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Regulatory Year in Review for the C-Suite

Nebraska Hospital Association Annual Convention

October 25, 2017
Michael W. Chase & Zachary J. Buxton


#1959233

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Agenda

- Year-in-review of current “hot” topics
 - Industry news
 - Program updates
 - Enforcement examples
- Exercise in issue spotting
- Strategies and best practices

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FY 2017 Statistics To Date

- October 2016 – March 2017
- OIG anticipates expected investigative recoveries of over \$2.04 *billion*
- FY16 recoveries: \$5.6 billion
 - 844 criminal actions
 - 708 civil actions
 - 3,635 excluded individuals and entities
- FY16 State Medicaid Fraud Units: \$2 billion in recoveries
 - Nebraska: 99 investigations; ~\$19.5 million total recoveries

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Fraud and Abuse

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More Money...

- Civil Monetary Penalties Law
 - Prohibits providing a Medicare or Medicaid beneficiary something of value that the person either knows or should know will influence the recipient's choice of provider
- Several exceptions, including gifts of “nominal value”
 - 2000: \$10 per gift; \$50 per year per patient
 - 2016: \$15 per gift; \$75 per year per patient

...More Problems

- CMP inflationary adjustments as mandated by the Federal Civil Penalties Inflation Adjustment Improvement Act of 2015

	Per Claim Range		
	Pre-FCPIAIA	08/16-02/17	02/17-Present
High	\$11,000	\$21,563	\$21,916
Low	\$5,500	\$10,781	\$10,957

- Stark Law violations for 2017: \$24,253 (adjusted from \$15,000 prior to 2016)
 - 82 FR 9174, 9179

Settlement Trends

Anti-Kickback Statute

- “Ambulance swapping” arrangement in Houston, Texas; Four hospitals settled for \$8.6 million; All hospitals affiliated with Hospital Corporation of America (HCA)
- Home health agency entered into sham physician employment and medical director contracts to disguise illegal kickbacks; Owner-COO sentenced to almost 7 years in prison and \$16 million in restitution to Medicare
- IU Health provided interest-free line of credit to Indiana's largest FQHC; the credit balance routinely hovered around \$10 million; Government alleged illegal remuneration in exchange for FQHC's OB/GYN patients

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Settlement Trends, cont.

Stark Law

- *Qui tam* suit alleged two New York hospitals entered into compensation arrangements and leases in violation of Stark; settled claims for \$4 million
- University Behavioral Health of El Paso paid \$860,000 to settle allegations that it paid a physician above fair market value and for services not rendered under a personal services arrangement
- Pacific Alliance Medical Center allegedly leased space in physician offices and paid above-market rates; whistleblower also alleged improper marketing payments; PAMC settled for \$42 million

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- July 2017: DOJ announced charges against 412 defendants for nearly \$1.3 billion in fraudulent billing; 115 doctors charged for alleged role in prescribing and distributing opioids
- Detroit physician conspired with owner of a physician clinic to prescribe medically unnecessary opioids to Medicare beneficiaries addicted to narcotics; required medically unnecessary facet joint injections

- AnMed Health entered \$7 million settlement; US alleged qualified practitioner wasn't "immediately available" during provision of radiation oncology services; billed clinic services as ED services; billed services furnished by mid-levels as physician services
- Between 2011 and 2015, Carolinas Healthcare System billed certain "moderate complexity" (G0434) labs as "high complexity" (G0431); \$20 difference per test; CHS entered \$6.5 million settlement

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“So pumped on the IV stuff”

- Dr. Seth Lookhart, 32
- Former employee alleged Lookhart used sedation to increase profits
 - Medicaid payments:
 - Jan.-June 2016: \$27,000 per month
 - January 2017: \$436,000
- “Seth Lookhart performed a dental extraction procedure on a sedated patient while riding a hover board and filmed the procedure and distributed the film to persons outside his dental practice.”

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OIG, Enforcement Activities, & Miscellany

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OIG's Top Cases

By Criminal or Civil Cases	By Monetary Receivables
Health Care Providers & Health Care Company Owners	Pharmaceuticals
Hospital	Hospital
DME	Home Health
Home Health	Health Care Providers & Health Care Company Owners
Pharmaceuticals	Labs
Ambulance	Health Care Corporations
Health Care Corporations	DME
Labs	Ambulance

Karen Glassman & Lindsey Beran, An Enforcement Update from USAO and OIG (2016) from Presentation for Health Care Compliance Association

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False Claims Act

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FCA Settlements

- TeamHealth to Pay \$60 Million to Resolve Allegations of Upcoding Claims (02/06/2017)
- CareCore to Pay \$54 Million in Resolving Medicare-Medicaid Fraud (05/11/2017)
- EHR vendor to pay \$155 million in first-of-its-kind False Claims Act Case (05/31/2017)
 - Yates Memo: Software Developer (\$50,000 settlement); Two Project Managers (\$15,000 settlement each)

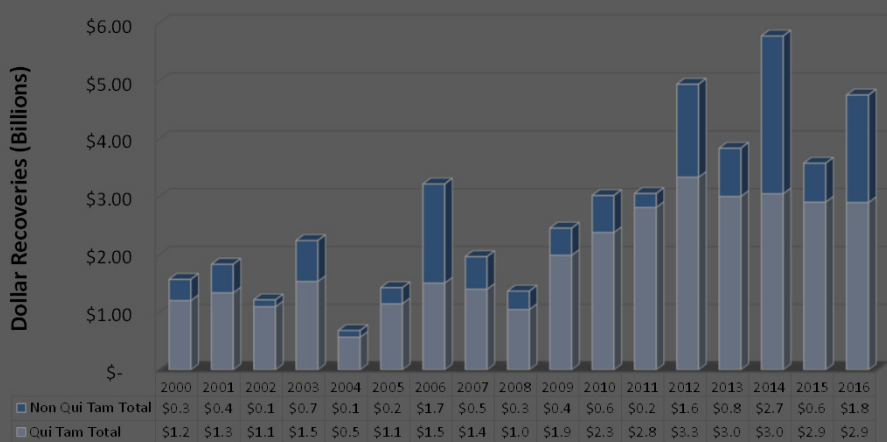
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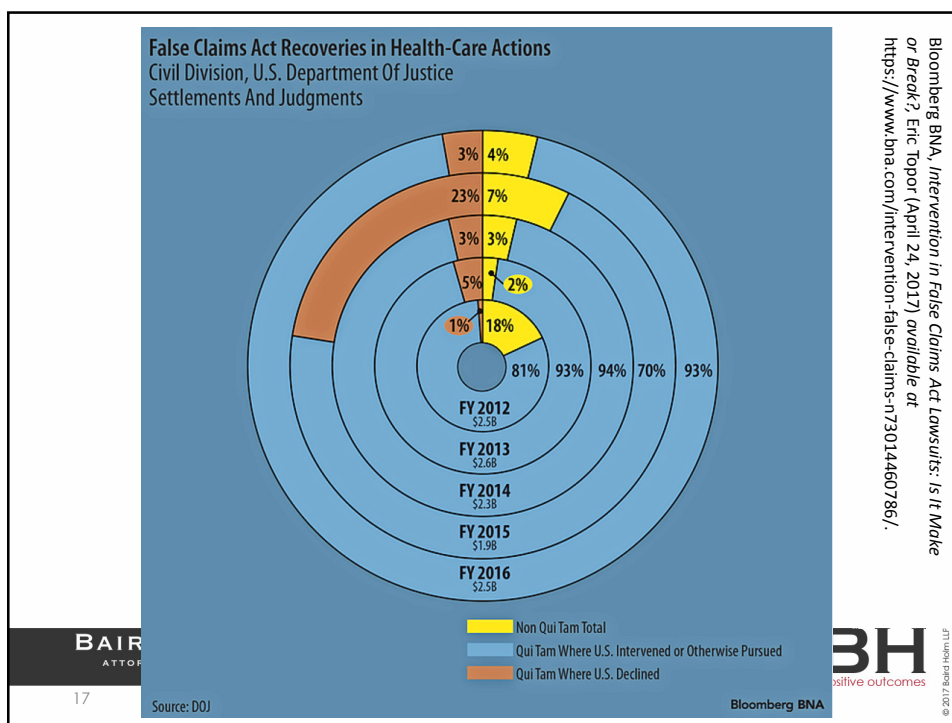
False Claims Act Recoveries - *Qui Tam* and Non-*Qui Tam* (2000-2016)



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Data Source: https://public.tableau.com/views/ToughFCAActsToFollow/FCA%3Aembed-y&%3AshowVizHome=no&%3Ahost_url=http%3A%2F%2Fpublic.tableau.com%2F%3A%2F%3AAtabs-no&%3Atoolbar=yes&%3Aanimate_transition=yes&%3Adisplay_static_image=no&%3Adisplay_spinner=no&%3Adisplay_overlay=yes&%3Adisplay_count=yes&%3AloadOrder=0



Escobar and Materiality

- Supreme Court: Is implied false certification a valid theory of liability under FCA?
 - (1) Claim must “make specific representations about the goods or services provided” and
 - (2) The misrepresentations must be with material laws, regulations, or contract provisions
- So, what's “material”?
 - Proliferation of lower court cases
 - Fifth Circuit Court of Appeals overturned \$663 million FCA judgment



ACA Updates

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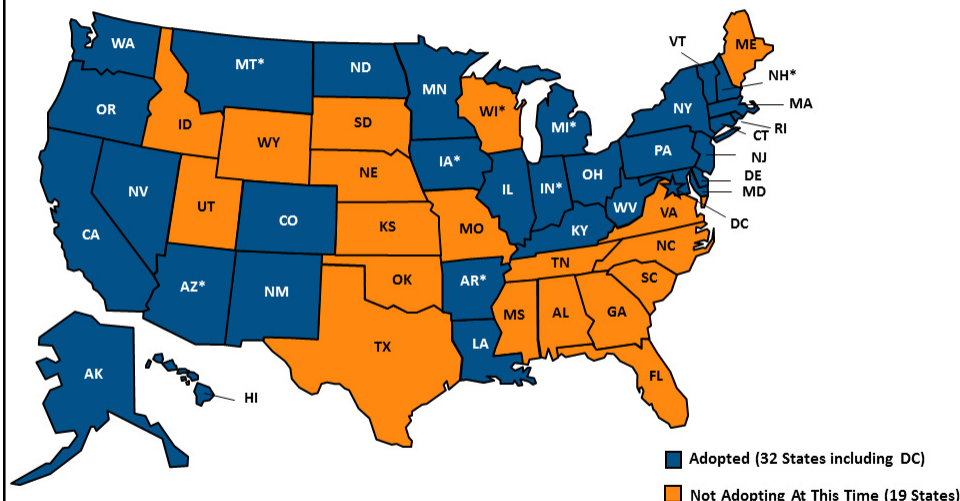
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Current Status of State Medicaid Expansion Decisions



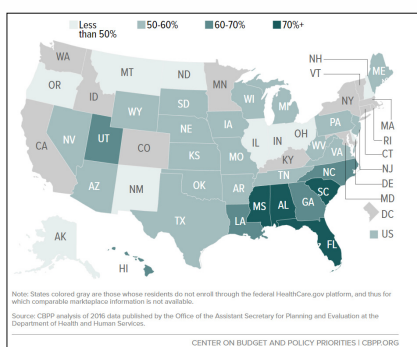
NOTES: Current status for each state is based on KCMU tracking and analysis of state executive activity. *AR, AZ, IA, IN, MI, MT, and NH have approved Section 1115 waivers. WI covers adults up to 100% FPL in Medicaid, but did not adopt the ACA expansion.

SOURCE: "Status of State Action on the Medicaid Expansion Decision," KFF State Health Facts, updated January 1, 2017.

<http://kff.org/health-reform/state-indicator/state-activity-around-expanding-medicare-under-the-affordable-care-act/>



Trump & the ACA



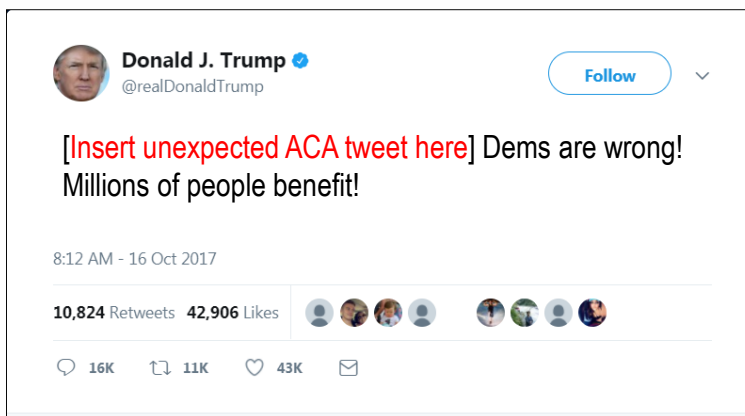
- Executive Order
 - Intent appears to be to increase consumer choice and competition in the healthcare market
 - Association Health Plans (AHPs); Short-Term, Limited Duration Insurance (STLDI); Health Reimbursement Arrangements (HRAs)
- Trump ends Cost Sharing Reduction (CSR) payments
 - Reduces costs for individuals between 100 and 250 percent of Federal Poverty Level
 - 6 million Americans receive CSR payment
 - Approximately \$7 billion in 2017

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ACA Section 1557

- *Franciscan Alliance, Inc. et al v. Price**
 - Case brought by Catholic Health System, a Catholic medical group, a Christian medical association, and five states
 - Challenged HHS's definition of the term "gender identity" under the final rule
 - Judge issued preliminary injunction enjoining HHS from enforcing prohibition on discrimination based on gender identity
 - Opinion issued 12/31/2016
 - HHS asked court in May 2017 to allow it to reconsider whether the rule should continue to ban gender identity discrimination
 - HHS filed status report 10/16/2017: New rule currently with DOJ; any new 1557 rule will go through notice and comment period

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Compliance Programs

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DOJ: Evaluating Corporate Compliance Programs

- Published by the DOJ's Fraud Section under its "Compliance Initiative"
 - February 2017
- Details several questions in 11 categories prosecutors use to evaluate corporate compliance programs

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DOJ: Evaluating Corporate Compliance Programs

- Analysis and remediation of underlying misconduct
- Senior and middle management
- Autonomy and resources
- Policies and procedures
- Risk assessment
- Training and communications
- Confidential reporting and investigation
- Incentives and disciplinary measures
- Continuous improvement, periodic testing, and review
- Third party management
- Mergers and acquisitions

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Measuring Compliance Program Effectiveness

- Published jointly by OIG & HCCA (March 2017)
- Tool to assist organizations—both large and small—to evaluate compliance programs
- Not intended to be used as a “checklist”
 - <https://oig.hhs.gov/compliance/101/files/HC-CA-OIG-Resource-Guide.pdf>

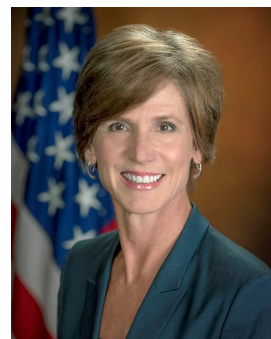
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Yates Memo

"[W]e're getting exactly what we wanted – companies showing up to their first meeting with the government **with information about who did what**, and our prosecutors are using that information both to build cases against individuals and to ensure that the companies are being **properly credited for their cooperation at the end of the investigation.**"



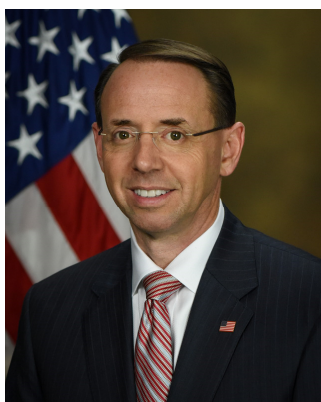
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But...Deputy AG Rod Rosenstein



"[The Yates Memo is] under review and I anticipate that there may be some change to the policy on corporate prosecutions [...] I don't have any announcement about that today, but I do anticipate that we may in the near future make an announcement about what changes we're going to make to corporate fraud principles."

https://www.justice.gov/sites/default/files/staff_profile/public/staff-profiles/Images/2017/05/10/170427_rod_rosenstein_port.jpg?itok=S70gvapo

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Yates Memo

DOJ website for Individual Accountability

<https://www.justice.gov/dag/individual-accountability>

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OIG Exclusion Authority

- Final rule published January 12, 2017
- Regulations revise and expand OIG's ability to exclude individuals and providers from participation in federal health care programs
- Highlights:
 - 10 year statute of limitations
 - Obstruction of audits
 - Ownership in excluded entities



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CMPs – ACA Exception

- ACA exception to “remuneration” for “any other remuneration which promotes access to care and poses a low risk of harm to patients and Federal health care programs”

CMPs–Promotes Access to Care

- “Care” = items and services that are payable by Medicare or a State health care program
- “Promotes Access” = improves beneficiary's ability to obtain items and services payable by Medicare or a State health care program”
 - Does not protect rewards for accessing care
 - But could include something that helps a patient comply with a treatment plan

CMPs – Low Risk of Harm

- (1) Be unlikely to interfere with, or skew, clinical decision making
- (2) Be unlikely to increase costs to Federal health care programs or beneficiaries through overutilization or inappropriate utilization
- (3) Not raise patient safety or quality of care concerns

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OIG Advisory Opinion 17-01

- Free or reduced-cost lodging and meals
- Promotes Access to Care
 - Removes socioeconomic and geographic barriers; facilitates attendance at appointments for medically necessary care
- Low Risk of Harm
 - Not conditioned on receipt of a particular service; no remuneration to clinicians; no shifting of costs to cost report; no advertising; applies to only a small fraction of hospital's population

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OIG Work Plan

- Assists entities plan compliance programs
 - Historically: Published twice per year
- Now updated monthly
 - OIG Work Plan webpage:
<https://oig.hhs.gov/reports-and-publications/workplan/updates.asp>

OIG Work Plan, cont.

- Recent Additions:
 - Medicare Part B Payments for Psychotherapy services (August 2017)
 - Medicare Part B Payments for Ambulance Services Subject to Part A Skilled Nursing Facility Consolidated Billing Requirements (July 2017)
 - Review of Medicare Payments for Nonphysician Outpatient Services Provided Under the Inpatient Prospective Payment System (July 2017)
 - Review of Medicare Payments for Telehealth Services (July 2017)

Highlights of 2018 Proposed Hospital OPPS, Physician Fee Schedule, and Final IPPS Rule

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Roadmap for the Proposed 2018 Physician Fee Schedule

- E/M Documentation Update
- New Telehealth Procedures
- Reimbursement Update
- Reduction in Payment – Provider-Based Departments
- Impact on Specialty Reimbursement
- MIPS and Quality Measures
- Behavioral Health Services Payment Increase
- Reduced Value-Based Payment Modifier Penalties
- Chronic Care Management Codes, New RHC & FQHC Care Coordination Codes & Diabetes Prevention Program Expansion
- Voluntary Use of Patient Relationship HCPCS Modifiers for MACRA

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Roadmap for the Proposed 2018 OPPS

- Changes to the 340B Program
- Reimbursement Update
- Provider-Based Departments – Expansion/Growth
- Laboratory Tests – Date of Service
- Hospital OQR Quality Measures
- Inpatient Only List Changes
- Direct Supervision Rules for Therapeutic Services
- Skin Substitutes

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Changes to the 340B Program

- Significant reduction in reimbursement
- Average sales price minus 22.5% “which we believe better represents the average acquisition cost”
- CMS concerned that 340B may lead to overutilization
- New modifier in 2018 for non-340B drugs

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Direct Supervision Rules for Therapeutic Services

- Moratorium on enforcement of direct supervision of outpatient therapies
- Critical access hospitals and rural hospitals with <100 licensed beds
- Extended through 2019

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CAH 96-Hour Certification Update

- CMS finalized its directive to QIOs, MACs, the SMRC, and RACs to make the CAH 96-hour certification requirement a low priority for medical record reviews
 - Can review if suspect “gaming” of the system or have requested records for another reason

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Meaningful Use

- Stage 3 objectives postponed to 2019
- 2014 edition CEHRT may be used through September 30, 2018
- Reporting may be from any continuous 90-day period during the year
- Response to providers; 70% surveyed had not received delivery of 2015 Edition CEHRT

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HIPAA Enforcement

Cybersecurity

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OCR Resolution Agreement

- *Metro Community Provider Network* (\$400,000 settlement)
 - January 2012 breach: hackers phished and accessed 3,200 individuals' ePHI
 - MCPN failed to conduct a risk analysis until mid-February 2012
 - OCR considered MCPN's status as an FQHC when balancing the significance of the violation with MCPN's standing to provide patient care

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OCR Resolution Agreement

- *CardioNet* (\$2,500,000 settlement)
 - Wireless health services provider (remote mobile monitoring and rapid response for arrhythmias)
 - January 2012 breach report: stolen laptop
 - Insufficient risk analysis and risk management process
 - Security Rule policies and procedures were in draft form and not implemented; unable to produce any final policies and procedures, including loss/theft of mobile devices

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OCR Resolution Agreement

- *Children's Medical Center of Dallas*
(\$3,200,000 civil monetary penalty)
 - Loss of unencrypted, non-password protected BlackBerry at DFW (2009); loss of unencrypted laptop (2013)
 - Failure to implement risk management plans, contrary to external recommendations, and failure to deploy encryption (continued to issue unencrypted devices)

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OCR Resolution Agreement

- *University of Massachusetts Amherst (UMass)*
(\$650,000 settlement)
 - Workstation infected with malware (remote access Trojan) in 2013
 - "Impermissible disclosure" of 1,670 individuals' PHI because it permitted "impermissible access"
 - No firewall in place; failure to implement technical safeguards; no SRA until 2015
 - Failed to designate covered and non-covered components

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Audit Controls

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OCR Resolution Agreement

- *South Broward Hospital District d/b/a Memorial Healthcare Systems (\$5.5M settlement)*
 - Login credentials of former employee used to access PHI (without detection) of 80,000 individuals
 - Failed to implement procedures to modify/terminate users' access; failed to regularly review information systems activity (despite identifying it on a risk analysis)

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Business Associates

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OCR Resolution Agreement

- *Center for Children's Digestive Health* (\$31,000 settlement)
 - August 2015 – OCR initiated a compliance review of CCDH following an investigation of a business associate, FileFax, Inc. which stored records for CCDH
 - CCDH began disclosing PHI to FileFax in 2003
 - Neither party could produce a signed BAA prior to October 12, 2015

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OCR Resolution Agreement

- *Care New England Health System* (\$400,000 settlement)
 - CNE is parent for several hospitals in New England; provides financial and administrative services to affiliate hospitals (including information security)
 - Hospital within CNE system lost unencrypted back up tapes containing ultrasound studies of 14,000 individuals
 - BAA between Hospital and CNE was in place since 2005, but **not updated for HITECH until 8/28/15**

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Breach Notification

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OCR Resolution Agreement

- *University of Mississippi Medical Center* (\$2,750,000 settlement)
 - Breach of unsecured ePHI (laptop stolen by visitor) (10,000 individuals)
 - OCR
 - UMMC was aware of risks/vulnerabilities (dating back to 2005)
 - No significant risk management
 - **Failure to notify affected individuals** (did notify through media and website)

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OCR Resolution Agreement

- *Presence Health* (\$475,000 settlement)
 - October 22, 2013: Presence discovered breach of 836
 - January 31, 2014: OCR breach notification
 - February 3, 2014 (104 days): Individual notification
 - February 5, 2014: Media notification
 - “Due to a miscommunication between its workforce members, there was a delay in breach notification”
 - Also reviewed past small breaches reported to OCR and found several with no notification to individuals

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Other Enforcement Highlights

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HIPAA Enforcement

- *St. Lukes-Roosevelt Hospital Center Inc.*
(\$387,200 settlement)
 - St. Luke's provides comprehensive services to persons living with HIV, AIDS, and other chronic diseases
 - September 2014 OCR complaint: impermissible disclosure to patient's employer (HIV status, medical care, STDs, sexual orientation, mental health diagnosis, etc.)
 - Investigation: impermissible fax (meant to send to patient's home mail box)
 - Also discovered similar incident that occurred 9 months earlier and failed to address the vulnerabilities to prevent similar disclosures

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HIPAA Enforcement

- *Memorial Hermann Health System*
(\$2,400,000 settlement)
 - OCR initiated compliance review based on media reports of inappropriate disclosure of PHI
 - Patient presented an allegedly fraudulent ID
 - Staff alerted law enforcement; patient arrested (permissible disclosure)
 - MHHS published a press release with patient's name in the title (impermissible disclosure)

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Blood Alcohol Tests

- *Birchfield v. North Dakota* (U.S. Supreme Court)
- Reviewed statute establishing implied consent to BATs related to drivers licensure
- Generally, law enforcement requested BAT and patient refusal was enforced through criminal penalties
- Illegal Search and Seizure – Constitutional right
- Illegal BATs not admissible in criminal prosecution to show BA level in excess of legal limits for driving

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Blood Alcohol Tests

- Suspected drunk driver may consent to BAT
 - But do they have capacity if drunk?
- Ideally, consent in writing; special consent form
- Drivers may postpone test by requiring law enforcement to obtain a search warrant for BAT
 - They may hope to have lower BA level by the time the warrant is presented to the hospital
- HIPAA implications for release of the BAT results
 - Warrant or patient authorization

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Quick Hits

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In Case You Missed It...

- IRS 501(r) audits
 - ACA requires IRS to audit 1/3rd of charitable hospitals each year
 - 6/30/2016: 692 reviews completed; 166 referred for field examination
- Increased attention to 340B program
- CMS Finalizes Emergency Preparedness Requirements (September 2016)
 - Applies to 17 provider types
 - Emergency plan; policies and procedures; communication plan; and training and testing program
- Updates to Self-Referral Disclosure Protocol (May 2017)
 - Applies to disclosures after June 1, 2017

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Well, uh, did you hear about this?

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Social Media #Fail

- Karrie Anne Runtz, Mount Sinai Hospital (Chicago, IL) trauma nurse
- Runtz ran Twitter account @traumanatrix with over 1,300 followers
- Regularly tweeted about incidents in ED, including a blood-soaked room after the death of a 24-year-old victim of gun violence
- Victim's family sued Hospital & Runtz

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A Night with Pauley LaPointe, Chicago's Nightcrawler

Anywhere there's a shooting or a knifing or a car crash in this city, you will likely find Pauley LaPointe, camera in hand.

PUBLISHED JULY 23, 2015, 47:10:22 AM

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and clicks on Twitter.

There are dozens of amateur scanner monitors in town—devotees who eavesdrop on the police and fire department chatter and tweet details in real time. But LaPointe has whittled those he follows to a hardcore few: Chicago Scanner ("Listening to Chicago's Finest & Bravest on 11 Scanners, as It Happens, Since 1992"); Traumanatrix a.k.a. Dixie McCall ("Diva of Death, Mistress of Mayhem"), who hints that she's an ER nurse; and Spot News, a freelance photojournalist who sometimes shoots for LaPointe and whose obsessive tracking (60,000 tweets and counting) makes him the go-to source for the scanner crowd.

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Paging @drbfixin



Happy Mother's Day 🌸👶👶 I don't think dr.bfixin is the baby daddy tho 😂😂

"With a newly removed mound of pink fat resting on his forearm, Blyer, in full surgeon regalia, shakes to [a song] by A Boogie and Don Q, as an anesthetized patient lays still."

Dr.Bfixin 🛠️🔒

@drbfixin

Love my job, My patients, & being LIT!
Cosmetic surgeon from New York 🇺🇸👨
Snapchat/Instagram : @DrBfixin . ~ Stay
fixin my friends 🛠️

📍 Islandia, NY

🌐 drbfixin.com

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Questions?

Michael W. Chase
mchase@bairdholm.com
(402) 636-8326



Zachary J. Buxton
zbuxton@bairdholm.com
(402) 636-8239



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