higher in health care than in private industry
  - *Secretary of Labor v. Integra Health Mgmt.* – Employers are required to protect employees from incidents of workplace violence.
- Physician-Patient relationship
  - *Warren v. Dinter* - Woman dies from sepsis three days after being declined admission at a local hospital, court rules that a physician-patient relationship was not necessary to maintain malpractice action under Minnesota law.
  - Distinguished case from curbside consults.

Other Cases

- *Brown v. Southern Nevada Adult Mental Health Services*
- A state psychological hospital used "greyhound therapy" on 1500 patients.
  - Bused patients with one-way tickets to other states with no access to resources, food, or medical supplies.
  - Resulted in several patients deaths, homelessness, and violent crimes.
- Federal court dismissed EMTALA claims and ruled Nevada had a right to institute a bussing policy to allocate their scarce financial resources.
- Class action in state court wins jury verdict: $250,000 for each patient, $22 million in total for 89 members in the class.

Public Health

He's one of the busiest men in town. While his door may say *Office Hours 2 to 4*, he's actually on call 24 hours a day.

The doctor is a scientist, a diplomat, and a friendly sympathetic human being all in one, no matter how long and hard his schedule.

According to a recent Nationwide survey:

MORE DOCTORS SMOKE CAMELS THAN ANY OTHER CIGARETTE

International Comparison

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- The US spends more on health care than any other high-income country.
- The US health-adjusted life expectancy is one of the lowest compared to other high-income countries:
  - Some individual states, however, have life expectancies that are on-par with other high income countries, including Hawaii, Minnesota, and Connecticut
- US infant mortality rates are the highest among high-income countries.
- The US spends the most compared to other high-income countries, mainly on physician compensation, pharmaceuticals, and health care administration.

Measles

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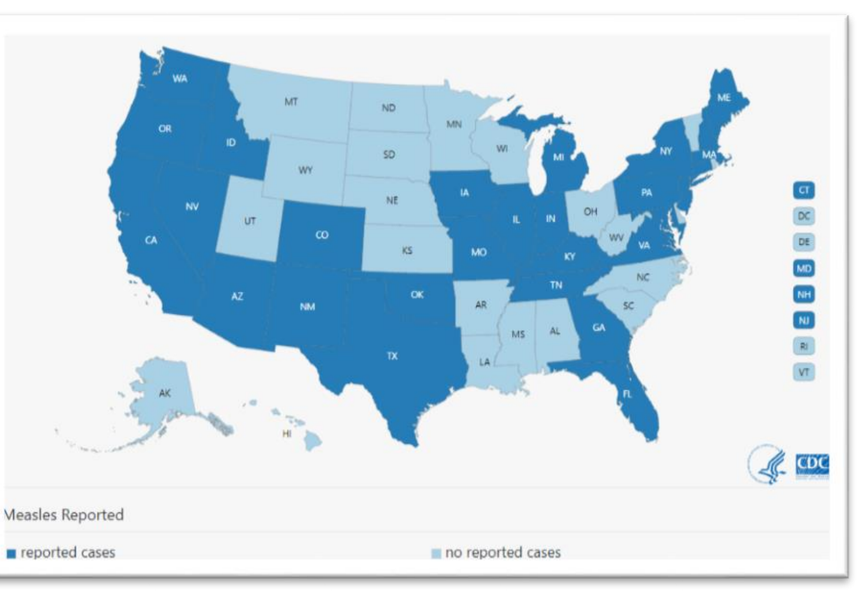
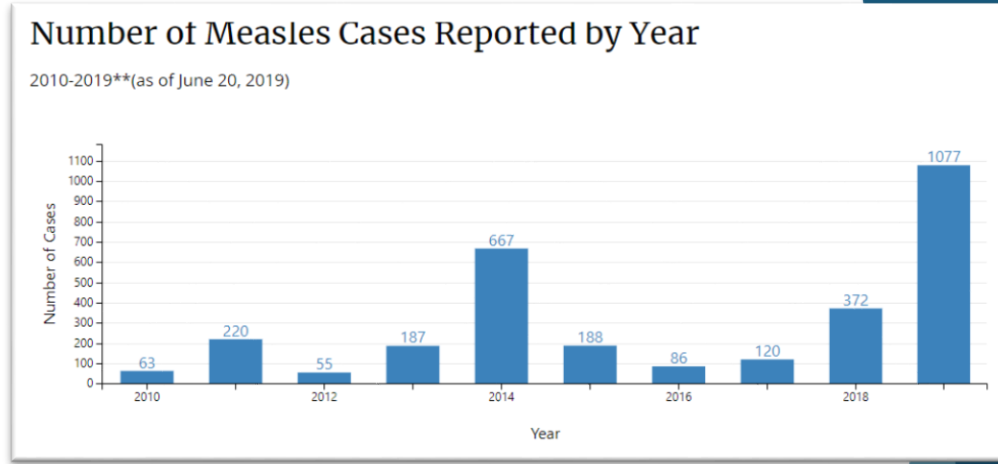
- 2019 is the worst year for measles in nearly three decades in the US
  - In 2000, there were zero cases of measles transmitted by patients within US.
- 1,077 reported cases in 28 states as of June 2019.





Contraception

- Nov. 2018 – Trump administration issues final rule expanding exemptions to contraceptive coverage without notice and comment.
- *Pennsylvania v. Trump* and *California v. Department of Health and Human Services* – lawsuits filed requesting preliminary injunctions against the final rule.
  - Oral arguments heard in *California v. HHS* in the 9th circuit in June 2019.

Abortion

- In May, Alabama passed a bill banning abortions with very limited exceptions and imposing criminal penalties on doctors who perform abortions.
- Since March, Louisiana, Mississippi, Ohio, Kentucky, and Georgia have all passed “heartbeat bills” that ban abortions if a fetal heartbeat can be detected.
- Missouri passed a bill that bans abortions after eight weeks, with exceptions for medical emergencies but not for rape or incest.
- Arkansas and Utah passed laws banning abortions after 18 weeks.
- Many of these laws are currently being challenged in court.

Abortion cont'd

- The AMA is weighing in on recent abortion legislation by suing North Dakota to block two abortion-related laws.
  - Claiming, in part, that the new laws would force doctors who perform abortions to lie to patients and legally require physicians to commit ethical violations.
- In March, the AMA sued in Oregon in response to the Trump administration's new rules for the federal family planning program which would ban doctors from referring pregnant patients for abortions.
- HHS announced it will push back the effective date of a challenged rule that would shield providers from having to take part in abortions if they have moral or religious objections.

Opioid Crisis

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484%

increase in naloxone prescriptions per month from January 2017 to February 2019[1]

$2 BILLION+

in grants from HHS to states, tribes, and local communities to fight the opioids crisis in FY 2018

162

defendants charged for prescribing or distributing opioids and other dangerous drugs as part of the largest Healthcare Fraud Takedown Day in history

64%

increase in medication-assisted treatment patients at HRSA-funded community health centers from 2016 to 2017

Approved

18

state waivers since Jan. 2017 in Medicaid to expand access to inpatient options for substance-use disorder

From Jan. 2017 to Feb. 2019

23%

increase in number of patients receiving buprenorphine monthly[2]

34%

decrease in total opioids dispensed monthly by pharmacies[3]

1.14M+

Americans now receiving medication assisted treatment

$350M+

awarded as part of Healing Communities initiative to reduce opioid overdose deaths by 40% in communities in four states

In 2018

provisional drug overdose deaths began to flatten and decline for the first time

US Department of Health and Human Services

Opioid Enforcement

- Apr. 2019—Charged Rochester Drug Co-Operative (and two executives) in scheme to sell painkillers despite evidence drugs were being diverted.
- Jul. 18, 2019—DOJ files indictment against drug distributor (Miami-Luken) and its president and compliance officer for distributing controlled substances without legitimate medical purpose.
  - Also charged two pharmacists who "ordered millions of opioid pills to facilitate illicit painkiller use"
  - Distributed more than 2.3 million oxycodone pills to two pharmacies located in town that had 1400 residents

Opioid Enforcement

- Temporary restraining orders were filed against two Ohio doctors to prevent them from writing prescriptions – the first-of-their-kind civil injunctions issued under the Controlled Substances Act.
- Jul. 12, 2019—Physician Assistant pleads guilty to federal drug charge For conspiring to distribute Oxycodone, Fentanyl, Methadone and Alprazaolam out of Maryland pain management clinic.
- In 2019, DOJ filed first two criminal cases against drug distributors alleging improper opioid sales

Medicaid's Role in the Opioid Crisis

THE OPIOID EPIDEMIC IS A MAJOR PUBLIC HEALTH CRISIS

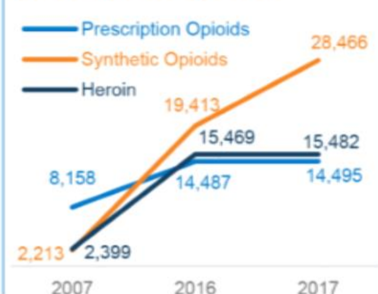
In 2017, **more than 2.1 million** people had an opioid use disorder.

Overdose deaths continue to increase and have more than **doubled** from 2007 to 2017.

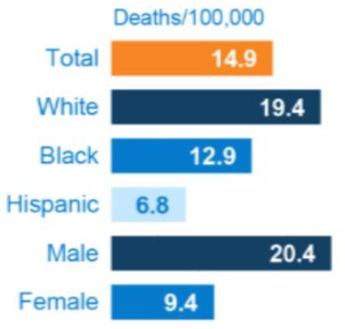
18,516 deaths 2007

47,600 deaths 2017

Overdose deaths from heroin & synthetic opioids are more common than prescription opioids.

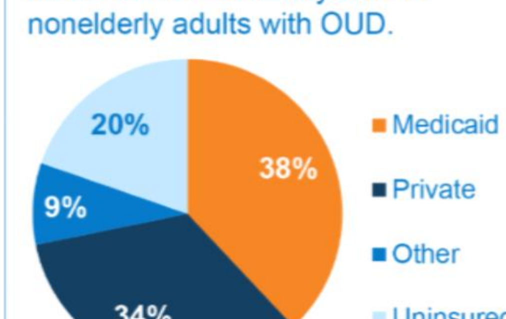


Opioid overdose death rates are highest among **whites** and **males**.



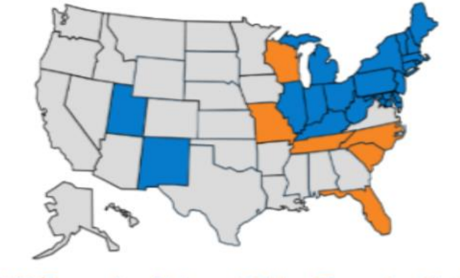
THE ACA BROADENED MEDICAID COVERAGE FOR ADULTS AND STATE CAPACITY TO ADDRESS THE EPIDEMIC

Medicaid covers nearly **4 in 10** nonelderly adults with OUD.



Total: 1.98 Million

26 states with above average opioid overdose death rates are mainly in the northeast, but include both expansion & non-expansion states.



■ 20 Expansion States ■ 6 Non-Expansion States

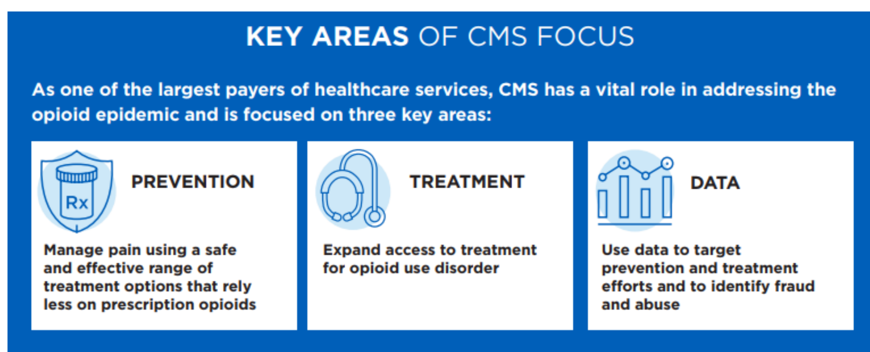
NALOXONE

Nearly all states have made naloxone, a medication that reverses the life-threatening effects of opioid overdoses, available without prior authorization.

Source: Kaiser Family Foundation

CMS and the Opioid Crisis: The SUPPORT Act

- June 2019 – CMS commits $50 million to planning grants to assist states with substance use disorder treatment and recovery.
- The application for planning grants is the first step CMS is taking in implementing section 1003 of the SUPPORT Act, which authorizes CMS to conduct a demonstration project to increase substance use provider capacity.



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SCOTUS

Azar v. Allina Health Services

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- In 2004 CMS published a final rule, with no notice and comment period, announcing that the Medicare Part C days would be included in the Medicare fraction of DSH calculation.
  - CMS uploaded new DSH calculation to internet (but no formal rulemaking process)
- D.C. District Court ruled in Jul. 2017 in favor of the providers, stating the CMS violated the Medicare Act by changing policy without notice and comment.
- Supreme Court determined that the rule created a “substantive legal standard” (under Medicare statute) which required that the agency allow for a 60 day notice-and-comment period.

Azar v. Allina Health Services

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- Implications of the case:
  - CMS may be required to recalculate the pre-FY 2014 Medicare/SSI fractions for potentially all hospitals.
  - Billions of dollars of reimbursement are at state, with potentially far reaching consequences for CMS' ability to issue substantive sub-regulatory guidance under the Medicare Act.
  - Recovery and enforcement actions based on CMS "sub regulatory guidance" is vulnerable.
  - Still not clear what a "substantive legal standard" means for purposes of Medicare statute.

Justice Kavanaugh on Healthcare

- In two ACA cases *(Seven-Sky v. Holder* and *Sissel v. U.S. Dep't HHS*), Kavanaugh dissented from the majority opinion that had rejected a challenge to the ACA. In both, however, he objected only to the reasoning of the court; he agreed with the majority that the complaint against the ACA should have been rejected.
- In a 2017 speech, Judge Kavanaugh praised former Chief Justice Rehnquist for his dissent in *Roe v. Wade* and his resistance to recognizing constitutional rights not explicitly granted by the Constitution.
  - The government has "permissible interests in favoring fetal life, protecting the best interests of a minor, and **refraining from facilitating an abortion**," and it "may further those interests so long as it does not impose an undue burden on a woman seeking an abortion," Kavanaugh wrote in a 2017 ruling.
- In *Hall v. Sebelius,* Kavanaugh wrote for the majority of a three-judge panel holding that an individual who is 65 years or older and who receives Social Security cannot decline an entitlement to Medicare Part A coverage.

Pending SCOTUS Cases

- In June SCOTUS agreed to hear ACA challenges from a number of health insurers who argue that the federal government owes them ACA-related payments.
- Insurers claim they are due money from ACA program that helps companies that attracted sick and expensive customers.
- An earlier appellate court ruling found that the federal government would not have to make the payments.
- SCOTUS will consider three cases in a combined hearing, but the eventual ruling with serve as precedent for other similar pending cases.
- Overall, insurers believe they are owed more than $12 billion by the federal government.

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Break

2019 Health Law Seminar

www.gpmlaw.com

CYBERSECURITY

Managing Threats, Protecting Patients, Responding to Breaches

Michael R. Cohen, CIPP/US,CIPP/E
Julia Reiland

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What We Will Cover Today

- Why healthcare is target for cyberthieves?
- HIPAA Breach Notification
- HIPAA Security Rule
- More than just HIPAA
- How to avoid and prepare for data breach?

Why Healthcare Organizations are Target

- Store a lot of detailed personal information about patients
- Social security numbers, addresses, credit card data, digital medical files.
- Hackers can sell this data on dark web or use it to commit medical fraud
- Free healthcare or medical equipment

Why Healthcare Organizations Vulnerable

- Legacy or outdated systems running outdated software
- Designed to minimize cost and maximize efficiency creating less security
- More focused on healthcare mission and not cybersecurity mission
- Leverage multiple external vendors that introduce risk

Five Cyber Risks for Healthcare

1. Email phishing attacks
2. Ransomware attacks
3. Loss or theft of equipment or data
4. Insider, accidental or intentional data loss
5. Attacks against connected medical devices that may affect patient safety

Cybersecurity and Patient Safety

- Malware capable of adding tumors into CT and MRI scans
- Vast majority of hospitals and physicians unprepared to handle cybersecurity threats
- Connection to the internet allows data integration, easy access to patient records, and improved patient care
- Increased reliance on technology and the internet makes one vulnerable to cyberattacks

HIPAA Security Rule

- HIPAA Privacy Rule deals with Protected Health Information (PHI)
- HIPAA Security Rule deals with electronic PHI
- Establishes a set of security standards for protecting important patient health information that is stored or transferred in electronic form

HIPAA Security Rule

Covered entity must maintain reasonable and appropriate administrative, technical, and physical safeguards to protect e-PHI.

Risk Analysis and Management

- The Administrative Safeguards provisions in the Security Rule require covered entities to perform risk analysis as part of their security management processes.
- Risk analysis is an ongoing process.

HIPAA Breach Notification Rule

- A **breach** of protected health information ("PHI") is defined as the acquisition, access, use, or disclosure of unsecured PHI, in a manner not permitted by **HIPAA**, which poses a significant risk of financial, reputational, or other harm to the affected individual.

HIPAA Breach Notification

- Impermissible use or disclosure of unsecured PHI is **presumed** to be a breach unless the CE/BA can demonstrate there is a **low probability** that the PHI was compromised

- CE/BA has burden to prove this low probability based on **four factors**:
  - Nature and Extent of Unsecured PHI Involved
  - The Unauthorized Person Who Used The Unsecured PHI / To Whom Unsecured PHI Disclosed
  - Whether Unsecured PHI Actually Acquired / Viewed
  - Extent To Which Risk to Unsecured PHI Has Been Mitigated

Notification Obligation

- Covered entity must notify affected individuals, HHS, and in some cases, the media of a breach of unsecured PHI.
  - HHS publishes list of 500+ person breaches on its website
- All notifications must be made without unreasonable delay
  - No later than 60 calendar days after discovery, or date the breach would have been discovered with reasonable diligence
  - 60 day period not tolled by time spent in analysis or investigation
  - Limited delay permitted if requested by law enforcement
- Business associate must notify covered entity of data breach

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Cyber Security Guidance Material

In this section, you will find educational materials specifically designed to give HIPAA covered entities and business associates insight into how to respond to a cyber-related security incidents.

Cyber Security Checklist and Infographic

This guide and graphic explains, in brief, the steps for a HIPAA covered entity or its business associate to take in response to a cyber-related security incident.

Cyber Security Checklist - PDF

Cyber Security Infographic [GIF 802 KB]

Ransomware Guidance

HHS has developed guidance to help covered entities and business associates better understand and respond to the threat of ransomware.

Ransomware - PDF

National Institute of Standards and Technology (NIST) Cybersecurity Framework

This crosswalk document identifies "mappings" between NIST's Framework for Improving Critical Infrastructure Cybersecurity and the HIPAA Security Rule.

NIST Cyber Security Framework to HIPAA Security Rule Crosswalk - PDF

OCR Cyber Awareness Newsletters

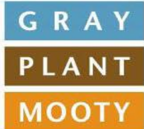
In 2019, OCR moved to quarterly cybersecurity newsletters. The purpose of the newsletters remains unchanged: to help HIPAA covered entities and business associates remain in compliance with the HIPAA Security Rule by identifying emerging or prevalent issues, and highlighting best practices to safeguard PHI. Visit our Cybersecurity Newsletter Archive page to view previous newsletters from 2016.

- Spring 2019 OCR Cybersecurity Newsletter: Advanced Persistent Threats and Zero Day Vulnerabilities - PDF

Compliance With Data Privacy and Security Laws –Not Just HIPAA

Healthcare organizations need to be familiar with HIPAA and other state, federal, and global data privacy laws that apply to the data they collect, store, and use when providing services.

WHY?



A Legal Guide To PRIVACY AND DATA SECURITY

A Collaborative Effort

Minnesota Department
of Employment and
Economic Development

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Not Just About HIPAA Protected Health Information (PHI)

- Protected health information under HIPAA as well as employee information, and other personal , sensitive or proprietary information collected and stored by organization
- All states have data breach notification laws with varying requirements and obligations
- California Consumer Privacy Act (CCPA) with private right of action takes effect January 1, 2020.

CALIFORNIA CONSUMER PRIVACY ACT

Alastair Mactaggart
California Real Estate Developer

"I just think the data use by these companies is out of control"

California Consumer Privacy Act

- Effective - January 1, 2020
- New consumer rights to access, deletion, and porting of personal data
- Specific disclosure requirements
- Penalties with statutory damages and **private right of action**

Who is Covered ?

- For profit companies doing business in California
- More than $25 million annual gross revenue
- Buy, sell, receive, or share personal information of 50,000 or more consumers or devices
- Derive 50% or more of annual revenue from selling personal information

Personal Information

- Identifies, relates to, describes or is capable of being associated with or could reasonably be linked, directly or indirectly, with a particular consumer or household.
- More expansive and ambiguous definition than any existing privacy law

Exemptions for Health Care data

- Protected Health information (“PHI”) collected by covered entity or a business associate governed by HIPAA exempt
- Certain clinical trial data exempt
- Healthcare entities including hospitals that operate as not-for profit organizations are exempt
- Patient information is not defined in CCPA
- Non PHI information may be covered by CCPA

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Private Right
of Action

Data Security Under CCPA

- CCPA allows for private right of action in event of unauthorized access and exfiltration, theft, or disclosure of non-encrypted personal information as a result of a business violation of their duty to maintain reasonable security procedures and practices.

Enforcement: Individual or Class Actions/CA Attorney General

- Consumers may bring private individual or class actions if:
  - The consumer's nonencrypted or nonredacted personal information (as defined by CA data breach notification statute) is subject to an unauthorized access and exfiltration, theft or disclosure
  - As a result of the businesses violation of the duty to implement and maintain reasonable security procedures and practices appropriate to the nature of the information
- May recover $100 to $750 per violation or actual damages, whichever is higher
- If the CA AG decides to pursue a case, civil penalties of $2,500 per violation, or $7,500 for each intentional violation
- CA AG Rulemaking – Final rules due by July 1, 2020

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Practical Approach...

TAKE
ACTION

Collect only the Data You Need

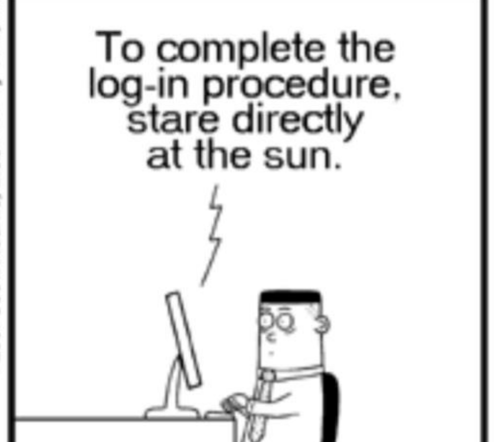
Develop a Foundational Understanding of Information Security

"The effective application of administrative, physical, and technical controls to protect the confidentiality, integrity, and availability of information"

Understand Your Unique Requirements

Maintain a Process for Information Governance

Security vs. Usability – It's a Balance



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Third Parties Are Weak Link

- Federal and state regulators investigate how businesses manage data security and entrust information and access to others
- Your business might be “business associate “ under HIPAA
- Managing vendors becoming key part of privacy risk management

Prepare an Incident Response Plan

Action Items-Practical Takeaways

- Review all vendor and contractor relationships to ensure BAAs are in place as appropriate and address breach/security incident obligations
- Risk analysis and risk management should be ongoing and integrated into organization’s processes

Action Items-Practical Takeaways

- Incorporate lessons learned from incidents into the overall security management process
- Provide training specific to organization and job responsibilities and on regular basis
- Reinforce critical role of all employees in protecting privacy and security

Not this...

Information Governance

- You can protect only the personal information you know you have.
- What are your information assets?
- What is your information lifecycle?
- Do you have clear policies and processes?
- Are they known and followed by everyone?

Consider ALL Potential Vulnerabilities

Common types of Security Threats ("Threat Vectors")

- Malware
- Phishing
- Vishing
- Ransomware
- Insider activity
- Social Media

Don’t Forget Human Element

Please read attach message from Helpdesk Administrator. You are required to follow the activation procedure.

Thank You.

Helpdesk Suport.

<u>Attacks are not this obvious!</u>

Engage Trusted Professionals

- Consultants to perform objective assessment and suggest remediation
- Follow NIST or similar framework
- Engage your organization's leadership

Patch Management

- Document and follow a patch management program
- Many data breaches result from exploiting known vulnerabilities with available patches
- Microsoft released a patch protecting systems from WannaCry but many organizations failed to install it and remained vulnerable

Use Encryption

- Use encrypted messaging software
- Encrypting data at rest and in transit
- Ensure service providers (vendors, cloud providers) comply with your encryption requirements
- Understand your requirements for encryption
- Not a data beach under HIPAA if data encrypted

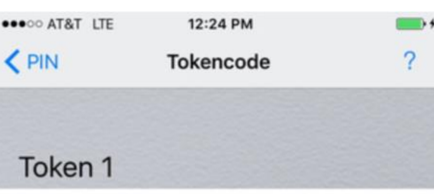
Passwords

THE WALL STREET JOURNAL

"Now I have to change my dog's name in order to remember my new password."

Strong Password Protection

- According to one survey 17% of users have 123456 as their password
- Choose strong passwords and have a password management program that requires changes
- Strong passwords are more effective than frequent password changes



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Log Off and Shut Down

- Best way to avoid unauthorized use and access is to log off and turn off devices when not in use.

Educate Everyone

User Awareness – Best Defense

Final Thoughts

- Train and educate all board members, management, and employees, regarding data security threats and how to avoid them
- Implement information governance policies and procedures
- Educate all board members, management, and employees on all relevant data privacy and security related policies and procedures

Final Thoughts

- Create Incident Response Team and Plan
- Data security is a challenge and demands constant attention and updating
- Engage Professionals to perform risk analysis

Cybersecurity Is A Team Sport

When, not if…

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There are only two types of companies: those that have been hacked and those that will be. And even they are converging into one category; companies that have been hacked and will be hacked again.

---Robert S.Mueller, III

Former Director, FBI

Questions?

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INSURANCE COVERAGE OPTIONS FOR HEALTHCARE ORGANIZATIONS

PRESENTED BY: CARLA BORDA

JULY 25, 2019

AGENDA

- Program Categories
- Management Liability Overview
- Strategies for Key Insurance Coverages
- Q&A

INSURANCE PROGRAM CATEGORIES

- Property
- General Liability
- Workers Compensation
- Auto
- **Management Liability**

MANAGEMENT LIABILITY OVERVIEW

- **Directors & Officers Liability (D&O)**
- Employment Practices Liability
- Fiduciary Liability
- Crime
- **Medical Malpractice/Medical Professional (E&O)**
- **Cyber Liability**
- Billing Errors & Omissions
- Managed Care Errors and Omissions

OVERVIEW OF D&O INSURANCE

Side A	Side B	Side C
Company pays loss on behalf of the insured persons resulting from claims against insured persons for wrongful acts except for loss which the insured organization pays as indemnification	Company pays loss on behalf of the insured organization resulting from claims against insured persons for wrongful acts which the insured organization pays as indemnification and loss resulting against the insured organization for wrongful acts	Company pays on behalf of insured organization for wrongful acts
Non-Indemnifiable	Indemnifiable	Entity Only

D&O COVERAGE SOLUTIONS

- Addresses Personal Liability for allegations of:
  - Mismanagement
  - Breach of fiduciary duty
  - Self-dealing

- Regulatory Coverage
  - False Claims Act
  - HIPAA
  - Anti-Trust
  - Billing Fraud – E&O

- Notable Points
  - Regulatory coverage is typically sublimited
  - Coordinate with E&O and Cyber programs
  - Ensure carrier has dedicated healthcare expertise

EMPLOYMENT PRACTICES

- Breach of employment contract
- Employment discrimination
- Employment Harassment
- Retaliation
- Workplace Tort
- Wrongful Termination
- Wrongful Employment Decision

FIDUCIARY

- Breach of the responsibilities, obligations or duties imposed by ERISA upon the fiduciaries of a sponsored Plan
- Negligent act, error or omission in the administration of any Plan
- Any other matter claimed against an insured by reason of service as a fiduciary

CRIME

- Employee Dishonesty
- Premises
- In Transit
- Forgery
- Computer Fraud
- Funds Transfer Fraud
- Money Orders & Counterfeit Currency
- Client Coverage
- Telephone Fraud
- Social Engineering Fraud
- Expense

MEDICAL MALPRACTICE/E&O SOLUTIONS

- Coverage Overview
  - Claims made or occurrence
  - Tail provisions
  - Covers physicians and other licensed healthcare professionals for defense and damages arising out of the rendering or failure to render professional services
  - Peer Review and Credentialling
  - Vicarious Liability for the corporation
  - Medical Directorships

- Regulatory Coverage
  - Disciplinary Board investigations

- Notable Points
  - Regulatory coverage is typically sublimited
  - Coordinate with D&O and Cyber programs
  - Partner with broker and carrier with dedicated expertise

CYBER LIABILITY INSURANCE

- What does it cover?
- Does it cover anything?
- How much should I buy?

ANATOMY OF A BREACH

Discovery of a Data Breach

- Theft, loss, or Unauthorized Disclosure of Personally Identifiable Non-Public Information or Third Party Corporate Information that is in the care, custody or control of the Insured Organization, or a third party for whom the Insured Organization is legally liable

Evaluation of the Data Breach

- Forensic Investigation and Legal Review

Managing the Short-Term Crisis

- Notification and Credit Monitoring
- Public Relations & Crisis Management

Handling the Long-Term Consequences

- Class-Action Lawsuits
- Regulatory Fines, Penalties, and Consumer Redress
- Reputational Damage
- Income Loss

Source: Beazley Insurance Company

CYBER INSURANCE OVERVIEW

Breach Response Team consultation

(carrier, broker, IRP)

1st Party Coverage: Forensics, Legal

(carrier/client vendors, IRP, carrier, broker)

1st Party Coverage: Notifications, Crisis Mgmt, PR, Legal, Data Restoration

(carrier/client vendors, IRP, carrier, broker)

3rd Party Coverage: Litigation, Regulatory

1st Party Coverage: Business Income/Extra Expense

(carrier/client vendors, IRP, carrier, broker)

CYBER INSURANCE COVERAGE – 1ST PARTY

Coverage	Description
Business income/contingent business income loss	• Reimbursement of loss of income due to a suspension of computer systems (time frame deductible). Reimbursing loss of income due to a data breach to a dependent business partner during the policy period.
Notification and credit monitoring/crisis management	• The cost of notifying the individuals whose data has been compromised and the offering of services to monitor suspicious credit activity.
Data asset restoration/forensics/legal/compliance	• Reimbursement of costs to recover, reinstate and recreate intangible assets destroyed during a cyber attack. Forensics obtained to determine what and whose information was stolen. Legal/compliance to determine regulatory and statutory requirements. Breach response assistance.
Cyber extortion/Ransomware	• Reimbursing investigation expenses and ransom payments resulting from malicious threats and actions to your organization’s computer system.

CYBER INSURANCE COVERAGE – 3RD PARTY

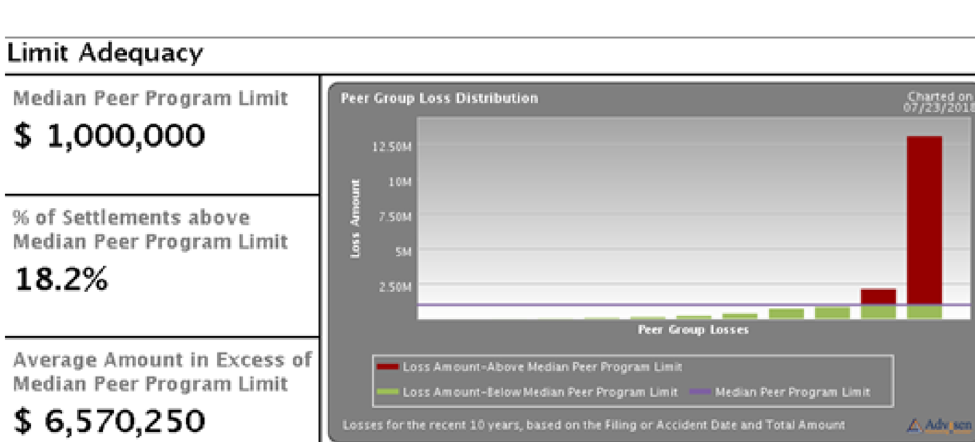
Network security/privacy	• Class actions and suits brought (including employees) which result in a monetary payment due to the disclosure of private and confidential information.
Regulatory defense and civil penalties	• Investigation, fines and penalties that you are legally required to pay
Media liability	• Legal liability arising from media content transmitted on any computer system. Harm suffered by others due to an infringement of an intellectual property right. Defamation and slander.

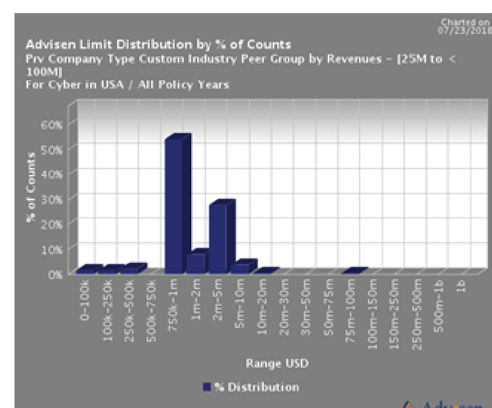
CYBER INSURANCE RESOURCES

- Post-Breach
  - Response team
  - Negotiated vendor relationships
  - Privacy attorneys/forensics/PR
- Pre-Breach
  - Employee training modules
  - Cyber risk assessments
  - Cybersecurity consultation
  - Hardware/software offerings
  - Discounted services (pen tests, scans, etc.)

HOW TO ASSESS CYBER RISKS?

- Understand critical assets
- Determine risk strategy
- Risk assessment
- Modeling/analytics
- Have a plan!





BILLING ERRORS & OMISSIONS

- Medicare/Medicaid Audit –defense and indemnity (fines & penalties)
- Commercial payor Audit – defense for billing fraud
- STARK investigations –defense and indemnity (fines & penalties)
- EMTALA – defense and indemnity (fines & penalties)

MANAGED CARE ERRORS & OMISSIONS

- Provider Selection
- Utilization Review
- Quality Improvement
- Claim services
- Pay for performance
- Advertising, marketing, selling or enrollment for health care, consumer directed health care, behavioral health, prescription drug, dental, vision, long or short term disability, establishing networks, design or implementation of financial incentive plans, development or implementation of clinical guidelines; services or activities performed in the administration or management of healthcare

QUESTIONS?

Intelligence is the ability to adapt to change. ~ Stephen Hawking

Lunch in Minnesota Ballroom

2019 Health Law Seminar

www.gpmlaw.com

Recent False Claims Act Developments and Trends

Moderator: Greg Merz, Gray Plant Mooty

Eric Yaffe, Gray Plant Mooty
Susan M. Coler, Halunen Law

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Break

2019 Health Law Seminar

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Exploring New Frontiers: Health Care Transactions

Mark Williamson
Sarah Duniway
Catie Bitzan Amundsen

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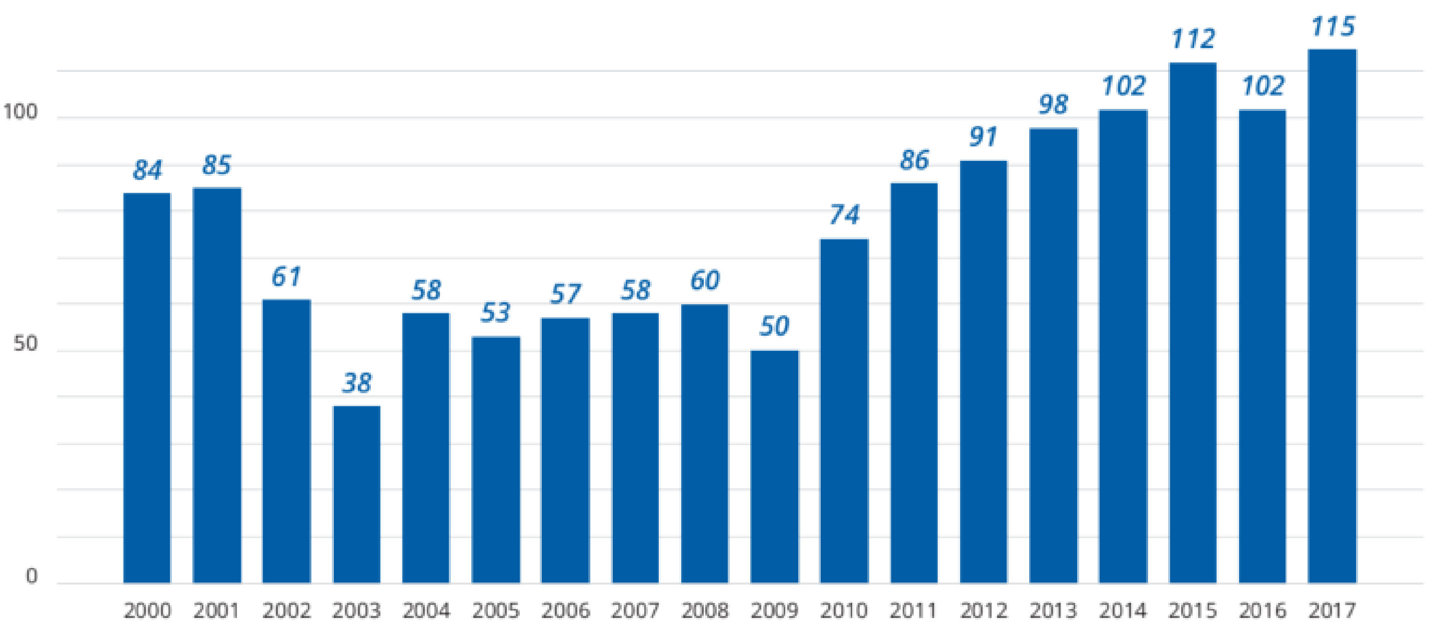
Overview

1. Who is driving transaction activity and why
2. Pre-deal planning
3. Deal process and key issues
4. Questions

Who is Driving Transaction Activity and Why

Hospital and Health Systems M&A Activity, 2000-2017

Figure 1. Hospital and Health System M&A Activity, 2000-2017



Source: Kaufman Hall Transactions Data

Skilled Nursing
M&A Activity, 2016-Q1 2019

U.S. Skilled Nursing Facilities M&A
Closed Transactions

25
20
15
10
5
-

Q1 '16 | Q2 '16 | Q3 '16 | Q4 '16 | Q1 '17 | Q2 '17 | Q3 '17 | Q4 '17 | Q1 '18 | Q2 '18 | Q3 '18 | Q4 '18 | Q1 '19

Source: S&P CapIQ

Home Health
M&A Activity, 2016-Q1 2019

U.S. Home Health M&A
Closed Transactions

16
14
12
10
8
6
4
2
-

Q1 '16 Q2 '16 Q3 '16 Q4 '16 Q1 '17 Q2 '17 Q3 '17 Q4 '17 Q1 '18 Q2 '18 Q3 '18 Q4 '18 Q1 '19

Source: S&P CapIQ

Hospitals and Health Systems: Nonprofit vs For-Profit Targets

Figure 8. Not-for-Profit versus For-Profit as Transaction Targets, 2012-2017

Transaction Target Split – % FP / % NFP

	2012	2013	2014	2015	2016	2017
% NFP	83.5%	89.4%	83.8%	79.5%	76.5%	67.8%
% FP	16.5%	10.6%	16.2%	20.5%	23.5%	32.2%

Source: Kaufman Hall Transactions Data

Hospitals and Health Systems: Nonprofit vs For-Profit Acquirers

Figure 9. Not-for-Profit versus For-Profit as Transaction Acquirers, 2012-2017

Transaction Acquirer Split - % FP / % NFP

	2012	2013	2014	2015	2016	2017
% NFP	78.0%	76.1%	75.7%	73.4%	73.5%	72.2%
% FP	22.0%	23.9%	24.3%	26.6%	26.5%	27.8%

Source: Kaufman Hall Transactions Data

Large Payor Vertical Integration

MN Hospitals Affiliated with a Health Care System, 1995-2016

Number of Hospitals

100
90
80
70
60
50
40
30
20
10
0

1995 1996 1997 1998 1999 2000 2001 2002 2003 2004 2005 2006 2007 2008 2009 2010 2011 2012 2013 2014 2015 2016

Affiliated No Affiliation

Source: MDH Health Economics Program analysis of hospital annual reports, February 2018.

MN Hospital Beds by Health System

Number of Hospitals

0 2 4 6 8 10 12 14 16

2001
2006
2011
2016

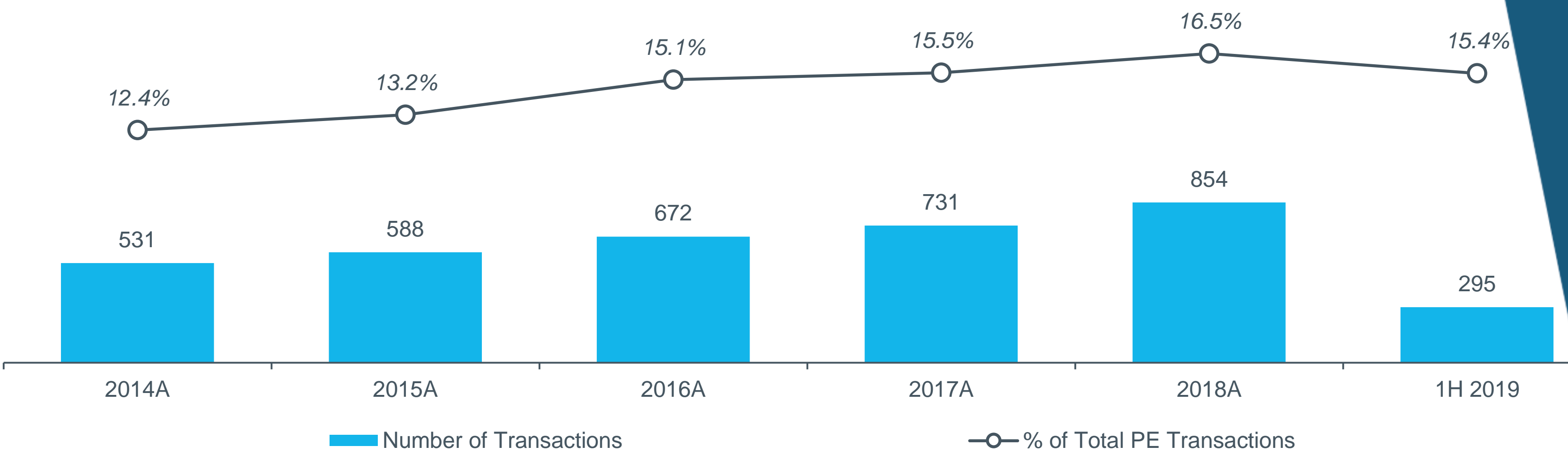
- Allina Health System
- Fairview Health Services
- Essentia Health
- Mayo Clinic
- Sanford Health
- CentraCare Health System

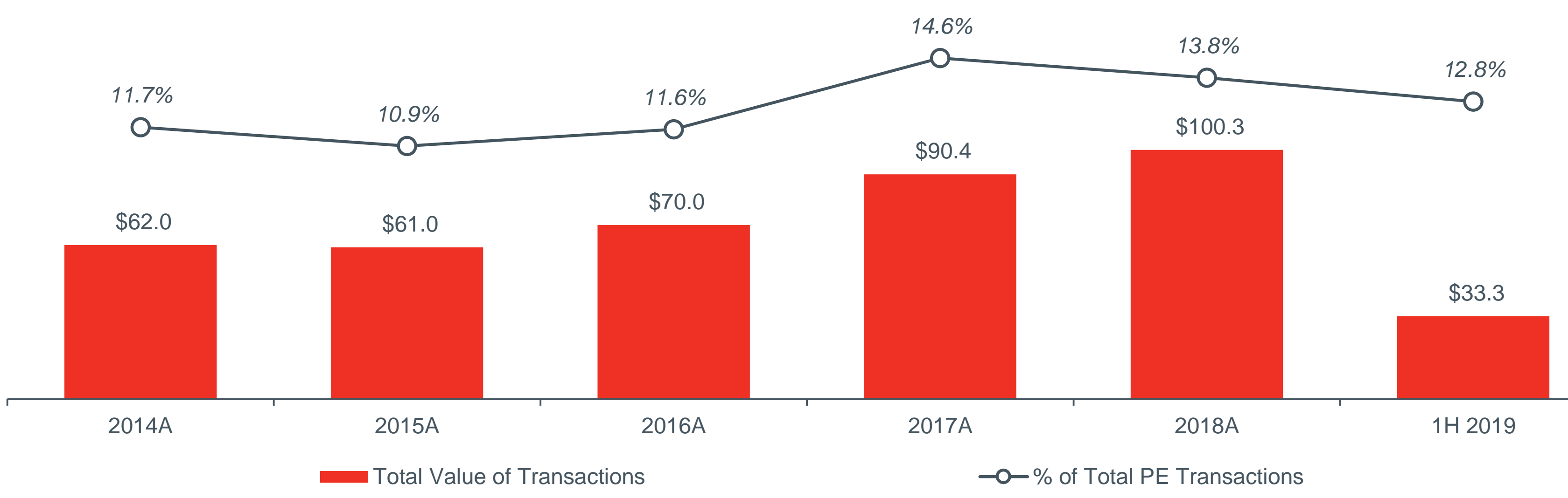
200 Beds 1,000 Beds 2,000 Beds

Source: MDH Health Economics Program analysis of hospital annual reports, February 2018.
Only includes systems with five or more hospitals in 2016.

14

Private Equity in Health Care





Source: Duff &Phelps

Common Purchasers

- Strategic
  - Other health care providers
  - Health plans
  - Technology companies
- Financial
  - Private equity
  - REITs

Strategic Purchasers

- Vertical integration
  - Patient convenience & improved continuum of care
  - Capture growth
  - Control quality & outcomes – better for outcome-based payment
- Pressure for scale and ability to share risk across service lines
- Technology costs
- Increase leverage with payors
- Generational shifts

Financial Purchasers

- Private Equity
  - Private Equity Fund
  - Independent Sponsor ("fundless sponsor")
  - Private-equity backed company
- REITs
  - Tax-preferred mechanism for investing in real estate
- Sources of Funds
  - Pension funds
  - Endowments
  - Foundations
  - Financial institutions (investment banks, commercial banks)
  - Hedge funds
  - Wealthy individuals

Financial Purchasers

- Responding to the same growth and demographic trends as strategic purchasers
- May have greater interest in ancillary/supportive services
  - IT, equipment, staffing, practice management, facilities, diagnostic imaging, packaging, sales
- What private equity investors look for
- Structure of deal, including rollover equity
- Quality of earnings analysis
- Management incentive programs

Pre-Deal Planning

Importance of Pre-Deal Efforts

- All parties understand the “why” and goals of a deal
- Identify strategic vision and rationale for each party
- Ensure parties’ cultures and organizational missions align
- Evaluate impact on current business and referral relationships
- Consider implications for other business & contractual relationships
- Identify potential obstacles
- Identify potential deal structure and process

Pre-Deal Legal Review

Depending on potential structure and parties:

- Anti-kickback Statute (42 USC 1320a-7b)
- FMV
- Commercial Reasonableness
- Stark (42 USC 1395m) physician self-referral law
- Civil Monetary Penalty (42 USC 1320a-7a(b)) against payments to reduce or limit services
- Antitrust
- Tax-Exemption
- Debt Covenants
- Religious Directives or other restrictions

Strategic Purchasers: Range of Options

Independent Operations

Purchased or Shared Services Agreement

Collaboration Agreement or True JV

Bring in as Subsidiary

Merger or Acquisition

Deal Process and Key Issues

Typical Deal Process

Due Diligence (4 – 6 Weeks)

- Preliminary discussions
- Sign **Confidentiality Agreement**
- Buyer conducts due diligence

Letter of Intent Stage (2 Weeks)

- Buyer continues due diligence
- Seller conducts due diligence on Buyer
- Draft, negotiate and sign **Letter of Intent**

Definitive Agreement *"Signing"* (4 Weeks)

- Buyer continues due diligence
- Draft and negotiate definitive and other agreements
- Seller prepares disclosure schedules
- Sign **Definitive Agreement**

Finalize Transaction *"Closing"* (4 – 8 Weeks)

- Obtain HSR approval (if necessary)
- Obtain other regulatory approvals
- Obtain third-party consents
- File documents with SEC (if necessary)
- Hold shareholder meeting (if necessary)
- Close transaction

1 4 8 12 16 20 24

Hot Button Issues

- Money/purchase price
- Commitments
  - Capital, funding, recruitment, retention
- Antitrust enforcement
- Governance
  - Who gets a seat at the table? For how long?
- Leadership
- Naming
- Control and ongoing support of existing programs & services

Hot Button Issues

- Breach/remedies
  - Financial penalties
  - Dilution of interests
  - Loss of governance or other rights
  - Corrective action
  - Termination

Due Diligence!

- Know yourself…
- Other party:
  - Learn about their business
  - Identify liabilities and compliance risks
  - Identify assets
  - Identify consents/notices that may be needed
- Start building your post-closing checklist
- Be prepared to revise deal structure or walk away, depending on results of due diligence

Other Issues to Consider

- 501(c)(3) analysis, if applicable
  - Transferability of assets
  - AG notice
  - Bond financing compliance
  - Community benefit 501(r) compliance
- Licensing
  - Transferable? How long?
  - Is buyer eligible to hold?
- Professional licensing/corporate practice of medicine

Other Issues to Consider

- Payor relationships
  - Will they follow?
- Stakeholder interests
  - Employees
  - Referral sources
  - Patients/residents
  - Community served
- Insurance coverage
- IT and operational systems integration

Other Issues to Consider

- Post-Deal Legal Considerations
  - Reps and Warranties Insurance
  - Who has ability to enforce deal terms after closing?

Post-Closing Operations

- Integration does not magically happen …
  - Form integration teams
    - Post-signing, pre-closing
    - Identify all promises and commitments and operationalize to ensure both sides get what they bargained for
    - Operation under new entity requires education (new policies, procedures, etc.)
  - Develop post-closing checklist & work plan

Questions?

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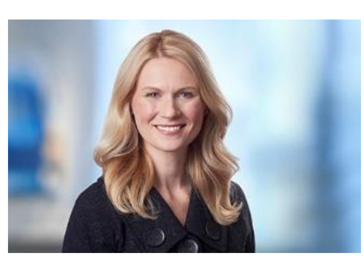

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2019 Health Law Seminar

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Employment Update:
Hot Topics for Health Care Providers

Megan Anderson

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Wage and Hour

FLSA Developments

March 7, 2019 – U.S. DOL issued proposed Final Rule on FLSA salary exemption requirements

- Replaces Obama-era Final Rule that was enjoined and later invalidated by Texas federal court
- Would increase $455 minimum weekly "white collar" salary to $679 per week ($35,308 annually) in states Would permit 10% of weekly amount to be satisfied by non-discretionary amounts (e.g. commissions)
- Would raise annual amount for "Highly Compensated Employee" exemption to $147,414 (currently $100,000)
- Increases every 4 years via notice and comment rulemaking

FLSA Developments

March 28, 2019 – U.S. DOL Proposed Rule on Calculation of "Regular Rate" for Overtime Purposes

- Currently included in "regular rate" of pay:
  - hourly wages, shift differentials, on-call pay, salary
  - non-discretionary bonuses/incentive pay
  - anything else not expressly excluded by FLSA statute
- Currently not included in "regular rate" of pay
  - Benefits (e.g. health insurance, retirement account contributions)
  - Discretionary bonuses
  - Paid time off and paid leave
  - Reimbursed business expenses

FLSA Developments

March 28, 2019 – U.S. DOL Proposed Rule on Calculation of "Regular Rate" for Overtime Purposes

- What proposed rule would exclude:
  - Wellness benefits, including gym access and on-site specialist treatment
  - Discounts on retail goods and services
  - Payouts of unused vacation, sick, or PTO time
  - Accident, unemployment, and legal services benefits
  - Tuition reimbursement/repayment of student loans
  - Payment of hours not worked (meal times, etc.)
  - Expense reimbursement even if not solely for employer's benefit

Other U.S. DOL Developments

April 1, 2019 – U.S. DOL announces that it will proposes FLSA joint employer regulation update

- Would create 4-factor balancing test that assesses if alleged joint employer actually (not theoretically) :
  1. hires or fires employee;
  2. supervises and controls employee's schedule or conditions of employment;
  3. determines rate and method of pay; and
  4. maintains employment records

Other U.S. DOL Developments

More U.S. DOL Opinion Letters

- Searchable online at: https://www.dol.gov/whd/opinion/search/fullsearch.htm
- FLSA
  - Classification of independent contractors
  - Self-reporting
  - Compensability of time spent in community service or wellness programs, travel time, breaks
  - Determining pay for employees with varying rates
  - Dual jobs and related duties

Other U.S. DOL Developments

More U.S. DOL Opinion Letters (cont.)

- FMLA
  - Obligation to designate FMLA-qualifying leave and prohibition on expanding FMLA leave
  - “No fault” attendance policies and roll-off attendance points
  - Qualifying organ donor surgery as a “serious health condition”

Paid Leave and Minimum Wage

Paid Leave and Minimum Wage - Federal

- In 2019 SOTU, President Trump called for 6 weeks of paid family and medical leave
- Feb. 2019 – "Family Act" reintroduced in Congress
  - Structure is akin to unemployment benefit system
  - Would pay 66% of wages for up to 12 weeks, subject to cap
- U.S. House recently passed $15 minimum wage bill; not expected to pass U.S. Senate

Paid Leave and Minimum Wage – State and Local Laws

- Growing number of states/counties/cities have enacted:
  - Paid family/medical leave laws (e.g. CA; MA, MI, NJ, NY, RI, WA)
  - Paid sick leave laws (e.g. AZ, CA, CT, MD, MA, NJ, OR, RI, VT, WA, Chicago, D.C., L.A., San Francisco, Seattle, NYC)
  - $15 or higher minimum wage laws (e.g. CA, IL, MA, MD, NJ, NY, D.C., Seattle)

Paid Leave and Minimum Wage – State and Local Laws

- Tracking resources on state, county, city paid leave or time off laws:
  - *http://http://www.nationalpartnership.org/our-work/resources/workplace/paid-sick-days/paid-sick-days-statutes.pdf*
  - *http://www.ncsl.org/research/labor-and-employment/state-family-and-medical-leave-laws.aspx*
  - *http://www.ncsl.org/research/labor-and-employment/state-minimum-wage-chart.aspx*
  - *laborcenter.berkeley.edu/minimum-wage-living-wage-resources/inventory-of-us-city-and-county-minimum-wage-ordinances/*

Paid Sick and Safe Leave - MN Cities

Minneapolis, St. Paul and Duluth sick and safe leave ordinances

- July 1, 2017 - Minneapolis and St. Paul ordinances effective
- April 2019 - Minneapolis ordinance upheld by MN Court Appeals; included amended extraterritorial effect
- March 2019 – Minneapolis announces citation of 60+ employers for violating

Paid Sick Leave - Duluth

- Effective 1/1/20
- Applies to employers with 5+ employees
- Covers employees based in Duluth or who spend 50%+ of working time in 12 months there
- Accrual of 1 hour paid sick leave for every 50 worked, up to 64 per year (or can frontload 40 hours each year)
- Annual usage may be capped at 40 hours / year
- Accrual starts at hire, and employee may use time after 90 days of employment

Minimum Wage Laws – MN Cities

- Minneapolis $15 minimum wage, with phase-in from 1/1/18 to 7/1/24 based on employer size
  - http://minimumwage.minneapolismn.gov/uploads/9/6/3/1/96313024/notice_poster_website_final_11_6_17.pdf
  - March 2019 – MN Court of Appeals upholds law
- St. Paul $15 minimum wage, with phase-in from 1/20/20 to 7/1/28 based on employer size
  - https://www.stpaul.gov/departments/human-rights-equal-economic-opportunity/15-minimum-wage

New MN Wage Theft Law

Law passed on May 30, 2019

- $3.1 million in new enforcement funding
- Substantive right to commissions and earned commissions must be paid every 3 months
- Increases civil penalties for wage and hour violations and new criminal penalties (up to 20 years if stolen wages greater than $35,000)
- Changes effective July 1, 2019 (except criminal penalties effective Aug. 1, 2019)

New MN Wage Theft Law

MN "wage theft" law (cont.)

- Employee notice requirements at start of employment:
  - Regular rate of pay and basis thereof
  - Any meal / lodging allowances
  - Paid time off accrual and usage terms
  - Exempt or non-exempt status
  - List of pay deductions
  - Number of days in pay period; regular and first pay date

New MN Wage Theft Law

MN "wage theft" law

- Employee notice requirements (cont.)
  - Employer's legal and operating names
  - Employer's phone number and main physical address and any different mailing address
- Notice in English, with instructions that can get notice in other languages
- Must retain employee signed copy of notice

New MN Wage Theft Law

MN "wage theft" law (cont.)

- Changes to information in wage notice, including for current employees
- New earnings statement items
- New recordkeeping requirements
- Summary of law and employer guidance available at:
  - https://www.dli.mn.gov/business/employment-practices/wage-theft-legislation-2019-and-summaries

#MeToo and Gender Equity Update

#MeToo to Time's Up

- EEOC sexual harassment charges and lawsuits increased in 2017 (charges up over 12%; 50% increase in lawsuits filed)
- EEOC recovered $80+ million for claimants - up 22% over 2017
- 2018 report by US National Academies of Science, Engineering, and Medicine identified sexual harassment as an enduring problem
- Time's Up Health Care – launched 3/1/19

  (https://www.timesuphealthcare.org/)

#MeToo – New Laws

- Federal Tax Code – no deduction for settlements and legal expenses if agreement includes confidentiality requirement
- 30+ states proposed laws in 2018 and trend continued this year
- Some states have enacted new laws
  - Bans or limits on confidentiality/ nondisparagement agreements (e.g. AZ, CA, MD, NY, TN, VT, WA)
  - Bans or limits on arbitration (e.g. MD, NY, VT, WA)
  - Anti-defamation protections (e.g. CA)

#MeToo Movement – New Laws

- New Laws (cont.)
  - Employer reporting requirements to state of harassment settlements (e.g. MD)
  - Expanded harassment protections for non-employees, such as interns and contractors (e.g. DE, NY, VT)
  - Education, policy, and/or training requirements (e.g. CA, DE, LA, MD, NY, OR, VT)
  - Changed liability standards (e.g. NY)

#MeToo – Pay Equity

- Uptick in pay equity claims
- Doximity's 2018 Physician Compensation Report: Gender wage gap grew in 2017; more than $100,000 gap in 25 of top 50 metro areas
- Reinstatement of EEO-1 pay data collection – filings due 9/30/19
- Uptick in state / local laws banning or limiting employer inquiries about salary history of applicants (e.g. CA, CT, DE, GA, HI, IL, KY, LA, MA, MI, MO, NJ, OR, PA, VT, WI, NYC, San Francisco)

Other Key Updates

Title VII - LGBTQ Developments

- U.S. Supreme Court has accepted review of three Title VII cases involving LGBTQ+ coverage debate

Title VII Coverage	Sexual Orientation	Gender Identity
Bostock v. Clayton Co., GA **(11th Cir. May 2018) (Covers AL, FL, GA)**	No	
Wittmer v. Phillips (5th Cir.) (Covers LA, MS, TX)	No	
Hively v. Ivy Tech Comm. College of IN (7th Cir. April 2017) (Covers IL, IN, WI)	Yes	Likely
Zarda v, Altitude Express **(2nd Cir. March 2018) (Covers CT, NY, VT)**	Yes	Likely
EEOC v. R.G. & G.R. Harris Funeral Home **(6th Cir. March 2018) (Covers KY, MI, OH, TN)**		Yes
Horton v. Midwest Geriatric Management (8th Cir.) (Covers AR, IA, MN, MO, ND, NE, SD)	??	??

New MN Anti-Retaliation Law

The Elder Care and Vulnerable Adult Protection Act of 2019

- Effective August 1, 2019
- Applies to nursing and assisted living facilities
- Prohibits retaliation against s resident or employee if the resident, employee, or a person acting on behalf of the resident, files a good faith complaint or grievance or maltreatment report or places an electronic monitoring device in the room

Workplace Violence Focus

- Growing push for federal and/or state laws setting standards for the prevention of and response to workplace violence in the healthcare and social service industries
- OSHA data for 2002-2013 indicates that incidents of serious workplace violence were four times more common in healthcare than in private industry
- U.S. Bureau of Labor Statistics – in 2017, 71% of nonfatal occupational injuries and illnesses involving days away from work, including "intentional injury by other person" were reported in the healthcare and social assistance sector

Labor Law Update

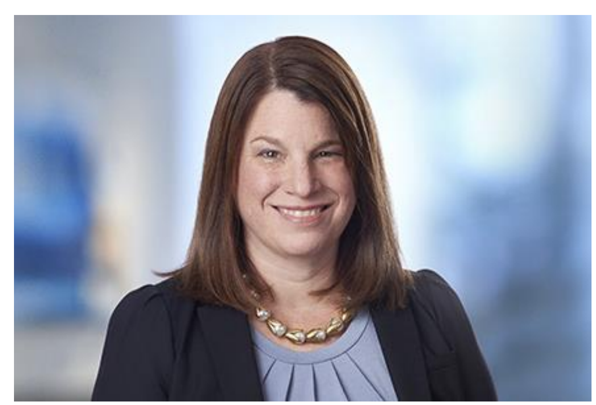
UPMC, et. al. d/b/a UPMC Presbyterian Hospital (NLRB Opinion 6/14/19)

- Reverses NLRB precedent
- Employer can ban all non-employee solicitations from public spaces within its privately owned property (e.g. gift store, cafeteria)

Job Applicants

- Are job ads a new discrimination frontier?
  - Uptick in allegations that social media ads target younger workers
  - Class action suit filed against Amazon, Cox Media Group, & T-Mobile in California
  - IL and WA Attorney General investigations
- *Kleber v. CareFusion Corporation* (7th Circuit)
  - No disparate impact claim under federal ADEA for job applicants (covers IL, IN, WI)
  - Case involved 7 year experience cap

Questions?



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Prize Drawing!

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